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PART II

ENVIRONMENTAL PROTECTION AGENCY

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TOXIC SUBSTANCES CONTROL

Premanufacture Notification Requirements and Review Procedures

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 720]

[OTS-050002; FRL—1022-6]

TOXIC SUBSTANCES CONTROL

Premanufacture Notification Requirements and Review Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rules and notice forms.

SUMMARY: These proposed rules and notice forms would implement the requirements of section 5 of the Toxic Substances Control Act (TSCA) concerning new chemical substances. TSCA requires each person who intends to manufacture or import a new chemical substance for commerical purposes to submit a notice to EPA at least 90 days before manufacture or import commences. At the end of the notification period, the person may manufacture or import the substance unless EPA has taken regulatory action under section 5(e) or section 5(f) to ban or otherwise regulate the substance.

These proposed rules and forms would define the applicability of these requirements, the information which must be submitted, optional information submissions, and Agency procedures for reviewing notices.

DATES: Interested persons, should comment on these proposed requirements on or before March 26, 1979.

PUBLIC MEETINGS: EPA has scheduled the following public meetings on these proposed rules and forms during the official comment period:

Atlanta, Georgia	January 31, 1979
Dallas, Texas	February 1, 1979
Los Angeles, California	February 2, 1979
Chicago, Illinois	February 6, 1979
Cleveland, Ohio	February 7, 1979
Newark, New Jersey	February 8, 1979
Washington, D.C	February 13 & 14, 1979

The purpose of these meetings is to enable interested persons to provide oral comments on the proposed rulemaking to EPA officials who are directly responsible for developing the rules and notice forms. See Part VI under "Supplementary Information" below.

ADDRESS: Written comments should bear the document control number OTS-050002 and should be submitted in triplicate to the Document Control Officer (TS-793), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

The addresses for the public meetings are provided in Part VI under "Supplementary Information" below.

FOR FURTHER INFORMATION CONTACT:

Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460; 800-424-9065 toll free; in Washington, D.C. call 554-1404.

SUPPLEMENTARY INFORMATION: The remainder of this preamble discusses EPA's approach to implementing the premanufacture notification requirements, the provisions of this proposal, major issues addressed in developing this proposal, and anticipated impact. The Agency also has prepared a Support Document which is available from the Industry Assistance Office. (See "Information Contact" above.) EPA requests comments on any aspect of this proposal and alternative approaches. The Agency has identified specific issues for comment in this preamble and in the Support Document.

Following is an index to the remainder of this preamble.

I. INTRODUCTION

A. STATUTORY FRAMEWORK

Under § 5 of the Toxic Substances Control Act (TSCA), 15 U.S.C. section 2604, any person who intends to manufacture a new chemical substance for commercial purposes in the United States must submit a notice to the Environmental Protection Agency (EPA) at least 90 days before he commences manufacture. Section 3(7) of the Act defines "manufacture" to include import into this country. Thus section 5 and this proposed rulemaking apply to imports of new chemical substances as well.

Section 3(9) of the Act defines a "new chemical substance" as any chemical substance which is not included on the list, or "inventory," of existing substances published by EPA under section 8(b). The Agency promulgated the inventory reporting rules on December 23, 1977, 40 CFR Part 710, (42 FR 64572) and supplemented these rules on March 6, 1978 (43 FR 9254) and April 17, 1978 (43 FR 16147). The Agency presently is compiling this inventory and intends to publish it during the first half of 1979. Thirty days after this publication, the requirements of section 5 are effective.

Section 5(d)(1) of the Act defines the contents of a premanufacure notice. It requires the manufacturer to report certain information described in § 8(a)(2) of the Act (e.g., chemical identity, uses, and exposure data) plus test data and descriptions of other data related to the effects on health and the environment of the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. In general, these data and information must be submitted to the extent they are known to or reasonably ascertainable by the submitter.

Section 5(b) of the Act contains additional reporting requirements for chemical substances subject to testing rules under section 4 of the Act and chemicals which the Administrator, by rules under § 5(b)(4) of the Act, has determined may present unreasonable risks of injury to health or the environment. Section 5(h) authorizes exemptions from some or all of the reporting requirements for new chemical substances which are used for certain limited purposes including in small quantities solely for purposes of research and development, for test marketing, or for use as intermediates if there is no exposure to the substances.

Once EPA receives a premanufacture notice, the Agency normally has 90 days within which to review it (§ 5(a)(1)). However, under section 5(c) of the Act, the Agency for good cause may extend the review period for up to an additional 90 days. During the premanufacture review period, EPA may initiate actions under sections 5(e) or 5(f) to regulate the production and use of the new chemical substance. Section 5(e) authorizes EPA to regulate the manufacture, processing, distribution in commerce, use or disposal of a new chemical substance pending development of sufficient data to evaluate the effects of the substance, if the Agency determines that the information available is insufficient to evaluate the health and environmental effects, and that the substance either (1) may present an unreasonable risk of injury to health or the environment or (2) will be produced in substantial quantities and there may be significant or substantial exposure to the substance. Under section 5(f), EPA may regulate a new chemical substance if the Agency finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance will present an unreasonable risk of injury to health or the environment before a rule promulgated under § 6 can protect against such risk. Under both § 5(e) and § 5(f), EPA may limit production and use or ban manufacture altogether.

Once the notification period expires, the submitter may commence manufacture of the substance if EPA or a Federal court has not banned production. When manufacture begins, EPA will add the substance to the inventory. Thereafter any person may produce the substance without giving notice to the Agency under § 5(a)(1)(A) of the Act. If the Agency has not prohibited manufacture, but has placed limitations on the chemical substance, others may manufacture it provided they comply with the requirements.

The Act requires EPA to publish in the FEDERAL REGISTER certain information on a chemical substance for which the Agency has received a premanufacture notice. Section 5(d)(2) requires EPA to publish, within five days of receipt of a notice, information on the identity and uses for the substance, as well as a description of test data required to be submitted under § 5(b) and the results of such tests. In addition, at the beginning of every month the Agency must publish a list of (1) each chemical substance for which a premanufacture notice has been received and for which the notification period has not expired, and (2) each chemical substance for which the notification period has expired since the last monthly FEDERAL REGISTER notice. Also, section 5(g) of the Act requires EPA to publish in certain cases a statement in the FEDERAL REGISTER of the reasons for not taking regulatory actions on substances for which the Agency has received notices.

B. PARTS OF THIS RULEMAKING

This rulemaking establishes the basic framework for the premanufacture program and has two components, premanufacture rules and notice forms. The rules will be codified as 40 CFR Part 720 and would contain the following subparts:

Subpart A, "General"—general scope and compliance provisions; definitions applicable to the entire Part 720.

Subpart B, "Applicability"—persons who must submit notices and those who need not; chemicals subject to notification and those excluded; exemptions.

Subpart C, "Premanufacture Notices"—general provisions concerning how, where, and when to submit notices; special provisions for imports; general content of notices; submittal of health and environmental effects data.

Subpart D, "Disposition of Notices"—EPA's procedures for receiving, processing, and reviewing notices; deficiencies and invalid notices; actions under § 5(e) and § 5(f) of the Act.

Subpart E, "Confidentiality and Public Access to Information"—general provisions for handling, protecting and disclosing confidential information; special provisions concerning information on chemical identity and use, and for data from health and safety studies; public files.

Subpart F "Supplemental Reporting Requirements"—additional reporting requirements under § 5, § 8(a), and § 8(d) of the Act; reporting concerning commencement of manufacture.

The general notice form is referenced in the regulations, and contains the specific information requirements applicable to new chemical substances. In particular, it contains both mandatory and optional parts: manufacturers must submit information concerning experimental testing performed and exposures to humans and the environment; at their discretion, they may submit other information concerning steps taken to control exposures and concerning certain non-risk factors. EPA also is publishing for public comment three other forms: one to be sent by manufacturers and importers to persons likely to process or use the substance; one for use by importers; and one to be sent by importers to the suppliers and manufacturers of their imported substances.

After evaluating comments, EPA will promulgate the final rules and forms, and in the future the Agency will follow notice and comment rulemaking procedures to make substantive changes in them. EPA will treat as technical amendments any minor changes which would not require public comment under the Administrative Procedure Act (APA). The forms will be available at EPA offices and other locations throughout the country for use in preparing premanufacture notices.

In addition to the rules, forms, and preamble, EPA has developed a Support Document which discusses in detail the basic issues in this rulemaking and includes (where appropriate) alternatives considered and EPA's rationale for its proposed approach. A separate document, *Impact of TSCA Premanufacturing Review Requirements* discusses the estimated economic impacts of the proposed program.

Three other documents supplement this rulemaking. First, Appendix II to this proposal contains a slightly amended version of the *Guidelines for Creating Proposed Generic Names*, originally made available by EPA in April 1978 (43 FR 16178) to assist in development of proposed generic names for the inventory. The Agency will use this document in implementing relevant parts of these premanufacture rules. Second, at a later date EPA will publish *Formats for Data Submitted Under the Toxic Substances Control Act*, for use by persons who submit health and environmental effects data as a part of their premanufacture notices. Third, when EPA promulgates the notice forms the Agency will publish an instruction manual for completing the forms, entitled *Premanufacture Reporting of New Chemical Substances Under TSCA*. For purposes of comment on the proposed forms, the Support Document describes the reporting requirements, what information should be reported and how, and the rationales for these requirements. In addition, the Agency is preparing an explanatory appendix to the forms, based on the Support Document, which we will make available as soon as possible.

Finally, in addition to this rulemaking EPA in the future will issue other rules and documents which will further implement the premanufacture program. These are summarized in the Support Document, "Supplements to this Proposal," and include significant new uses rules under § 5(a)(2), the § 5(b)(4) "risk list," § 4 testing rules, and premanufacture testing guidelines.

C. GENERAL APPROACH

EPA's implementation of TSCA § 5 will focus upon the assessment of risks presented by the manufacture, processing, distribution in commerce, use, and disposal of new substances and decisions concerning the reasonableness of such risks. Manufacturers must design a testing scheme and should

make an initial determination that any risks are not unreasonable.

Section 5 does not establish a certification or registration program for new chemical substances. Rather, it requires a manufacturer to notify EPA of his intent to manufacture (or import) a new chemical substance, and to submit information concerning that substance which the Agency can use to assess the risks associated with its manufacture, processing, distribution in commerce, use, or disposal. On the basis of this assessment and an evaluation of relevant non-risk factors, EPA will make decisions concerning the reasonableness of any risk, and will take appropriate action to obtain more information or data, to regulate production or use, or to follow up the substance once it is commercialized. If EPA does not regulate the substance during the premanufacture notification period, the manufacturer may begin production (subject to regulation under any other laws). However, the fact that EPA does not take regulatory action does not imply that the substance is "safe" or has been "approved" by the Agency.

EPA considered several different approaches to implementing the premanufacture review program. The alternative approaches are described below (see "Regulatory Analysis"), and the advantages, disadvantages, and economic consequences of each are discussed. The alternatives considered consist of different combinations or modifications of three elements: notification rules, notice forms, and testing guidelines.

Testing guidelines would assist manufacturers in designing testing programs to evaluate the potential effects which new chemical substances might have on health or the environment. Although EPA believes that testing guidelines are an important part of a premanufacture review program, the Agency is not including a specific guidelines approach as a part of this proposal. In the near future EPA will publish for public comment a detailed discussion of the major testing issues and guidelines alternatives. Subsequently, the Agency will propose testing guidelines.

Notification rules provide the regulatory basis for the submittal and review of notices. The rules specify the chemical substances for which reporting is required, who must report, what information is to be submitted to EPA, and when and where that information should be submitted. The rules also describe how EPA will process notices, handle claims of confidentiality for data submitted in notices, and take action under § 5(e) or § 5(f) of the Act. For a detailed description of the contents of this proposed rule, see below, "Provisions of this Proposal".

Notice forms establish the specific reporting requirements for manufacturers. EPA has designed the notice forms to serve four basic purposes:

(1) To provide EPA the information and data necessary to assess risks associated with the production, use, and disposal of new chemical substances;

(2) To enable EPA to determine the need for additional reporting or for the imposition of controls on production, use, or disposal;

(3) In particular, to provide an initial information and data base which the Agency can use to evaluate chemical exposures, including specific populations exposed and the levels and durations of exposure; and

(4) To enable manufacturers to provide information concerning their own activities to limit exposure, plus information which may explain why risks presented by their new substances are reasonable.

The proposed forms contain both mandatory and optional parts. The manufacturers must submit certain information which is most relevant to EPA's assessment of risks, but are not required to submit extensive information concerning other aspects of production and use. This minimizes the general reporting burden of the forms while enabling individual companies to provide additional information which they believe EPA should consider in its evaluation of their new substances.

The proposed forms would require reporting of information necessary to perform risk assessments on new substances. Thus in addition to certain basic information (e.g., chemical identity, anticipated production volumes and uses), the forms would require information concerning possible exposures throughout the life cycle of new substances, such as information associated with various aspects of these substances' commercial development (e.g., manufacture, processing, use, transport, and disposal), and relative to the expected routes of exposure and populations to be exposed. To obtain information concerning the effects of the chemical substances on health and the environemnt, the forms would require submitters to explain their testing programs, including tests performed and the scientific rationales for their testing decisions. Finally, manufacturers must submit reports of test data in their possession or control and descriptions of certain other data.

In most cases the submitter will be the person most likely to have information relevant to his new substance. The Act requires persons to submit this information insofar as it is known to or reasonably ascertainable by them. Thus a manufacturer must make good faith efforts to obtain such information, including that which is not immediately known to him. In particular, EPA interprets this to require submitters to contract certain other persons and to request them voluntarily to supply information relevant to their own anticipated handling and uses of the new substance.

Because chemical risk is a function of both effects and exposure, most manufacturers probably will employ various engineering safeguards and industrial hygiene practices to limit exposure and thereby reduce risk. The proposed notice forms would permit, but do not require, manufacturers to describe such safeguards and practices for consideration by EPA in its risk assessments. In addition, the forms include provisions for reporting concerning structure-activity correlations, and industrial process and use restrictions. Information on both may be relevant to the Agency's decisions concerning the need for more data and the levels of risk associated with particular substances, and manufacturers may wish to provide this information so that the agency does not feel it necessary to take any action with respect to a substance.

At his discretion, a manufacturer also would be able to report any information which explains why any risk presented by his new substance is reasonable. Such information should focus upon the economic and other non-risk factors identified by EPA for optional reporting in the notice forms. Further, the information should relate to the possible exposures and exposure levels described by the manufacturer and to the consequences of imposing controls upon the manufacturer and any others who may produce or use the new substance.

EPA will use the notices as a point of departure for performing its risk assessments and unreasonable risk judgments, and not as the exclusive source of information for such decisions. However, the agency will be limited in its ability to obtain information not included in the premanufacture notices within the statutory review period. To the extent time will permit, EPA will use its statutory authorities and other means (e.g., literature searches, contractor support, consultations with scientific and engineering experts) to supplement and verify submittals by manufacturers. In some cases where data in the notices are incomplete or otherwise inadequate, the Agency may make worst case assumptions about possible exposures and risks associated with particular chemical substances.

The Agency intends to provide to the Occupational safety Health Administration (OSHA) all information concerning worker exposures, for use by OSHA in establishing its own standards. EPA and OSHA will work together in evaluating reisks and the need for regulatory actions, but OSHA

will have primary responsibility for evaluation of occupational risks.

If on the basis of its risk assessment EPA determines that a substance may present significant risk to health or the environment, the Agency may evaluate its regulatory options. There are a number of options under TSCA for regulating when EPA finds that a chemical presents an unreasonable risk. These include regulation under § 5(f), § 6(a), and § 7. If the Agency finds that a substance may present an unreasonable risk, it may designate the substance for inclusion on the § 5(b)(4) "risk list," perhaps in conjunction with a significant new use rule for the substance. If additional information about the chemical is required by EPA before making a decision to regulate a chemical under one of these sections, the Agency may issue a testing rule under § 4. Alternatively, under § 5(e), EPA may prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a substance pending development of that information EPA can also use § 8(a) rules to require manfacturers to report information to EPA to fill data gaps.

The Agency may determine that regulation under laws other than TSCA may be appropriate to control or limit risk to health and the environment. If so the Agency may take action under § 9 of the Act to refer actions to other EPA program offices or Federal agencies. Other laws administered by EPA that will be considered include the Clean Water Act, Clean Air Act, Resource Conservation and Recovery Act, and Safe Drinking Water Act. In recommending action under laws administered by other agencies (e.g., Consumer Product Safety Act, Occupational Safety and Health Act), EPA is authorized by TSCA § 9(a) to submit to the other agency a report describing the nature of the risk associated with a given chemical substance. That agency then may take the appropriate action under its statute to control the risk.

During the commercial life of a chemical, exposures and risk may change from those which manufacturers project prior to production. Therefore EPA will follow up certain new substances after their introduction into commerce. Follow-up may be appropriate for new substances with moderate or high toxicities but for which the information contained in premanufacture notices indicates limited exposure. Further, for chemicals for which little or no toxicity data are available, EPA may initiate follow-up action to guard against risk which may result from future increases in exposure.

TSCA provides EPA two basic tools for follow-up of substances once the premanufacture notification period has ended. Under § 8(a), the Agency can require reporting on such matters as changes in chemical production and uses, including increased volumes and new commercial activities which may result in new exposures. EPA also may issue significant new use rules (SNURs) under § 5(a)(2) which would define new uses of existing substances that the Agency determines would be significant. (E.g., uses with resulting exposures which may result in risk to health or the environment.) TSCA requires persons to submit § 5(a) notices before they manufacture or process substances for uses covered by SNURs, thereby enabling EPA to review the substances prior to their production for such uses. The Agency intends to propose initial SNURs for public comment during the latter part of 1979.

D. INTERIM POLICY—SUBMITTAL OF PREMANUFACTURE NOTICES PRIOR TO PUBLICATION OF THE INVENTORY

The premanufacture notification requirement of § 5(a)(1) applies to any new chemical substance which a person intends to manufacture or import on or after the 30th day after publication of the initial § 8(b) inventory. TSCA also establishes a minimum 90-day period, after submittal of a premanufacture notice, during which the submitter may not commence manufacture or import of the substance. Taken together, these provisions may pose a dilemma for a person who intends to commerce manufacture of a new chemical substance within 120 days after publication of the initial inventory. If he is not allowed to submit a premanufacture notice until 30 days after publication of the inventory, he may not be able to commence manufacture on his intended date of manufacture.

To address this practical difficulty, EPA will implement, effective immediately, the following policy with respect to pre-inventory submittals of premanufacture notices. This policy applies only to chemical substances which are believed to be "new," and for which manufacture or import is intended to commence between the effective date of the premanufacture notification requirement (30 days after publication of the initial inventory) and 90 days thereafter.

Persons may submit notices for such substances at any time, but are encouraged not to submit notices more than 60 days prior to publication of the inventory. This is because if a person first manufactures a substance less than 30 days after publication of the inventory he may report it for the inventory under § 710.6(b) and thereby avoid the requirement to submit a premanufacture notice. EPA currently estimates that it will publish the initial inventory in April 1979. The Agency will publish a notice in the FEDERAL REGISTER of the publication date as soon as this date is firmly established.

The official review period for any such premanufacture notice will begin 90 days before the projected commencement of manufacture, and not on the date of submittal. The projected date of commencement of manufacture must be identified in the notice. Manufacture may commence on that date unless EPA acts to control the substance. However, if manufacture commences at a later date, EPA's authority to act under § 5(e) or § 5(f) will extend automatically to the actual date of manufacture, but in no event to a date later than 90 days after premanufacture requirements become effective. The Agency will not use its authority under section 5(c) of the Act to extend the review period beyond the latter date.

Any such notice should be filed on the appropriate notice form which is included in this proposed rulemaking, and in accordance with the proposed rules, 40 CFR Part 720. When the person commences manufacture or import, he must submit a notice of this fact in accordance with proposed § 720.52. At that time, EPA will add the substance to the inventory.

II. PROVISIONS OF THIS PROPOSAL

These rules are modeled in part on the inventory reporting rules, 40 CFR Part 710, promulgated on December 23, 1977 (42 FR 64572). To best understand this proposal, one should be familiar with those rules.

A. APPLICABILITY

1. *Who Must Report.* Section 5(a)(1)(A) of the Act requires any person who intends to "manufacture" a new chemical substance for a commercial purpose to submit a premanufacture notice to EPA. Section 3(7) of the Act defines "manufacture" to include import of a substance into the United States.

Sections 720.10 and 720.11 of the proposed regulations contain EPA's proposed identification of the persons who must submit premanufacture notices and those who are not subject to the notification requirements. These provisions closely follow those established for the initial inventory; see generally § 710.3. Following is a detailed discussion of who must report.

Domestic Manufacturers

Beginning 30 days after publication of the initial inventory any person who intends to manufacture a new chemical substance in the United States for a commercial purpose must submit a premanufacture notice. This reporting requirement also applies to a person who originally manufactures a

new chemical substance for a use which is specifically exempt from these requirments, and who later decides to either manufacture the substance for a non-exempt use or use the already-Manufactured substance for a non-exempt purpose. (See § 720.10(a)(3) & (4).)

Manufacturers of Chemicals Solely for Export

Section 12(a) of the Act states that, except for section 8, TSCA does not apply to a substance which is manufactured solely for export. This general principle is qualified by § 12(a)(2), which provides that the Act applies to such a substance if EPA finds that it will present an unreasonable risk to health within the United States or to the environment of the United States. In addition, section 12(a)(2) authorizes the Agency to impose testing requirements under § 4 upon a substance manufactured solely for export to determine whether it presents such an unreasonable risk.

Section 12(a) indicates the Congress' intent that EPA should protect against unreasonable risks to the United States, but not seek to regulate activities which do not present risk to health or the environment in the U.S. Section 12(a) also might be interpreted to mean that EPA should not require premanufacture notification for new substances intended solely for export. However, this would create a major gap in the statutory scheme. Although a person manufactures or processes a substance solely for export, there may be significant exposure to workers in the United States, as well as release of the substance to the air or water in this country. Section 12(a)(2) indicates that Congress did not intend to exempt such a substance from coverage by the Act if it presents an unreasonable risk within the United States. But if EPA is not aware that a new substance is being manufactured domestically, the Agency could not require testing of, or otherwise control, the substance. Without a notice that a substance is being manufactured, EPA may not be able to act until a significant health or environmental problem occurs, and this is contrary to the preventive approach to toxic substances embodied in § 5. Therefore when read in light of the Congressional purposes, § 12 authorizes EPA to require premanufacture notices for new chemical substances manufactured solely for export.

Section 720.10(a)(1) would apply the premanufacture notification requirements to new substances manufactured in this country solely for export. Manufacturers of substances for export also were subject to reporting for the initial inventory under § 710.3(a). EPA will implement this provision in the spirit of § 12d(a) by limiting its information requirements and notice review to risk to persons and the environment within the U.S. In addition, because the exported substances will be added to the inventory, EPA will evaluate the substances to determine whether the Agency should issue significant new use rules to anticipate end uses within the U.S. Notice requirements for manufacturers of substances intended solely for export are discussed below under "Information Submittals." (For a further discussion of this issue, see Section II-A-1-b of the Support Document.)

Importers

Under § 720.10(a)(2), persons who intend to import new chemical substances "in bulk form" would be subject to premanufacture notification requirements beginning 30 days after publication of the initial inventory. Under § 720.10(b)(1), persons who intend to import new chemical substances as a part of mixtures would be subject to premanufacture reporting beginning 30 days after publication of the revised inventory. The proposed rules do not require persons to submit notices for new substances which they import as part of articles. However, EPA is continuing to evaluate the issue of reporting by importers of articles, and in the future may propose rules to apply the premanufacture reporting requirements to chemical substances imported as part of articles.

Proposed § 720.2 defines "import in bulk form," and specifies that chemical substances imported in containers used for transportation or containment are not substances imported as a part of articles. Therefore such chemicals would be subject to the premanufacture notice requirements.

The term "importer" was defined for purposes of the inventory. In this proposal, EPA has revised that definition, on the basis of Customs' Regulations, (19 CFR Part III) to include a list of the types of persons which are included in the term. Each of the persons listed would be responsible for ensuring that a premanufacture notice is submitted to EPA. In this rulemaking, the Agency is proposing a special form for use by importers, plus special reporting procedures which apply to imported substances. These provisions are discussed below under "Information Submittals." Also see § 720.21 of the proposed rules.

In the near future, the Department of Treasury will propose regulations concerning import of chemical substances. These regulations would implement § 13 of TSCA, and may include provisions for identifying and preventing entry into this country of new substances which are not imported in compliance with the premanufacture requirements.

Processors

In § 720.11(b), EPA proposes that persons who only process new chemical substances are not subject to the premanufacture notification requirements of § 5(a)(1)(A) of the Act. If EPA receives a notice from a processor or user, the Agency will consider the notice to be invalid under § 720.34(b)(1)(vii) and will not process it. Of course, a processor may take part in the notification process by submitting information under § 720.20(e). Also, a processor may prepare the premanufacture notice as an agent of the appropriate manufacturer or importer, provided the latter signs the notice form.

A substance may have been manufactured previously solely for a use which is exempt from coverage by the Act, such as a pesticide, food, drug, or cosmetic. If such a substance subsequently is manufactured for a "TSCA use," the manufacturer then would be subject to the premanufacture notification requirement. However, a special reporting problem would arise if the manufacturer intends to produce a substance for a use excluded from TSCA, but another person intends to process the substance for a TSCA use. If the manufacturer knows of the processor's intended use of the chemical, the manufacturer would be required to submit a premanufacture notice. However, for a variety of reasons the processor may not inform the manufacturer that a TSCA use of the substance is intended, and if the manufacturer has no knowledge of this intended TSCA use, he may not know that he should report.

In the immediate future, processors can resolve this problem by reporting substances for the revised inventory. EPA is exploring various alternatives to address the problem after expiration of the revised inventory reporting period. One alternative would be to develop significant new use rules under § 5(a)(2) which would require reporting by both manufacturers and processors.

2. *What Chemical Substances Must Be Reported.* Section 5(a) of the Act provides that the premanufacture notification requirements extend to all new chemical substances manufactured for commercial purposes, except to the extent that notification is exempted by § 5(h). Under § 5(h) chemical substances manufactured only "in small quantities" solely for purposes of research and development are excluded from the premanufacture notification requirements, provided that certain conditions are observed. The other exemptions provided by

§ 5(h) require application to, and a determination by, EPA.

Under §710.4 of the Inventory Reporting Requirements, EPA identified those substances subject to reporting for the inventory. In general, reporting was required for substances manufactured or imported for commercial purposes since January 1, 1975. Section 710.4(c) of those regulations exempted substances excluded from reporting by the Act. In addition, in § 710.4(d) EPA excluded certain other substances which have no commercial purpose separate from substances, mixtures, or articles of which they are a part.

Sections 720.12 through 720.15 of these proposed regulations identify those substances subject to premanufacture notification requirements. These sections are largely identical in language to the analogous inventory provisons. The following discussion focuses on the most significant changes.

General. The most fundamental distinction between inventory and premanufacture reporting is that notification is required under these proposed rules only for *new* chemical substances, i.e. those not included on the inventory to be published by EPA.

Chemical substances will be included on the inventory of chemical substances in a variety of forms. Some substances will be included in a category. For example, any chemical which is "naturally occurring" and which meets the other criteria of § 710.4(b) of the inventory rules will be included on the inventory under the category of naturally-occurring substances. Most other substances will be identified individually by their specific chemical identities (i.e. molecular formulae, chemical structures). It is not feasible to report the composition of certain substances by definite chemical structure diagrams. On the inventory these may be identified by descriptions of the final steps of the methods used to manufacture them. In any event, the published inventory should be sufficient to enable persons to determine whether most chemical substances are included. However, for those substances for which identification is more difficult, EPA will be prepared to assist manufacturers in determining whether substances which they intend to produce already are included in the published inventory.

Persons who reported chemical substances for inclusion on the inventory, and persons who will commence manufacture or import after submittal of premanufacture notices, may assert claims of confidentiality with respect to the specific identities of their chemical substances. In general, if EPA determines that the fact that a particular substance is manufactured or imported in the U.S. for a commercial purpose is confidential, the Agency will not place the specific identity on the published inventory. Instead EPA will publish a generic chemical name in an appendix to the inventory. In general, the Agency will disclose the specific identity of a substance represented by such a generic name only if it is necessary to inform a person who demonstrates a *bona fide* intent to manufacture a substance whether his substance is on the inventory. (Also see below "Major Issues—Confidentiality for Specific Chemical Identity.") The procedures which a *bona fide* manufacturer must follow to make such an inquiry are included in proposed § 720.12(b) and are based upon those which EPA previously promulgated for inventory reporting.

Small Quantities for R&D

Chemical substances intended to be manufactured or imported only in small quantities solely for purposes of research and development would be exempt from premanufacture notification if the submitter complies with proposed § 720.14. Like the inventory rules, this proposal defines "small quantities for R&D" to mean quantities that are no greater than reasonably necessary for scientific experimentation, research, or analysis, including that involved in product development. However, the terms of this exemption differ from the inventory language in two ways.

First, the proposal would delete a note included in the inventory definition which may result in misconceptions regarding the scope of the exemption. That note provided that for purposes of the inventory any substance manufactured, imported, or processed in quantities of less than 1000 pounds annually would be presumed to be manufactured solely in small quantities for R&D purposes, unless the submitter could certify that the substance was used for other purposes, unrelated to R&D. Although the note did not affect the scope of the inventory requirements, it provided guidance concerning certain chemicals which must be evaluated carefully to determine whether they were eligible for inclusion on the inventory. The criteria used to determine whether a substance is manufactured only in small quantities solely for purposes of R&D were whether the substance is (1) used solely for R&D purposes, (2) manufactured in quantities no greater than reasonably necessary for such purposes, and (3) used under the supervision of a technically qualified individual.

With regard to premanufacture notification, the Agency is concerned that submitters may misconstrue the note to mean that premanufacture notices are not required for substances produced in quantities of less than 1000 pounds annually. That is, they may think the note creates an absolute exemption rather than a presumption which must be justified. In addition, persons also could interpret the note to mean that premanufacture notice must be submitted for all substances produced in quantities greater than 1000 pounds annually. Therefore the proposal would delete the note.

This deletion does not affect the scope of the "R&D" exemption. The Agency feels that this deletion will result in manufacturers more clearly understanding the criteria to be used in determining whether a substance qualifies for an exemption under § 5(h)(3) of the Act. These are the same three criteria described above. The Agency intends to establish in future rulemakings numerical or other more precise definitions of "small quantities" for specific substances or groups of substances.

This proposed revision to the inventory definition would not affect the applicability of the inventory reporting requirements and therefore would not, by itself, require EPA to provide manufacturers an opportunity to revise their inventory reporting submittals.

Second, this proposal further implements the terms of the § 5(h)(3) exemption by placing responsibility on the manufacturer to notify certain persons of any risk to health which the manufacturer believes may be associated with the substance. Any such notification must go to all persons engaged in the manufacture, processing, use, transport, storage, or disposal of the substance. This ensures that all persons who may be at risk are apprised of that fact, and not just those who are directly involved in the specific R&D activities. These rules do not prescribe specific methods of notification. Rather, they identify certain acceptable procedures, and leave it to the individual manufacturers to ensure that they adequately inform all of the persons who should be notified. In addition, proposed § 720.14(d) states that upon request manufacturers must make available to EPA, or to any person who may be exposed to the substance, any information on the risk of the chemical.

Test Marketing

Section 720.15 of the proposed rules addresses the test marketing exemption authorized by § 5(h)(1) of the Act. The Act and this rule provide that the exemption may be granted only upon a showing that the test marketing of the substance will not present an unreasonable risk of injury to health or the environment. EPA expects that in most cases this showing will require the same information, and impose sim-

ilar reporting burdens upon manufacturers, as for premanufacture notices. Therefore manufacturers should use the premanufacture notice form to file for any test marketing exemptions. This will facilitate timely Agency review.

Other Exemptions

These proposed rules do not address the three remaining exemptions provided in § 5(h), either because further guidance is not necessary at this time, or because there appear to be no cricumstances at present under which persons will apply for these exemptions.

Intermediates

The inventory rules defined the term "intermediate" in § 710.2 as a substance which is consumed in whole or in part in chemical reactions used for the intentional manufacture of other substances, or which is intentionally present for the purpose of altering the rate of such reactions. However, the inventory rules stated that to be considered an "intermediate" the substance also must be "intentionally removed from the equipment in which it is manufactured." Substances which are not intentionally removed from the equipment in which they are manufactured, were excluded from the definition and from reporting for the inventory. For these premanufacture rules, EPA proposes to change the definition of the term "intermediate," by removing the proviso. Further the Agency is proposing a new term, "non-isolated intermediate," to describe those intermediates which are excluded from premanufacture notification. These modifications are for the purposes of clarity. At this time, EPA does not intend to change the applicability of the premanufacture rules from that set out in the inventory rules.

However, TSCA authorizes EPA to require the submittal of premanufacture notices for non-isolated intermediates. Thus far the Agency has exempted these substances for several reasons. First, such substances often are extremely difficult to identify. In developing the inventory rules EPA received numerous comments on this point. Second because there often will be limited exposure to such substances, often they will result in insignificant exposure, and thus minimal risk, to humans and the environment. But there may be exceptions to this general statement. For example, there is no requirement in these regulations that non-isolated intermediates be produced and handled in closed systems. Further, they may accumulate in residue materials or may be released accidentally as a result of spills or process upsets. In these and other situations, there may be exposure to humans and the environment.

Although at this time EPA is not changing the applicability of § 5 to non-isolated intermediates, the Agency is considering exempting from the premanufacture requirements only those intermediates to which there is, in fact, no exposure, in accordance with § 5(h)(5) of the Act. Therefore EPA solicits comments on how best to achieve this result.

Byproducts, Co-products

As with intermediates, the proposed definition of "byproduct" modifies that contained in the inventory rules without altering the general applicability of § 5. The definition would provide that to be considered a byproduct (and thus excluded from the premanufacture requirements under proposed § 720.13(e)(2)), a substance must be produced *solely* without commercial purpose during the production, use, or disposal of another substance. In addition, EPA is proposing a definition of "co-product." The notice forms would require certain information on both byproducts and co-products, and these proposed definitions should help define those reporting requirements.

B. General Notice Procedures

1. *General Provisions.* Subpart C would require a person who submits a premanufacture notice to use forms developed by EPA. A submitter would be required to provide the information requested by the applicable notification form, unless questions are designated optional, or particular information is not known to or reasonably ascertainable by the submitter. In addition to completing the notice form itself, the person must report test data and other data concerning the environmental and health effects of the manufacture, processing, distribution in commerce, use, and disposal of the substance. The information to be submitted with the notice is discussed below, under the heading "Information Submittals."

A person must submit a notice to the OTS Document Control Officer, at the address indicated on the form, at least 90 calendar days before he commences manufacture or import of his new substance. Submittal of notices to the Document Control Officer will ensure safe handling of any confidential information submitted. Proposed § 720.31 explains when EPA will consider a notice to be officially submitted.

Persons who intend to submit premanufacture notices may contact EPA prior to submittal to resolve certain questions. In addition to the pre-notice consultations which would be specifically authorized by § 720.12(b) and § 720.41(a)(2), persons may seek the Agency's assistance in determining whether they have described their new substances with sufficient specificity, whether specific substances are included on the inventory with non-confidential identities, or whether the use or exposure descriptions for the § 5(d)(2) Federal Register notice are adequate.

2. *How to Assert a Claim of Confidentiality.* Section 14(c) of the Act authorizes EPA to prescribe the manner in which persons assert claims that information is entitled to confidential treatment. EPA has proposed under § 720.40 certain general procedures for asserting such claims; in addition, § 720.41, § 720.42, and § 720.43 contain particular requirements with respect to claims of confidentiality for chemical identity, intended uses of a substance, and information included in health and safety studies.

Any information submitted to EPA in connection with TSCA may be claimed confidential. All claims must be made when the information is submitted. Persons may assert claims of confidentiality for information on the notice form by marking the box provided for that purpose beside the particular item of information. Information other than that entered on the notice form, such as a health and safety study, also may be claimed confidential. If only a portion of a document is claimed confidential, the person must submit a second copy of the material from which he has deleted the information claimed to be confidential. This sanitized copy will be placed in the public file.

Proposed § 720.40(c) provides that submitters must substantiate their claims with respect to specific chemical identity and health and safety studies at the time the information is submitted to EPA. In addition, EPA has considered requiring substantiation for certain exposure information which the Agency believes should be included in the § 5(d)(2) Federal Register notice. To satisfy this substantiation requirement, a person must provide written answers to a series of questions developed by EPA. The basis for this requirement, and the draft substantiation questions, are included in Section III-A of the Support Document.

EPA's treatment under these proposed rules of information for which a claim of confidentiality is asserted is discussed below under "EPA's Processing of Notices."

3. *Early Notices.* Some persons may wish to sumit premanufacture notice substantially more than 90 days before the date of intended manufacture or import. EPA recognizes that early review and, if necessary, regulation of new substances will reduce the adverse economic impacts of such review and

regulation. In addition, early notification provides EPA with more time to review substances before their manufacture. However, some proportion of such substances will not be manufactured for commercial purposes because of changing market conditions. Reviewing such notices will consume scarce Agency time and resources. Furthermore, EPA often may have difficulty reviewing these notices because they may contain highly speculative, or little, information. The proposed rules do not prohibit submittal of notices significantly earlier than the 90 day minimum period established by the Act. However, the rules and form contain special requirements for persons who submit certain early notices. Any person who submits a premanufacture notice must certify that he intends to manufacture or import the substance for a commercial purpose other than only in small quantities solely for R&D. In addition, if a manufacturer submits a premanufacture notice more than three years prior to the date on which he intends to commence manufacture, § 720.20(h) of the proposed regulations requires him to submit evidence of his commitment to manufacture the substance for a commercial purpose. The following types of evidence may satisfy this standard: descriptions of R&D efforts to date and of those planned for the future; information concerning zoning approvals, building permits, contracts, and other licenses or permits to construct and operate production facilities. In addition, EPA is considering requiring the submitter to report more detailed and accurate use and exposure information as it becomes available, up to the commencement of manufacture, to compensate for the fact that information submitted several years early may be highly speculative. The Agency welcomes comment on the feasibility of these approaches, and on the types of information which should be required for early notices.

4. *Chemical Identity.* The specific chemical identity of a new substance is a critical component of a premanufacture notice. If the notice does not include this information, § 720.20(f) would provide that the notice is invalid and that the 90-day revciew period will not begin. If the submitter does not know the specific chemical identity because, for example, the new substance results from the reaction of one or more unknown substances (such as trademarked products), § 720.50(b) would require the person to attempt to obtain this information. If he is unable to secure the identity of the final product or of the reactants, under proposed §720.50(b) EPA may require his supplier to submit that information to the Agency.

5. *New Information or Data.* A submitter may obtain new information relevant to EPA's premanufacture review after he submits the notice. Section 720.20 (i) of the proposed rules would require him to make some of this information available to EPA, to ensure that the information which the Agency reviews is as complete and accurate as possible. This requirement would apply only during the notification period, and would cover new information or data which the manufacturer obtains after he submits his notice, and which materially adds to, changes, or otherwise makes significantly more complete the information included in his notice. EPA has considered extending the time period for submittal of new data to run from the date a notice is submitted until manufacture actually begins, and invites comments on this issue.

6. *Notice of Commencement of Manufacture or Import.* Section 8(b) of the Act requires EPA to add to the inventory new chemical substances, for which notices were submitted under section 5, "as of the earliest date . . . on which such substance [were] manfactured or processed in the United States." EPA proposes to determine this "earliest date" by requiring under § 720.52 that a person submit a separate notice to EPA no later than the day on which manufacture or import of the substance commences. This brief, routine notice would be required under the authority of section 8(a) and section 8(b) of the Act.

C. Information Submittals

1. *General.* Section 5(d)(1) of the Act, "Content of Notice," describes the information which shall be included in premanufacture notices. Section 5(d)(1)(A) references the provisions of § 8(a)(2)(A)-(G) (excluding § 8(a)(2)(e)), which list various types of information including chemical identity, amounts, uses, disposal practices, and byproducts. Sections 5(d)(1) (B) and (C) require a manufacturer to submit test data in his possession or control, and a description of any other data known to or reasonably ascertainable by him, that are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use or disposal of the chemical substance.

In the proposed notification rules and forms, EPA further specifies the information to be submitted. The rules establish the general contents of the forms (§ 720.22) and the legal duty to complete them (§ 720.20). The rules also define the terms "known to or reasonably ascertainable" and "possession or control" (§ 720.2), and provide detailed guidance on the data submittal requirements of § 5(d)(1) (B) and (C) (§ 720.23). The forms themselves specify the information to be submitted, including that referenced in § 5(d)(1)(A). The submitter must provide the information identified on the appropriate form as mandatory, insofar as it is known to or reasonably ascertainable by him. In addition, in his discretion he may provide information in the optional part of the form.

In proposed § 720.2 EPA defines "known to or reasonably ascertainable" to include all information in a person's possession or control, as well as other information that a reasonable person similarly situated might be expected to know or could obtain without unreasonable burden or cost. EPA has interpreted this legal standard to require the following. First, § 720.20(e) identifies certain persons whom the manufacturer must contact concerning their anticipated uses of his new substance. Second, for purposes of test data and other data submittals, § 720.23(b)(3) further defines the term to include data known to certain of the submitter's employees or other agents.

The following two sections, "Notice Form Information" and "Test Data and Other Data," identify in greater detail the information to be submitted. The first discusses the scope and level of detail of the notice form requirements, which ones are optional, and the procedures for contacting certain persons for information. The second discusses the scope of and compliance with the requirements concerning test data in the possession or control of the submitter and other data known to or reasonably ascertainable by him.

2. *Notice form information.—Scope.* EPA considered several options for the scope of the requirements specified by the rules and notice forms. First, the Agency could limit the information required to that specifically listed in § 8(a)(2). Second, EPA could expand upon the § 8(a)(2) list by requiring other information which relates to exposures throughout the "life cycle" of a chemical, i.e. manufacture, processing, distribution in commerce, use, and disposal. Third, the Agency not only could expand upon the § 8(a)(2) list for exposure-related information, but also could require other information which explains how and why the submitter (or others) will control possible exposures (e.g., engineered safeguards, industrial hygiene considerations), information explaining risk assessments, and information concerning the reasonableness of certain risks. (These options are further discussed in Section II-C-1-a of the Support Document.)

EPA's proposed rules and forms would implement a modification of the second option. Thus EPA would require submission of the specific infor-

mation listed in Section 8(a)(2) plus other exposure-related information, and would encourage (but not require) submisson of other relevant information which the Agency may consider in determining the need for regulatory controls. Proposed § 720.22 identifies the types of information covered, including each of the items listed in section 8(a)(2). Taken together the rules and form serve the basic purpose of providing EPA the information necessary to evaluate risks associated with new substances and to determine the need for additional effects information, follow-up reporting, or regulatory control. Further, the optional reporting enables manufacturers to submit additional information relevant to EPA's review of new substances (e.g., manufacturing and use safeguards that affect levels of risk; non-risk factors relevant to the reasonableness of particular risks).

In distinguishing between mandatory and optional data requirements EPA sought to balance the types of data and information necessary to perform risk assessments, whether the information is necessary to review all new substances or only some, and the reporting burdens on the submitters. The information designated "optional" is the type of information which a manufacturer of a chemical would want EPA to review, with the hope that the Agency would not take regulatory action, including action under Section 5(e), because of a lack of information. By making this information optional, EPA would reduce the reporting burden on industry without reducing the Agency's ability to perform risk assessments, and would allow submitters to report detailed information if they think it would be important in EPA's review of the notices.

EPA further proposes to limit the scope of these requirements in certain special cases. The information required for imported substances and for substances manufactured solely for export (discussed in greater detail below) would be limited to that necessary for assessing potential risk to health or the environment in the United States. Also, the reporting requirements for byproducts, co-products and other substances related to a new substance would be more limited than for the new substance itself.

Finally, EPA welcomes comments on whether the various questions on the general form are appropriate for substances produced in low volumes by batch production operations. Depending on these comments, EPA may promulgate a briefer form for such substances at the time these rules are promulgated, or thereafter if the need arises. (Also see III-C, "Small Business; Low Volume Chemical," below.)

Mandatory and Optional Data Requirements. EPA Proposes that manufacturers must provide the information contained in the mandatory Parts I and II of the form insofar as the information is known to or reasonably ascertainable by them. At their discretion, they may submit any other information including that requested in the optional Part III.

Part I of the form would require general information necessary to identify the submitter and his new chemical substance. In addition, estimated production volume would be reported (in ranges) for the first five years, with an indication whether the estimates are based on firm orders, forecasts, or speculation. Information on anticipated uses must be reported by function and application. The submitter also would provide the information to be published in the § 5(d)(2) FEDERAL REGISTER notice, including chemical identity, uses, exposure and environmental release estimates, and a description of tests related to health and environmental effects. Finally, the submitter would provide a schematic flow diagram of his manufacturing and processing operations involving the new substance.

Part II of the form would require information and data that will serve as the primary basis for EPA's risk assessments. In section A, the submitter would indicate the properties and effects of the substance which he has evaluated, and would explain any conclusions, evaluations, or assessments he has made concerning the results of such tests. Also, if the submitter has performed a risk assessment he would explain his evaluations of risk. In particular, the submitter must explain any evaluation he has performed of whether the reported data are sufficient to assess the risk associated with a particular property or effect.

Sections B and C would require information related to human exposure and environmental release, at manufacturing and processing sites respectively. Section B would require information on worker exposure, environmental release, disposal, and transport of the new chemical substance and of other substances associated with its manufacture. For worker exposure the submitter would describe the routes of exposure that are expected to occur; the magnitude, duration, and frequency of exposure; and the number of persons that will be exposed. For environmental release, the submitter would estimate the maximum and average amounts of the substance that will be discharged and the concentrations of these discharges. If these concentrations are based on the use of pollution control equipment, the notice would describe the types of equipment, the emission or effluent streams they serve, and the expected efficiency of the equipment. Section C would require similar information on worker exposure, environmental release, and disposal of the chemical substance associated with processing operations.

Section D would require information on general population exposures that may result from use of products that contain the substance. The submitter would identify such products, describe their uses, and estimate the total amount of the substance devoted to each use. In addition, he would estimate the consumer market population and the frequency and duration of human exposures. The submitter also would be required to complete Sections C and D for other persons' operations to the best of his ability, including reasonable estimates when he does not know with factual certainty the answers to particular questions.

In addition to the information required by Parts I and II, a manufacturer may report any other information that he believes is important for a review of the chemical substance. Part III identifies the types of information EPA expects would most often be useful for Agency decisionmaking. Using Part III, the submitter may explain his overall testing and evaluation scheme, and why it is not necessary to develop additional data. Also, he may provide detailed information on structure-activity correlations used in assessing the toxicity of the new substance and related chemicals. The submitter may describe conditions of maximum exposure that may occur through misuse, expanded production, accidental exposure, or new uses, and industrial hygiene programs and engineered safeguards that will be used to prevent or control human exposure and environmental release. Finally, this optional part requests specific information related to the economic significance and benefits of the new substance.

EPA believes that TSCA grants the authority to require submission of the information designated as optional, and will review public comments to determine whether some of the "optional" information should be "mandatory."

Level of Detail. The proposed notice form would require information in varying levels of detail, to the extent known to or reasonably ascertainable by the submitter. For example, the form would require the minimal estimates of human exposure and environmental release data that are necessary to perform general exposure modeling for chemical substances. In addition, the form would require each submitter to provide a manufacturing and processing schematic flow diagram for his new substance, which EPA and the Occupational Safety and Health Ad-

ministration (OSHA) would use to assess potential workplace exposures and environmental releases. Questions on substances associated with the production, use, and disposal of the new substance (e.g., byproducts and coproducts) would require less detail than questions on the new substance itself.

This proposed approach attempts to balance the burden placed on the submitter, the information likely to be known to or ascertainable by him, and the scope and level of information required to perform risk assessments. This approach will enable EPA to perform risk assessments commensurate with the level of detail that submitters are able to provide and to identify potential problem areas for further investigation.

Information From Other Persons. Under Section 5(d)(1) of the Act, submitters must provide the requested information insofar as it is "known to" or "reasonably ascertainable" by them. EPA could interpret this statutory language in a number of different ways. First, the Agency could offer no guidance or interpretation of this language and allow manfacturers and importers to complete the notice forms in good faith to the best of their ability. Second, EPA could estabish a legal standard for the phrase "known to or reasonably ascertainable," to provide general guidance for manufacturers. Third, EPA could identify certain types of information which the Agency assumes to be known to or reasonably ascertainable by all manufacturers. Fourth, the Agency could establish procedures for submitters to identify and obtain information "known to or reasonably ascertainable" by them, identifying persons whom a submitter should contact and specifying types of information which the submitter should request. (These alternatives are discussed further in Section II-C-1-c of the Support Document.)

EPA has incorporated a combination of the second and fourth options into the proposed rules. In proposed § 720.2 EPA defines "known to or reasonably ascertainable" to include all information in a person's possession or control, as well as other information that a reasonable person similarly situated might be expected to know or could obtain without unreasonable burden or cost. Complementing this definition, proposed § 720.20(e) identifies persons whom each manufacturer must contact concerning their anticipated processing uses of his new chemical substance. EPA proposes to treat compliance with these procedures as minimum compliance with the Act's notification requirements.

In general, the proposed rules would require a manufacturer to contact persons to whom he may subsequently supply the substance, and whom he is able to identify without undue effort or cost. However, a manufacturer need not contact all such persons, if he believes that they will provide duplicative information (in which case he may contact a representative sample of them) or if he believes that their information will not materially add to, change, or otherwise make significantly more complete that which he himself includes in his notice. Thus a manufacturer would have considerable discretion to reduce his responsibilities to contact others.

In a separate Processing and Consumer Use Form, EPA has specified the information which a submitter must request from other persons. Most of the questions in this form concern exposures resulting from processing, use, and disposal. A submitter would be required to send this form to the appropriate persons prior to submittal of his premanufacture notice. Section 720.20(e)(4) would require him to include in his notice all information which other persons provide to him. However, the manufacturer need not delay submittal until his customers respond, and any failure of theirs to respond would not affect the validity of his notice.

The persons contacted would not be under any legal obligation to respond to these requests for information. However, EPA would be able directly to require the information under the supplementary reporting provisions of § 720.50, or could make worst case assumptions about possible exposures associated with processing and use, and initiate control actions based upon such assumptions. Therefore those contacted may decide that it is in their own best interests to provide the information.

Because much of the information requested may be confidential, the proposed rules authorize persons contacted to respond directly to EPA and to make claims of confidentiality for any information submitted. Further, the rules and forms would require a submitter to tell all persons whom he contacts that they are not legally obligated to respond, and that they may report either to the submitter or directly to EPA.

Finally, the manufacturer would be required to certify in the notice his compliance with these procedures, including the names and addresses of the persons he contacted, and a designation of those who have provided information to him or who have indicated that they intend to respond directly to EPA. Also, if a manufacturer limits the number of persons whom he contacts, he must briefly explain in his certification how and why he did so.

Reporting Requirements For Substances Manufactured Solely For Export. Proposed § 720.10(a)(1) requires persons who intend to manufacture substances solely for export to submit premanufacture notices. Manufacturers of chemical substances solely for export would use the same premanufacture notice form as manufacturers for domestic use, except that questions on end uses and exposures outside the United States (which do not present risks to the United States) would be optional. In addition, a submitter would not be required under § 720.20(e) to contact persons who may process or use the substance in another country unless the uses and exposures outside the United States may present a risk to the health or environment of the United States. EPA requests comments on how such uses and exposures could be identified.

Reporting Requirements For Importers. Section 720.21(b) would require importers to use a special reporting form which is similar in many respects to that for domestic manufacturers. One major distinction is the deletion of questions pertaining to human or environmental exposures which may occur abroad as a result of the manufacturing or processing of new substances. As with the reporting requirements for substances manufactured solely for export, exposures resulting from those phases of a substance's life-cycle which occur outside of the United States generally are not of concern to EPA unless they present a risk to health or the environment in the United States. The Agency requests comments on how exposures presenting such a risk can be identified.

Like domestic manufacturers, importers must contact potential processors or users of their new substances to obtain use and exposure information. In addition, § 720.21(c) would require importers to request certain information from their foreign suppliers and manufacturers: importers would send these persons a specially prepared form which requests several types of information for the new substances, including all existing test data. The foreign manufacturers and suppliers would not be legally obligated to provide the information requested. However, EPA believes that in many cases foreign companies would find it in their best interest to cooperate, to avoid possible EPA regulatory actions.

EPA recognizes that foreign companies may have legitimate concerns about the confidentiality of information which they submit to the Agency. To encourage their cooperation, the rules permit foreign manufacturers and suppliers to report directly to EPA, rather than through their importers, and permit them to assert claims of confidentiality with respect to any data which they provide in ac-

cordance with the Act. The proposed rules do not specifically address the situation in which the importer is the same person as the foreign manufacturer or supplier, or in which the companies are separate entities but part of the same corporate structure. In such cases, an importer should consult the definition of "possession or control" to determine the information which he must submit.

3. *Test Data and Other Data.—Scope.* Section 720.23 of the proposed rules requires manufacturers to submit reports and studies of test data in their possession or control, descriptions of other data (e.g., data concerning structure activity relationships) in their possession or control, and descriptions of any data (test data or otherwise) not in their possession or control but known to or reasonably ascertainable by them. These requirements would apply to data concerning the new chemical substance. They also would include data for impurities, byproducts, coproducts, degradation products, or other chemical substances which are related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Under § 720.23(c), data on related chemicals would be required only if the chemicals are not on the inventory of existing chemical substances. The Agency believes that effects data on such related substances are necessary to effectively evaluate risks which may result from activities involving the new substance.

Proposed § 720.2 defines "test data" to include data and information which result from a variety of methodological approaches. Thus the definition applies to data from studies, experiments, recorded observations, monitoring, and measurements—all of which EPA considers to be covered by the word "test" as it is used in the Act. In addition, the proposed definition includes both formal and informal tests. (See EPA's proposed definition of "health and safety study" in § 720.2, which clarifies EPA's interpretation that test for which data are submitted under section 5(d)(1)(B) are the same as health and safety studies.) The definition also provides that "test data" includes not only the raw data *per se*, but other information which is relevant to the development and analysis of the data. This specifically includes any risk assessments concerning the data, as well as protocols, results, and conclusions. Also, chemical identity is included as a part of the data.

Test Data in the Possession or Control of the Submitter. Pursuant to section 5(d)(1)(B) of the Act and § 720.23 of the proposed rules, a manufacturer must submit with his notice (in the form and manner prescribed by EPA) any test data in his possession or control which are related to the effects of the manufacture, processing, distribution in commerce, use or disposal of the new substance upon health or the environment.

EPA's proposed definition of "possession or control" in § 720.2 contains a number of provisions which specifically identify persons or organizations related to the manufacturer and whose information or data EPA presumes to be in the submitter's possession or control. These include subsidiary and parent companies, plus certain other related companies which are associated with development and commercialization of the chemical substance. With regard to employees or other agents of the submitter, the proposed definition would apply to information in the business files of those who are associated with R&D, or with test or commercial marketing of the new substance. As proposed, "possession or control" also includes information in the possession of certain contractors and shared funding facilities. Finally, the proposed definition applies to the information which is known to or reasonably ascertainable by the submitter and which must be given to him upon request. Basically, this interprets the word "control" and clarifies that some, but not all, of the information which is known to or reasonably ascertainble by a person is in his possession or control. (Note that EPA's proposed definition of "known to or reasonably ascertainable" includes all information in a person's possession or control.)

The proposed rules require manufacturers to submit full reports on test data relevant to certain health effects, ecological effects, physical and chemical properties, and environmental fate characteristics which are listed in § 720.23(a)(3). To mitigate the reporting burden of this requirement, § 720.23(a)(5)(i) would allow submitters to provide abstracts for any other test data, provided the submitters agree to submit full reports upon request by EPA. In addition, under proposed § 720.23(a)(4)(ii) manufacturers need not reorganize reports which have been published prior to the effective date of the final premanufacture regulations. Finally, if test data have been published in the open scientific literature, § 720.23(a)(2) would authorize submitters to provide the papers in which they appear, instead of the full reports.

In the future the Agency will publish guidance on the form of test data submittals, "Formats for Data Submitted Under the Toxic Substances Control Act." Use of these formats will facilitate EPA's review of premanufacture notices, including the use of electronic data processing techniques. Pending publication of these formats, the following interim guidance applies. In general, a full report on the effects and properties listed in § 720.23(a)(3) should include the following parts: abstract, introduction, experimental methods and materials, results, discussion of data analyses, conclusions, and references. (Briefer reports may be appropriate for certain effects. See Section II-C-2 of the Support Document.) An abstract for other test data should briefly describe the purposes, methodolgy, results, and conclusions of the study.

Other Data Known to or Reasonably Ascertainable by the Submitter. Section 5(d)(1)(C) of the Act requires a manufacturer to submit descriptions of any other data concerning the environmental and health effects of the manufacture, processing, distribution in commerce, use or disposal of his new substance, insofar as the data are known to or reasonably ascertainable by him. Proposed § 720.23(b) implements this provision. Section 720.2 would define "known to or reasonably ascertainable" to mean "all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost." For the purposes of data submittal requirements, § 720.23(b)(3) further would construe this term to include data which are known to the submitter's employees or other agents who are associated with research, development, test marketing, or commercial marketing of the substance. As further guidance, § 720.23(b)(3) would include examples of test data for which descriptions should be submitted. These include data which such employees or agents learn about through discussions, attendance at symposia, or by reading scientific articles.

Incomplete Reports. Sections 720.23(a)(4)(iii), (a)(5)(ii), and (b)(4) of the proposed rule exempt incomplete reports and studies from the full data submittal requirements of § 720.23. However, the submitter would be required to describe the nature and objective of any such study, report or test, its principal investigator, laboratory contacts, progress to date, types of data collected, significant preliminary results and anticipated completion date. In addition, if the study or report yields significant results prior to the expiration of the notification period, and if the results were not submitted with the premanufacture notice, the manufacturer would be required to immediately submit the relevant study, report, or test results to EPA.

Data That Need Not be Submitted. Proposed § 720.23(c) contains provisions for data which need not be submitted to EPA. First, manufacturers may submit standard literature cita-

tions for data which appear in periodicals listed in Appendix I of the rules. These are periodicals to which EPA has immediate access, and the number of periodicals listed will increase as the Agency's access capacity increases. Second, persons are not required to resubmit any data previously submitted to EPA or another Federal agency, provided EPA is not now prevented from accessing those data because of prior claims of confidentiality. Third, efficacy data need not be submitted. Fourth, test data on exposure to human or ecological populations outside the United States need not be submitted. Finally, persons need not submit data on impurities, byproducts, co-products or other related chemicals which are themselves included on the inventory.

D. EPA'S PROCESSING OF NOTICES

1. *Acknowledgement of Receipt.* Under the procedures proposed in Subpart D, EPA would acknowledge receipt of each premanufacture notice. This receipt would bear the date when the OTS Document Control Officer receives the notice, and the 90-day notice review period would begin on this date. As discussed below, under § 720.34 and § 720.35 EPA may extend the review period for up to 90 additional days.

2. *Confidential Treatment of Information Contained in Premanufacture Notices.* When information is submitted and is covered by a claim of confidentiality asserted in accordance with these rules, EPA will disclose that information only to the extent permitted by the Act, these rules, and EPA's Public Information rules, 40 CFR Part 2. Basically, this means that EPA will not disclose information claimed as confidential without prior notice to the submitter. If a person asserts a claim, but fails to submit any substantiation or, in the case of a health and safety study, fails to submit a sanitized copy, he will be given an opportunity to correct this problem before EPA releases the information.

EPA will review all confidentiality claims asserted for information in health and safety studies, to assure the maximum availability of such information to the public. In addition, the Agency will in every case review a claim with respect to specific chemical identity prior to adding a substance to the inventory. EPA may review claims with respect to other information at any time; however, the Agency will review most claims only upon receipt of Freedom of Information Act requests.

EPA will deny confidentiality claims if it finds that disclosure of the relevant materials would not reveal confidential business information. In general, EPA will grant confidentiality to materials in health and safety studies only if the Agency determines that release would disclose confidential information concerning the manufacturing or processing process for a chemical, or the proportions of a mixture. However, for the period prior to commencement of manufacture, EPA will withhold the chemical identity of a substance as part of a health and safety study if the person shows that release would disclose confidential business information. (EPA's proposed resolution of the question of confidentiality for specific chemical identities is discussed in detail in Section III A of this supplementary information.)

3. *Federal Register Notice.* Under section 5(d)(2) of the Act, five days after EPA receives a premanufacture notice the Agency must publish in the FEDERAL REGISTER, subject to § 14, a notice which includes information identifying the new substance, its "uses or intended uses," and any data developed pursuant to a § 4 rule or to a designation under § 5(b)(4) that the substance may present an unreasonable risk. In implementing § 5(d)(2), EPA faces a conflict between the need to keep certain information confidential, and the need to make information public and thus facilitate public oversight of new substances as intended by Congress. Section 720.32 contains EPA's proposed resolution of this conflict.

As a general rule, EPA will identify the substance in the FEDERAL REGISTER notice by its specific identity. However, if the submitter claims identity to be confidential, the Agency will identify the substance by a generic name.

If a person asserts a valid claim of confidentiality for use information submitted in a notice, EPA will protect this information. However, § 720.42 provides that when a person asserts such a claim, he must at the same time provide non-confidential information concerning the generic uses of the substance and the human and invironmental exposure which may occur. This exposure information will focus on identifying the populations which may be exposed to the substance (e.g., consumers, workers), and the extent of the exposure which is likely to occur. In addition, the person would indicate the degree of environmental release of the substance at various stages in its life cycle. This non-confidential data will be published in the § 5(d)(2) FEDERAL REGISTER notice.

EPA believes that Congress intended information on uses of new substances to be published so that the public can estimate the types and extent of potential human and environmental exposures to the substances. With an understanding of likely exposure, the public more effectively may exercise its opportunities for participating in review of chemical risks. By providing for the submittal and publication of exposure information, EPA will address this public need for information without releasing technical use information, which may be the most commercially sensitive type of information included in the premanufacture notice.

Under § 720.32(b)(3), in the section 5(d)(2) notice EPA would list all test data reported as part of a premanufacture notice, and would publish submitter-prepared abstracts for much of this test data. These abstracts would not contain any confidential information. EPA rejected a suggestion that it publish only those data developed in connection with § 4 testing requirements or § 5 (b)(4) designations. Much of the test data submitted with section 5 notices will have been developed independently of the section 4 and section 5(b)(4) requirements, but are relevant to the public's interest in new chemical substances.

Proposed § 720.32 provides that EPA will file this notice with the FEDERAL REGISTER within five days after the Agency receives the premanufacture submittal. Because of this time constraint, the Agency will utilize elements of the notice form for the Federal Register notice, including the submitter's proposed generic chemical identity and use information. However, if any of this information proves inaccurate or significantly more generic than necessary, EPA may publish and amended FEDERAL REGISTER notice, subject to the Agency's confidentiality rules in 40 CFR Part 2.

4. *Deficient Notices.* The information required to be submitted by these rules and the forms is necessary for EPA's effective review of new substances. If a person does not follow these rules, EPA may consider his notice to be deficient.

In §720.34, EPA proposes that its response to a deficient notice would depend upon the nature of the deficiency, distinguishing between those deficiencies of a relatively minor nature for which the Agency may request corrections, and those which are more serious and which will render a notice invalid. Section 720.34(a) provides that within 30 days after receipt of a notice EPA may request a submitter to correct minor or technical deficiencies (e.g., failure to date the notice; typographical errors which render entries unclear or ambiguous.) For thse types of deficiencies, the Agency will suspend the notification period for up to 30 days, pending correction of the notice. If the submitter does not make the correction within this time period, EPA may declare the notice to be invalid.

Section 720.34(b) identifies grounds for invalidation of a notice. These in-

clude failure to comply with the procedures for obtaining information from other persons, in accordance with § 720.20(e) or § 720.21(c); submittal of a notice by a person other than the one who intends to manfacture or import the substance; failure to provide any information requested on the notice form, unless the form clearly indicates that the information is optional; and failure to provide any information required by § 5(d)(1)(B) and (C) of the Act, in accordance with § 720.23. EPA would be able to determine at any time during the notification period that a notice is invalid for these reasons.

Finally, § 720.34(c) provides that if EPA discovers after expiration of the notification period that a person submitted intentionally false or misleading statements concerning a material aspect of his notice, the Agency may find that the notice itself was invalid. If so, the manufacture of that substance will constitute a violation of the Act.

5. *Extension of Notification Period.* Section 5(c) of the Act provides that EPA can extend the original 90-day notification period by up to an additional 90 days for "good cause." Section 720.35 of the rules provides that EPA will notify the submitter by certified mail if the Agency extends the period, and provides examples of situations which EPA believes could constitute good cause for extension. In addition, § 720.35(c) provides that EPA may issue a Notice of Continuing Review if the Agency is actively evaluating the substance for regulatory action after expiration of the notification period. This Notice of Continuing Review would be for informational purposes only, and would not extend the notification period or prevent a person from beginning to manufacture or import the substance.

6. *Supplementary Reporting.* Despite the reporting requirements proposed in these regulations and in the forms, for some substances of particular concern the premanufacture notices may not contain sufficient information for EPA to evaluate the chemical substance and to initiate regulatory actions or prescribe follow-up reporting requirements. In particular, it is possible that some of the information specified in the notice form may not be known to or reasonably ascertainable by the submitter. Further, for some substances of particular concern, the Agency will need informatin in addition to that required by the form.

To deal with these information gaps, in § 720.50 and § 720.51 EPA is proposing rules pursuant to § 5 and § 8 of the Act under which EPA may require defined classes of persons (including submitters, potential processors of new substances, and manufacturers of reactant products) to report specific types of information with respect to new chemical substances for which premanufacture notices have been submitted. Under these proposed rules EPA may require the specified information either during the premanufacture review period or after its expiration. These requirements would be issued administratively and not through independent rulemakings for each individual case. The issuance of each such reporting requirement would be subject to the approval of the Assistant Administrator for Toxic Substances or the Deputy Assistant Administrator for Program Integration and Information.

Timely availability of information is particularly important to EPA's decision-making concerning actions under § 5(e) or § 5(f). Further, this approach would enable EPA to direct information requirements to identified persons, and thereby diminishes the need to promulgate rules of general applicability to large numers of manufacturers. It also precludes the need for more extensive and burdensome initial notification requirements for all new substances by permitting the Agency to acquire necessary information on selected substances of concern to supplement that in the notice form.

7. *Supplementary Reporting—Small Business Definition.* To the extent that supplemental reporting under § 720.50 of these proposed rules is based upon the authority of § 8(a), EPA generally may not impose a reporting requirement on a "small manufacturer or processor." EPA must define or otherwise construe "small" in a manner which balances EPA's need for this information with the reporting burden placed upon small companies.

For purposes of these supplemental reporting requirements, EPA is proposing to define as a "small" business any company with annual sales of less than $1,000,000. EPA estimates that this would exclude from such requirements 44% of the chemical manufacturers in this country, who account for 0.8% of manufacturers' sales and 1.4% of manufacturers' employment. When considered with the estimated average reporting costs (which are relatively low) and the probably infrequent use by EPA of the proposed supplemental reporting authority, this definition will not result in a significant burden upon industry.

EPA has considered several other options to this single definition of "small business." First, the Agency could define the term (and hence the applicability of the supplemental reporting requirements) on a case-by-case basis, balancing the costs to the particular person reporting the specific information against EPA's need for it. Second, the Agency could define "small business" according to annual sales in conjunction with the projected sales volume of the new substance. Third, EPA could develop a multiple definition which assigns a separate number (based, for example, upon annual sales) to each type of data or task which the Agency may require. Fourth, the Agency could use a dual definition: companies under a lower limit (expressed in terms of sales, number of employees, or other factors) generally would not be subject to supplemental reporting; firms above an upper limit always would be covered; and for those in between EPA would decide on a case-by-case basis. These options are discussed further in II-D-8 of the Support Document, where EPA has estimated the impact of the reporting requirements at five different levels of annual sales.

8. *Actions under section 5(e) or section 5(f) of the Act.* Under section 5(e) of the Act EPA may issue a proposed order to regulate the manufacture, processing, distribution in commerce, use or disposal of a new substance if the Agency determines that the information available is insufficient to evaluate its health or environmental effects, and that the substance either (1) may present an unreasonable risk of injury to health or the environment, or (2) will be produced in substantial quantities and there may be significant or substantial exposure to the substance. If a manufacturer or porcessor objects to a proposed order, or if EPA has not issued a proposed order 45 days before expiration of the notification period, EPA may apply to a U.S. District Court for an injunction to regulate a new substance under § 5(e). Such an order or injunction remains effective pending development and submittal to the Agency of sufficient data to evaluate the substance's effects.

Section 5(f) authorizes EPA to regulate a new substance if there is a reasonable basis to conclude that the substance will present an unreasonable risk to health or the environment before a rule promulgated under Section 6 can protect against such risk. To ban manufacture of a chemical, EPA may issue a proposed order; if EPA has not issued a timely order, or if a manufacturer or porcessor objects to the order, EPA must apply to a U.S. District Court for an injunction. Otherwise the Agency may regulate a chemical under section 5(f) by issuing a section 6(a) rule which is immediately effective upon publication in the FEDERAL REGISTER. Sections 720.36 and 720.37 of these rules would establish procedures for actions under these authorities.

Sections 5(e)(1)(B) and 5(f)(3)(C) of the Act provide that, on or before the

issuance of a proposed order, EPA must notify "each manufacturer or processor, as the case may be" of the basis of EPA's determination to regulate a substance under these authorities. Any such person may object to the order within 30 days after he receives it. The Act is unclear whether EPA must notify only the submitter of the notice (which in the case of a new substance will be the manufacturer or importer). It is possible that Congress intended the term "processor" to apply only with respect to proposed orders concerning "significant new uses"; both manufacturers and processors may be required to submit notices for such uses. In § 720.36 and § 720.37, EPA proposes that the Agency will send notices of proposed orders concerning new substances not only to the manufacturers but also to other persons who would be affected by the orders, including processors and users. Because EPA may not be able to identify all interested persons, the Agency proposes both to inform directly the submitter and other persons whom he has identified in accordance with § 720.20(e), and to publish a FEDERAL REGISTER notice which describes the proposed order and persons who may object to it.

The Act does not provide a particular mechanism for the modification or revocation of orders issued under § 5(e) or § 5(f). Sections 720.36(b)(5) and (6), and § 720.37(b)(5), provide that any person who is affected by an order may petition EPA for its modification or revocation if there has been a change in the factors relevant to EPA's decision to issue the order.

Section 5(e)(2)(D) of the Act does not state how long EPA may evaluate test data submitted pursuant to an injunction (issued under § 5(e)(2)(A)) before the appropriate United States District Court may dissolve the injunction. Section 720.36(c)(2) would establish an administrative procedure whereby EPA will inform the submitter within 90 days of receipt of the data whether EPA will petition the court to modify or dissolve the injunction; whether the Agency intends to propose a rule under § 6(a); or whether, because of the bulk or complexity of data, the Agency has not completed its review and will oppose and petition to dissolve the injunction at that time.

9. *Compliance and Enforcement.* EPA considers the success of the premanufacture notification program to be vital to the effectiveness of the TSCA chemical control program as a whole. Consequently, the Agency will make every effort to ensure compliance with the mandates of § 5 of the Act and with the rules promulgated thereunder.

EPA will make a major effort to identify and take enforcement action against violators of the premanufacture notification rules. Pursuant to § 15 and § 16 of the Act, any person who does not comply with the premanufacture requirements may be liable for a civil penalty of up to $25,000 for each violation. For the purposes of § 16, each day a violation continues constitutes a separate violation. In addition to any such civil penalty, knowing or willful violations of these rules may lead to the imposition of criminal penalties in the amount of up to $25,000 for each day of violation and to imprisonment for up to one year. In addition, the Agency may utilize any of the remedies available to it under section 17 of the Act, including seeking injunctions to restrain persons from violating the premanufacture rules, and seizing any substances manufactured in violation of the rules.

Individuals as well as corporations will be subject to enforcement actions. Sections 15 and 16 apply to "any person" who violates various provisions of TSCA. Thus in actions under § 16, EPA may at its discretion proceed against individuals, such as corporate officials, as well as the companies themselves. In particular, this includes individuals who report false information or who cause false information to be reported.

Persons who are subject to these rules should be fully aware of the potential magnitude of penalties for violations. Section 5 and these rules require manufacturers to submit complete and valid premanufacture notices at least 90 days before the start of manufacture of new substances. If a person does not submit a complete and valid notice he may be subject to penalties of up to $25,000 per day. Persons who submit false information may be subject to penalties calculated as if they never filed their notices. EPA also may impose penalties for reporting false data and tests, although the reporting is done pursuant to the optional reporting sections of the notice form. Such false information would have a damaging impact on the effectiveness of the program because it could result in the Agency's failing to take action under § 5(e) and § 5(f) during the premanufacture period in cases where such action was appropriate. Such violations, however, are largely a matter of degree and may be the subject of lesser penalties as particular cases warrant. Further, EPA will direct its resources to the detection of violations of other aspects of the premanufacture rules, particularly the exemption for research and development. Finally, the Agency will apply a less vigorous enforcement approach towards minor deviations from and technical violations of the rules and forms.

III. MAJOR ISSUES

A. CONFIDENTIALITY FOR SPECIFIC CHEMICAL IDENTITY

If a person claims that the fact that he intends to manufacture, import or process a particular chemical substance is confidential, several issues arise under TSCA. EPA's proposed approach to confidentiality of specific chemical identity is set forth in § 720.41. In choosing this proposed approach, EPA balanced the competing concerns of Sections 5, 8 and 14 of TSCA.

Section 5(d)(2) of the Act requires EPA, within five days of receipt of the notice, to publish in the FEDERAL REGISTER a notice identifying, among other things, the substance for which a premanufacture notice has been received. This notice is to identify the chemical substance by a generic chemical name unless EPA determines that a more specific identification is in the public interest. The statute provides that publication of this notice is subject to the disclosure of data provisions in Section 14 of the Act.

Section 14 of the Act states that if information reported to EPA under TSCA is exempt from disclosure under the fourth exemption of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)), it may not be disclosed except in the specific circumstances set out in the section. In particular, Section 14(b) of the Act provides that, except for the two classes of information identified below, the Administrator cannot deny a request for information concerning data from a health and safety study with respect to a chemical substance which has been offered for commercial distribution, for which testing is required under Section 4 of the Act, or for which notification is required under Section 5. Two two classes of information which are exempt from disclosure as part of a health and safety study are data which disclose confidential processes used in the manufacture or processing of a chemical substance or mixture, and the confidential proportions of a chemical substance in a mixture.

Section 8(b) of the Act requires EPA to publish an inventory of chemical substances which are manufactured, imported or processed in the United States for commercial purposes, and requires the Administrator to add a chemical, for which notice is submitted under Section 5, to the inventory as of the earliest date that it is manufactured, imported or processed for a commercial purpose in the United States.

EPA believes that Congress intended the Agency to publish a generic chemical name in the FEDERAL REGISTER notice of receipt of a premanufacture notice under Section 5(b)(2) of the

Act, if the fact that anyone intends to manufacture, import or process the chemical substance for a commercial purpose is confidential. This policy is reflected in Sections 720.41(a) and 720.32 of these proposed regulations. Because of time constraints, EPA will not review the claim of confidentiality or the adequacy of the generic name prior to publication of the FEDERAL REGISTER notices. EPA may review the claim of confidentiality and the generic name at a later date, either on its own initiative or in response to an FOIA request or a petition under § 720.41(a)(4)(iii). If EPA denies the claim of confidentiality or determines that the generic name is inadequate, it may publish an amended notice in the FEDERAL REGISTER.

EPA also believes that, *in the absence of submission of a health and safety study,* Congress intended the Agency to hold in confidence a specific chemical identity if the submitter complies with the requirements of the regulations and EPA determines that the fact that the particular chemical substance is manufactured, imported or processed for commercial purposes in the United States by anyone is confidential. This is the policy established in § 710.7 of the inventory reporting rules. EPA is not now proposing to amend that policy.

However, it is likely that many, if not all, premanufacture notices will contain health and safety studies. In addition, while EPA estimates that only 1 or 2 percent of specific chemical identities reported for the inventory will be confidential, comments already submitted to the Agency suggest that persons submitting premanufacture notices will be making such claims in a high percentage of cases.

Thus, for the purposes of premanufacture notices, the more difficult and significant issue is how EPA should handle claims of confidentiality for specific chemical identity if a health and safety study has been submitted. It is clearly implicit in the statute that chemical identity is part of a health and safety study; § 720.2 of these proposed regulations would define the term "health and safety study" to explicitly include chemical identity. Section 3(6) of the statute defines "health and safety study" to include "any study of any effect of a *chemical substance* * * * on health or the environment or on both, including *underlying data* * * *" (emphasis added). It is difficult to imagine any data more basic to a study than the identity of the chemical substance tested. For example, identity allows one to interpret the results of a study and determine whether the appropriate test methodology was followed for the particular chemical.

The legislative history of TSCA indicates that Congress intended the term "health and safety study" to be interpreted broadly. If Congress had intended that chemical identity would not be considered part of a health and safety study, it would have so provided. The statute does provide that in disclosing a health and safety study, the Administrator is not to disclose data on confidential processes used in the manufacture or processing of a chemical substance in a mixture, or the confidential proportions of a chemical substance in a mixture. However, in explaining § 14(b) of the Committee bill, which became § 14(b) of TSCA as enacted, the House report explains:

> In referring to "disclosing the portion of the mixture," the Committee intends to protect confidential trade secret information respecting the specific formulation of a mixture. However, the Committee does not intend to prohibit the Administrator from disclosing the chemical substances comprising the mixture by their order of quantity in the mixture. H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 51 (1976).

Thus EPA considers chemical identity to be part of a health and safety study.

A mechanical reading of the statute would suggest that EPA is required to disclose specific chemical identity as part of a health and safety study (unless that would disclose confidential data on the processes used in the manufacture or processing of a chemical substance or mixture or the proportions of a chemical substance in a mixture) on any chemical which has been offered for commercial distribution, for which testing is required under § 4 of the Act, or for which notification is required under § 5. There are, however, indications in the statute that Congress intended the Agency to draw a distinction between disclosure of specific chemical identity for substances which are being manufactured for "non-exempt commercial purposes," as that term is defined in § 720.2, and chemicals which a person merely *intends* to manufacture for such purposes at some point in the future. In particular, § 5(d)(2) of the Act unmistakably provides that the notice of receipt of a premanufacture notice is to identify the chemical by generic name unless the Administrator determines that more specific identification is required in the public interest. Congress, accordingly, seemed to recognize the importance of confidentiality prior to manufacture of a chemical for commercial purposes. Thus EPA considers chemical identity to be part of a health and safety study.

A variety of policy considerations reinforce the idea that premanufacture confidentiality for chemical identities was intended by Congress. Prior to manufacture of a chemical for non-exempt commercial purposes, exposure of the public to the chemical is minimized. The chemical will usually be manufactured solely in small quantities for research and development, and under § 5(h)(3) of the Act (and § 720.14 of the proposed regulations) all persons engaged in the manufacture, processing, use, transport, storage or disposal of the substance must be notified of any risk to health which may be associated with the chemical. There also is the possibility that the chemical will never be manufactured for non-exempt commercial purposes, either because of a business judgment on the part of the submitter or because of regulation by EPA. If the chemical is not to be manufactured, imported or processed in the United States for non-exempt commerical purposes, there may be no reason to disclose its confidential chemical identity to the general public or a business competitor. Lastly, manufacturers and importers have impressed upon the Agency the special importance of confidentiality during the period prior to commencement of manufacture. Often the first entrant into a new market has a very real competitive advantage. Disclosure of confidential identity at that time could result in competitive harm and, more broadly, in reduction of technological innovation. Manufacturers may protect their investment in reserach and development of a new substance in some cases by obtaining a patent. While disclosure of chemical identity of a substance does not appear to affect U.S. patent rights, various industry comments have indicated that premature publication may endanger patent rights in certain foreign countries. EPA welcomes comment on the relationship between the disclosure of identity and competitive effects abroad.

Accordingly, EPA is not persuaded that Congress intended the Agency to take a mechanical approach to disclosure of specific chemical identity as part of a health and safety study. Therefore, the Agency in these regulations is proposing a pragmatic position with regard to disclosure of health and safety studies submitted under § 5 of TSCA. (The Agency is not here proposing a policy for disclosure of identity as part of a health and safety study if the chemical is subject to a testing rule under § 4 or a reporting rule under § 8.)

Under § 720.41(a), prior to commencement of manufacture or import of a substance for a non-exempt commercial purpose, EPA would disclose only a generic chemical name as part of a health and safety study if public disclosure of the fact that anyone intends to manufacture, import or proc-

ess the specific chemical substance for a non-exempt commercial purpose would reveal confidential business information. After a chemical begins to be manufactured, imported or processed for a non-exempt commercial purpose, EPA would deny, under § 720.41(b), any claim for confidentiality of specific chemical identity as part of a health and safety study, unless release would disclose confidential processes used in the manufacture or processing of a chemical substance or mixture, or confidential proportions of chemical substances in a mixture. In that case, EPA would disclose the health and safety study and identify the specific chemical substance by a generic chemical name. EPA intends to make these studies routinely available to the public, within the limits of the policy described above.

Under the Agency's proposed approach, it is very important to determine what types of information would disclose confidential "processes used in the manufacture or processing of a chemical substance or mixture." It is difficult to define this phrase so as to identify clearly the particular situations to which it applies. The terms "manufacturing" and "processing" are defined by sections 3(7) and 3(10) of the Act and in § 720.2 of the proposed rules. EPA will refer to these definitions in deciding what information would be included within this phrase. The following are examples of the kinds of information which may fall within the category of data which disclose processes: physical parameters of reactions vessels; methods of purification of reactants or reaction products; whether substance is incorporated into an article; and information on how an article is made or how an article works if this would reveal how it is made. These examples are very general. Application of the exception will turn on particular factual circumstances and will involve a determination of whether a particular item of information, when added to other information generally known, would disclose a confidential process. The Agency specifically welcomes comment on this issue.

If the specific chemical substance could be disclosed as part of a health and safety study, EPA would deny any claim for confidentiality of the specific chemical identity for purposes of adding the substance to the inventory. On the other hand, if specific chemical identity was not subject to disclosure as part of a health and safety study, and if the submitter complied with the provisions of the regulations, EPA would not publish the specific chemical identity in the inventory. Instead, as was the policy under the inventory reporting regulations, EPA would publish a generic chemical name in an appendix to the inventory. Thereafter, a person with a bona fide intent to manufacture a substance is included on the inventory as confidential identity. See proposed § 720.41.

The Agency recognizes that it is sometimes difficult to choose an appropriate generic name. Under § 720.41, the generic chemical name must be only as generic as necessary to protect the confidential identity of the particular chemical substance. EPA has already made available for use in inventory reporting its *Guidelines for Creating Proposed Generic Names*, 43 FR 16178, April 17, 1978. As part of this rulemaking, the Agency again specifically solicits comment on the *Guidelines*, which is published as Appendix II to these proposed rules. In addition, EPA is proposing in the rules an additional standard to assure that generic chemical names not only satisfy the regulatory standard ("only as generic as necessary"), but also provide as much information as possible on toxicologically significant aspects of the substance's structure. EPA welcomes comment on this standard and on whether it should be incorporated in the *Guidelines* document. Section 720.41(a)(2) of these proposed regulations establishes a voluntary procedure for prenotice consultation with the Agency concerning selection of a generic name.

The Agency believes that its proposed approach balances the competing concerns of the public interest and industrial sectors and is a rational resolution. Moreover, this approach has the advantage of straightforward administration which is important because of the potential volume of confidentiality claims and of requests by the public to examine these materials.

Because of the complexity of this issue, EPA has considered a large number of alternatives. The major alternatives considered are identified below. These are discussed in greater detail in the Support Document.

1. Do not disclose a confidential specific chemical identity as part of a health and safety study before or after commencement of manufacture for commercial purposes.

2. Disclose specific chemical identity as part of a health and safety study both prior to and after commencement of manufacture for commercial purposes unless such disclosure would release confidential processes used in the manufacture or processing of a chemical substance or mixture or the confidential proportions of a chemical substance in a mixture.

3. Establish a panel of experts, with no commercial interest in chemicals, to review all health and safety studies on new chemical substances with confidential identities prior to commencement of manufacture for commercial purposes. If the health and safety study, including specific chemical identity, is not disclosed to the public after the commencement of manufacture for commercial purposes, the panel would have continued access to the data.

4. Disclose specific chemical identity as part of a health and safety study, both prior to and after commencement of manufacture, to any person who can establish a *bona fide* public interest in obtaining the identity and who has no commercial interest in chemical substances.

5. Disclose specific chemical identity as part of a health and safety study only with the consent of the submitter. EPA would be a middleman and relay requests for information to the submitter.

6. Rather than routinely making identity available (such as through a public reading room), await receipt of an FOIA request before determining whether to disclose identity after commencement of manufacture. Until that time, EPA would hold identity confidential

7. After commencement of manufacture, publish the generic name on the inventory even if the specific identity has been released in connection with a health and safety study.

8. Require a minimum level of test data on any new chemical substance whose specific chemical identity is claimed as confidential.

Any of these alternatives might be selected in the final regulation. EPA intends to further evaluate each of them before determining how to handle claims of confidentiality for specific chemical identity with respect to health and safety studies submitted under TSCA § 5. EPA specifically solicits comment on these various altenatives and any other possible approaches.

B. TESTING FOR NEW CHEMICAL SUBSTANCES

EPA has given considerable attention to testing for new chemical substances and, in particular, the need for and possible contents of testing guidelines. At this time, the Agency is not proposing guidelines for public review and comment. However, in the near future EPA will publish in the FEDERAL REGISTER a detailed discussion of the major testing issues and guidelines alternatives considered by the Agency. The publication also will contain a number of recommended testing methods which EPA considers to be appropriate for estimating a wide range of health and ecological effects and environmental fate characteristics. The Agency will request interested persons to comment on the issues, alternatives, and testing methods, and subsequently will propose testing guidelines for use with new chemical substances.

EPA's long term strategy is to issue § 4 testing rules which apply to specific categories of chemical substances and which require testing for a significant number of effects. However, it may be several years before the Agency issues enough such rules to require testing of a substantial proportion of new chemical substances. Further, the § 4 rules will not cover all or even most chemical substances for all effects of concern to EPA. Therefore the Agency intends to issue testing guidelines to supplement the § 4 rules. The guidelines would be consistent with the testing rules, but they will be discretionary. The Agency will revise the guidelines and § 4 rules to reflect changes in scientific knowledge and EPA's experience in reviewing chemical substances.

With regard to both § 4 and § 5 guidelines, EPA's goal is a tiered scheme of testing for health and ecological effects. The scheme will be designed to develop, in the most cost-effective manner possible, data needed for assessments of risk. It will be constructed so that data from the initial tier of tests will help determine whether more testing should be performed. Decision rules for passing from one tier of tests to another will be explicit in the § 4 rules. In the § 5 guidelines, the decision rules will be as explicit as possible, considering the broader range of circumstances which the guidelines must accommodate. To the extent possible, EPA will harmonize its testing schemes under TSCA with those developed by other federal agencies, nations, and international organizations.

Both prior to and after establishment of the guidelines for testing of new chemical substances under § 5(e), EPA may take action to assure, on a case-by-case basis, that substances are tested before commencement of manufacture or import. While § 5(e) does not authorize the imposition of a testing requirement *per se*, the section does authorize the Agency to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a substance pending development of test data sufficient to evaluate the health and environmental effects of a substance.

C. SMALL BUSINESS; LOW VOLUME CHEMICALS

EPA is acutely aware of the impacts which the premanufacture program may have upon small companies, low volume chemicals, and general innovation in the chemical industry. Those impacts will vary considerably depending upon the Agency's decisions on certain key issues.

Section 5 does not exempt small businesses from the premanufacture notification requirements or otherwise qualify their legal responsibilities. Congress recognized that chemical risks are a function of effects and exposure and are not correlated with company size. (Further, because many large companies produce low volume chemicals, and certain small companies manufacture chemicals in high volumes, it is not accurate to use the terms "small business" and "low volume" interchangeably.) Because EPA's primary focus is upon limiting risks to health and the environment, the Agency will not give small companies exemptions or other special provisions which would minimize their responsibilities to prevent unreasonable risks. However, EPA recognizes that it must balance the need to protect humans and ecological populations from unreasonable risks against possible impacts upon the economy and technological innovation which may result from implementation of § 5. (See § 2(b)(3) of the Act.)

The consequences of regulatory actions particularly may impact small businesses and the innovations for which they are responsible. The ability of many such companies to compete with larger ones often is tied directly to their ability to reach commercial production from product R&D in a short period of time. If as a result of government regulation (or of other similar outside factors) this time frame is lengthened, this may effectively reduce the capability of small chemical manufacturers to introduce new chemical substances into commerce. Further, to the extent that larger businesses rely upon and use smaller companies' innovations in their own new products, innovation in the industry in general could be impeded.

Small manufacturers may be less able to absorb the costs of introducing new chemical substances into the market because their total sales volumes are relatively low. Although low volume chemicals may have relatively high profit margins. if costs are increased by R&D expenditures, testing costs, compliance with premanufacture notification requirements, or other factors, it may become less profitable to commercialize new products. This might be true for all new chemical substances produced in low volumes regardless of the size of the companies which introduce them. However, larger manufacturers may be able to spread these costs across product lines to higher volume, higher profit products, whereas small manufacturers may not have this option.

The extent to which innovation is primarily the domain of small companies is not clear. At this time there are no detailed studies or analyses which adequately characterize the various types of innovations in the chemical industry and the sources of the innovations. Thus it is unclear whether innovation is evenly distributed throughout the industry or concentrated in certain types of companies. Only gross estimates can be made as to the percentage of various-sized companies' productive efforts which are tied to the development of TSCA "new chemical substances."

In light of these and other similar considerations EPA solicits comments on how the Agency should implement the premanufacture program as it relates to small businesses and low volume producers. Comment also is requested regarding the impact of the program on innovation in general within the chemical industry. In particular, the impacts of two parts of EPA's premanufacture activities merit special attention: (1) the notice forms, and (2) the premanufacture testing guidelines.

The general notice form which EPA is proposing at this time would apply to all new chemical substances. This form would require detailed reporting on exposure and use. EPA welcomes comments on whether the Agency should develop a separate, briefer form for certain new substances produced in low volumes. Depending on these comments, EPA may promulgate such a form either at the time these rules and forms are promulgated, or thereafter if the need arises.

Any such comments should focus upon two related, but distinct, issues. First, to whom or for which new substances should a separate form apply? EPA could use any of several criteria to define applicability, including production volumes, anticipated issues (e.g., intermediates, consumer products), production processes (i.e. batch, continuous) and size of manufacturer (e.g., annual sales or profits, number of employees). If the Agency promulgates two forms, it must clearly distinguish between them concerning the situations in which each must be used. Thus comments should include any proposed definitions or criteria (qualitative or quantitative) for applicability and estimates of the percentage and types of new substances which thereby would be covered.

Second, what should be the contents of any such form? This preamble and the support document for this rulemaking discuss the contents of the proposed general form, including EPA's rationale for requesting the various types of information. If the Agency develops a separate, briefer form, it must decide that it does not need to receive all of this information for all new substances. Therefore comments should indicate not only the information which should be requested in a separate form, but also the reasons why such information would be

adequate for EPA's review of those new substances subject to the form. Further, consistent with the development of a briefer form the Agency may need to require subsequent reporting as production and use—and thus exposure—increase. Commenters are encouraged to address this issue as well.

With regard to the testing guidelines, a major issue concerns their impact upon low volume chemicals. For many such chemicals, it may be commercially feasible to perform certain health and environmental effects testing. Because EPA is not proposing testing guidelines for public review and comment at this time, this preamble does not focus upon specific approaches to the low volume chemical testing issue. When EPA publishes its document on premanufacture testing guidelines, the Agency will discuss this issue.

EPA is examining whether it is feasible for the Agency to provide technical and other nonfinancial assistance to small companies to facilitate their ability to comply with the premanufacture requirements. EPA's Industry Assistance Office now provides general information and nonfinancial assistance to businesses (both large and small) concerning the Agency's implementation of the Act. EPA is considering how it could expand upon these activities to be more supportive to small companies in their efforts to provide notices and to otherwise comply with the premanufacture requirements. For example, EPA might be able to provide help in completing the notice forms. Similarly, the Agency might assist in various aspects of testing, including the determination of the need to test (e.g., literature searches, structure-activity work), and general guidance concerning appropriate test methods and schemes. And EPA could provide technical and other support in the development of organizations or shared facilities in the private sector which could enable small companies to test on a more cost-effective basis than is otherwise the case. EPA also is exploring with the Small Business Adminstration ways to mitigate the financial hardships which small businesses may incur in complying with TSCA.

Finally, Congress limited EPA's authority to issue § 8(a) reporting requirements by limiting their use to other than "small business" unless the chemicals for which information is sought are subject to Agency regulatory actions. (Section 8(a)(3)(A)(ii) of the Act.) As noted in the "General Approach" section, EPA intends to use § 8(a) reporting rules to obtain additional information necessary to review premanufacture notices, and to follow-up certain new substances once they enter commercial production. Therefor EPA must define the term "small business" as it applies to this § 8(a) reporting. (See § 720.50 of the proposed rules, and "Supplementary Reporting" above. Also see Sections II-D-7 and II-D-8 of the Support Document.)

IV. Impacts

A. Regulatory Analysis

The following discussion describes the major alternative approaches considered by EPA in implementing the premanufacture program. There are three possible parts to any of these alternatives—notification rules, notice forms, and testing guidelines. Each serves a specific purpose, and when taken in various combinations they comprise the major alternatives available to the Agency in implementing § 5. The proposed premanufacture program is consistent with Alternative 3, including premanufacture rules and notification forms. In this discussion, the alternatives are presented in order from the least to the most resource-intensive. Further, in the interest of brevity the advantages of each component are described only in the alternative in which it first appears.

Alternative 1—"Do Nothing"

TSCA does not require EPA to promulgate rules relating to premanufacture notification. Thus § 5 could become self-implementing 30 days after the publication of the initial inventory of existing chemical substances. The Act provides direction as to who must submit notices and when, the information which must be included in the notices, the length of the premanufacture notification period, and EPA's authorities to regulate new substances. Thus the Agency could adopt a "do nothing" approach, under the assumption that the Act is self-explanatory.

Advantages. The major advantage to this approach is that in the short run the Agency would avoid the burden of a complex and controversial rulemaking. Persons subject to § 5 could avoid the effort and expense of participating in the rulemaking process and of familiarizing themselves with the final rules. Manufacturers would give notification to EPA in the quickest, least burdensome, most expedient manner.

Disadvantages. Short-run expediency quickly would turn to long-run ineffectiveness. Individual manufacturers often would interpret vague and ambiguous provisions in the Act in different ways, resulting in inconsistency and inefficiency for both EPA and submitters. For example, TSCA requires notices to include information on chemical identity, uses, disposal, production volume, exposure, and by-products. With no clarification from EPA, the imprecise nature of many of these terms may result in different interpretations and responses. Some would be incomplete or of insufficient detail, thus greatly complicating EPA's task of assessing risk. In these cases, EPA might find the notices to be invalid and return them to the manufacturers, with considerable expense and delay for submitters.

This approach also could create confusion concerning a manufacturer's rights to confidentiality and EPA's handling of confidential information. Further, there are many chemical fate characteristics and health and environmental effects which the Agency might want to evaluate with respect to new chemical substances. Without any statements from EPA on effects of concern, manufacturers may find it difficult to allocate scarce testing dollars appropriately.

Economic Consequences. The initial economic impact from this approach might be minimal. Manufacturers probably would submit very general information in areas required by the statute. Normally, much of this information is available prior to manufacture of any new substance. Lacking specific direction from EPA, submitters may not collect the specific information which the Agency would find most useful.

The initial impact from complying with the premanufacture requirements may be minimal. However, there could be secondary effects if EPA (1) considers notices with insufficient data to be invalid and returns them to the submitters; (2) utilizes its § 8(a) reporting authority to fill in important data gaps; or (3) decides to make worst case assumptions about effects and exposures as a basis for its regulation of new substances. Delays and resubmittals could be costly and time consuming.

This alternative likely would avoid some of the possible anti-competitive effects of the more costly alternatives. As compliance costs increase, they will tend to have disproportionate impacts upon smaller firms which are unable economically to justify significant regulatory expenditures.

Alternative 2—Develop Notification Rules

A second option is to issue rules which amplify and clarify the requirements of § 5. (Such rules make up a portion of EPA's proposed premanufacture program.) The rules could establish policy and procedures for (1) handling of confidential information, (2) processing and handling of notices, and (3) use of the regulatory authorities in section 5(e) and section 5(f). In addition, rules could define phrases in the law such as "known to or reasonably ascertainable," "possession or

control," and "small quantities for research and development." The rules also could more precisely identify the information and data which EPA considers necessary to comply with the general notification requirements of § 5. Finally, rules could inform manufacturers of the Agency's policy on such issues as the applicability of § 5 to exporters and importers, the role of § 8 reporting in the implementation of the premanufacture program, and the content of the section 5(d) (2) & (3) FEDERAL REGISTER notices.

Advantages. This approach could eliminate much of the confusion and inconsistency discussed in the first alternative. Submitters would be more certain concerning EPA's interpretation of key provisions in the Act. Once promulgated, the rules would provide the basis for the future implementation of the premanufacture review program.

In particular, the rules would help to clarify the Agency's definition of a valid notice. Thus submitters could avoid costly delays due to the submittal of insufficient information and data. Further, EPA could save the resources necessary to obtain information omitted from notices as a result of manufacturers' individual interpretations of the Act. Agency staff would be able to provide a more consistent and uniform review of notices. Important data gaps could be closed considerably, facilitating the performance of preliminary risk assessments from the information in the premanufacture notices.

Disadvantages. Submitters would present information to EPA in the form and manner convenient to themselves. This could force the Agency to utilize considerable resources to place the information in standard formats prior to review. Additionally, there are many test protocols available for evaluating health and environmental effects and the rules would not give guidance concerning the protocols which EPA considers to be most appropriate. Consequently, submitters would use vastly different test methods, making uniform review of tests results more difficult. Further, Agency reviewers might be required to spend a significant amount of time and resources to understand the protocols followed. Subsequently EPA might decide that some of the tests performed were not acceptable bases from which to draw conclusions.

Economic Consequences. The cost and economic impacts of this option are dependent on: (1) the cost of developing information and data to EPA's specifications, (2) the levels of detail required in the rules, (3) the number of uses for a chemical substance (and the different types of exposure and disposal which may result), and (4) the resources of the company submitting the notice. Given the program which EPA contemplates, the cost probably would exceed that for data submitted under the first approach. However, the economic and scientific significance of the chemicals which might not be developed under this alternative likely would be minor in view of the modest expenditures involved.

ALTERNATIVE 3—DEVELOP RULES AND NOTICE FORMS

In addition to the rules discussed in alternative 2, EPA could develop standard notice forms for use in submitting the information and data required by the rules. This alternative—development of forms, in addition to rules—is reflected in this proposed rulemaking.

Advantages. The notice forms would provide consistent and standard formats for the submittal of information. This would greatly facilitate EPA's screening and review of premanufacture notices. In addition, although the rules could specify the information requirements (as discussed in alternative 2), they would be much less complex if the rules simply instruct submitters to complete standard notice forms. The information requirements then could be explained clearly in the notice forms. This would avoid the need to include detailed data descriptions in the rules.

Disadvantages. This option would not provide manufacturers with guidance concerning standard test protocols which are considered to be most appropriate for evaluating health and environmental effects. In the absence of such guidance, submitters may use different test methods, and this would make uniform review of test results more difficult.

Economic Consequences. The additional cost to manufacturers of filing standard EPA notice forms should be minor and should not significantly increase the economic impact discussed for alternative 2.

ALTERNATIVE 4—DEVELOP RULES, NOTICE FORMS, AND "REFERENCE TESTS"

In addition to the rules and notice forms, EPA could publish "reference tests" for important effects. The reference tests would contain recommended test methods and protocols for use in evaluating the likelihood that specific chemical substances cause particular effects, including any effects identified in the rules. Thus the reference test guidelines would state, "These are specific tests which EPA believes are appropriate for testing for certain effects. If you test your new substance for these effects, the Agency recommends that you use the following test methods or protocols."

Advantages. For manufacturers, this would eliminate uncertainty concerning the test methods which EPA considers to be appropriate for premanufacture testing. For the Agency, the reference tests should result in the use of consistent testing methods by submitters. This consistency would greatly facilitate the notice review and risk assessment processes. (However, because any such reference tests would be optional, manufacturers would retain the flexibility to follow other test methods which they believe to be more appropriate in particular situations.)

Disadvantages. The reference tests would not address the applicability issue, i.e. the circumstances in which new substances should undergo specific tests for particular effects. lacking direction from EPA, manufacturers would decide whether to test, and to what extent, using varying and inconsistent criteria.

Economic Consequences. EPA does not have the legal authority to require premanufacture testing of all new substances, though, as indicated in the testing discussion above, EPA may regulate a substance in certain cases pending the development of test data. Therefore to the extent manufacturers conduct the reference tests, the economic impact will depend upon (1) the costs of the reference tests and (2) the amount of testing which manufacturers undertake in excess of testing they would conduct in the absence of identification of such reference tests.

ALTERNATIVE 5—DEVELOP RULES, NOTICE FORMS, AND TESTING GUIDELINES WITH DECISION CRITERIA

In addition to identifying certain effects of priority concern and standardized testing methods, this option would include a set of decision criteria which would explain which tests EPA considers to be necessary for a substance given its unique structure, physical and chemical properties, uses, exposures, and production volume. These criteria would guide the Agency in determining cases in which it should not act under § 5(e). Decision criteria could be based on scientific or economic and other non-risk considerations. The following examples are illustrative:

(1) Scientific decision criteria—Most high molecular weight polymers might require only minimal health effects testing if they are non-reactive, if their particle size is large enough to prevent absorption through the lungs, and if there are no low weight monomers present that could be leached out. Most new substances may need to be tested consistent with their primary routes of anticipated human exposure (oral, dermal, or inhalation).

(2) Economic and non-risk decision criteria—EPA could predicate a recommendation for certain testing of new chemical substances upon annual production volume thresholds (e.g., 10,000 lb.) unless there is reason to suspect adverse effects based on structure activity relationships, data from pre-existing studies, or other relevant information.

(For a further discussion of the testing guideline alternatives, see III-B of the Support Document, "testing for New Chemical Substances.")

Advantages. This approach would most effectively encourage manufacturers to evaluate the health and environmental impacts of new chemical substances prior to their premanufacture notification submittals. EPA would be in a position to perform more thorough reviews and to make more informed regulatory decisions. Submitters would have more and better information available to use in designing necessary safeguards into their manufacturing processes or as a basis for withholding commercialization altogether. Manufacturers also would have guidance from the Agency concerning appropriate types and levels of testing, and this should greatly reduce the necessity for EPA to regulate substances under section 5(e).

Disadvantages. The principal disadvantage of this approach is the difficulty in implementing it. It will be difficult to develop useful decision criteria except in reference to particular chemical and exposure/use situations. Also, to the extent that this approach calls for increased testing for new substances, it may result in substantial expenses and delays, and a number of foregone investments for manufacturers who develop economically marginal chemicals.

Economic Consequences. The costs and impacts of this option are dependent upon: (1) the costs of the tests requested in the guidelines and (2) the extent to which chemical manufacturers perform the recommended tests. It is probable that the economic costs of this alternative would exceed those of the other four. In general, the impacts could include substantial compliance costs, reduced numbers of new substances, longer new product development lead times, and increased industry concentration.

EPA's Preferred Approach

EPA's preferred approach is Alternative 5—rules, notice forms, and testing guidelines with decision criteria. If the Agency is able to develop decisions criteria based upon scientific, economic, and other non-risk factors which focus resources upon those substances most likely to present significant risks, the health and environmental benefits of this alternative would far exceed the economic costs.

However, the time needed to develop a quality program of this complexity is substantial, and EPA does not expect to develop complete testing guidelines with decision rules before the premanufacture notification program begins in early 1979. Consequently, EPA will pursue Alternative 3 as an interim strategy, and this rulemaking proposes notification rules and notice forms which are compatible with testing guidelines currently under development. In a separate publication in the near future, EPA will publish for public comment a detailed discussion of testing guidelines issues and alternatives, and will propose reference tests and guidelines in 1979.

B. ECONOMIC IMPACT

The notification form has three parts: Part I—General Information, Part II—Risk Assessment Data, and Part III—Risk Analysis and Optional Data. Each manufacturer of a new chemical substance must complete Parts I and II. Manufacturers may complete Part III as well, although it is optional. EPA has made a preliminary analysis of the cost of completing both the mandatory and optional parts in the interest of understanding the potential total costs to submitters. In this analysis, EPA has not considered the cost of any increased health and safety testing undertaken by manufacturers as a result of premanufacture notification.

The estimates cited below are judgmental and are not the result of an actual simulation of the completion of the notice form. The following general approach was utilized. Estimates were made of the time necessary to complete each subsection of the form. Costs then were calculated using assumed hourly labor rates multiplied by the hourly requirements identified. Estimates therefore may give an impression of preciseness that is not intended. Final estimates should be rounded to the nearest thousand dollars.

Due to several factors, the cost of filling out the form may vary over a wide range. The following factors account for most of this variation:

1. Company size and resources.

The amount and quality of data "known to" the company, including all relevant information in its possession or control.

The amount and quality of data "reasonably ascertainable" by the company.

2. The number and types of uses of the new chemical substance.

3. Distribution and fate of the new chemical substance.

Nature of human and environmental release and exposure.

Physical and chemical properties which may influence environmental release, persistence, and transport of the substance.

Considering these factors, EPA estimates the costs of completing the notice form as follows:

Form Sections	Cost Ranges
Mandatory Information	
Part I: General Information	$800-2,900
Part II: Risk Assessment Data:	
Section A: Physical and Chemical Properties, Environmental Fate Characteristics, and Effects Data	900-4,800
Section B: Exposure from Manufacture	800-6,400
Subtotal (Minimum Mandatory Form)	$2,500-14,000
Section C: Exposure from Processing Operations	600-6,400
Subtotal (Maximum Mandatory Form)	$3,100-20,500
Section D: Exposure from Consumer Use	600-1,700
Subtotal (Maximum Mandatory Form)	$3,700-22,200
Optional Information	
Part III: Risk Analysis and Optional Data	5,500-19,200
Total (Maximum Total Cost)	$9,200-41,400

All manufacturers must complete Part I and Part II-A of the Notification Form. The remainder of Part II is divided into 3 subparts that deal with exposure at manufacturing sites (II-B), industrial processing facilities (II-C), and from consumer use (II-D). Manufacturers must complete each subsection that applies to their specific chemical. Thus all manufacturers must complete Section II-B. In certain special cases, however (e.g., captively consumed chemical intermediates), portions of Sections II-C and II-D may be inapplicable. In other instances the data requested in these sections may not be known or reasonably ascertainable. The "minimum mandatory" cost of completing the form is therefore the cost of completing Parts I, II-A, and II-B ($2,500-14,100). The "maximum mandatory" cost is to complete Parts I and II in their entirety ($3,700-$22,200). The "maximum total" cost includes all optional data in Part III ($9,200-$41,400).

EPA estimates that in the past five-year period, 700-1300 new chemicals have been introduced for commercial purposes each year. If there chemicals were subject to the proposed requirements, the Agency estimates that a significant but uncertain number might not have been introduced due to their low sales volumes and profitability. Questions have been raised concerning the types and general commercial significance of chemicals likely to be foregone as a result of this pro-

posed regulation. EPA will address this issue in the future as part of a more extensive study.

EPA expects to receive between 150 and 550 premanufacture notices per year. Total reporting costs as a function of level of reporting would be as follows:

Total Regulatory Costs per Year

(In millions of dollars)

Level of reporting:		
Minimum Mandatory		2.0-5.6
Maximum Mandatory		2.8-6.6
Maximum Total	Total	4.1-5.0

EPA believes that the above figures may overstate the cost and impact of the premanufacture program for two reasons. First, depending upon comments received in this rulemaking, the Agency may promulgated a briefer form for low volume, batch process chemicals. Such a form probably would be less costly than the one now proposed for all new chemical substances. Second, costs of completing the forms should decrease in the future because manufacturers will begin to generate data in the formats requested in the notice form. Thus they would no longer incur that portion of the costs which are attributable to re-formatting data.

Further, this analysis is based upon the assumption that the submitter of a notice has a minimum level of knowledge, expertise, and sophistication typical of a moderate-sized chemical company with some specialized technical resources. This may be appropriate for companies with annual sales of $5 million or more. However, the cost may be significantly lower for small companies which do not have this minimum level of specialization and expertise.

The economic impacts are discussed in greater detail in *Impact of TSCA Proposed Premanufacturing Notification Requirements* (EPA Report No. EPA 230/2-12/78-005), which is available from the EPA . (See "Information Contact" above).

C. OTHER IMPACTS

Aside from the economic impacts described above, there may be other impacts associated with the development of the premanufacture notification program. Many of these impacts derive directly from the legislative mandate for premanufacture notification, rather than from the particulars of this proposal. Further, at this stage these other impacts cannot be projected with certainty but only can be discussed in general qualitative terms.

For example, this proposed action will benefit health and the environment to the extent that the submittal of notices and any subsequent regulatory actions prevent the production, use, or disposal of new substances which present unreasonable risks. Moreover, this proposal may foster heightened awareness on the part of industry concerning its responsibilities to test and otherwise evaluate new substances prior to production, so that companies will limit exposures which otherwise may result in unreasonable risks.

The proposal has a potential for affecting both the production and consumption of fuels in the United States, insofar as EPA regulates any new substances intended to improve the efficiency of the fuel production process or the combustion efficiency of vehicles. The nature and extent of such impacts cannot be evaluated at this time, because this rulemaking establishes the general frame work for the premanufacture program and does not focus upon specific substances. However, consistent with § 2(c) of the Act, the Agency will consider the environmental, economic, and social impacts of any proposed actions.

D. EVALUATION PLAN

While EPA's new "sunset policy" on reporting requirements does not apply to the statutory requirement to submit premanufacture notification, EPA will evaluate these rules within five years after their effective date. In this review, EPA will assess the impacts of the rules, compliance with them, and alternative approaches. Pursuant to this review EPA will make appropriate changes to the rules, providing notice of an opportunity for comment on any substantive changes.

EPA will include in the final rules a plan for conducting this evaluation, describing the sources and availability of data needed for the evaluation and providing a schedule for conducting the review.

V. PUBLIC PARTICIPATION

In developing the proposed rules and notice forms, EPA has provided extensive opportunity for public participation. On March 29, April 20, May 18, July 12, July 19, and July 24, 1978, the Agency held public meetings to discuss major program issues with representatives from environmental and other public interest groups, organized labor, and the chemical industry. Further, EPA has met on numerous other occasions with representatives of individual constituencies to discuss specific issues, and has provided early drafts of this proposed rulemaking to the public for comment. This public participation has significantly influenced the development of these rules and forms.

EPA will hold public meetings during the comment period to provide the public an opportunity to present comments and questions (as described in Part VI below), and will continue to meet with smaller groups of interested persons on specific issues. The Agency will transcribe the general public meetings and will keep summary minutes of the smaller meetings.

VI. PUBLIC MEETINGS

EPA has scheduled the following public meetings on these proposed rules and forms during the official comment period:

Atlanta, Georgia—January 31, 1979

Sheraton Atlanta, 590 West Peachtree, N.W., Atlanta, GA 30308, (404) 881-6000 or 800-325-3535.

Dallas, Texas—February 1, 1979

EPA Conference Room, 29th Floor, 1st International Building, 1201 Elm Street, Dallas, TX 75270.

Los Angeles, California—February 2, 1979

Wilshire Hyatt House, 3535 Wilshire Blvd., Los Angeles, CA 90010, (213) 381-7411 or 1-800-228-9000.

Chicago, Illinois—February 6, 1979

Hyatt Regency Chicago, 151 East Wacker Drive, Chicago, IL 60601, (312) 556-1000 or 1-800-228-9000.

Cleveland, Ohio—February 7, 1979

Stouffer's Somerset Inn, 3550 Northfield Road, Shaker Heights, OH 44122, (216) 752-5600.

Newark, New Jersey—February 8, 1979

Hilton Gateway, 810 McCarter Highway, Newark, NJ 07102, (201) 622-5000.

Washington, D.C.—February 13 and 14, 1979

North Building Auditorium, Department of Health, Education and Welfare, 330 Independence Avenue, S.W., Washington, D.C. 20201.

The purpose of these meetings is to enable interested persons to provide oral comments on the proposed rulemaking to EPA officials who are directly responsible for developing the rules and notice forms.

All meetings will begin at 9:00 a.m. and end at 4:30 p.m., with a one-hour recess for lunch. The meetings will start with a short summary by EPA of the proposed rules and notice forms to be followed by oral presentations from the floor of no more than 10 minutes per person, company, or organization. (Less time may be allotted depending upon the number of presentations.)

Persons who wish to present their comments at any one of the meetings should contact EPA no later than four days before the meeting date by calling Mr. Doug Bannerman toll-free at 800-424-9065 (in Washington, D.C., call 554-1404), or by writing to the address listed above under "For Further Information Contact." EPA will allot speaking times on a first-come basis, although the Agency reserves the

right to alter the order depending upon the nature of the particular comments and other relevant factors. If time permits, following these prepared presentations EPA will receive any other comments from the floor.

Presenters are urged, but not required, to submit copies of their statements on the day of the meeting. All such written materials will become a part of EPA's record for this rulemaking. In addition, the Agency will transcribe each meeting and will include the written transcripts in the public record.a

VII. Public Record

EPA has established a public record for this rulemaking (docket number OTS 050002) which is available for inspection in the OTS Reading Room from 9:00 a.m. to 5:00 p.m., on working days (Room 710E, 401 M Street SW., Washington, D.C. 20460.) This record includes all the information considered by the Agency in developing this proposal. The Agency will supplement the record with additional information as it is received. the record includes the following categories of information:

(1) USEPA-OTS. "Premanufacture Notification Requirements and Review Procedures": Notice of Proposed Rulemaking.

(2) USEPA-OTS. "Premanufacture Notification Requirements and Review Procedures": Support Document.

(3) USEPA-OTS. "Impact of TSCA Premanufacturing Review Requirements" (EPA 230/2-12/78-005).

(4) Seven working drafts of proposed 40 CFR Part 720 dated from June 20, 1978 to December 3, 1978; three working drafts of the premable to proposed 40 CFR Part 720 dated from October 28, 1978 to December 3, 1978; eight working drafts of the proposed Premanufacture Notice Form dated from July 30, 1978 to December 3, 1978; two working drafts of the Premanufacture Notice Form for Importers dated October 5, 1978 to December 3, 1978; three working drafts of the Premanufacture Notice Form for Foreign Manufacturers/Supplier dated from October 5, 1978 to December 3, 1978; and one draft of the Processing and Consumer Use Form dated December 3, 1978.

(5) All factual information and raw data of any sort considered during the rulemaking (including such information in comments from EPA personnel);

(6) EPA correspondence to persons outside the Agency;

(7) Correspondence (including comments on the rule) received from persons outside the Agency before the close of the comment period, and correspondence received after the close of the comment period if actually considered;

(8) EPA memoranda summarizing meetings and telephone conversations with outside persons relevant to the development of this rulemaking;

(9) Transcripts of hearings and advisory committee meetings.

The docket of the record which details its specific contents to date is available in the OTS Reading Room. EPA welcomes comment on any additional material that should be part of the record to date. EPA will identify the complete rulemaking record on or before the date of promulgation of these requirements, as prescribed by TSCA § 19(a)(3).

Note.—The Environmental Protection Agency has determined that this document does not contain a major proposal requiring preparation of an economic impact analysis under Executive Order 12044 and OMB circular A-107.

Dated: December 29, 1978.

Douglas M. Costle,
Administrator.

It is proposed that a new Part 720 be added to Chapter I of Title 40 as follows:

Part 720

Premanufacture Notification for New Chemical Substances

Authority: Sections 5, 8, and 14 of the Toxic Substances Control Act, 15 U.S.C. 2604, 2607, and 2613.

Subpart A—General

§ 720.1 Scope and compliance.

(a) This Part establishes procedures for the reporting of new chemical substances by manufacturers and importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604 (hereinafter "the Act"). The rules define the persons and chemical substances subject to the reporting requirements, prescribe the contents of premanufacture notices, and establish procedures for filing notices. The rules also specify the procedures EPA will follow in processing premanufacture notices, and explain the Agency's policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with premanufacture notices.

(b)(1) Beginning 30 days after publication of the initial inventory, the manufacture or import of a new chemical substance can be undertaken only if the manufacturer or importer has complied with these premanufacture notification requirements. Sections 15(1) and 15(3) of the Act make it unlawful for any person to fail or refuse to submit information required for premanufacture notification. If a person submits information in a premanufacture notice that is intentionally false or misleading, contains significant omissions, or otherwise does not fulfill the requirements of section 5(d) of the Act, EPA will consider the notice to be invalid. If the person commences to manufacture or import the chemical substance and if EPA subsequently determines that his notice is invalid because it contains intentionally false or misleading information, the manufacturer or importer will have been in violation of section 15 starting 90 days before manufacture began and continuing every day thereafter until

he ceases manufacture. Also under section 15(1), it is unlawful for a person to manufacture or import a new chemical substance for a non-exempt commercial purpose during the notification period described in § 720.35. Section 15(3) makes it unlawful for any person to fail to keep records which support information that these regulations require to be submitted to EPA, or to fail to permit access to these records. In addition, section 15(2) makes it unlawful for any person to use for commercial purposes a chemical substance which the person knows or had reason to know was manufactured or imported in violation of section 5.

(2) Section 16(a) provides that any person who violates any provision of section 15 shall be liable to the United States for a civil penalty of up to $25,000 per violation, with each day of violation constituting a separate violation. If a violation is knowing or willful, criminal penalties of up to one year in prison and $25,000 per day of violation may also be assessed. Section 17 (and, in imminent hazard cases, section 7) provides EPA with a number of specific enforcement remedies, including injunctions to restrain any section 15 violators and in particular to restrain persons from taking actions prohibited by section 5 or any rules or orders under section 5. EPA is also empowered to compel the taking of actions required under TSCA, and is authorized to seize any substance manufactured, processed or distributed in commerce in violation of the Act. EPA intends to use these remedies, separately or in combination, to assure compliance with the section 5 rules. The Agency will utilize whatever injunctive remedies are appropriate; for example, to stop manufacturing when no section 5(a) notice has been filed for a new substance, as well as to assess appropriate civil or criminal penalties.

(c) Any person who submits a premanufacture notice must retain health and safety data which is referenced in the notice for 30 years following the date of commencement of manufacture or importation of the chemical substance, and must retain other documentation for five years following the date of commencement of manufacture or importation.

§ 720.2 Definitions.

For the purposes of this Part: The following terms shall have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under such Act: "cosmetic," "device," "drug," "food," and "food additive." In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 et seq.; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 et seq.; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 et seq.

The term "pesticide" shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the regulations issued thereunder.

The following terms shall have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 et seq., and the regulations issued thereunder: "byproduct material," "source material," and "special nuclear material."

"Act" means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

"Administrator" means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any other person who shall by operation of law be authorized to carry out such functions.

An "article" is a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.13 (e)(5), except that fluids and particles are not considered articles regardless of shape or design.

"Byproduct" means a chemical substance produced solely without a commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

"Chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that "chemical substance" does not include:

(1) Any mixture

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide;

(3) Tobacco or any tobacco product, but not including any derivative products;

(4) Any source material, special nuclear material, or byproduct material;

(5) Any pistol, firearm, revolver, shells, and cartridges; and,

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

"Commerce" means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce described in clause (1).

"Co-product " means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

"Distribute in Commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce, or deliver for introduction into commerce or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

"EPA" means the U.S. Environmental Protection Agency.

"Health and safety study" means any study or test of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data (such as the chemical identity of the substance(s) being tested), and epidemiological studies, studies of the physical and chemical properties of the substance, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

"Importer" means any person who imports a chemical substance, including a chemical substance as a part of a mixture or article, into the Customs Territory of the United States, and includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf. Importer also includes, as appropriate:

(1) The consignee;

(2) The importer of record;

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20; or,

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR 144. For the purpose of this definition, the Customs Territory of the U.S. consists of the 50 States, Puerto Rico, and the District of Columbia.

"Import in bulk form" means to import a chemical substance (other than as part of a mixture or article) in any quantity, in cans, bottles, drums, barrels, packages, tanks, bags, or other containers used for purposes of transportation or containment, if the chemical substance is intended to be removed from the container and the substance has an end use or commercial purpose separate from the container.

"Impurity" means a chemical substance which is unintentionally present with another chemical substance.

"Intermediate" means any chemical substance which either is consumed in whole or in part in a chemical reaction(s) used for the intentional manufacture of another chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

"Known to or reasonable ascertainable" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

"Manufacture" means to produce or manufacture in the United States or import into the Customs Territory of the United States.

"Manufacture or import for commercial purposes" means to manufacture or import:

(1) For distribution in commerce, including for test marketing purposes;

(2) For use by the manufacturer, including for use as an intermediate.

NOTE.—The fact that a chemical substance is manufactured or imported solely for research and development does not determine whether it is manufactured or imported "for commercial purposes." If the chemical substance is manufactured or imported solely for research and development purposes, and is either distributed in commerce, or is used by its manufacturer or importer for research and development of a potential commercial product, it is manufactured or imported "for commercial purposes." However, this does not mean that it is subject to the premanufacture notification requirements. See § 720.13(a) and § 720.14.

"Manufacture or import for non-exempt commercial purposes" means to manufacture or import for any commercial purpose for which a person would be required to submit a premanufacture notice. Specifically, the term excludes any manufacture or importation:

(1) In small quantities solely for research and development, in accordance with § 720.14;

(2) For test marketing purposes, under restrictions imposed by EPA in conjunction with an exemption granted under § 720.15;

(3) For commercial purposes enumerated in § 720.13(d) and § 720.13(e); and

(4) For commercial purposes exempted under section 5(h)(4) or section 5(h)(5) of the Act.

"Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date of these regulations, none of the chemical substances comprising the combination is a new chemical substance, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water so long as the non-hydrated form is itself not a new chemical substance.

NOTE.—The term "mixture" includes alloys, inorganic glasses, ceramics, frits and cements, including Portland cements.

"New chemical substance" means any chemical substance which is not included in the inventory compiled and published under subsection 8(b) of the Act.

"Non-isolated intermediate" means any intermediate which is not intentionally removed from the equipment in which it is manufactured.

NOTE.—The "equipment in which it is manufactured" includes the reaction vessel in which the chemical substance is manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

"Person" means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

"Possession or control" means in possession or control of the submitter, or of any subsidiary, parent company, or any company which the parent company owns or controls if the subsidiary, parent company, or other company is associated with the submitter in the research, development, test marketing, or commercial marketing of the substance. (A parent company owns or controls another company if the parent owns or controls 50% or more of the other company's voting stock.) Information is included within this definition if it is: (1) in the submitter's own files, (2) in commercially available data bases to which the submitter has purchased access, or (3) maintained in the files in the course of employment by employees or other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the substances.

"Process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

"Process for commercial purposes" means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.

"Processor" means any person who processes a chemical substance or mixture.

"Site" means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site shall be the business address of the importer.

"Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product" (hereinafter sometimes shortened to "small quantities for research and development") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that (1) are not greater than reasonably necessary for such purposes and (2) after the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

"State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

"Technically qualified individual" means a person (1) who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision, (2) who is responsible for enforcing appropriate

methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in clause (3) of this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in clause (1) of this paragraph.

"Test data" means: (1) data, including chemical identity, from a formal or informal study, test, experiment, recorded observation, monitoring, or measurement; and (2) information concerning the objectives, experimental methods and materials, protocols, results, data analyses (including risk assessments), and conclusions from a study, test, experiment, recorded observation, monitoring, or measurement.

"Test marketing" means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture or article in commerce.

"United States," when used in the geographic sense, means all of the States, territories, and possessions of the United States.

§ 720.3 Reporting requirements of this Part.

The following reporting requirements are established or implemented under this Part:

(a) Each person who intends to manufacture or import a new chemical substance for a commercial purpose (as defined in § 720.2) is subject to these regulations. Subpart B describes who must report and which chemical substances must be reported. Subpart C sets out reporting procedures and describes in greater detail the information which such persons must submit to EPA.

(b) In accordance with § 720.50(e), EPA may require any person who intends to manufacture, import, or process a new chemical substance for a commercial purpose to report information on uses and exposures of the substance, the benefits of and alternatives to the substance, and the economic consequences of potential regulatory actions with respect to the substance.

(c) In accordance with § 720.51(b), EPA may require any person in possession of a health and safety study to submit a copy of the study to the Agency.

(d) Any person who commences to manufacture or import a new chemical substance for which he had previously submitted a premanufacture notice must submit a Notice of Commencement of Manufacture in accordance with § 720.52.

Subpart B—Applicability

§ 720.10 Persons who must report.

(a) Beginning 30 days after publication of the initial inventory (40 CFR § 710.3(a)) the following persons must submit premanufacture notices under the provisions of this Part:

(1) Any person who intends to manufacture a new chemical substance (as defined in § 720.2) in the United States for commercial purposes, including manufacture of a substance solely for export from the United States;

(2) Any person who intends to import a new chemical substance in bulk form (as defined in § 720.2) into the United States for commercial purposes;

(3) Any person who originally manufactured, or imported in bulk form, a new chemical substance under the terms of an exemption authorized in § 720.14 or § 720.15, and who intends to distribute in commerce or to otherwise use the substance in a manner inconsistent with the terms of the applicable exemption, even if he does not intend to continue or resume manufacture or import of the substance; and,

(4) Any person who intends to manufacture a new chemical substance, or import a new chemical substance in bulk form, in a manner inconsistent with any exemption authorized under § 5(h) of the Act, and §§ 720.14 and 720.15 of this Part.

(b) In addition to the persons listed in paragraph (a) of this section, beginning 30 days after publication of the revised inventory (40 CFR § 710.3(b)) the following persons must submit premanufacture notice under the provisions of this Part:

(1) Any person who intends to import a new chemical substance into the United States for a commercial purpose as part of a mixture;

(2) Any person who originally imported as a part of a mixture a new chemical substance under the terms of any exemption authorized in § 720.14 or § 720.15, and who intends to distribute in commerce or to otherwise use the substance in a manner inconsistent with the terms of an applicable exemption, even if he does not intend to continue or resume import of the substance; and

(3) Any person who intends to import a new chemical substance as part of a mixture in a manner inconsistent with an exemption authorized under § 5(h) of the Act, and §§ 720.14 and 720.15 of this Part.

§ 720.11 Persons not subject to premanufacturer notification requirements.

The following persons are not subject to the premanufacturer notification requirements of this Part:

(a) Any person who intends to import a new chemical substance into the United States for commercial purposes as part of an article;

NOTE.—In the future, EPA may by rule designate categories of chemical substances imported as part of articles to which these premanufacture notice requirements will apply.

(b) Except as provided by § 720.10(a)(3) and 720.10(b)(2), any person who intends only to process or use a new chemical substance for commercial purposes, including processing for or use of the substance in research and development, as an intermediate, or for distribution in commerce.

NOTE.—A notice is invalid under § 720.34(b) if it is submitted by a person other than a manufacturer or importer. Filing of such a notice will not satisfy the premanufacture notice requirement of section 5(a) of the Act. If a person intends to process or use a new chemical substance for a commercial purpose, and the chemical substance is not excluded from premanufacture notice regulations under § 720.13, he must rely on the manufacturer or importer to submit the notice. In accordance with § 720.20(e), the manufacturer or importer may request the processor or user to participate in the filing of the notice by providing information on uses and exposures, either to the manufacturer or importer, or directly to EPA.

§ 720.12 Chemical substances for which premanufacture notices must be submitted.

(a) A person described in § 720.10 must submit a premanufacture notice for any chemical substance which he intends to manufacture or import for commercial purposes which (1) is not included on the inventory, and (2) is not exluded from the reporting requirements of this Part by § 720.13. Chemical substances on the inventory include those specifically identified, and those which are identified by use of the procedures established in paragraph (b) of this section.

(b)(1) If a particular chemical substance is not included on the inventory by specific chemical name but falls within one of the generic chemical names in the appendix to the inventory entitled "Confidential Chemical Substance Identities," a person who intends to manufacture or import that substance may ask EPA whether it is included on the inventory. EPA will answer such an inquiry only if the Agency determines that the person has a *bona fide* intent to manufacture

or import the substance for a non-exempt commercial purpose.

(2) To establish a *bona fide* intent to manufacture or import the specific chemical substance, the person who proposes to manufacture or import the substance must submit to EPA:

(i) A signed statement that he intends to manufacture or import the chemical substance for non-exempt commercial purposes.

(ii) A description of the research and development activities he has conducted to date, and the purpose for which he will manufacture or import the substance;

(iii) An elemental analysis;

(iv) Either an X-ray diffraction pattern (for inorganic substances) or a mass spectrum (for most other substances) of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance; and,

(v) If requested by EPA, a sample of the substance in its purest form.

(3) EPA will compare the information submitted by the proposed manufacturer or importer under this paragraph with either the information requested for the confidential chemical under § 710.7(e)(2)(v) of this chapter or the information requested under § 720.40(b)(2).

(4) If (i) the comparisons of the elemental analyses, and of either the X-ray diffraction patterns or mass or alternative spectra, are sufficiently similar to be consistent with a presumption that the chemical substance for which information is requested is the same as a substance on the inventory, and (ii) comparison of any other submitted information affirms or does not contradict this presumption, EPA will tell the person proposing to manufacture or import the particular chemical substance that the substance is included on the inventory and that a premanufacture notice is not required. At the same time, EPA will notify the person(s) who originally reported the substance that another person has demonstrated a *bona fide* intent to manufacture or import the substance, and has been notified that the substance is included on the inventory.

(5) If (i) the comparisons of the elemental analyses, and of either the X-ray diffraction patterns or the mass or alternative spectra, are not sufficiently similar to be consistent with a presumption that the chemical substances are the same, and (ii) comparison of the other information does not rebut this conclusion, EPA will tell the person proposing to manufacture or import the particular chemical substance that the information submitted does not support a conclusion that the substance is included on the inventory and that a premanufacture notice is required if the person intends to manufacture or import the substance for a non-exempt commercial purpose.

(6) A disclosure of chemical identity to a person with a *bona fide* intent to manufacture or import a particular chemical substance will not be considered a disclosure of confidential information.

(7) EPA will provide a final response to an inquiry under these procedures as to whether a particular chemical substance is included on the inventory within 45 days after the Agency's receipt of a complete submission under paragraph (b)(2) of this section.

§ 720.13 Chemicals not subject to premanufacture notification requirements.

The following chemicals are not subject to the premanufacture notification requirements of this Part:

(a) Any chemical substance which will be manufactured or imported solely in small quantities for research and development in accordance with § 720.14;

(b) Any chemical substance which will be manufactured or imported solely for test marketing purposes under the terms of an exemption granted under § 720.15;

(c) Any chemical which is not a "chemical substance" as defined in § 720.2 of the Part, and any mixture as defined in § 720.2 of this Part.

NOTE.—A new chemical substance that is manufactured, or is imported as part of a mixture, is subject to the requirements of this Part. This exclusion applies only to a mixture and not to any new chemical substances which are part of the mixture.

(d) Any co-product if its only commercial purpose is for sale to municipal or private organizations who (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances which have commerical value. However, a manufacturer may submit a premanufacture notice for a co-product described by this paragraph.

NOTE.—If a person intends to extract a component chemical substance from a co-product, that person is considered to be a manufacturer of the component substance, and if the component is a new chemical substance the extractor-manufacturer must submit a premanufacture notice for the substance.

(e) The chemical substances described below: [Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the substance, mixture, or article of which they are a part.]

(1) Any impurity.

(2) Any byproduct.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel or fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints; or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(7) Any chemical substance which results from a chemical reaction that occurs when (i) any of the following functions as intended: a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, sufactant, plasticizer, corrosion inhibitor, anitfoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(8) Any non-isolated intermediate.

§ 720.14 Exemptions for research and development.

(a) This Part does not apply to a chemical substance if:

(1) The chemical substance is manufactured or imported or is proposed to be manufactured or imported only in small quantities for research and development (as defined in § 720.2); and,

(2) The manufacturer or importer notifies all persons engaged in the manufacture, processing, use (including use in research and development), transport, storage or disposal of the substance of any risks to health which may be associated with the substance,

in accordance with paragraph (c) of this section.

(b) The manufacturer or importer may notify persons by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, a system of oral or written notification to each person who may be exposed to the substance, or any other method of notification which adequately informs persons of risk which the manufacturer or importer believes may be associated with the substance. The adequacy of the notification is the responsibility of the manufacturer or importer and, after publication of the revised inventory, shall be assured by a technically qualified individual (as defined in § 720.2). If the importer is not also the manufacturer, it is the importer's responsibility to make the necessary evaluation and notification of any risks to health which may be associated with the substance. In making such evaluations, the importer shall obtain the information described in paragraph (c) of this section from the manufacturer.

(c)(1) The manufacturer or importer shall evaluate any information or test data in his possession or control (the terms "possession and control" and "test data" have the meanings defined in § 720.2). Such information shall include:

(i) Any information concerning any significant adverse reaction to persons exposed to the substance which may reasonably be associated with such exposure; and,

(ii) Any information provided to the manufacturer or importer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(2) In addition, the manufacturer or importer shall notify all persons exposed to the substance if the substance is subject to any rule or order proposed or promulgated under §§ 4, 5, or 6 of the Act; or an action filed under § 7 of the Act; or the notice requirements of § 8(e) of the Act. In addition, the manufacturer or importer shall notify all persons of any risk to health which EPA, under § 5(h)(3) of the Act, has determined may be associated with the substance.

(d) Upon request, the manufacturer shall make available to EPA, or any person who may be exposed to the substance, any information (described in paragraph (c) of this section) evaluated by the manufacturer in determining the need for notification under paragraph (a)(2) of this section.

(e) It is unlawful for any person to manufacture or import a chemical substance under the terms of this exemption without meeting all of the provisions of paragraphs (a)-d) of this section.

§ 720.15 Exemptions for test marketing.

(a) Any person may apply for an exemption from any requirement of this Part to permit such person to manufacture or import a new chemical substance for test marketing purposes (as defined in § 720.2). EPA may grant such an exemption if the person demonstrates that the substance will not present an unreasonable risk of injury to health or the environment as a result of the test marketing activities.

(b) The EPA will consider the following information in determining whether to grant an exemption:

(1) All existing data regarding health and environmental effects of such substances, including physical-chemical properties;

(2) The maximum quantity of the substance which the applicant will manufacture for test marketing purposes;

(3) The maximum number of persons that may be provided the substance for test marketing purposes;

(4) The maximum number of mixtures or articles containing the substance that would be distributed during the test marketing activities;

(5) The maximum number of persons who may be exposed to the substance as a result of test marketing activities (including information regarding duration, concentration, and route of such exposures); and,

(6) Information regarding the period during which test marketing will occur.

(c) No later than five days after EPA receives an application for exemption under this section, the Agency will file with the Office of the FEDERAL REGISTER a notice which will contain, subject to § 14:

(1) A summary of the information provided in the application;

(2) An address and telephone number where inquiries and requests for copies of the full application may be directed (release of the full application will be subject to the confidentiality provisions of this Part); and,

(3) A request for written comments regarding the appropriateness of granting such an exemption.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter EPA will publish in the FEDERAL REGISTER a notice which explains the reasons for approval or denial.

(e) If EPA approves an application for exemption, the Agency may impose such restrictions as are necessary to insure that the substance will not present an unreasonable risk of injury to health and the environment as a result of the test marketing activities. Such restrictions may include, but are not limited to, restrictions on workplace concentration, quantity distributed, or populations exposed to the substance.

Subpart C—Premanufacture Notices

§ 720.20 General provisions.

(a) *Use of notice forms.* Each person who is required by subpart B to submit a premanufacture notice must complete in English, sign, and submit the information in the form and manner set forth on the appropriate EPA premanufacture notice forms published by and available from EPA. Except as otherwise provided in this subpart C, each notice must be submitted as a complete package, including all referenced attachments and enclosures. In submitting a notice, a person should carefully follow the reporting instructions, "Premanufacture Reporting of New Chemical Substances Under TSCA," published by and available from EPA. Premanufacture notice forms and reporting instructions are available from EPA by calling this toll-free number: 800-424-9065. In Washington, D.C., call 554-1404.

(b) *When to submit notices.* Each person who is required to submit a premanufacture notice must submit the notice at least 90 calendar days before he begins to manufacture or import the new chemical substance for non-exempt commercial purposes.

(c) *Where to submit notices.* Each person who submits a premanufacture notice must submit it to the address listed in the notice form.

(d) *General notice requirements.* Each person who submits a premanufacture notice must provide the information described in § 720.22 and requested in the applicable notice form, plus any other information requested in the form and not designated "optional," insofar as such information is known to or reasonably ascertainable by him. In addition, in accordance with § 720.23, the submitter must append to the form any test data in his possession or control and descriptions of other data reasonably ascertainable by him concerning the environmental and health effects of the substance.

(e) *Information from other persons.* At a minimum, the submitter must follow the procedures outlined below to identify and obtain information which is not known to him but which is reasonably ascertainable by him.

(1) Except as provided in paragraphs (e) (5) and (6) of this section, the submitter must contact in writing:

(i) Each person who is a party to a contract to obtain the substance from the submitter for processing or use; and

(ii) Each person who has contacted the submitter and indicated an interest in obtaining the substance for processing or use;

(iii) Each person who has obtained a sample of the substance from the submitter and who has indicated an interest in purchasing the substance; and

(iv) Each person whom the submitter has contacted or intends to contact concerning the substance and who the submitter firmly believes will purchase the substance from the submitter during the first three years of commercial production.

(2) The submitter must request each person contacted to complete the Processing and Consumer Use form.

(3) The submitter must offer each such person the option either to provide the requested information to the submitter for inclusion by him in the premanufacture notice or to provide the information directly to EPA in accordance with the notice form and reporting instructions. The submitter must state in his request that the other person is not under a legal obligation to provide the requested information.

NOTE.—If the submitter complies with these procedures, EPA will not consider the notice to be invalid under § 720.34 for the reason that the other persons do not provide the information requested. However, if the information is not provided, EPA subsequently may require any other persons to provide the information directly to the Agency. (See § 720.50.)

(4) The submitter must include in his premanufacture notice all information which is provided to him by other persons in accordance with this paragraph (e).

(5) If the submitter identifies a significant number of persons under paragraphs (e)(1) (ii), (iii), and (iv) of this section, and if he has reason to believe that the information which they provide will be duplicative, instead of contacting all such persons he may contact a sample of them which he has reason to believe is representative of the types of persons who will process and use the substance.

(6) The submitter need not contact any person who the submitter has reason to believe will not provide information which materially adds to, changes, or otherwise makes significantly more complete the information which the submitter himself includes in his notice.

(7) The submitter must certify in the premanufacture notice his compliance with this paragraph. The certification must include:

(i) The names and addresses of the persons whom the submitter contacted, and a designation of those who have provided information to him or who have indicated that they intend to provide information directly to EPA; and

(ii) If the submitter relies upon paragraph(s) (e) (5) or (6) of this section, a brief explanation of how and why he did so.

(f) *Specific chemical identity.* A premanufacture notice is not valid, and the notification period does not begin, unless the notice contains the specific chemical identity of the substance for which the notice is submitted.

(1) A manufacturer may authorize another person to report to EPA on his behalf concerning the specific chemical identity, if both the manufacturer and the other person sign the declaration provided on the premanufacture notice form.

(2) An importer may authorize the foreign manufacturer or supplier of an imported chemical substance to report to EPA on his behalf concerning the specific chemical identity, if both the importer and the other person sign the declaration provided on the Foreign Manufacturer or Supplier Form identified in § 720.21(c)(1)(ii).

(3) If EPA receives a premanufacture notice which does not include the specific chemical identity of the substance, but the notice indicates that the submitter has authorized another person to provide the chemical identity, the premanufacture notification period will begin when EPA receives the chemical identity.

(4) If EPA receives a premanufacture notice which does not include the specific chemical identity of the substance, and the notice indicates that the submitter has attempted without success to obtain information concerning the identity of reactants used to produce the substance, EPA may issue a supplemental reporting requirement under § 720.50(b) to obtain this information from the manufacturer or importer of the reactants. In such cases, the premanufacture notification period will begin when EPA, on the basis of identification of the reactants and other information, is able to identify the new substance.

(g) *Reporting polymers.* (1) To report a polymer, a person must list in the description of the polymer composition at least those monomers used at greater than two percent (by weight) in the manufacture of the polymer.

(2) Those monomers used at two percent (by weight) or less in the manufacture of the polymer may be included as part of the description of the polymer's composition.

NOTE.—The "percent (by weight)" of a monomer is the weight of the monomer expressed as a percentage of the weight of the polymeric chemical substance manufactured.

(h) *Intent to manufacture or import.* Each person who submits a premanufacture notice for a substance, with the intent to commence manufacture or import of the substance more than three years after the date of such submittal, must provide in conjunction with his notice evidence of his commitment to manufacture or import the substance for a non-exempt commercial purpose.

(i) *New information or data.* Following submittal of a notice and prior to the expiration of the notification period, if the submitter possesses, controls, or knows of new information or data which materially add to, change, or otherwise make significantly more complete the information and data included in his notice, he must submit the new information or data to EPA immediately. Except where it is impracticable to do so, the person must submit the new information on the relevent premanufacture notice form(s) and must clearly identify himself and the premanufacture notice to which the new information or data are related.

(j) *Chemical substances subject to section 4 testing rules.* (1) Except as provided in paragraph (j)(3) of this section, if

(i) A person intends to manufacture or import a new chemical substance which is subject to the premanufacture notification requirements of this Part; and

(ii) The person is subject to a testing rule applicable to the new chemical substance promulgated under section 4 of the Act before the notice is submitted, the person must submit the test data required by the testing rule with the premanufacture notice, in the form and manner specified in the testing rule and in accordance with § 720.23 of this Part. If the person does not submit the test data, the notice is incomplete and EPA will follow the procedures in § 720.34(b)(2) for invalid notices.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, he may not submit a premanufacture notice until the test data are submitted to EPA.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the premanufacture notice:

(i) The name, address, and other information which identifies the person who submitted the test data to EPA;

(ii) The date the test data were submitted to EPA;

(iii) Information which identifies the section 4 testing rule; and,

(iv) Information which identifies and describes the exemption.

§ 720.21 Imports.

(a) Except as otherwise provided in this section, the provisions of this subpart C apply to each person who sub-

mits a premanufacture notice for a new chemical substance which he intends to import for a commercial purpose.

NOTE.—As specified in § 720.10(a)(2) of this Part, these rules apply to any person who intends to import a new chemical substance in bulk form into the United States for commercial purposes. In addition, following publication of the revised inventory, these rules will apply to any person who intends to import a new chemical substance as a part of a mixture(s).

(b) Each importer who submits a premanufacture notice must use the Premanufacture Notice Form for Imported Chemical Substances. He must provide the information described in § 720.22 and requested in the form, plus any other information requested in the form and not designated "optional," insofar as such information is known to or reasonably ascertainable by him. In addition, in accordance with § 720.23, the importer must append to the form any test data in his possession or control and descriptions of other data concerning the environmental and health effects of the substance.

(c) In addition to following the requirements in § 720.20(e), each importer must follow the procedures outlined below to identify information and data which are not known to him but which are reasonably ascertainable by him.

(1) The importer must contact in writing the manufacturer of the substance and the person who supplies the substance to the importer. The importer must request both the manufacturer and the supplier to:

(i) Provide all test data in their possession or control which are related to the effects of the substance on health or the environment, in accordance with § 720.23; and

(ii) Complete the Foreign Manufacturer or Supplier Form.

(2) If the importer does not know the identity of the manufacturer of the substance, the importer also must request his supplier to provide the identity of the manufacturer.

(3) The importer must offer the person contacted the option either to provide the requested information to the importer for inclusion by him in the premanufacture notice or to provide the information directly to EPA in accordance with the notice form and reporting instructions. The importer must state in his request that the other person is not under a legal obligation to provide the requested information to the importer or to EPA.

NOTE.—If the importer complies with these procedures, EPA will not consider the notice to be invalid under § 720.34 for the reason that the other persons do not provide the information requested. However, if the notice does not contain such information, EPA subsequently may require any other persons who are under the jurisdiction of the United States to provide the information directly to the Agency. (See § 720.50.)

(4) The importer must include in his premanufacture notice all information which is provided to him by the manufacturer or supplier in accordance with this paragraph (c).

(5) The importer must certify in the premanufacture notice his compliance with this paragraph (c). The certification must include the names and addresses of the persons whom the importer contacted, and a designation of those who have provided information or test data to him or who have indicated that they intend to provide information or test data directly to EPA.

(d) The importer has the ultimate responsibility for complying with this Part and for completing the Premanufacture Notice Form for Imported Chemical substances, and for the completeness and truthfulness of all information and data which he submits except for that included by him pursuant to paragraph (c)(4) of this section and § 720.20(e)(4).

§ 720.22 Information relating to chemical identity; manufacture, processing, distribution in commerce, use, and disposal; amounts; byproducts and other related chemicals; exposure; safeguards and controls.

The premanufacture notice forms request the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. Each person who submits a premanufacture notice must include the information as specified in the forms (unless it is designated "optional"), to the extent it is known to or reasonably ascertainable by him. This does not include information which relates solely to exposure of human or ecological populations to the substance outside of the United States.

(a) A description of the new chemical substance, including the chemical identity, molecular structure, Chemical Abstracts Service (CAS) registry number, and the common or trade name;

(b) The estimated total amount to be manufactured and processed;

(c) The proposed categories of use;

(d) The estimated amount to be manufactured and processed for each proposed category of use;

(e) The manner and methods of distribution in commerce (including transportation) and disposal;

(f) The estimated amount of the substance for each manner and method of distribution in commerce (including transportation) and disposal;

(g) Descriptions of direct and indirect exposure of humans and of ecological populations, including exposure levels, as a result of manufacture, processing, distribution in commerce, use, and disposal of the chemical substance;

(h) Descriptions of releases to the air, land, and water (including emissions, effluents, and other discharges), whether intentional or unintentional;

(i) Explanations of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, including explanations of test programs used to assess risk;

(j) Descriptions of any engineering safeguards and controls, industrial hygiene considerations, and other measures to be used to limit exposure;

(k) descriptions and other information concerning related chemical substances and mixtures, including feedstocks, byproducts, co-products, impurities, degradation products, and unintended reaction products and other chemical substances which are related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance;

(l) Descriptions of mixtures and articles which contain or may contain the new chemical substance.

§ 720.23 Submittal of test data and other data concerning the health and environmental effects of a substance.

(a) *Test data in the possession or control of the submitter.* (1) Except as provided in paragraph (c) of this section, each person who submits a premanufacture notice must report, as provided below, all test data in his possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of any mixture or article containing such substance, or any combination of such activities. This includes test data concerning the chemical substance in a pure, technical grade, or formulated form. This also includes test data concerning any impurity, byproduct, coproduct, degradation product, unintended reaction product, or other chemical substance or mixture which is related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, except as excluded under paragraph (c)(5) of this section. All test data described by this paragraph (a)(1) are subject to these requirements regardless of their age, quality, or results.

(2) If the test data have been published in the open scientific literature, the person may submit a copy of the paper(s) in which they appear and, if necessary, an indication of where the test data appear in the paper(s). Otherwise, he must submit the test data as

specified in paragraph (a)(3) of this section.

(3) Test data which pertain to the health and ecological effects, physical and chemical properties, and environmental fate characteristics listed below, must be submitted in accordance with paragraph (a)(4) of this section. Data regarding effects, properties, and characteristics which are not listed in this paragraph (a)(3) must be submitted in accordance with paragraph (a)(5).

(i) Health Effects.

(A) Carcinogenesis
(B) Mutagenesis
(C) Teratogenesis
(D) Reproductive toxicity
(E) Behavioral disorders
(F) Neurotoxicity
(G) Hepatotoxicity
(H) Cardiovascular toxicity
(I) Renal toxicity
(J) Acute toxicity
(K) Dermal sensitization
(L) General subchronic and chronic toxicity
(M) Cumulative, synergistic, antagonistic, additive, and potentiating effects

(ii) Ecological Effects

(A) Microbial inhibition
(B) Algal inhibition
(C) Aquatic macrophyte inhibition
(D) Seed germination inhibition
(E) Seedling growth inhibition
(F) Invertebrate acute toxicity
(G) Fish acute toxicity
(H) Avian dietary toxicity
(I) Invertebrate chronic toxicity
(J) Fish critical life stage toxicity
(K) Fish bioconcentration

(iii) Physical and Chemical Properties; Environmental Fate Characteristics

(A) Corrosion potential and redox potential
(B) Tropospheric degradation and transformation studies
(C) Stratospheric degradation studies
(D) Atmospheric transport studies
(E) Vapor phase uv absorption spectra
(F) Solubility studies
(G) Octanol/water partition coefficient (measurements and calculations)
(H) Vapor pressure measurements
(I) Soil sorption studies
(J) Vapor phase sorbent studies
(K) Olfactory threshold studies
(L) Combustion and pyrolysis studies and theoretical analyses
(M) Measurements of the permeability of the chemical through gloves used by workers or consumers
(N) Boiling/melting/sublimation point determinations
(O) Density (gas, liquid, or solid) measurements
(P) Dissociation constant measurements
(Q) Flammability/explodability studies
(R) Particle size measurements
(S) pH measurements
(T) Chemical incompatibility studies and theoretical analyses
(U) Biodegradation studies
(V) Hydrolysis studies
(W) Aquatic oxidation studies
(X) Aquatic photochemical degradation studies
(Y) Any environmental fate studies in natural waters
(Z) Spectral data

(iv) Test data related to the exposure of the substance to humans or the environment.

(4)(i) Except as provided in paragraphs (a)(4) (ii) and (iii) any test data on the health and environmental effects listed in paragraph (a)(3) of this section must be submitted in a full report format containing the following parts: abstract, introduction, experimental methods and materials, results, discussion and data analysis, conclusions, and references. After publication by EPA of *Formats for Data Submitted Under the Toxic Substances Control Act* the person must submit data in the manner specified in that document.

(ii) If a report was completed prior to the effective date of this Part, the submitter may submit that report instead of using the full report format.

(iii) If a study, report, or test is incomplete when a person submits a premanufacture notice, the submitter must identify its nature and purpose, the principal investigators, laboratory contacts, progress to date, types of data collected, significant preliminary results and anticipated completion date. If a study, report, or test is completed prior to expiration of the premanufacture notification period, the person must immediately submit the study, report, or test to EPA as specified in paragraph (a)(4)(i) of this section.

(5)(i) For any test data in the submitter's possession or control which are not listed in paragraph (a)(3) of this section, a person may submit the data in summary form, (utilizing a standard scientific abstract format) if he agrees to submit a full report upon request by EPA. Otherwise, he must submit the test data in the appropriate full report format. After publication of *Formats for Data Submitted Under the Toxic Substances Control Act*, the person must prepare the abstract in accordance with that document.

(ii) If a test for an effect, property, or characteristic not listed in paragraph (a)(3) is incomplete when a person submits a premanufacture notice, the submitter must identify it in accordance with paragraph (a)(4)(iii). If the test is completed prior to the expiration of the premanufacture notification period or if significant results become known during that period, the person must submit an abstract in accordance with paragraph (a)(5)(i).

(b) *Other data concerning the environmental and health effects of a substance that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in paragraph (c) of this section, each person who submits a premanufacture notice must describe:

(i) Any data, othe than test data, that are in the submitter's possession or control, and

(ii) Any data, including test data, that are not in the submitter's possession or control but that are known to or reasonably ascertainable by him, which are contained in completed studies or reports and which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of any mixture or article containing such substance, or any combination of such activities. This includes data concerning the chemical substance in a pure, technical grade, or formulated form. This also includes data concerning any impurity, byproduct, co-product, degradation product, unintended reaction product, or other chemical substance or mixture which is related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, except as exluded under paragraph (c)(5) of this section. All data described by this paragraph (b)(1) are subject to the requirements of this paragraph regardless of their age, quality, or results.

(2) The description of data reported under this paragraph shall include:

(i) An abstract or other summary of the contents of the study or report;

(ii) A standard literature citation, if the data are contained in the open scientific literature; or

(iii) If the data are not contained in the literature, the names and addresses of persons the submitter believes may have possession or control of the data.

(iv) In addition, upon publication of *Formats for Data Submitted Under the Toxic Substances Control Act*, these data must be described as specified in that document.

(3) For the purposes of this paragraph, data are known to or reasonably ascertainable by the submitter if the data are known to his employees or other agents who are associated with research, development, test marketing, or commercial marketing of a substance. The following data are among those which are known to such employees or agents:.

(i) Data which they discuss orally with other persons;

(ii) Data contained in papers presented at symposia, seminars, and conferences which they attend; and,

(iii) Data which they read about in scientific articles.

(4) For incomplete studies, reports, or tests, the description of data must

include the information specifdied in paragraph (a)(4)(iii) of this section.

(5) The submitter must include in the premanufacture notice a brief description of his procedures for identifying data that are known to or reasonably ascertainable by him.

(c) *Data that need not be submitted.*—(1) *Published studies.* A person need not submit any data that appear in the periodicals listed in Appendix I if he submits a standard literature citation which includes author, title, periodical name, date of publication, volume number, pages, and year

(2) *Data previously submitted to EPA or another Federal agency.* A person need not submit any data previously submitted to EPA or another Federal agency with no claims of confidentiality if he provides in the premanufacture notice the agency name, the office or person to whom the data were submitted, the date of submittal, and, if appropriate, a standard literature citation as specified in paragraph (c)(1) of this section. This paragraph also applies to data previously submitted to EPA or another Federal agency with claims of confidentiality if the person who submitted the data specifically authorizes EPA to have immediate access to the data.

(3) *Efficacy data.* A person need not submit any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraphs (a) and (b) of this section.

(4) *Exposure data.* A person need not submit any data which solely concern the amounts of release, or levels and routes of exposure, resulting from the manufacture, processing, distribution in commerce, use, or disposal of the substance outside the United States.

(5) *Data concerning related chemicals.* A person need not submit any data concerning any impurity, byproduct, co-product, degradation product, unintended reaction product or other chemical substance or mixture which is related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance if the substance to which the data pertain is listed on the TSCA inventory of existing chemicals.

Subpart D—Disposition of Notices

§ 720.30 General.

This subpart establishes procedures that EPA will follow in reviewing premanufacture notices.

§ 720.31 Acknowledgment of receipt of notice.

EPA will acknowledge receipt of each premanufacture notice by sending to the submitter a notification of the date on which the Agency received the notice. EPA will consider a person to have submitted the notice on the date the notice is received by the EPA office designated on the notice form as the proper recipient of the notice. The acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this Part. See § 720.34.

§ 720.32 Notice in the Federal Register.

(a) *Initial notice.* Not later than five days after receipt of a premanufacture notice (excluding Saturdays, Sundays, and legal holidays), EPA will file with the Office of the FEDERAL REGISTER a notice containing the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, EPA will publish the specific chemical identity of the substance for which premanufacture notice is given, unless the submitter has claimed confidentiality for this identity in accordance with § 720.41(a). If confidentiality is claimed, EPA initially will publish the generic name proposed in the premanufacture notice in accordance with § 720.41 (a)(3)(ii). If subsequently EPA either denies this claim of confidentiality for the chemical identity, or determines that the original proposed generic name is more generic than necessary to protect the confidential business information, EPA may publish an amended FEDERAL REGISTER notice in accordance with the procedures in paragraph (c) of this section.

(2) EPA will publish the specific function(s) and application(s) of the new chemical substance as reported to EPA either by the submitter, or by any person under § 720.20(e) or § 720.21(c) unless this information is claimed confidential in accordance with § 720.42. If confidentiality is claimed, EPA will publish the additional information which is required to be submitted by § 720.42(b).

(3) EPA will publish a list of data submitted in accordance with § 720.23(a). In addition, for test data submitted in accordance with § 720.20 (j), test data on any of the effects, properties, and characteristics listed in § 720.23(a)(3), and data from other tests which the person has performed, EPA will publish a summary of the data including, where appropriate, abstracts prepared as specified in the *Formats for Data Submitted Under the Toxic Substances Control Act.*

(4) EPA will also publish procedures for examining the public file for the premanufacture notice, and on the filing of comments on the notice.

(c) *Amended notices.* If EPA does not publish in the initial notice some of the information specified in paragraph (b) of this section because the submitter claims confidentiality for the information, and if EPA subsequently denies a claim of confidentiality in accordance with §§ 720.40–720.43, EPA may publish an amended notice in the FEDERAL REGISTER containing the additional information.

§ 720.33 Notice that premanufacture notification is not required.

When EPA receives a premanufacture notice, the Agency will review it to determine whether the chemical is subject to the requirements of this Part. If EPA determines that the chemical is not subject to these requirements, the Agency will notify the submitter that § 5 of the Act does not prevent him from beginning manufacture or import.

§ 720.34 Deficiencies in the premanufacture notice.

(a) *Request for correction.* (1) Within 30 days of receipt of the premanufacture notice (as defined by § 720.31), EPA may request the submitter to correct or remedy minor or technical deficiencies in the premanufacture notice. Such deficiencies include:

(i) Failure to date the notice form(s);

(ii) Typographical errors which render answers to any questions unclear or ambiguous;

(iii) Confusing responses; and,

(iv) Answers which do not conform to premanufacture notice instructions.

(2) EPA will transmit a request for correction to the submitter by certified mail, return receipt requested. In the request, the Agency will state the basis for its determination that the notice is deficient in its present form and will explain the action which the submitter must take to correct the deficiency.

(3) EPA will suspend the premanufacture notification period from the date the Agency sends the certified letter until the date the Agency receives the requested corrections. If the person fails to submit the requested information within 30 days of receipt of the request, EPA may determine that the notice is invalid under paragraph (b) of this section.

(b) *Invalid notice.* (1) At any time during the notification period, EPA may determine that a premanufacture notice is invalid. Grounds for this determination include the following:

(i) Failure to sign the premanufacture notice form;

(ii) Failure to comply with the procedures for obtaining information from other persons, in accordance with § 720.20(e), or to certify that the procedures have been complied with;

(iii) Failure by an importer to comply with the procedures for obtaining information from foreign manufacturers or suppliers, in accordance with § 720.21(c);

(iv) Failure to provide any information requested on the premanufacture

form, unless the form clearly indicates that a response is optional. For the purposes of this determination, indication that a question is "not applicable" because the information is either "unknown" or not "reasonably ascertainable", together with an explanation of this fact, where necessary, does not necessarily constitute a failure to provide information;

(v) Failure to remedy any deficiency for which EPA issued a request for correction under paragraph (a) of this section, within 30 days following a person's receipt of the request;

(vi) Submittal of intentionally false or misleading responses to questions on the premanufacture notice form;

(vii) Except as specifically authorized by § 720.10(a)(3) and (b)(2), submittal of a premanufacture notice by other than the person who intends to manufacture or import the chemical substance, or his designated agent;

(viii) Failure to provide any information required by §§ 5(d)(1)(B) and (C) of the Act, in accordance with § 720.23;

(ix) Failure of a notice to include the test data or other information which the submitter is required to submit pursuant to a rule promulgated under § 4 of the Act, in accordance with § 720.20(j);

(x) Failure to include the specific chemical identity of the substance for which the notice is submitted, unless it is impossible to do so, in accordance with § 720.20(f);

(xi) If EPA has listed a chemical substance under § 5(b)(4) of the Act, failure to submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment.

(2) If EPA determines that a premanufacture notice is invalid, the premanufacture notification period specified in § 720.35 of this Part will not begin.

(3) If EPA determines that a premanufacture notice is invalid, the Agency will notify the submitter by certified mail, return recepit requested. The notification will state the basis for the determination, and will explain the actions which are necessary to render the notice valid. Following receipt of a notice of invalidity, the person must submit a new notice for the chemical substance if he intends to manufacture or import the substance for a non-exempt commercial purpose. The person need not resubmit any information that he submitted with the first notice. The premanufacture notification period will commence upon acknowledgment of receipt, under § 720.31, of the required revisions.

(c) *Intentionally false or misleading statements.* If EPA discovers after expiration of the notification period that a person submitted intentionally false or misleading statements concerning a material aspect of his notice, EPA may find that the notice was invalid from the time of it initial submittal. If EPA makes this finding, the submitter will have failed to comply with the Act and these rules, and any manufacture, import, processing, distribution in commerce, use, or disposal of the substance by that person constitutes a violation of the Act.

§ 720.35 Premanufacture notification period; reports on status of new chemical substances.

(a) *Length of notification period.* The premanufacture notification period specified in § 5(a) of the Act runs for 90 days from the date EPA acknowledges receipt of premanufacture notice under § 720.31, unless the Agency extends the period in accordance with paragraph (b) of this section or suspends or invalidates the notice in accordance with § 720.34.

(b) *Extension of notification period.* (1) At any time during the notification period, EPA may determine that good cause exists to extend the notification period specified in paragraph (a).

(2) If EPA makes such a determination, the Agency will:

(i) Notify the submitter by certified letter, return receipt requested, that EPA is extending the period for a specified length of time, and state the reasons for the extension; and,

Publish a notice in the FEDERAL REGISTER which states that EPA is extending the period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the extension is for less than 90 days, EPA may make additional extensions. However, the total of the extensions may not exceed 90 days for any premanufacture notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notification period:

(i) EPA has reviewed the notice, and has determined that there is a significant possibility that the chemical will be regulated under section 5(e) or section 5(f) of the Act, but the Agency is unable to initiate regulatory action within the initial 90-day period;

(ii) EPA has reviewed the notice and has determined that information on the chemical is incomplete, and the Agency is seeking additional information;

(iii) Based on EPA's priorities and resources, the Agency is unable to process and review the notice within the initial notification period; and

(iv) EPA has found it necessary to publish an amended notice under § 720.32(c).

(c) *Notice of continuing review.* Upon expiration of the notification period, if EPA has identified a substance for possible regulatory action under the Act (other than imposition of a significant new use rule under section 5(a)(2) of the Act, or any requirement under section 8 of the Act) and is actively considering such an action, the Agency will notify the submitter of this fact. This continuing review has no effect on the submitter's right to commence manufacture or import of the new chemical substance upon expiration of the notification period. In addition, such notification is not a prerequisite to any regulatory action by EPA with respect to the chemical substance at any time after expiration of the notification period.

(d) *Monthly status report.* Subject to section 14, at the beginning of each month EPA will publish in the FEDERAL REGISTER a list of:

(1) Each chemical substance for which a premanufacture notice has been recieved, and for which the notification period described in paragraphs (a) and (b) of this section has not expired;

(2) Each chemical substance for which the notification period has expired since the last monthly status report; and,

(3) Each chemical substance that has been added to the inventory since the last monthly status report.

§ 720.36 Actions under section 5(e) of the Act.

(a) *Insufficient information.* Section 5(e) of the Act authorizes EPA to issue an order or to apply to a United States District Court for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance for which the Agency has received a premanufacture notice. In general, EPA may act under section 5(e) if the Agency lacks sufficient information to make a reasoned evaluation of the health and environmental effects of the substance, and the substance either

(1) May present an unreasonable risk of injury to health or the environment, or

(2) Will be produced in substantial quantities, and either it may enter the environment in substantial quantities, or there may enter the environment in substantial quantities, or there may be significant or substanital human exposure to the substance.

(b) *Order.* (1) EPA may issue a proposed order under § 5 (e) of the Act no later than 45 days before expiration of the applicable notification period (including any extensions which the Agency makes prior to issuance of the order).

(2) Before or on the date EPA issues a proposed order, the Agency will send a copy of the order by certified mail, return receipt requested, to the person who submitted the premanufacture notice, and to any other person who EPA believes intends to manufacture, import, or process the substance. The order will:

(i) State the basis for the determination required by § 5(e)(1)(A) of the Act; and

(ii) Indicate the type of information which would enable EPA to evaluate the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the substance. In addition, EPA will publish a notice in the FEDERAL REGISTER which describes the proposed order.

(3) Any manufacturer, importer, or processor of a chemical which is the subject of an order, or any other person who will be affected by the order, may file with EPA a written objection to the proposed order. EPA must receive the objection no later than 30 days after the person who files it receives the order sent under paragraph (b)(2) of this section; or, for any other person, no later than 30 days after the order appears in the FEDERAL REGISTER. The objection must specify with particularity the provisions of the order which the person finds objectionable, and state the grounds for these objections. If an objection is filed in accordance with this paragraph (b)(3), the provisions in the order to which the person objected will not take effect.

(4) Any provisions of the proposed order to which no person files an objection, in accordance with paragraph (b)(3) of this section, will take effect upon the expiration of the applicable notification period, and will remain in effect until EPA modifies or revokes them.

(5) If a person obtains new information which he believes is sufficient (alone or in combination with information previously submitted to EPA) to evaluate the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the substance, the person may petition EPA to modify or revoke the order based on the Agency's evaluation of the new information. EPA will publish a notice of the petition in the FEDERAL REGISTER.

(6) Any person who is affected by the order may petition EPA to modify or revoke the order if he believes there has been a substantial change in the factors relevant to EPA's decision to issue the § 5(e) order. EPA will publish a notice of the petition in the FEDERAL REGISTER.

(c) *Injunctive relief.* (1) At any time during the notification period, EPA may apply to a United States District Court for an injunction under the authority of § 5(e) of the Act.

(2) After an injunction is granted, any person may submit to EPA new information which he believes is sufficient to permit a reasoned evaluation of the health and environmental effects of the substance or which otherwise justifies modification or dissolution of the injunction. EPA will evaluate the information and, within 90 days after receiving it, will inform the submitter whether the Agency intends to petition the court for a modification or dissolution of the injunction.

§ 720.37 Actions under section 5(f) of the Act.

(a) *Unreasonable risk.* Under § 5(f) of the Act, if EPA determines that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance for which it has received a premanufacture notice will present an unreasonable risk of injury to health or the environment before a rule promulgated under § 6(a) of the Act can protect against such risk, the Agency may issue an order or apply to a United States District Court for an injunction to prohibit the manufacture, processing, or distribution in commerce of a substance, or may issue a proposed rule under § 6(a)(2)-(7) of the Act.

(b) *Order.* (1) EPA may issue a proposed order under section 5(f) of the Act no later than 45 days before expiration of the applicable notification period (including any extensions which the Agency makes prior to issuance of the order).

(2) Before or on the date EPA issues a proposed order, the Agency will send a copy of the order by certified mail, return receipt requested, to the person who submitted the premanufacture notice, and to any other person who EPA believes intends to manufacture, import, or process the substance. The order will state the basis of the determination required by section 5(f) of the Act. In addition, EPA will publish a notice in the FEDERAL REGISTER which describes the proposed order.

(3) Any manufacturer, importer or processor who is subject to an order, or any other person who will be affected by the order, may file with EPA a written objection to the proposed order. EPA must receive the objection no later than 30 days after the person who files it receives the order sent under paragraph (b)(2) of this section, or for any other person, no more than 30 days after the order appears in the FEDERAL REGISTER. The objection must specify with particularity the provisions of the order which the person finds objectionable, and state the grounds for these objections. If an objection is filed in accordance with this paragraph (b)(3), the provisions in the order to which the person objected will not take effect.

(4) Any provisions of the proposed order to which no person files an objection in accordance with paragraph (b)(3) of this section will take effect upon the expiration of the applicable notification period, and will remain in effect until EPA modifies or revokes them.

(5) Any person who is affected by the order may petition EPA to modify or revoke the order if he believes that new information has been developed, or that there has been a substantial change in the factors relevant to EPA's decision to issue the section 5(f) order. EPA will publish a notice of the petition in the FEDERAL REGISTER.

(6) If a person subsequently submits a premanufacture notice for a chemical substance which is subject to a section 5(f) order, EPA will consider the notice to be an application for modification or revocation of the order, and not a valid premanufacture notice.

(c) *Injunctive relief.* At any time during the notification period, EPA may apply to a United States District Court for an injunction under the authority of § 5(f) of the Act.

(d) *Proposed rule.* (1) If EPA proposes a rule in accordance with § 5(f) of the Act, the Agency will notify interested persons of this action within five days from the date of publication of the proposed rule in the FEDERAL REGISTER. The FEDERAL REGISTER notice will state the basis for the findings required by § 5(f), and also will include information concerning procedures for requesting a hearing on the proposed rule and for filing written comments with the Agency.

(2) If a hearing is requested, EPA will convene an informal hearing within five business days of the Agency's receipt of the request, unless the person(s) making the request and EPA agree on a later date. The hearing will be conducted in accordance with the provisions of section 6(c) of the Act, except as modified in accordance with the expedited schedule mandated by section 6(d)(2) of the Act.

(3) Within ten days of the conclusion of the informal hearing, EPA will either promulgate the rule as proposed or modified, or revoke it.

§ 720.38 Statement of reasons for not taking action.

(a) If: (1) EPA receives a premanufacture notice for a chemical substance for which a person is required to submit test data under § 4 and § 5(b)(1) of the Act, or for which the person is required under sections 5(b)(2) and (4) of the Act to submit data which he believes show that the chemical substance will not present an

unreasonable risk of injury to health or the environment; and (2) before expiration of the notification period EPA does not initiate any action under sections 5, 6, or 7 of the Act to prohibit or limit manufacture, processing, distribution in commerce, use, or disposal of the substance, EPA will publish in the FEDERAL REGISTER, before expiration of the notice period, a statement of the Agency's reasons for not initiating any such action.

(b) Publication of the statement will not prevent EPA from taking future regulatory actions with respect to the substance, and is not a prerequisite to the manufacture or processing of the substance.

Subpart E—Confidentiality and Public Access to Information

§ 720.40 General provisions.

(a) A person may assert a claim of confidentiality for any information which he submits to EPA under this Part.

(b) Any claim of confidentiality must accompany the information at the time it is submitted to EPA.

(1) For any information which a person submits on forms provided by EPA, he must assert his claim(s) on the form, and in the manner prescribed on the form and in the reporting instructions.

(2) For any information which a person does not submit on an EPA premanufacture form, he must submit two copies of the document in which the information appears.

(i) One copy of the document must be complete. In that copy the submitter must clearly identify the data which are claimed confidential by marking the specific information on each page with a label such as "confidential business information," "proprietary," or "trade secret."

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the person does not provide the second copy, EPA will notify him of this fact by telephone or certified mail. If EPA does not receive the second copy within ten days after the person receives this notice, the Agency will place the first copy in the public file.

(c) (1) At the time a person submits the information to EPA, he must substantiate any claim of confidentiality for chemical identity and for information contained in health and safety studies. The person must provide substantiation in the manner specified in the reporting instructions.

(2) If a person does not submit any substantiation, EPA will notify him of this fact by certified mail. If EPA does not receive the substantiation within ten days after the person receives this notice, the Agency will place the information in the public file.

(d) EPA will disclose information that is covered by a claim of confidentiality asserted in accordance with this section only to the extent permitted by, and in accordance with the procedures set forth in the Act, this subpart, and Part 2 of this Title.

(e) If a person does not assert a claim of confidentiality for information at the time he submits it to EPA, the Agency may make the information public, including placement in the public file, without further notice to the person.

§ 720.41 Specific chemical identity.

(a) *Claims applicable to period prior to commencement of manufacture or import for non-exempt commercial purposes.* (1) A person who submits information to EPA under this Part may assert a claim of confidentiality concerning the specific chemical identity of a particular chemical substance for the period prior to the commencement of manufacture or import for a non-exempt commercial purpose. A submitter may assert this claim only if he believes that public disclosure of the fact that anyone intends to manufacture or import the specific chemical substance prior to the commencement of manufacture or import for a non-exempt commercial purpose would reveal confidential business information.

(2)(i) Any person who intends to assert a claim of confidentiality with respect to the specific chemical identity of a new chemical substance under this paragraph should, before submitting a premanufacture notice, seek an advance determination by EPA of an appropriate generic name for the substance. For this purpose, a person should submit to EPA:

(A) The specific chemical identity of the substance;

(B) A proposed generic name(s) which is only as generic as necessary to protect the confidential identity of the particular chemical substance. In addition, the name should reveal to the maximum extent possible toxicologically significant aspects of the molecular structure. Before proposing a generic name to meet these criteria, the submitter should consult the *Guidelines for Creating Proposed Generic Names*, published as Appendix II to these rules; and

(C) An explanaton of why a more specific name would reveal confidential business information.

(ii) Within 30 days, EPA will inform the submitter either that the proposed generic name is adequate or that it may be inadequate and further consultation is necessary.

(3) Any person who asserts a claim of confidentiality for a specific chemical identity under this paragraph, at the time the premanufacture notice is submitted, must:

(i) Report the information identified in paragraph (a)(2)(i) of this section; and

(ii) Provide a detailed written substantiation of the claim, as specified in the reporting instructions.

(4)(i) If a submitter asserts such a claim, and if he complies with the procedures specified in paragraph (a)(3) of this section, EPA will publish the generic name in the FEDERAL REGISTER notice specified in § 720.32.

(ii) In response to a petition under paragraph (a)(4)(iii) of this section, or for any other reason, EPA subsequently may review the validity of the claim of confidentiality, including the substantiation of the claim required in paragraph (a)(3)(ii) of this section and the extent to which the generic name complies with EPA requirements.

(iii) Any person may petition EPA to review a generic name which has appeared in the FEDERAL REGISTER notice described in § 720.32. In his petition, the person must explain why the public interest would be served by a more specific name, why the existing generic name may not be in accord with EPA requirements, and why there is some characteristic of the class of chemicals included in the generic description which makes it imperative to make available a more specific name to allow more effective public evaluation of the likely health and environmental effects of the substance. EPA will examine the petition and, if the Agency determines that the petitioner has made an adequate justification for a more specific name, the Agency will evaluate the name in accordance with this paragraph.

(iv)(A) If at any time EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, the Agency will request the submitter to submit further proposed generic names.

(B) If EPA does not agree with the further proposed generic names, the Agency will choose a generic name that the Agency believes is in accordance with the principles set forth in paragraph (a)(2)(i)(B) of this section, and will notify the submitter concerning this choice. Thirty days after this notification, EPA will publish the chosen generic name in an amended FEDERAL REGISTER notice under § 720.32.

(b) *Claim applicable to the period after commencement of manufacture or import.* (1) Any claim of confidentiality under paragraph (a) of this section is applicable only until the substance is manufactured or imported

for non-exempt commercial purposes and becomes eligible for inclusion on the inventory. To maintain the confidential status of the specific chemical identity after the substance is added to the inventory, a person must assert an additional and independent claim of confidentiality concerning the specific chemical identity of a particular chemical substance. The submitter may assert this claim in the premanufacture notice if he intends to commence manufacture or import within one year from the date of the notice. If the projected date of commencement of manufacture or import for a non-exempt commercial purpose is more than one year from the date of the premanufacture notice, or if the person otherwise does not assert the claim in the premanufacture notice, he must assert the claim at least sixty days prior to the date of commencement of manufacture or import for non-exempt commercial purposes.

(2)(i) A person who believes that public disclosure of the fact that anyone manufactures or imports a specific chemical substance for a non-exempt commercial purpose would reveal confidential business information may assert a claim of confidentiality under this paragraph.

(ii) Notwithstanding the validity of a claim asserted under paragraph (b)(1) of this section, if the specific chemical identity is part of a health and safety study as defined in § 720.2, and if the claim for confidentiality with respect to that identity is denied in accordance with § 720.43, EPA will deny a claim asserted under this paragraph (b). EPA will notify the submitter concerning this determination, and thirty days after this notification, EPA will place the specific chemical identity on the inventory.

(3) Any person who asserts such a claim shall:

(i) Comply with the requirements of paragraph (a)(3) of this section;

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the substance (as defined in §720.12(b)) the fact that the particular substance is included on the inventory for purposes of TXCA §5(a)(1)(A) premanufacture notification; and

(iii) Have available for the particular substance, and agree to furnish to EPA upon request:

(A) An elemental analysis;

(B) Either an X-ray diffracton pattern (for inorganic substances) or a mass spectrum (for most other substances) of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance:

(C) A sample of the substance;

(iv) Provide a detailed written substantiation of the claim, as specified in the reporting instructions.

(4) If the submitter does not meet the requirements of this paragraph EPA will deny the claim of confidentiality.

(5)(i) EPA will publish a generic name in an appendix to the inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph;

(B) No claim for confidentiality of the specific chemical identity as part of a health and safety study has been denied in accordance with § 720.43; and

(C) The EPA General Counsel has made a determination (in accordance with Part 2 of this Title) that the particular chemical identity should not appear on the inventory because inclusion would disclose confidential business information.

(ii) Publication of a generic name in the appendix does not create a category for purposes of the inventory. Any person who has a *bona fide* intent to manufacture or import a substance which he believes may be on the inventory under a generic name may submit an inquiry to EPA under § 720.12(b) of this Part to determine whether a particular chemical is included in the inventory.

(iii) Upon receipt of the information specified in § 720.12(b), EPA may require the submitter who originally asserted confidentiality for a specific chemical substance to submit to EPA:

(A) An elemental analysis;

(B) Either an X-ray diffraction pattern (for inorganic substances) or a mass spectrum (for most other substances) of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance; and,

(C) A sample of the substance in its purest form.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within ten days of notification by the Agency under this paragraph is a waiver of the original submitter's confidentiality claim. In this event, EPA will place the specific chemical identity on the inventory without further notice to the original submitter.

(6) If a person asserts a claim of confidentiality under this paragraph, EPA will examine the generic chemical name proposed by the submitter who claims confidentiality.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular chemical substance, the Agency will place the generic name in an appendix to the inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, the Agency will request the submitter to submit further proposed generic names.

(iii) If EPA does not agree with the further proposed generic names, the Agency will choose a generic name that is only as generic as necessary to protect the confidential identity and will notify the submitter concerning this choice. Thirty days after this notification, EPA will place the chosen generic name in an appendix to the inventory.

§ 720.42 Uses and intended uses of a new chemical substance.

(a) A person who submits information to EPA under this Part with respect to the uses or intended uses of a new chemical substance may assert a claim of confidentiality for this information. A submitter may assert this claim only if he believes that public disclosure of the uses or intended uses of the substance would reveal confidential business information.

(b) If a submitter asserts such a claim, he must:

(1) Report the uses or intended uses of the substance;

(2) Provide, in non-confidential form, a description of the uses that is only as generic as necessary to protect the confidential business information; and

(3) Characterize, in accordance with the premanufacture notice form, the intended or projected exposure to persons in occupational, consumer, and other situations; the intended or projected releases of the substance to the general environment; and routes and levels of intended or projected exposure to humans and the environment.

(c) The person must submit the information required by paragraph (b) of this section in the manner specified in the premanufacture reporting instructions.

(d) If the person does not submit all of the information required by paragraph (b) of this section, EPA will deny the claim of confidentiality.

§ 720.43 Data from health and safety studies.

(a) *Information other than specific chemical identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of business confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential information concerning:

(1) Processes used in the manufacturing or processing of a chemcial substance or mixture;

(2) In the case of a mixture, the portions of a mixture comprised by any of the chemical substances in the mixture; or

(3) Information which is not in any way related to the effects of a substance on human health or the environment, including the name of the submitting company, cost or other financial data, product development or marketing plans, advertising plans, and use information for which the person submits a claim of confidentiality in accordance with § 720.42, but not including the specific chemcial identity of the substance(s) tested.

(b) *Specific chemical identity prior to commencement of manufacture or import for non-exempt commercial purposes.* (1) Notwithstanding paragraph (a) of this section, for the period prior to the commencement of manufacture or import, EPA will not deny a claim of business confidentiality with respect to the specific chemical identity of the substance if public disclosure of the specific identity would reveal confidential business information. This claim of confidentiality will be applicable only until the substance is manufactured or imported for non-exempt commercial purposes.

(2) A claim of confidentiality for the period prior to commencement of manufacture with respect to the specific chemical identity included in a health and safety study shall be asserted and substantiated in conjunction with a claim asserted under § 720.41(a).

(c) *Specific chemical identities after commencement of manufacture or import.* (1) To maintain the confidential status of a specific chemical identity as part of a health and safety study after the commencement of manufacture or import, a person must assert an additional and independent claim of confidentiality. This claim should be asserted in conjunction with a claim under § 720.41(b)(3), and the substantiation should particularly address whether disclosure of the specific chemcial identity would reveal confidential business information concerning the processes used in the manufacture or processing of a chemical substance, or the portions of a mixture comprised by any of the chemical substances in the mixture.

(2) EPA will deny a claim of business confidentiality under this paragraph, unless the information would disclose:

(i) Processes used in the manufacture or processing of a chemical substance or mixture; or

(ii) In the case of a mixture, the portions of the mixture comprised by any of the substances in the mixture.

(d) *Use of generic names.* When EPA discloses a health and safety study for which the person has asserted a claim of confidentiality with respect to the specific chemical identity, and if the Agency has not denied the claim in accordance with paragraphs (a) or (b) of this section, EPA will identify the substance by its generic name as proposed by the submitter, or as modified by EPA in accordance with § 720.41.

§ 720.44 Public files.

All information submitted with a premanufacture notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are subject to any claims of confidentiality. In addition, EPA may add materials to the public file, subject to § 14 of the Act and subpart E of this Part. Any of the non-confidential material described above will be available for public inspection in the Office of Toxic Substances Public Reading Room, EPA, 401 M Street, S.W., Washington, D.C. 20460, during normal business hours.

Subpart F—Supplemental Reporting Requirements

§ 720.50 Reporting requirements under Section 8(a) and Section 5 of the Act.

(a) *General.* (1) EPA may use the procedures established in paragraph (e) of this section to require persons to report supplemental information with respect to the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance for which the Agency receives a premanufacture notice. Except as provided in paragraph (a)(2) of this section, paragraphs (b), (c), and (d) of this section describe the persons who may be subject to such reporting requirements.

(2) Except with respect to reporting under paragraph (c)(2)(i) of this section, no person whose total annual sales are less than $1,000,000, based upon the person's latest complete fiscal year, shall be subject to a reporting requirement under this section.

(b) *Manufacturer or importer of an unknown reactant.* If EPA receives a premanufacture notice from a person who identifies the new chemical substance as a product of a reaction which includes at least one unknown reactant, and if the person demonstrates that he has attempted to obtain information concerning the identity of the reactant from the manufacturer or importer of the reactant, EPA may require the manufacturer or importer of the unknown reactant(s) to report its identity or composition to EPA.

(c) *Person who submits a premanufacture notice.* (1) EPA may require the person who submits a premanufacture notice to report the information specified in paragraph (c)(2) of this section if the Agency believes that the information would be relevant to determine whether EPA should require the substance to be tested under § 4 of the Act, control the substance under §§ 5(e), 5(f), or 6(a), or follow up on the substance under the authorities of §§ 5(a)(2) or 8(a).

(2) EPA may require submittal of the following types of information if the information is known to or reasonably ascertainable by the submitter:

(i) Information which supplements, provides further detail on, or otherwise clarifies the information which a person was required to submit in his premanufacture notice;

(ii) Information which was identified as optional in the premanufacture notice, or information which supplements, provides further detail on, or otherwise clarifies such information;

(iii) Information concerning the benefits of the substance for various uses and the availability of substitutes for those uses; and,

(iv) Information concerning the reasonably ascertainable economic consequences of any specified regulation under the Act including the national economy, small business, technological innovation, the environment, and public health.

(d) *Processor.* (1) EPA May require any person who intends to process a substance for which a premanufacture notice was received to report the information specified in paragraph (d)(2) of this section, if the Agency believes that the information would be relevant to determine whether EPA should require the substance to be tested under section 4 of the Act, control the substance under sections 5(e), 5(f), or 6(a), or follow up on the substance under sections 5(a)(2) or 8(a).

(2) EPA may require submittal of the following types of information, if the information is known to or reasonably ascertainable by the intended processor:

(i) Information requested on the premanufacture notice form and instructions with respect to that person's processing of the substance, including categories of use, amounts to be processed for each use, the manner and method of disposal of such substance, and human and environmental exposures which may result from his processing of the substance and from subsequent distribution in commerce, use, or disposal of the substance or of mixtures or articles containing the substance;

(ii) information concerning the benefits of the substance for uses resulting from the person's processing of the substance, and "the availability of substitutes" for such uses; and,

(iii) Information concerning the reasonably ascertainable economic consequences of any specified control meas-

ure under the Act, including impact on the national economy, small business, technological innovation, the environment, and public health.

(e) *Procedures for reporting.* EPA will notify in writing any person subject to a reporting requirement under this section. The notification will be sent by certified mail, with return receipt requested. The written notification will include:

(1) A copy of this § 720.50;

(2) A detailed description of the information which is required to be submitted;

(3) The name, address, and telephone number of the person to whom the information must be submitted; and,

(4) The date by which the information must be submitted, which shall be no sooner than 15 days after the person receives the notification.

§ 720.51 Requirements for submittal of health and safety studies under § 8(d) of the Act.

(a) *Applicability.* EPA may use the procedures established in paragraph (b) of this section to require any person who has possession of a health and safety study to submit the study, if the Agency believes that the study would assist in the evaluation of the health or environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance for which the Agency received a premanufacture notice.

(b) *Procedures.* EPA will notify in writing any person subject to a requirement under this section. The notification will be sent by certified mail, with return receipt requested. The written notification will include:

(1) A copy of this § 720.51;

(2) A description of the requested study;

(3) The name, address, and telephone number of the person to whom the study must be submitted; and,

(4) The date by which the study must be submitted, which date shall be no sooner than 15 days after the person receives the notification.

§ 720.52 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences to manufacture or import for a non-exempt commercial purpose a new chemical substance for which the person previously submitted a premanufacture notice under this Part shall submit the notice prescribed by this section.

(b) *When to report.* The person must submit the notice to EPA no later than the day the person first manufactures or imports the substance for a non-exempt commercial purpose.

(c) *Information to be reported.* (1) To report a chemical substance, a person shall complete, sign, and submit to EPA. a "Notice of Commencement of Manufacture or Import." This form has OMB No. ———. The notice must include a reference to the relevant premanufacture notice as required by the form instructions. In addition, if the person has asserted a confidentiality claim under § 720.41(b) he must certify that any substantiation previously submitted to the Agency is materially accurate as of the date of commencement of manufacture or import indicated by the notice.

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PREMANUFACTURE NOTIFICATION FOR NEW CHEMICAL SUBSTANCES

APPENDIX I

Sections 5(d)(1)(B) and (C) of TSCA require persons to submit in their premanufacture notices all test data in their possession or control, plus descriptions of any other data which are known to or reasonably ascertainable by them. Section 720.23 of the Premanufacture Notification Rules implement these provisions of the Act. In particular, § 720.23(c)(1) provides that persons need not submit data that appear in periodicals which are listed in this Appendix I, provided they submit standard literature citations for the data.

The periodicals listed are those to which EPA's Office of Toxic Substances (OTS) has immediate access on a regular on-call basis. From time to time EPA will amend this list, primarily to add new listings as OTS's access to periodicals improves.

APPENDIX I—PERIODICAL TITLES AND DATES

1. Accounts of Chemical Research, 1976-present
2. Air Pollution Control Association Journal, 1974-present
3. American Chemical Society Journal, 1968-present
4. American Industrial Hygience Association Journal July 1969-present
5. American Scientist, 1953-present
6. Analytical Chemistry Journal, 1957-present
7. Annual Review of Ecology and Systematics, 1970 Vol. 1-present
8. Archives of Environmental Contamination and Toxicology, 1973-present
9. Archiv fur Toxicology, 1958-present
10. Archive of Environmental Health, 1960-present
11. Atmospheric Environment, an Industrial Journal, 1967-present
12. Biochemical Pharmacology, 1958-present
13. British Journal of Industrial Medicine, 1973-present
14. Bulletin of Environmental Contamination and Toxicology, 1976-present
15. Cancer Research, 1962-present
16. Chemosphere, 1972-present
17. CRC Critical Reviews in Toxicology, 1978-present
18. Ecology, 1970-present
19. Environment Health Perspectives, 1978-present
20. Environment Science and Technology, 1967-present
21. Food and Cosmetics Toxicology, 1963-present
22. Health Physics, 1958-present
23. I.A.R.C. Monographs, all volumes
24. Inorganic Chemistry, 1962-present
25. Journal of Agricultural and Food Chemistry, 1953-present
26. Journal of the Fisheries Research Board of Canada, 1972-present
27. Journal of Organic Chemistry, 1962-present
28. Journal of Pharmacology and Experimental Therapeutics, 1969-present
29. Journal of Physical Chemistry, 1963-present
30. Journal of Physical Chemical Reference Data, 1978-present
31. Mutation Research, 1964-present
32. National Academy of Sciences Proceedings, July 1978-present
33. National Cancer Institute Journal, 1978-present
34. Nature, 1960-present
35. New England Journal of Medicine, 1969-present
36. Pesticides Monitoring Journal, 1967-present
37. Residue Review, 1970 (Vol. 3)-present
38. Science, 1960-present
39. Teratology, 1978-present
40. Toxicology and Applied Pharmacology, December 1974-present
41. Water Pollution Control Federation Journal, 1960-present
42. Weed Science, 1968-present
43. Xenobiotica, 1978-present

APPENDIX II.—GUIDELINES FOR CREATING PROPOSED GENERIC NAMES FOR CONFIDENTIAL CHEMICAL SUBSTANCE IDENTITIES FOR PREMANUFACTURE NOTIFICATION

This document contains guidelines for creating proposed generic names for chemical substances whose identities are claimed confidential for purposes of EPA's Premanufacture Notification Program. These guidelines are an amended version of guidelines which EPA first made available in April, 1977, to assist persons who claimed specific chemical identity confidential for purposes of the Chemical Substance Inventory. The Agency has modified them to conform to the premanufacture notification rules. These proposed rules would require persons who claim confidentiality with respect to specific chemical identity to follow these guidelines in creating a proposed generic name. EPA solicits comments concerning the applicability of these guidelines in implementing the confidential identity requirements of the premanufacture notification rules.

I. BACKGROUND AND PURPOSE

Proposed § 720.41 would require any person who claims the identity of his new chemical substance confidential to provide a detailed, written substantiation to support the claim. In addition the rules would require such a person to submit a proposed generic name for the substance which "is only as generic as necessary to protect the confidential identity of the chemical substance."

EPA designed these guidelines to assist submitters in developing proposed generic names to meet these requirements. They offer a systematic means of masking selected parts of a specific chemical identity to construct an appropriate generic name.

In general, adherence to these guidelines should result in development of a generic name which is acceptable to EPA. If the manufacturer does not adhere to these guidelines, he must submit a written justification for the proposed generic name. This justification must include an explanation of why a more specific name than the one which was proposed would not adequately mask the confidential substance identity. If EPA determines that the proposed generic name is more generic than is necessary to protect the confidential identity of the substance, the Agency, in accordance with 720.41(a)(4)(ii) will request the submitter to propose other less generic names for EPA consideration. The name justification referred to above is necessary in order to provide EPA with a basis for review of the generic name proposed.

The proposed rules also state that the generic name should reveal, to the maximum extent possible, "toxicologically significant aspects" of the molecular structure. Thus in creating a generic name which adequately masks the specific chemical identity, the submitter should choose the name which most closely meets this requirement. EPA is considering how it should modify these guidelines to provide explicit guidance in this regard. The Agency specifically solicits comments concerning the practicability of creating generic names which would reveal toxicologically significant aspects of the chemical identity, and concerning any criteria or procedures which would achieve this objective.

II. BASIC APPROACH

The procedures presented below for creating a proposed generic name are based on the masking of selected, revealing parts of the specific substance name which most precisely describe the identity of a particular chemcial substance.

The specific name for a Class 1 chemical substance (a substance whose composition, except for impurities, may be represented by a definite chemical structure diagram) will invariably permit the unambiguous identification of the substance in terms of its molecular formula and chemical structure diagram. However, the specific name for a Class 2 chemical substance (a substance whose composition, except for impurities, *cannot* be represented by a definite chemical structure diagram) may or may not reveal all of the supporting information which is reported to establish the substance's identity. This supporting information, required in the Premanufacture Notice Form, will identify the method by which the substance was manufactured, including its precursors and other reactants, the nature of the reaction or derivation used to produce the chemical substance and its chemical composition.

Because of differences inherent in naming Class 1 and Class 2 chemical substances, these procedures address each separately. However, the procedures for creating proposed generic names for Class 1 substances may be applicable, in certain instances, to the creation of proposed generic names for Class 2 substances.

III. CLASS 1 CHEMICAL SUBSTANCES

The composition of a Class 1 chemical substance, except for impurities, can be represented by a definite chemical structural diagram. For identification purposes, a substance of this type is specified by three items of information: 1) its specific chemical name, 2) its molecular formula, and 3) its chemical structure diagram. The specific chemical name for a Class 1 substance is so precisely descriptive of the exact substance identity, however, that the other two items of information can be generated easily.

The names of Class 1 chemical substances normally disclose the following chemical structure information:

Identity of parent structure (i.e., a chain of carbon atoms, a ring system, or a coordinated metal).

Identity, number, and position of each chemical group which is attached to the parent structure(s) or to other chemical groups.

Identity and number of counter ions (for salts).

Stereochemical relationships.

Generic chemical names may be created for Class 1 chemical substances by masking structurally descriptive parts of their specific chemical names. Masking may be accomplished by substituting less descriptive terms for descriptive parts of the name. Proposed generic names created by eliminating stereochemical indicators (if appropriate) from the specific chemical name and by masking *one* other structure detail, as specified below, will, in most cases, be acceptable to EPA.

The structurally descriptive parts of a Class 1 chemical name, any *one* of which may be masked when creating a proposed generic name, are listed below:

1. A locant which specifies the placement of a single chemical group.
2. Locant and multiplicative prefixes (e.g., di-, tri-, tetra-) which together specify the number and placement of a given chemical group.
3. Identity (but *not* placement and number) of a given chemical group.
4. Identity of a given parent structure, and locants of substituent chemical groups.
5. Identity and multiplicative prefixes (specifying the number) of a given simple cation or anion of a salt.

Chemical Group Masking

Table 1 of this procedure lists by name and molecular formula the chemical groups which may be masked to create a proposed generic name for a Class 1 chemical substance. As stated above, only one such group or multiple occurrence of the *same* group should be masked in the specific chemical name for the substance.

The groups of atoms found in Table 1 are common chemical structural units; a given group may be listed under more than one name. Each group includes at least one atom other than carbon or hydrogen.

A chemical group which includes a carbon atom having more than one single free valence (e.g., carbonyl -CO-) should not be masked if the carbon atom is directly attached to an acyclic carbon atom or is included within a ring system; in this circumstance, only the atom or group of atoms attached to the carbon atom should be masked. (See Example 2, below, where the oxo group is masked.)

Certain chemical groups in Table 1 include hydrogen atoms which are often additionally substituted, e.g., an ethyl group may be substituted for a hydrogen of the sulfamyl group (H_2NSO_2-) to give $C_2H_5NHSO_2$-. If additionally substituted, *only* the chemical group listed in Table 1 should be masked, *not* the substituent.

Table 1 lists most of the *common* chemical functional groups which contain oxygen, e.g., H_2NCO-. While not always listed, the Periodic Chart Group VIa element (sulfur, selenium, and tellurium) analogs of these functional groups, e.g., H_2NCSe-, are considered included within Table 1 and, accordingly, may be used in masking.

Parent Masking

A parent structure which is a chain of carbon atoms or a ring system may be masked in the chemical name only by the following generic terms:

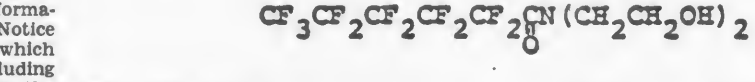
- alkyl *or* alkane
- alkenyl *or* alkene
- alkynyl *or* alkyne
- carbomonocyclic *or* carbomonocycle (e.g., benzene, cyclopentane)
- carbopolycyclic *or* carbopolycycle (e.g., naphthalene, spiroundecane)
- heteromonocyclic *or* heteromonocycle (e.g., pyrrole, p-dioxane)
- heteropolycyclic *or* heteropolycycle (e.g., indole, benzothiazole)

In the case of a coordinated metal compound, the identity of the metal atom may be masked by the term "metal" in the chemical name.

Only one such parent group or multiple occurrences of the *same* parent group should be masked.

The following examples show how several hypothetical compounds could be identified by names which mask only *one* structural detail (other than stereochemistry).

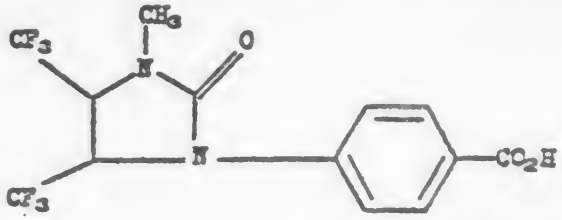
EXAMPLE 1



Fully defined name:
2,2,3,3,4,4,5,5,6,6,6-undecafluoro-*N*,*N*-bis(2-hydroxyethyl)hexanamide

Acceptable generic names:
- fluorine atoms masked: *N*,*N*,-bis(2-hydroxyethyl)-2,2,3,3,4,4,5,5,6,6,6-undescasubstituted hexanamide
- number of fluorine atoms masked: polyfluoro-*N*,*N*-bis(2-hydroxyethyl)hexanamide
- hydroxyl groups masked: 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-*N*,*N*-bis(2-substituted ethyl)hexanamide
- hexane parent (plus locants) masked: undecafluoro-*N*,*N*-bis(2-hydroxyethyl)alkanamide
- amide group (plus nitrogen locants) masked: 2,2,3,3,4,4,5,5,6,6,6-undecafluorobis (2-hydroxyethyl)hexane derivative

EXAMPLE 2

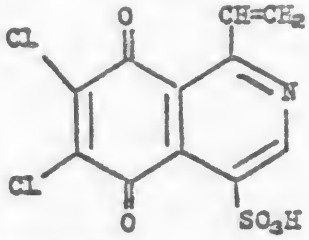


Fully defined name:
4-[3-methyl-2-oxo-4,5-bis(trifluoromethyl)-1-imidazolidinyl] benzoic acid
Acceptable defined names:
oxo group masked: 4-[3-methyl-2-substituted-4,5-bis(trifluoromethyl)-1-imidazolidinyl]benzoic acid

(NOTE.—Only the oxo and not the carbonyl group has been masked.)

fluorine atoms masked: 4-[3-methyl-2-oxo-4,5-bis(trisubstituted methyl)-1-imidazolidinyl]benzoic acid
benzene ring (plus locant) masked: [3-methyl-2-oxo-4,5-bis(triflurormethyl)-1-imidazolidinyl]carbomonocyclic carboxylic acid
imidazolidine ring (plus locants) masked: 4 - [methyloxobis (trifluoromethyl) heteromonocycle] benzoic acid

EXAMPLE 3



Fully defined name:
6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid
Acceptable generic names:
chlorine atoms masked: 1-ethenyl-5,8-dihydro-5,8-dioxo-6,7-disubstituted-4-isoquinolinesulfonic acid
vinyl group masked: 1-alkenyl-6,7-dichloro-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid
oxo group masked: 6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-disubstituted-4-isoquinolinesulfonic acid
sulfo group masked: 6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-substituted isoquinoline
isoquinoline ring (plus locants) masked: dichloroethenyldihydrodioxo heteropolycyclic sulfonic acid or dichloroethenyldihydrodioxosulfo heteropolycycle

IV. CLASS 2 CHEMICAL SUBSTANCES

The composition of a Class 2 chemical substance cannot be represented by a definite chemical structure diagram. The specific name which is used to describe such a substance for the Premanufacture Notice Form may be based, in whole or in part, on the supplemental information—information which further establishes the identity of the substance.

The composition of some Class 2 substances can be represented by a partial or incomplete chemical structure diagram, similar to those shown on page 113 of "Reporting for the Chemical Substance Inventory" (December 1977). In other instances, the composition can only be described in terms of a complex combination of several different known or unknown components.

The method by which a Class 2 substance was manufactured can also serve to identify the substance. For a substance manufactured by chemical reaction, identification can be stated in terms of the immediate precursor substances and other reactants which participate in the final reaction sequence used to manufacture the substance, and the nature of the reaction, e.g., ethoxylation, or bromination. For a substance derived from a source without chemical reaction, processing information will identify the source and method of derivation, e.g., distillation, or extraction with methylene chloride.

Because Class 2 chemical substance names may be based on such variable types of information, these procedures are stated in only the most general terms. Nonetheless, in instances such as those described below, the procedure presented earlier for creating generic names for Class 1 substances may be applicable.

The composition of a Class 2 chemical substance which can be represented by a partial or incomplete chemical structure diagram can generally be described by a specific chemical name which encompasses the variability or incompleteness in the structure, yet which is as descriptive as possible of the structure in other respects. EPA will generally accept a proposed generic name for such a substance if created by following the procedure specified for masking Class 1 chemical substances.

In other instances, the specific name for a Class 2 chemical substance may identify, by specific chemical name, a predominant component or components of its composition, an immediate precursor or precursors, and other reactants. EPA will generally accept a proposed generic name for such a substance if it is constructed by masking the chemical name of *one* such component, precursor, or reactant according to the procedure specified for Class 1 substances.

Clearly, the procedure in this document are most useful for masking the identity of Class 1 chemical substances, and will only be useful for some kinds of Class 2 substance names. Persons who attempt to apply the procedures to mask other Class 2 chemical substance names may find, in certain instances, that the guidelines have little applicability. They will, therefore, need to base their choice of a generic name on the general principle that the name should be "only as generic as necessary to protect the confidential identity of the particular chemical substance." These persons should attach a written statement to the Premanufacture Notice Form explaining their choice of the generic name for the substance. Each feature that is masked should be discussed separately. The statement should specifically address why a more specific name than the one proposed would not adequately mask the confidential substance identity. EPA will consider each such proposed generic name on a case-by-case basis.

V. JUSTIFYING THE USE OF ADDITIONAL MASKING

Persons who determine that strict application of these procedures would not adequately mask the confidential substance identity may propose a generic name which masks the substance identity to a greater extent than provided for by these procedures. Such additional masking should be in a written statement, headed "Justification for Additional Masking," and attached to the Premanufacture Notice Form. The statement should be prepared in the following manner:

1. Construct each reasonably applicable generic name provided for by following the procedure specified here.

2. For each generic name constructed by Step 1, explain the reason why the name is inappropriate for masking the confidential substance identity. For example, the number of substances encompassed by the generic name may be very small. Or, the generic name may still reveal information about the chemical substance which in and of itself formed the basis for the confidential chemical substance identity claim. Such reasons should be clearly explained.

3. Select a suitable generic name which masks two aspects of the chemical substance identity. If such double masking is perceived as still inappropriate, state the reason for rejecting each reasonably applicable, doubly-masked generic name (as discussed in Step 2) before proceeding to propose a generic name that masks three or more aspects of the chemical substance name. In proposing a generic name for a chemical substance, explain the reasons for rejecting each reasonably applicable generic name which would mask the specific chemical identity to a lesser degree.

TABLE 1 *List of Common Chemical Structural Units*

aldo O=
amidino $H_2NC(=NH)$—
amino H_2N—
(aminoamidino) $H_2NC(=NNH_2)$— or $H_2NNHC(=NH)$—
(aminocarbonyl) H_2NCO—
[(aminocarbonyl)amino] H_2NCONH—
[2-(aminocarbonyl)hydrazino] $H_2NCONHNH$—
[(aminocarbonyl)hydrazono] $H_2NCONHN=$
(aminohydrazonomethyl) $H_2NC(=NNH_2)$—
[(aminohydroxymethylene)hydrazino] $H_2NC(OH)=NNH$—
(aminoiminomethyl) $H_2NC(=NH)$—
(aminoiminophosphoranyl) $H_2NPH(=NH)$—
(P-aminophosphinimyl) $H_2NPH(=NH)$—
(aminosulfinyl) H_2NSO—
(aminosulfonyl) H_2NSO_2—
(aminothio) H_2NS—
(aminothioxomethyl) H_2NCS—
ammonio H_2N^+—
antimono —Sb=Sb—
arseno —As=As—
arsenoso OAs—
arsinico $HOAs(O)=$
arsinidene AsH=
arsinidyne As≡
arsinimyl $AsH_2(=NH)$—
arsino AsH_2—
arsinothioyl $AsH_2(S)$—
arsinyl $AsH_2(O)$—

arsinylidene AsH(O)=
arso O_{2As}—
arsono $(HO)_2As(O)$—
(arsonooxy) $(HO)_2As(O)O$—
arsonoitridyl AsH(≡N)—
arsoranyl AsH_4—

arsoranylidyne AsH_2≡
arsylene AsH=
arsylidyne AsH≡
astato At—
astatoxy O_2At—
astatyl O_2At—
azi —N=N—
azido N_3—
(azidocarbonyl) N_3CO—
(azidoformyl) N_3CO—
(azidosulfonyl) N_3SO_2—
azino =NN=
azo —N=N—
azoxy —N(O)N—

bismuthino BiH_2—
bismuthylene BiH=
bismuthylidyne Bi≡
borono $(HO)_2B$—
(boronooxy) $(HO)_2BO$—
boryl BH_2—
borylene BH=
borylidyne B≡
bromo Br—
(bromocarbonyl) BrCO—
(bromoiminomethyl) BrC(=NH)—
(bromosulfonyl) $BrSO_2$—

carbamido H_2NCONH—
carbamoyl H_2NCO—
carbamyl H_2NCO—
carbonimidoyl —C(=NH)—
(carbonimidoylamino) HN=C=N—
carbonothioyl —CS—
carbonyl —CO—
(carbonyldiimino) —NHCONH—
(carbonyldioxy) —OC(O)O—
carboxy HO_2C—
chloro Cl—
(chlorocarbonyl) ClCO—
(chloroformyl) ClCO—
(chloroiminomethyl) ClC(=NH)—
(chlorosulfinyl) ClSO—
(chlorosulfonyl) $ClSO_2$—
chlorosyl OCl—
(chlorothio) ClS—
chloryl O_2Cl—
cyanato NCO—
cyano NC—

1,2-diarsenediyl —As=As—
diarsenyl HAs=As—
diarsinetetrayl =AsAs=
diarsinyl H_2AsAsH—
1,2-diazenediyl —N=N—
diazeno HN=N—
diazo N_2=
diazoamino —NHN=N—
diazonio N_2^+—
1,2-diborane(4)diylidene =BB=
diborane(4)tetrayl =BB=
digermanylene $—GeH_2GeH_2$—
digermathianyl $H_3GeSGeH_2$—
dioxy —OO—
1,2-diphosphenediyl —P=P—
1,2-diphosphinediyl —PHPH—
1,2-diphosphinediylidene =PP=
diphosphinetetrayl =PP=
diphosphinyl H_2PPH—
diseleno —SeSe—
1,2-disilanediyl $—SiH_2SiH_2$—
disilanoxy H_2SiSiH_2O—
disilanyl H_2SiSiH_2—
disilanylene $—SiH_2SiH_2$—
(disilanyloxy) H_2SiSiH_2O—
(disilathianyloxy) $H_2SiSSiH_2O$—
disilazanoxy $H_2SiNHSiH_2O$—
disilazanyl $H_2SiNHSiH_2$—
2-disilazanyl $(H_3Si)_2N$—
(disilazanyloxy) $H_2SiNHSiH_2O$—
1,3-disiloxanediyl $—SiH_2OSiH_2$—
1,3-disiloxanediylidene =SiHOSiH=
disiloxanoxy $H_2SiOSiH_2O$—
disiloxanylene $—SiH_2OSiH_2$—
(disiloxanyloxy) $H_2SiOSiH_2O$—
disilthianoxy $H_2SiSSiH_2O$—
1,2-distannanediyl $—SnH_2SnH_2$—
distannanylene $—SnH_2SnH_2$—
1,3-distannathianediylidene =SnHSSnH=
1,2-distibenediyl —Sb=Sb—
disulfinyl —S(O)S(O)—
dithio —SS—
(dithiocarboxy) HSCS—
(dithiohydroperoxy) HSS—

epidioxy —OO—
epidiseleno —SeSe—
epidithio —SS—
epioxy —O—
episeleno —Se—
epithio —S—
epoxy —O—

fluoro F—
(fluorocarbonyl) FCO—
fluoryl O_2F—
formamido HCONH—
1,5-formazandiyl —N=NCH=NNH—
1,formazano $H_2NN=CHN=N$—
5,formazano HN=NCH=NNH—
formazanyl HN=NC(=NNH_2)—
formimidoyl HC(=NH)—
formyl HCO—
(formylamino) HCONH—

germanetetrayl =Ge=
germyl H_3Ge—germylene H_2Ge=
germylidyne HGe≡
guanyl $H_2NC(=NH)$—

hydrazi —NHNH—
1,2-hydrazinediylidene =NN=
hydrazino H_2NNH—
(hydrazinocarbonyl) H_2NNHCO—
(hydrazinoiminomethyl) $H_2NNHC(=NH)$—
(hydrazinosulfinyl) H_2NNHSO—
(hydrazinosulfonyl) H_2NNHSO_2—
(hydrazinothioxomethyl) H_2NNHCS—
1-hydrazinyl-2-ylidene —NHN—
hydrazo —NHNH—
hydrazono H_2NN=
hydroperoxy HOO—
(hydroperoxycarbonyl) HOOCO—
(hydroperoxyiminomethyl) HOOC(=NH)—
(hydroperoxysulfinyl) HOOS(=O)—
(hydroperoxysulfonyl) $HOOS(=O)_2$—
(hydroperoxythioxomethyl) HOOCS—
hydroxy HO—
(hydroxyamino) HONH—
(hydroxyimino) HON=
(hydroxyiminomethyl) HOC(=NH)—
hydroxyl HO—
(hydroxyphosphinyl) HOPH(O)—

imidocarbonyl —C(=NH)—
(imidocarbonylamino) HN=C=N—
imino HN=
(iminomercaptomethyl) HSC(=NH)—
[imino(mercaptooxy)methyl]
HSOC(=NH)—
(iminomethyl) HN=CH—
(iminontrilo) —NHN=
(iminophosphoranyl) $H_2P(=NH)$—
(iminosulfenomethyl) HOSC(=NH)—
iodo I—
(iodocarbonyl) ICO—
iodosyl OI—
iodyl O_2I—
isocyanato OCN—
(isocyanatocarbonyl) OCNCO—
(isocyanatosulfonyl) $OCNSO_2$—
isocyano CN—
(isocyanocarbonyl) CNCO—
isonitro HON(O)=
isonitroso HON=
isosemicarbazido $H_2NC(OH)=NNH$—
isothiocyanato SCN—
(isothiocyanatocarbonyl) SCNCO—
(isothiocyanatosulfonyl) $SCNSO_2$—
isothiocyano SCN—

keto O=

mercapto HS—
(mercaptoamino) HSNH—
(mercaptooxy) HSO—
[(mercaptooxy)carbonyl] HSOCO—
[(mercaptooxy)sulfinyl] HSOS(=O)—
[(mercaptooxy)sulfonyl] $HSOS(=O)_2$—
[(mercaptooxy)thioxomethyl] HSOCS—
(mercaptotelluro) HSTe—

nitramino O_2NNH—
aci-nitramino HON(O)=N—
nitrilio HN^+≡
nitrilo N≡
(nitrilophosphoranyl) HP(≡N)—
nitro O_2N—
aci-nitro HON(O)=
(nitroamino) O_2NNH—
(*aci*-nitroamino) HON(O)=N—
(nitrooxy) O_2NO—
nitroso ON—
(nitrosoamino) ONNH—
(nitrosoimino) ONN=
(nitrosooxy) ONO—
(nitrothio) O_2NS—

oximido HON=
oxo O=
(oxoboryl) OB—
oxy —O—

1,3-pentazadienyl $H_2NN=NN=N$—
perchloryl O_3Cl—
perseleno Se=Se=
perthio S=S=
phosphinico HOP(O)=
phosphinidene HP=
phosphinidyne P≡
phosphinimyl $H_2P(=NH)$—
phosphino H_2P—
phosphinothioyl $H_2P(S)$—
phosphinothioylidene HP(S)=
phosphinyl $H_2P(O)$—
phosphinylidene HP(O)=
phosphinylidyne P(O)≡
phospho O_2P—
phophono $(HO)_2P(O)$—
(phosphonocarbonyl) $(HO)_2P(O)CO$—
phosphononitridyl HP(≡N)—
(phosphonooxy) $(HO)_2P(O)O$—
phosphoranyl H_4P—
phosphoranylidene H_2P=
phosphoranylidyne H_2P≡
phosphoro —P=P—
phosphoroso OP—
plumbanetetrayl =Pb=
plumbyl H_3Pb—
plumbylene H_2Pb=
plumbylidyne HPb≡

seleneno HOSe—
selenino HOSe(O)—
seleninoselenoyl Se=Se=
seleninyl OSe=
seleno —Se—
selenocyanato NCSe—
selenono $(HO)SeO_2$—
selenonyl O_2Se=
selenoxo Se=
selenyl HSe—
semicarbazido $H_2NCONHNH$—
semicarbazono $H_2NCONHN$=
silanetetrayl =Si=
silyl H_3Si—
silylene H_2Si=
silylidyne HSi≡
(silyloxy) H_2SiO—
stannanetetrayl =Sn=
stannono HOSn(O)—
stannyl H_3Sn—
stannylene H_2Sn=
stannylidyne HSn≡

stibinico HOSb(O)=
stibino H_2Sb—
stibo O_2Sb—
stibono $(HO)_2Sb(O)$—
(stibonooxy) $(HO)_2Sb(O)O$—
stiboso OSb—
stibyl H_2Sb—
stibylene HSb=
stibylidyne Sb≡
sulfamino $HOSO_2NH$—
sulfamoyl H_2NSO_2—
sulfamyl H_2NSO_4—
sulfeno HOS—
(sulfenocarbonyl) HOSCO—
(sulfenosulfinyl) $HOSS(=O)$—
(sulfenosulfonyl) $HOSS(=O)_2$—
(sulfenothioxomethyl) HOSCS—
sulfhydryl HS—
sulfinimidoyl HN=S=
sulfino HOS(O)
(sulfinooxy) HOS(O)O—
sulfinothioyl S=S=
sulfinyl OS=
sulfo HO_3S—
(sulfoamino) $HOSO_2NH$—
sulfonimidoyl HN=S(O)=
sulfonodiimidoyl $(HN=)_2S=$
sulfonyl $—SO_2—$
(sulfooxy) HO_3SO—
sulfuryl $—SO_2—$

telluro —Te—
telluroxo Te=
telluryl HTe—
1,4-tetraphosphinediyl $—(Ph)_4—$
1,7-tetrasiloxanediyl $—SiH_2(OSiH_2)_2OSiH_2—$
tetrathio—SSSS—
1,4-tetrazanediyl $—(NH)_4—$
1,4-tetrazanediylidene $=N(NH)_2N=$
1-tetrazenyl $H_2NNHN=N—$
thio —S—
(thioarsenoso) S=As—
(thiocarbamoyl) $H_2NCS—$
thiocarbamyl $H_2NCS—$
(thiocarbonyl) —CS—
(thiocarboxy) HOSC—
thiocyanato NCS—
thiocyano NCS—
(thioformyl) HCS—
thiohydroperoxy HOS— or HSO—
(thiohydroxy) HS—
(thionitroso) SN—
thionyl —SO—
thioseleneno HSSe—
(thiosulfeno) HSS—
(thiosulfo) (HO_2S_2)—
thioxo S=
(thioxoarsino) S=As—
(thioxomethyl) HCS—
thiuram $H_2NCS—$
triazanyl $H_2NNHNH—$
1-triazene-1,3-diyl $—NHN=N—$
1-triazenyl $H_2NN=N—$
triseleno —SeSeSe—
1,3-trisilanediyl $—SiH_2)_3—$
1,3,5-trisiloxanetriyl $—SiH(OSiH_2—)_2$
trithio —SSS—

uramino $H_2NCONH—$
ureido $H_2NCONH—$
ureylene $—NHCONH—$

Proposed Forms for Premanufacture Notification

The following are the proposed reporting forms for premanufacture notification.

PREMANUFACTURE NOTICE

CERTIFICATION STATEMENT: I hereby certify that, to the best of my knowledge and belief: (1) I intend to manufacture for a commercial purpose the chemical substance for which this notice is submitted, other than in small quantities for research and development, and that the substance is not excluded from premanufacture notification (40 CFR 720.13); (2) All information entered on the Premanufacture Notice Form is complete and truthful as of the date of submittal; and (3) I am submitting with this form all test data in my possession or control concerning effects of the substance on health or the environment and a description of any other data known to or reasonably ascertainable by me, in accordance with 40 CFR 720.23. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator in accordance with the Toxic Substances Control Act and any regulations issued thereunder, to document any information reported in this form.

Signature of Authorized Official _____

Date _____

When completed, send this notice to:

Document Control Officer
Office of Toxic Substances
TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

CONFIDENTIALITY INSTRUCTIONS: If you are asserting a claim of confidentiality for any data or information contained in this notice you should place a check in the box in the left hand margin immediately adjacent to the data or information entry. If you do not assert a claim of confidentiality on this form at the time of submission of the information, EPA may make the information public without further notice to you. Claims of confidentiality must be made in accordance with 40 CFR 720, Subpart E. Confidentiality claims related to chemical identity or to health and safety data must be substantiated in accordance with 40 CFR 720.40(c).

FOR EPA USE ONLY
Date of receipt _____

GENERAL INSTRUCTIONS

These instructions are intended to assist the submitter of a premanufacture notice in the use of the following forms:

Premanufacture Notice Form

Processing and Consumer Use Form

The submitter must complete the mandatory parts of the Premanufacture Notice Form to the extent the information required is known to or reasonably ascertainable by him. In addition, the submitter must contact certain other persons and request them to complete the Processing and Consumer Use Form as discussed below.

Premanufacture Notice Form

The Premanufacture Notice Form consists of the three parts listed below. Each part consists of two or more sections.

Part I - General Information

Part II - Risk Assessment Data

Part III - Risk Analysis and Optional Data

All sections of Parts I and II must be completed by the submitter as appropriate in accordance with Section 720.20 of the Premanufacture Notification Rules. Section B of Part II must be completed for each site where the new chemical substance will be manufactured. The submitter must complete Section C of Part II for each site where he will process the new chemical substance and Section D of Part II if he intends to produce consumer products that contain the new chemical substance. In addition, the submitter must complete Section C of Part II for processing operations which will be conducted by other persons and Section D of Part II if other persons will produce consumer products that contain the new chemical substance.

The Premanufacture Notification Rules do not require the submission of Part III. This part, or selected sections, may be completed at the discretion of the submitter.

In completing Parts I and II, the submitter must provide all of the information and data requested that are known to or reasonably ascertainable by him. Thus he must answer all questions to the best of his ability, including reasonable estimates where he does not know with factual certainty the answers to particular questions. In cases where the submitter cannot provide a reasonable estimate (i.e., the information is unknown and is not reasonably ascertainable), he should enter NA (not available).

Processing and Consumer Use Form

In accordance with 40 CFR 720.20(e) the submitter must contact certain other persons and request them to complete the Processing and Consumer Use Form concerning their own processing and use of the new chemical substance. He must send them copies of this form and state that the recipient is not under a legal obligation to provide the requested information. He must also offer them the option either to provide the requested information to him for inclusion in his notice, or to provide the information directly to EPA. The submitter must certify below his compliance with these procedures, and provide a summary of those whom he contacted and the disposition of their responses.

For further information on these procedures, including the persons that must be contacted and exceptions to these requirements, see 40 CFR 720.20(e).

Certification

I hereby certify that I have contacted the persons listed below and requested them to complete the Processing and Consumer Use Form in accordance with the requirements of 40 CFR 720.20(e). If no persons were contacted or if a representative sample of persons was contacted I have attached an explanation in accordance with the provisions of 40 CFR 720.20(e).

Signature of Authorized Official _____

List those persons you have contacted (if appropriate) and check if you have attached their responses to this notice, if you expect them to send information directly to EPA or if you do not know whether the information will be supplied.

Name	Address	Response Attached	Response To Be Sent To EPA	Response Unknown
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]

Part 1

GENERAL INFORMATION

All data requested in this Part must be provided insofar as they are known to or reasonably ascertainable by the submitter. A notice is not valid unless the chemical identity is reported. In cases where the requested data are unknown and not reasonably ascertainable enter NA (not available).

Section A. Manufacturer Identification

1. Person Filing Notice

[ ] Name of Authorized Official _____

[ ] Title _____

[ ] Organization _____

[ ] Mailing Address _____

_____

_____

_____

[ ] 2. Incorporation Information

[ ] Legal Title of Organization _____

_____

Place of Incorporation

Street _____

City _____

State _____

[ ] 3. Principal Place of Business

Street _____

City _____

State _____

4. Technical Contact

[ ] Name/Title _____

[ ] Address _____

[ ] Telephone Number _____

5. Related Companies

a. Other Persons Authorized to Manufacture Chemical

(i) Identify any other persons who may manufacture the chemical substance in the U.S. or import the chemical substance to the U.S. within five years after you commence manufacture, by virtue of an existing or planned business arrangement (e.g., contract, license, or other form of legal permission) between you and the person.

	Name	Address	Business Arrangement	Anticipated Date of Manufacture or Import
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____

(ii) If such a business arrangement exists or is planned, do the responses on this form include production volume, uses, and exposure information concerning the activities of these persons?

Yes [ ] No [ ]

If no, estimate the production or import volumes expected during the first 5 years after you commence manufacture.

[ ] b. Parent Company

Name _____

Address _____

_____

_____

[ ] c. List any subsidiary companies that are or hav been associated with research, development, test marketing or other commercialization activities involving the new chemical substance.

	Name	Address
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

[ ] 6. Intended date of commencement of manufacture for commercial purposes.
Month _____ Year _____

If the intended date of commencement of manufacture is more than 3 years after the date of this notice, submit evidence of intent to manufacture in accordance with 40 CFR 720.20(h).

Section B Chemical Identity

Complete either 1, 2, or 3 as appropriate. Complete 4. If chemical identity is claimed confidential also complete 5.

1. Class 1 chemical substance (other than polymers)

[ ] a. CAS Registry No. (if known) _____

[ ] b. Specific Chemical Name _____

[ ] c. Molecular Formula _____

[ ] d. Synonyms _____

[ ] e. Trademarks _____

[ ] Structural Diagram

2. Class 2 chemical substance.

[ ] a. CAS Registry No. (if known) _____

_____

b. Specific Chemical Name _____

_____

[ ] c. Synonyms _____

[ ] d. Trademarks _____

[ ] e. List the immediate precursor substance(s) and/or reactants with their respective CAS Registry Number(s) and the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

3. Polymers

a. (1) Provide the specific chemical name and the CAS Registry Number of those monomers and other reactants used at greater than two percent (by weight) in the manufacture of the polymer. Monomers used at two percent (by weight) or less need not be listed as part of the polymer description; (2) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). Calculate the percent based on the composition of the polymer formed. If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition; (3) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

	(1) Monomers and CAS Registry #	(2) Range of Composition	(3) Maximum Residual (Weight Percent)
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

[ ] b. List any monomers used at 2% (by weight) or less in the manufacture of the polymer which are not listed in 3(a) above. For each such monomer indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

[ ] c. Indicate the minimum molecular weight, compositional restrictions or other restrictions of the polymeric compositions to which this notice applies.

4. Impurities

List the identities and estimate the maximum percent (by weight) of those impurities which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. Consider information developed during

R&D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. Check if the concentration of an impurity will be specifically controlled based upon your knowledge of potential adverse health or environmental effects. Estimate the maximum total percent (by weight) of the impurities that may be present.

Total Percent _____

	Identity	Maximum Percent	Specifically Controlled
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]

5. Chemical Identity Claimed Confidential

a. If claimed for period prior to commencement of manufacture:

Proposed Generic Name: _____

b. If claimed for period following commencement of manufacture:

Proposed Generic Name: _____

Substantiation and other materials required to be submitted with a claim of confidentiality must be attached in accordance with 40 CFR 720.40(c).

Section C Production and Marketing Data

1. Estimated Production and Sales Volume (See ranges in Support Document)

		Production	Sales
[ ]	a. First Year		
[ ]	b. Third Year		
[ ]	c. Maximum Annual Demand (fifth year or beyond)		

2. Basis of Production Estimate

	% of First Year	% of Third Year	% of Maximum Annual Demand
[ ] Firm Order			
[ ] Forecast			
[ ] Speculative	_____	_____	_____
	100%	100%	100%

3. Chemical Use Assumptions Used in Production Estimate

In the following questions, list each use by function, and as specific an application as possible. (Example: function-solvent; application-paint used in automotive finishes.) List partial information if complete information is not known. (Example: function-solvent; application-unknown.) Uses reported elsewhere in this form should also be reported here.

a. List those uses on which your production estimates are based. List uses in descending order of the anticipated production volume devoted to each use.

	Function	Application
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

b. List any other uses that you believe the chemical substance could have.

	Function	Application
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

c. Do you intend or expect the new chemical substance to be used to treat water or drinking water supplies or to be used in coatings, paints, liners, pipes or other products that will come in contact with drinking water?

[ ] Yes [ ] No [ ]

[ ] d. Will the new chemical substance be distributed from its site of manufacture?

Yes [ ] No [ ]

4. Historical Production Information

a. Has the new chemical substance been manufactured before?

Yes [ ] No [ ] Don't Know [ ]

If yes, estimate the average annual domestic production or import volume and the number of years it was produced or imported. (see Support Document for production ranges).

b. Was production or use of this chemical restricted because of governmental action, litigation, or voluntarily because of adverse health or environmental effects?

[ ] Yes [ ] No [ ] Don't Know [ ]

If yes, cite references or attach information or data.

5. Hazard Warnings

[ ] Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions, technical data sheet, Material Safety Data Sheet and any other information which will be provided to purchasers regarding the safe handling, use, disposal, treatment upon accidental exposure, or recommendations concerning the formulation, construction or labeling of products containing the chemical substance.

Section D Federal Register Notice

Information provided in this section will be published in the Federal Register in accordance with Section 5(d)(2) of the TSCA. Separate sections are provided for presentation of data related to confidential information where appropriate. Do not enter any information in this section which you consider confidential.

1. Chemical Identity

a. If chemical identity was not claimed confidential in Section B, enter the specific chemical name which you reported in Section B. For polymers enter those monomers which were listed in Section B(3)(a).

_____

b. If chemical identity was claimed confidential in Section B, enter the proposed generic name which you reported in Section B(5).

_____

2. Use Data

a. If use data were not claimed confidential in Section C, list the proposed uses of the chemical substance by function and as specific an application as known. List industrial uses and consumer uses separately.

Industrial Uses

Function	Application
_____	_____
_____	_____
_____	_____

Consumer Uses

Function	Application

b. If use data were claimed confidential in Section C, report a generic description of the proposed industrial and consumer use(s) of the chemical substance. This description should be as specific as possible without revealing confidential information.

Industrial Uses

Consumer Uses

3. Check below the populations that will be exposed to the new chemical substance during manufacture, processing or use, and estimate the maximum number of persons exposed during a one year period (see Support Document for ranges). Base your estimate on the maximum annual production and use rate anticipated within the first 5 years of production, and include all uses, processing and manufacturing operations.

Population	Exposure Yes	Exposure No	Numbers Exposed
Workers			
manufacturing	[ ]	[ ]	
processing	[ ]	[ ]	
Consumers (through use of a product(s))	[ ]	[ ]	
General Population (in the vicinity of manufacturing, processing operations)	[ ]	[ ]	

4. For each population group listed in question 3, describe the maximum level, duration and frequency of exposures expected.

5. Estimate the percent of the total manufactured volume, for the first 5 years of production that will be released to the environment under normal conditions of manufacture, processing, use and disposal.

Activity	Percent Release
Manufacturing/Processing Operations	
Industrial Disposal	
Consumer Use	
Consumer Disposal	

6. Test Data

List all data that are being submitted, described or cited as part of this notice in accordance with §720.23 of the premanufacture notification rules. Identify whether the data relate to the new chemical substance or to substances associated with the new chemical substance (e.g., byproducts, co-products, feedstocks, intermediates, degradation products). For all data that are submitted in accordance with 720.23(a), 720.20(j) and data that are submitted for any other tests you have performed concerning health and the environment, provide a brief abstract of the results.

[ ] Section E Schematic Flow Diagram

For each manufacturing or processing operation you conduct, attach to this notice a schematic flow diagram. This diagram must graphically illustrate (1) each manufacturing step and the type of equipment involved; (2) the major components of the process streams at each step; (3) the points of environmental release to the air, water or land; and (4) the manufacturing and processing steps that account for release of the new chemical substance into the workplace. In addition, provide a mass balance around the entire process and list the major chemical reactions and significant side reactions which account for the chemical substances listed in Section B(4)(b) of Part II.

Section F

Provide a list of all attachments which are submitted with this form.

Part II

RISK ASSESSMENT DATA

All the data requested in this Part must be provided insofar as they are known to or reasonably ascertainable by the submitter. In cases where the requested data are unknown and not reasonably ascertainable enter NA (not available).

Section A Chemical Properties, Environmental Fate Characteristics, and Human and Ecological Effects Data

Under Section 5(d)(1)(B) and (C) of TSCA and 40 CFR 720.23, a manufacturer must submit all test data in his possession and control and a description of any other data which are reasonably ascertainable and are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of the chemical substance on health or the environment. The regulations detail which data must be submitted with the notice and which data may be referenced by a literature citation. In addition, the regulations prescribe formats for data concerning certain effects.

Table 1 lists what EPA considers to be the most important basic physical and chemical properties and potential effects that should be considered in an assessment of risk. This section of the form requires additional information concerning the relationship of the test data and information submitted with this form to the properties and effects listed in Table 1.

[ ] 1. Using Table 1, check the property(ies), characteristic(s) or effect(s) for which you have submitted: (1) data, (2) a description of data, and/or (3) a literature citation. Enter the name of the specific technique or methodology of those tests for which you have submitted data next to the property(ies), characteristic(s) or effect(s) to which each pertains. (A given test may be pertinent to two or more properties, characteristics or effects.)

[ ] 2. Discuss any conclusions, evaluations or assessments which you have made concerning the implications of the test data results or descriptions of other data you have submitted for each particular property, characteristic or effect.

[ ] 3. Have you evaluated the health or environmental risks associated with the manufacture, processing, distribution in commerce, use or disposal of the chemical substance?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 4. Have you evaluated the health or environmental risks presented by substances associated with the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance (e.g., byproducts, co-products, feedstocks, intermediates, degradation products)?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 5. Have you evaluated whether the data you have submitted are sufficient to assess the risk associated with the property(ies), characteristics(s) or effect(s) to which they pertain?

Yes [ ] No [ ]

If yes, explain your evaluations. Provide references to any factors discussed in other sections of this notice.

If you have not reported any information for a particular property or effect listed in Table 1 because you believe that such information is either unnecessary or impractical, or if data you are submitting may indicate adverse health or environmental effects, you may wish to provide additional information or explanation to EPA. Section A of Part III is an optional section which provides a format for the presentation of such information.

Table 1

CONFIDENTIALITY: The information that is required to be entered in this table is limited to the identification of: (1) the physical/chemical properties and health and environmental effects for which data or a description of data have been submitted with this notice and (2) the specific technique or methodology used to develop such data. If you are asserting a claim of confidentiality for any of these data you must mark the attached document(s) which contain(s) the data in accordance with Section 720.40(b) of the Premanufacture Notification Rules.

PHYSICAL/CHEMICAL PROPERTIES

(1) data submitted
(2) description submitted
(3) literature citation

Property	(1)	(2)	(3)	Test Methodology or Technique
Spectra (ultraviolet, visible, infrared)	[ ]	[ ]	[ ]	_____
Density	[ ]	[ ]	[ ]	_____
Solubility in water	[ ]	[ ]	[ ]	_____
Melting point	[ ]	[ ]	[ ]	_____
Boiling point	[ ]	[ ]	[ ]	_____
Sublimation point	[ ]	[ ]	[ ]	_____
Vapor pressure	[ ]	[ ]	[ ]	_____
Dissociation constant	[ ]	[ ]	[ ]	_____
Particle size distribution	[ ]	[ ]	[ ]	_____

Table 1 continued

Property	(1)	(2)	(3)	Test Methodology or Technique
pH	[ ]	[ ]	[ ]	_____
Other physical/chemical or fate characteristics tests (specify)	[ ]	[ ]	[ ]	_____
Chemical Reactivity:				
Photochemical degradation	[ ]	[ ]	[ ]	_____
Hydrolysis	[ ]	[ ]	[ ]	_____
Chemical oxidation	[ ]	[ ]	[ ]	_____
Chemical reduction	[ ]	[ ]	[ ]	_____
Chemical incompatibility	[ ]	[ ]	[ ]	_____
Flammability	[ ]	[ ]	[ ]	_____
Explodability	[ ]	[ ]	[ ]	_____
Other	[ ]	[ ]	[ ]	_____
Biodegradation	[ ]	[ ]	[ ]	_____
Adsorption/desorption characteristics	[ ]	[ ]	[ ]	_____
Formation of persistent transformation products	[ ]	[ ]	[ ]	_____

Table 1 continued

HEALTH AND ENVIRONMENTAL EFFECTS DATA

(1) data submitted
(2) description submitted
(3) literature citation

Effect	(1)	(2)	(3)	Test Methodology or Technique
Acute animal effects	[ ]	[ ]	[ ]	_____
Genetic effects	[ ]	[ ]	[ ]	_____
Subchronic	[ ]	[ ]	[ ]	_____
Teratogenicity	[ ]	[ ]	[ ]	_____
Reproductive effects	[ ]	[ ]	[ ]	_____
Oncogenicity	[ ]	[ ]	[ ]	_____
Other health effects (chronic or latent animal effects)	[ ]	[ ]	[ ]	_____
Microbial effects	[ ]	[ ]	[ ]	_____
Aquatic invertebrate effects	[ ]	[ ]	[ ]	_____
Plant effects	[ ]	[ ]	[ ]	_____
Fish effects	[ ]	[ ]	[ ]	_____

Table 1 continued

Effect	(1)	(2)	(3)	Test Methodology or Technique
Bioconcentration	[ ]	[ ]	[ ]	_____
Community or ecosystem level effects	[ ]	[ ]	[ ]	_____
Other environmental effects* (specify)	[ ]	[ ]	[ ]	_____

*"Other environmental effects" refer to any direct or indirect effect on any environmental entity, process, function, or amenity not specifically included in another category. Example: weather modification, stratospheric ozone depletion, property damage, agricultural or silvicultural damage, or aesthetic effects.

Section B Exposure From Manufacture

This section must be completed for each site where the new chemical substance will be manufactured. If more than one manufacturing site will be used, attach supplementary sections.

[ ] Site Name _____

[ ] Address _____

_____

_____

1. Worker Exposure

[ ] a. Check the routes of exposure to the new chemical substance that may occur at the manufacturing site during normal operation. For each route checked, estimate the maximum number of workers exposed to the new chemical substance during a one-year time period in the first 5 years (see Support Document for ranges).

Exposure Route		Maximum Number Exposed
Inhalation	[ ]	
Ingestion	[ ]	
Skin contact	[ ]	

[ ] Describe the magnitude, duration and frequency of the exposures that may occur through ingestion or skin contact. Include a description of inhalation exposure if the information in question b is unknown and not reasonably ascertainable.

b. State the maximum level of the new chemical substance in the workplace air that workers are expected to be exposed to during normal operations in the first 5 years. If appropriate, include levels for the following types of exposure situations (1) direct exposure that occurs in close proximity to manufacturing equipment and/or from direct handling of the chemical substance and (2) exposure to ambient workplace concentrations that may be experienced by any worker normally in the general vicinity of the manufacturing operation.

		Levels	
		Direct	Ambient Workplace Air
[ ]	(i) Time-weighted average concentration in air for an 8-hour day, 40-hour work week schedule ([ ] ppm or [ ] mg/m^3)	_____	_____
[ ]	(ii) Peak concentration in air for 15 minutes ([ ] ppm or [ ] mg/m^3)	_____	_____

[ ] c. Explain how the workplace exposure estimates in questions a and b were derived.

[ ] d. Based on your analytical and instrument capabilities, what is the minimum level of the new chemical substance which you can detect in the workplace air? Describe the analytical and sampling techniques on which you have based the minimum detectable level.

[ ] e. Estimate the maximum number of workers exposed to the levels of the new chemical substance in the workplace air reported in question b during a one-year time period in the first 5 years as listed below (see Support Document for ranges). Estimate the maximum number of days per year and hours per day that any person may be exposed to the chemical substance.

Exposure	Maximum Number Exposed	Maximum Hours/Day	Maximum Days/year
[ ] Direct			
[ ] Ambient Workplace			

2. Environmental Release

a. Indicate, as required in Table 2, the maximum amount of the new chemical substance intended to be manufactured at the site to one significant figure (kg/yr), the hours of operation, the type of manufacturing operation and the estimated average and maximum environmental release rates and concentrations of the new chemical substances at the manufacturing site during normal operation. Enter the minimum level of the new chemical substance that you have analytical and sampling capability to detect in air emission streams and water effluent streams and describe your method of detection. Enter the specified stack parameters for each air process emission point listed. Place the following letters in the appropriate range estimates to indicate the range of the maximum and average release rates or concentration expected. Base your estimates on the year of maximum release during the first 5 years.

A - average discharge rate or average hourly concentration in air emission streams, average daily concentration in water effluent streams.

M - maximum discharge rate or concentration

TABLE 2

ENVIRONMENTAL RELEASE FROM MANUFACTURING SITES

Amount Manufactured kg/yr _____ Hours of Operation/Yr. _____

Type of Operation [ ] Batch [ ] continuous Hours/day _____

	Type of Level	Range					
Air							
[ ] a.	estimated discharge to the air from an entire site (kg/hr)	<.1 [ ]	.1-1 [ ]	1-10 [ ]	10-100 [ ]	>100 [ ]	
[ ] b.	hourly concentration in process emission streams [ ] ppm [ ] mg/m_3	<10	10-100	100-1,000	1,000-10,000	10,000-100,000	>100,000

	Stack	Stack Dia.	Stack height	Velocity	Temp						
[ ]	1.	_____	_____	_____	___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	2.	_____	_____	_____	___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	3.	_____	_____	_____	___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

[ ] c. minimum detectable level in process emission streams [ ] ppm [ ] mg/m^3 _____ Method of Detection: _____.

WATER [ ] POTW[1] [ ] Navigable Waterway or Tributary [ ] Other

[ ] a.	estimated discharge rate in effluent streams (kg/day)	<1 [ ]	1-10 [ ]	10-100 [ ]	100-1,000 [ ]	>1,000 [ ]
[ ] b.	daily concentration in effluent streams [ ] ppm [ ] ppb	<1	1-10	10-100	100-1,000	>1,000
[ ]	1. _____ flow rate GPD[2]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	2. _____ flow rate GPD	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	3. _____ flow rate GPD	[ ]	[ ]	[ ]	[ ]	[ ]

[ ] c. minimum detectable level in effluent streams [ ] ppm [ ] ppb _____ Method of Detection: _____.

1-POTW - Publicly Owned Treatment Works
2-GPD - gallons per day

b. Enter the name of the receiving water body(ies) or name and location of the POTW listed in Table 2 to which you will be discharging.

c. If the concentration levels listed in Table 2 result from treatment of the wastewater stream or use of air pollution control equipment, describe the type of treatment or control equipment, identify the air emission stream or water effluent stream it serves, and state the expected efficiency of the equipment (i.e., the percent of emission or effluent reduction).

d. Explain how the environmental release estimates in Table 2 were derived.

e. List any degradation products that may be formed as a result of the release of the new chemical substance to the environment for which you have knowledge of data indicating the potential for adverse health and/or environmental effects.

3. Disposal

[ ] a. Describe any material(s) known to you that are associated with the manufacture of the new chemical substance and which require disposal. Include the new chemical substance itself, byproducts, unreacted feedstocks, intermediates, or other chemical substances. Estimate the maximum amount to be disposed of in a one-year period in the first 5 years (see Support Document for ranges), the percent of the new chemical substance contained in the materials(s) requiring disposal and indicate the anticipated method of disposal. Also enter the name of the commercial disposer (if applicable) and location of the site of disposal if known.

	Material Requiring Disposal	Amount (kg/yr)	Percent of New Chemical Substance	Anticipated Method of Disposal	Name and Site Location
[ ]					
[ ]					
[ ]					
[ ]					

[ ] b. If substances containing the new chemical substance that require disposal are incinerated or otherwise treated to destroy or remove the chemical substance, indicate the efficiency of this operation.

[ ] c. Attach to this notice a copy or reasonable facsimile of any warning statement, labels, labeling or instructions that will be provided by you to persons who may dispose of the new chemical substance in order to inform them of disposal procedures you recommend.

[ ] d. Estimate the maximum number of workers that may be exposed to the new chemical substance during normal disposal operations (see Support Document for ranges) and characterize the magnitude, duration and frequency of such exposures.

4. Byproducts, Co-products, Feedstocks and Intermediates

a. List any other substances (e.g. byproducts, co-products, feedstocks and intermediates) associated with the manufacture of the chemical substance that may be present in the workplace which (1) are listed on the NIOSH Registry of Toxic Effects of Chemical Substances, or (2) for which you have submitted data related to health effects. Estimate the maximum number of workers exposed to these substances at the industrial site in a one-year time period (see Support Document for ranges).

	Substance	CAS Reg. Number	NIOSH Registry	Data Submitted	Max. Number Exposed
[ ]			[ ]	[ ]	
[ ]			[ ]	[ ]	

b. Identify the byproducts, co-products, feedstocks and intermediates of manufacturing that may be reasonably anticipated to be in any water effluent stream or air emission stream based upon a consideration of process chemistry, pollution control safeguards and information acquired during R&D activities. As a minimum, you should identify and provide the information requested for substances (1) for which you have attached data concerning health or environmental effects or (2) which EPA

has indicated should be reported (see Support Document). Provide the CAS Registry Number, if known. Estimate the maximum amount of each substance released to the environment during the year of maximum production of the new chemical substance during the first 5 years (see Support Document for ranges). Check those substances for which you have reported data concerning health or environmental effects.

	Substance	Amount Released	CAS Registry No.	Data Submitted
[ ]	_____	_____	_____	[ ]
[ ]	_____	_____	_____	[ ]
[ ]	_____	_____	_____	[ ]

c. Using the concentration ranges for effluent streams in Table 2, estimate the concentration (ppm) of the substances (byproducts, co-products, feedstocks and intermediates) listed in question b that are expected to be in water effluent streams. Estimate the flow rate (GPD) associated with those concentrations.

	Substance	Conc. (ppm)	Flow Rate (GPD)
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

d. Using the ranges in Table 2 for discharge to the air, estimate the amount of the substances (byproducts, co-products, feedstocks and intermediates) listed in question b that will be emitted to the air (kg/hr) and estimate the maximum number of days per year that the releases will occur.

	Substance	Days/Year	Kg/hr
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

5. Transport

Complete this section if the new chemical substance will be transported.

a. Enter the DOT hazard class and shipping name of your chemical substance (if applicable).

[ ] Shipping Name _____

[ ] Hazard Class _____

The DOT criteria for hazardous materials are found in 49 CFR Section 171.8 and Part 173. For listing of proper shipping name see 49 CFR 172.101. For more information, call the U.S. Department of Transportation at (202) 426-9280.

[ ] b. Indicate the mode(s) of transport which you believe will be used for the new chemical substance.

Truck [ ]

Railcar [ ]

Barge/Vessel [ ]

Pipeline [ ]

Plane [ ]

Other, specify

For each mode of transport:

[ ] c. Describe the potential hazards to operators exposed to the new chemical substance during handling and/or loading operations.

[ ] d. Describe the potential hazards in the event of spill or accident. Indicate the maximum amount that may be transported in a single transportation unit (e.g., rail tank car, tank truck, etc.) and estimate the magnitude of a potential spill.

[ ] e. Describe any safeguards taken to prevent or reduce these hazards.

Section C. Exposure From Processing Operations

This section must be completed by the submitter for each site where the submitter or certain other persons (as specified in Section 720.20(e) of the Premanufacture Notification Rules) intend to process the new chemical substance. If more than one processing site will be used attach supplementary sections.

[ ] Site Name _____

[ ] Address _____

_____

_____

[ ] Technical Contact _____

The information in this section is for:

[ ] submitter's processing site [ ]

[ ] other person's processing site [ ]

1. Worker Exposure

a. Check the routes of exposure to the new chemical substance that may occur at the processing site during normal operations. For each route checked, estimate the maximum number of workers exposed to the new chemical substance during a one-year time period in the first 5 years (see Support Document for ranges).

	Exposure Route		Maximum Number Exposed
[ ]	Inhalation	[ ]	
[ ]	Ingestion	[ ]	
[ ]	Skin contact	[ ]	

[ ] Describe the magnitude, duration and frequency of the exposures that may occur through ingestion or skin contact. Include a description of inhalation exposures if the information in question b is unknown and not reasonably ascertainable.

b. State the maximum levels of the new chemical substance in the workplace air that workers are expected to be exposed to during normal operations at the processing site during the first 5 years. If appropriate, include levels for the following types of exposure situations: (1) direct exposure that occurs in close proximity to processing equipment and/or from direct handling of the chemical substance and (2) exposure to ambient workplace concentrations that may be experienced by any worker normally in the general vicinity of a processing operation.

		Levels	
		Direct	Ambient Workplace Air
[ ] (i)	Time weighted average concentration in air for an 8 hour day, 40 hour work week schedule ([ ] ppm or [ ] mg/m^3)		
[ ] (ii)	Peak concentration in air for 15 minutes ([ ] ppm or [ ] mg/m^3)		

[ ] c. Explain how the workplace exposure estimates in questions a and b were derived.

[ ] d. Based on your analytical and instrument capabilities enter the minimum level of the new chemical substance which you can detect in the workplace air. Describe the analytical and sampling techniques on which you have based the minimum detectable level.

[ ] e. Estimate the maximum number of workers exposed to the levels of the new chemical substance in the workplace air reported in question b during a one-year time period in the first 5 years as listed below (see Support Document for ranges). Estimate the maximum number of days per year and hours per day that any person may be exposed to the chemical substance.

Exposure	Maximum Number Exposed	Maximum Hours/day	Maximum Days/year
[ ] Direct			
[ ] Ambient Workplace			

f. Describe the use(s) of the new chemical substance at this site by function and application and estimate the amount devoted to each use to one significant figure.

	Uses		
	Function	Application	Amount
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

g. Describe any products produced by your processing operations which intentionally contain the chemical substance and are intended for use at industrial sites only.

2. Environmental Release

[ ] a. Indicate, as required in Table 3, the maximum amount of the new chemical substance intended to be processed at the site to one significant figure (kg/yr), the hours of operation, and the estimated average and maximum environmental release rates and concentrations of the chemical substance at the processing site during normal operation. Enter the minimum level of the new chemical substance that you have analytical and sampling capability to detect in air emission streams and water effluent streams and describe your method of detection. Enter the specified stack parameters for each air process emission point listed. Place the following letters in the appropriate range estimates to indicate the range of the maximum and average release rates or concentrations expected. Base your estimates on the year of maximum release during the first 5 years.

A - average discharge rate or average hourly concentration in air emission streams, average daily concentration in water effluent streams.

M - maximum discharge rate or concentration.

[ ] b. Enter the name of the receiving water body(ies) or name and location of the POTW listed in Table 3 to which you will be discharging.

[ ] c. If the concentration levels listed in Table 3 result from treatment of the wastewater stream or use of air pollution control equipment, describe the type of control equipment, identify the air emission stream or water effluent stream it serves, and state the expected efficiency of the equipment (i.e., the percent of emission or effluent reduction).

[ ] d. Explain how the environmental release estimates in Table 3 were derived.

3. Disposal

[ ] a. Describe any materials associated with the processing operation that contain the new chemical substance and require disposal. Estimate the maximum amount of each material to be disposed of in a one-year period during the first 5 years (see Support Document for ranges), the percent of the new chemical substance contained in the

TABLE 3

ENVIRONMENTAL RELEASE FROM PROCESS SITES

Amount Manufactured kg/yr _____ Hours of Operation/Yr. _____
Hours/day _____

Type of Level		Range					
Air							
[ ] a.	estimated discharge to the air from an entire site (kg/hr)	<.1 [ ]	.1-1 [ ]	1-10 [ ]	10-100 [ ]	>100 [ ]	
[ ] b.	hourly concentration in process emission streams [ ] ppm [ ] mg/m^3	10	10-100	100-1,000	1,000-10,000	10,000-100,000	>100,000
	Stack / Stack Dia. / Stack height / Velocity / Temp						
[ ] 1.	_____ _____ _____ ___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] 2.	_____ _____ _____ ___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] 3.	_____ _____ _____ ___	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] c.	minimum detectable level in process emission streams [ ] ppm [ ] mg/m^3	_____ Method of Detection: _____.					
WATER	[ ] POTW[1] [ ] Navigable Waterway or Tributary [ ] Other						
[ ] a.	estimated discharge rate in effluent streams (kg/day)	<1 [ ]	1-10 [ ]	10-100 [ ]	100-1000 [ ]	>1000 [ ]	
[ ] b.	daily concentration in effluent streams [ ] ppm [ ] ppb	<1	1-10	10-100	100-1000	>1000	
[ ]	1. _____ flow rate [ ] GPD[2]	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ]	2. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ]	3. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ] c.	minimum detectable level in effluent streams [ ] ppm [ ] ppb	_____ Method of Detection: _____.					

1-POTW - Publicly Owned Treatment Works
2-GPD - gallons per day

materials requiring disposal and enter the anticipated method of disposal. Also enter the name of the commercial disposer (if applicable) and the location of the site of disposal if known.

	Material Requiring Disposal	Amount (kg/yr)	Percent of New Chemical Substance	Anticipated Method of Disposal	Name and Site Location
[ ]	_____	_____	_____	_____	_____
[ ]	_____	_____	_____	_____	_____
[ ]	_____	_____	_____	_____	_____

[ ] b. If substances containing the new chemical substance that require disposal are incinerated or otherwise treated to destroy or remove the chemical substance, indicate the efficiency of this removal.

[ ] c. Attach to this notice a copy or reasonable facsimile of any warning statement, labels, labeling or instructions that will be provided by you to persons who may dispose of the new chemical substance in order to inform them of disposal procedures you recommend.

[ ] d. Estimate the maximum number of workers that may be exposed to the new chemical substance during normal disposal operations and characterize the magnitude, duration, and frequency of such exposures (see Support Document for ranges).

Section D. Exposure From Consumer Use

Complete this section if you or certain other persons (as specified in 40 CFR 720.20(e)) will manufacture a product(s) that contains the new chemical substance and that will be distributed for use by the general population or for use in products to which the general population may be exposed. A separate section should be completed for products intended to be produced by the submitter and products the submitter believes other persons intend to produce.

The information in this section is for:

products produced by the submitter [ ]

products produced by other persons [ ]

[ ] 1. Using Table 4, list the anticipated products by function and application and the total amount of the new chemical substance devoted to each product to one significant figure. Estimate the consumer market population which will be exposed to the product (see Support Document for ranges), the route of exposure and the frequency and duration of exposure based on each use. For products which are mixtures indicate the maximum percent by weight of the chemical substance in the product. Check those products which are constructed or formulated so as to limit potential exposure.

[ ] 2. Describe the level of human exposure that may occur through use of products that contain the new chemical substance. Where possible provide quantitative estimates of exposure levels such as the maximum concentration of the substance in air during normal use.

[ ] 3. Describe how the estimates in question 2 were derived.

[ ] 4. For each article checked in Table 4 explain those aspects of its construction or formulation which will affect the potential for exposure to the new chemical substance.

[ ] 5. Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions which will be provided with each product regarding the prevention of adverse health and/or environmental effects upon use or disposal.

TABLE 4

CONSUMER EXPOSURE

	Product Function/ Application	Amount For each Use	Consumer Market Population for each use	Frequency of Exposure	Duration of Exposure	Exposure Route Through Use			% in formulated Mixture	Controlled Exposure Construction
						Inhal.	Ingest.	Derm.		
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]

Part III

Risk Analysis and Optional Data

(Optional)

A reasonable evaluation of the health and environmental effects of a chemical substance requires basic data relating to the primary factors of health effects, ecological effects, chemical properties (transport and persistence), and exposure. Information on such factors is required in Part II of this form.

Other factors can affect the magnitude of human and environmental risk from chemicals or influence the analysis of risk. These additional factors include structure/activity relationships, engineered safeguards, industrial hygiene programs, and consideration of intended restrictions on chemical use. This part of the form (Part III) is optional and provides the form and manner in which data and information pertaining to these factors can be submitted to EPA. The submitter may complete any section or portion of a section in this Part. In addition to this part the submitter may attach any information which he believes EPA should consider in assessing this notice.

Section A Risk Analysis

[ ] 1. Describe your overall testing/evaluation scheme and discuss the scientific rationale underlying your scheme.

[ ] 2. If no data are submitted concerning a particular effect or property listed in Table 1 (pages 15 through 18 of Part II) explain why the development of additional data concerning such properties or effects are unnecessary for the chemical substance. In the absence of such data explain why you believe the information which you have submitted allows a reasoned evaluation of the health and environmental effects of the new chemical substance. Provide references to any mitigating factors discussed in the other sections of this notice (e.g., structure/activity relationships, safeguards, etc.).

[ ] 3. For each of the properties, characteristics, or effects listed in Table 1 (pages 15 through 18 of Part II), if any of the applicable data indicate a potential for adverse health or environmental risk, alone or in combination with other data, discuss any information which you feel mitigates such risk.

[ ] 4. If testing for any effect or property listed in Table 1 was not done because of economic impracticality, explain why you reached such a conclusion.

[ ] 5. One common approach utilized in risk assessment methodology consists of identifying conditions of maximum exposure or susceptible segments of the population in order to identify maximum potential for risk. You may assist EPA by providing estimates of maximum exposure (considering or speculating upon new uses, expanded production, accidental exposure, misuse of the chemical, etc.) or identifying those uses that affect the most susceptible segments of the population (e.g., children, the infirm, etc.). Further, you may wish to provide EPA with your own analysis of risk under these same conditions.

Section B Structure/Activity Relationships

[ ] 1. Have you attached a description of any data or information to this notice concerning properties or effects of chemical substances or classes of substances that are related to the new chemical substance on the basis of structural similarity, chemical reactivity or other characteristics and that relate to an evaluation of the risks posed by the new chemical substance? [ ] Yes [ ] No

If yes, identify the related chemical(s) and explain what makes these related chemicals similar (e.g. functional group, characteristic chemical reactivity, other chemical or physical property).

[ ] 2. Explain why you concluded that this similarity presents a valid basis for evaluating the activity of the new chemical substance.

[ ] 3. Explain how properties or effects of these related chemical substances affect the risk associated with the new chemical substance.

[ ] 4. Are there other structurally related chemical substances which you have not discussed here? [ ] Yes [ ] No

If yes, explain why.

Section C Industrial Hygiene

The establishment of safe working conditions and industrial hygiene practices can result in substantial reductions in chemical concentrations and worker exposure in the workplace environment. Prudence dictates the use of such practices for any chemical, but in the case of toxic chemical substances and substances for which there are limited health effects data, the establishment of sound industrial hygiene programs is one essential way of reducing risk to workers from chemical hazards. This section permits a response by the manufacturer in cases where an industrial hygiene program is thought to be an important control strategy which should be considered in EPA's risk assessment. If more than one manufacturing site will be used, attach supplementary forms.

[ ] Site Name _____

[ ] Address _____

_____

_____

1. Industrial Hygiene Considerations

Will you have an industrial hygiene program?

[ ] Yes [ ] No

If "yes",

[ ] a. Will you employ a full or part-time hygienist?
[ ] Yes [ ] No

[ ] b. Will you provide periodic instruction and training of workers on chemical hazards, and proper use of personal protective equipment?
[ ] Yes [ ] No

[ ] c. Will you provide information to workers on the chemical identity and toxicity at their work stations?
[ ] Yes [ ] No

[ ] d. Will you post workplace instructions for workers on how to handle and cope with chemical hazards routinely and in emergencies? [ ] Yes [ ] No

[ ] e. Will you establish procedures and personnel responsibilities for chemical emergency evacuations? [ ] Yes [ ] No

[ ] f. Will you have a respiratory protection program? [ ] Yes [ ] No

[ ] g. Is knowledge of the chemical hazards in your plant communicated to local fire/police authorities? [ ] Yes [ ] No

[ ] h. Will periodic inspections of production facilities be performed by an industrial hygienist or other knowledgeable personnel? [ ] Yes [ ] No

2. Control of Worker Exposure

[ ] a. Have you established an action level (air concentration level, particulate level, etc.) for the new chemical substance or other chemical substances associated with its manufacture for purposes of worker protection? [ ] Yes [ ] No

b. If 'yes' to question (a), identify the chemical substances and levels.

	Chemical	Concentration
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

c. Will you monitor to assure that concentration levels for the new chemical substance or other chemicals identified in question (b) are not exceeded?

[ ] Yes [ ] No

If yes, provide the information in the table below.

	Chemical	Sampling Frequency	Instrument or Analytical Procedure	Monitoring Locations
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____

d. Check what procedures will be taken when an action level is exceeded.

[ ]	1. Process shutdown pending correction.	[ ]
[ ]	2. Protective equipment used pending correction.	[ ]
[ ]	3. Alarm and personnel evacuation from plant.	[ ]
[ ]	4. Corrections made during normal plant operations.	[ ]
[ ]	5. Increased monitoring and medical surveillance activities.	[ ]
[ ]	6. Other, describe:	

e. Based on your experience or projections estimate the frequency of incidents that may occur during a one-year time period which would result in worker exposure at or above the action levels stated in question 2b of this section. Estimate the maximum number of workers exposed.

	Chemical	Frequency	Number Exposed
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

[ ] f. Characterize the duration and magnitude of the potential exposures you have reported in question e.

3. Worker Health Considerations

[ ] a. Will you establish a medical program with periodic medical examinations?

[ ] Yes [ ] No

[ ] b. If yes, will employee participation in the program be mandatory?

[ ] Yes [ ] No

[ ] c. How will medical examinations be used to detect or prevent occurrence of health effects related to the new chemical substance?

4. Other Considerations

[ ] a. Are there any other industrial hygiene considerations that EPA should be made aware of in its assessment of risk associated with production of the new chemical substance? For example, describe the relationship between action levels and risk to human health.

Section D Engineered Safeguards

The use of engineered safeguards can result in substantial reduction in worker exposure and environmental release of the chemical substance. Prudence dictates the use of these safeguards for any chemical, but in the case of toxic chemical substances and substances for which there are limited health and environmental effects data, these safeguards can mitigate the risk associated with a chemical. This section permits a response by the manufacturer in cases where engineered safeguards are considered to be important input into EPA's risk assessment. If more than one manufacturing site will be used, attach supplementary forms.

[ ] Site Name _____

[ ] Address _____

_____

_____

1. Workplace Safeguards

a. Check the safeguards that will be used to prevent or control worker exposure to the new chemical substance at the manufacturing site.

	Safeguards	
[ ]	(i) Production plant design features and maintenance procedures for production equipment which will contain the substance.	[ ]
[ ]	(ii) Explicit manufacturing, processing, and handling procedures concerning prevention of worker exposure.	[ ]
[ ]	(iii) Local ventilation of work area and/or selected activities.	[ ]
[ ]	(iv) Other, explain.	[ ]

[ ] b. Provide a flowchart depicting each safeguard's location in the manufacturing operation.

[ ] c. Describe the function of each safeguard.

[ ] d. Describe the efficiency and relative contribution to the reduction in exposure associated with each safeguard under normal operating conditions.

[ ] e. Describe how production or process equipment malfunctions may result in the release of the new chemical substance. Include instrumentation, mechanical and/or electrical failures.

[ ] f. Based on your experience, describe the potential frequency of manufacturing/processing accidents and the resultant worker exposure. If you have completed question 2e and 2f in Section C of this part, omit this question.

[ ] g. How are releases due to production or process malfunctions controlled? Include a description of redundant controls and emergency procedures. Describe what is done with that portion of the chemical substance that has been released.

2. Environmental Release Safeguards

a. Check the safeguards that will be used to prevent or control environmental release of the new chemical substance at the manufacturing site.

[ ] (i) Processes are designed to prevent environmental release of the new chemical substance. [ ]

[ ] (ii) Water and/or air pollution control equipment will control releases. [ ]

[ ] (iii) Production plant design features and maintenance procedures for production equipment will contain the new chemical substance to control fugitive emissions. [ ]

[ ] (iv) Operating procedures limit the frequency, concentration and/or amount of air and water releases. [ ]

[ ] (v) Emergency control procedures and equipment will contain spills due to process upsets or accidents. [ ]

[ ] (vi) Other, explain. [ ]

[ ] b. Describe the function of each safeguard.

[ ] c. Describe the efficiency and relative contribution to the reduction in release associated with each safeguard under normal operation conditions.

[ ] d. Discuss the possible adverse effects if the equipment malfunctions. Describe redundant controls and emergency procedures that are used to prevent or control release of the chemical substance in the event of malfunctions.

[ ] e. Describe the emergency procedures and redundant controls that are used to prevent or control release of the chemical substance during startups, shutdowns, and in the event of an accident.

[ ] f. Describe how the new chemical substance is disposed of during maintenance procedures.

[ ] g. Will quality control sampling of production or processing streams containing the new chemical substance result in direct environmental release of the substance?

[ ] Yes [ ] No

If yes,

(a) Are the samples continuous, and

(b) Estimate the quantity of the release during a one-year time period.

[ ] h. Will measurement of any process parameter result in direct environmental release of the new chemical substance?

[ ] Yes [ ] No

If yes,

(a) Are the measurements continuous, and

(b) Estimate the quantity of the release during a one-year time period.

3. Environmental Release Action Levels

a. Will you establish action levels for plant releases to air, water, or land for new chemical substances?

[ ] Yes [ ] No

For other process related chemicals?

[ ] Yes [ ] No

b. If yes to (a), identify chemical, media, concentration level, and release rate, as appropriate.

	Chemical	Media land, air, water	Concentration Level	Rate
[ ]	_____	_____	_____	____
[ ]	_____	_____	_____	____
[ ]	_____	_____	_____	____

c. Will you monitor to assure that action levels are not exceeded?

[ ] Yes [ ] No

If yes, provide the information in the table below.

	Chemical	Sampling Frequency	Instrument/or Analytical Procedure	Media
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____

[ ] d. What procedures are taken when action levels are exceeded?

[ ] e. What is the frequency, maximum concentration, maximum release rate, and duration of periods when action levels are exceeded?

	Chemical	Frequency	Duration	Maximum Conc.	Maximum Release Rate
[ ]	_____	_____	_____	_____	_____
[ ]	_____	_____	_____	_____	_____
[ ]	_____	_____	_____	_____	_____

Section E Industrial Process and Use Restriction Data

Many chemical substances are manufactured for exclusive and highly specialized industrial use and consumption (e.g., chemical intermediates and catalysts). Other chemical substances are manufactured and processed under the exclusive control of the manufacturer. Because of the exclusive use and control within the industrial environment, these types of chemicals can present different risk considerations than other chemicals that are utilized by many processors and manufacturers for a diverse variety of industrial and consumer products and uses. The purpose of this section is to assist the manufacturer of highly specialized or industrially controlled chemicals in reporting any unique risk considerations. Complete this section only if your new chemical substance will be limited to exclusive and specialized industrial uses.

1. Describe those exclusive specialized industrial uses for which the new chemical substance will be used.

[ ] _____

[ ] _____

[ ] _____

[ ] 2. Explain any factor concerning restricted use or exclusive control of the chemical substance which is not addressed in other sections of this form and which should be considered by EPA in assessing the risk associated with the substance.

Section F Process Chemistry

[ ] An understanding of the actual process chemistry of the chemical substance may permit a conclusion that impurity or byproduct concentrations can be kept at safe levels by appropriate control of the process conditions. You may wish to provide information on the process chemistry in order to substantiate such a conclusion. For instance, the particular reaction may have been chosen so as to preclude the formation of toxic impurities or byproducts which would have been produced via an alternate route. Similarly, the dependence of the course of reaction upon temperature, pressure, or solvent may allow the minimization of toxic impurities through control of the reaction conditions. Also, direct monitoring of the composition of the reaction mixture for impurity concentrations may provide additional safeguards. Provide any information about the process chemistry which you believe will assist EPA in evaluating your submission.

Section G Non-Risk Factors: Economic and Non-Economic Benefits

The economic significance and benefits associated with a chemical substance are relevant to determining whether the risks associated with the manufacture, processing, distribution, use, and disposal of the chemical substance are unreasonable. This section assists the manufacturer in providing his assessment of certain economic and benefit factors that he believes EPA should consider when evaluating the chemical's risks and benefits.

1. Economic changes resulting from availability/production of the new chemical.

[ ] a. Estimate the total five-year projected gross market value of the new chemical.

[ ] b. What effect will production of the new chemical have on the price of any existing feedstocks, raw materials, intermediates, end-products or non-chemical products? Identify any affected products and indicate the expected effect by means of the appropriate price change symbol.

	Affected Product	Price Change	Current Price
[ ]	1.	[ ]	[ ]
[ ]	2.	[ ]	[ ]
[ ]	3.	[ ]	[ ]

Key: 1 = Decrease in excess of 25%
2 = Decrease between 10% and 25%
3 = Some decrease but less than 10%
4 = No change
5 = Some increase but less than 10%
6 = Increase between 10% and 25%
7 = Increase in excess of 25%

c. What effect will production of the new chemical have on the volume of production of any existing feedstocks, raw materials, intermediates, end-products or non-chemical products? Identify any affected products and indicate the expected effect by means of the appropriate production change symbol.

	Affected Product	Production Change
[ ]	1.	[ ]
[ ]	2.	[ ]
[ ]	3.	[ ]

Key: 1 = Decrease in excess of 50,000 pounds
2 = Decrease between 10,000 and 50,000 pounds
3 = Some decrease but less than 10,000 pounds
4 = No change
5 = Some increase but less than 10,000 pounds
6 = Increase between 10,000 and 50,000 pounds
7 = Increase in excess of 50,000 pounds

d. What employment effects will result from production of the new chemical? Indicate the source and magnitude of any employment change below, using the appropriate symbol.

	Affected Product	Employment Change
[ ]	A. Production of the chemical itself	[ ]
[ ]	B. Production of any raw materials, feedstocks, intermediates, end products or non-chemical products (Identify below)	
[ ]	_____	[ ]
[ ]	_____	[ ]
[ ]	_____	[ ]

Key: 1 = Decrease in excess of 25 people
2 = Decrease between 10 and 25 people
3 = Some decrease but less than 10 people
4 = No change
5 = Increase but less than 10 people
6 = Increase between 10 and 25 people
7 = Increase in excess of 25 people

[ ] e. Describe any significant regional or community effects resulting from production of the new chemical, such as a significant reduction in the rate of unemployment.

f. What effects on the balance of trade will result from production of the new chemical? Indicate the source and magnitude of export and import changes by the appropriate symbol.

Source		Changes in Exports	Changes in Imports
[ ]	A. Production of the new chemical itself	[ ]	[ ]
	B. Production of any feedstocks, raw materials, intermediates, end products or non-chemical products (Identify below)		
[ ]	_____	[ ]	[ ]
[ ]	_____	[ ]	[ ]
[ ]	_____	[ ]	[ ]

Key: 1 = Decrease in excess of $25 million annually
2 = Decrease between $10 million and $25 million annually
3 = Some decrease but less than $10 million annually
4 = No change
5 = Some increase but less than $10 million annually
6 = Increase between $10 million and $25 million annually
7 = Increase in excess of $25 million annually

g. Are any plant and equipment outlays planned in conjunction with production of the new chemical? Estimate the timing of investment, the amount of investment, and the production capacity created.

Investment

Year	Amount	Production Capacity Created
[ ]		

[ ] h. What are the (unique) properties of this chemical that will be the basis of its value in the marketplace? (Include such factors as contribution to reliability or durability of intermediates or end products, increases in productivity, convenience factors, and aesthetic factors).

[ ] i. What existing substitute products or processes (if any) have any of the properties listed in 1h? In what ways do the properties of the new chemical exceed those of existing substitutes?

2. Non-economic benefits resulting from production of the new chemical.

[ ] a. Are there any uses for the new chemical which contribute directly or indirectly to human health or safety?

[ ] b. What existing substitute products or processes (if any) have any of the uses listed in 2a? In what ways do the use properties of the new chemical exceed those of existing substitutes?

[ ] c. Are there any uses for the new chemical which result in environmental benefits or conservation of energy or natural resources?

[ ] d. What existing substitute products or processes (if any) have any of the uses listed in 2c? In what ways do the use properties of the new chemical exceed those of existing substitutes?

PREMANUFACTURE NOTICE FOR IMPORTERS

CERTIFICATION STATEMENT: I hereby certify that, to the best of my knowledge and belief: (1) I intend to import for a commercial purpose the chemical substance for which this notice is submitted, other than in small quantities for research and development, and that the substance is not excluded from premanufacture notification (40 CFR 720.13); (2) All information entered on the Premanufacture Notice For Importers Form is complete and truthful as of the date of submittal; and (3) I am submitting with this form all test data in my possession or control concerning effects of the substance on health or the environment and a description of any other data known to or reasonably ascertainable by me, in accordance with 40 CFR 720.23. I agree to permit access to, and the copying of, records by a duly authorized representative of the EPA Administrator in accordance with the Toxic Substances Control Act and any regulations issued thereunder, to document any information reported in this form.

Signature of Authorized Official _____

Date _____

When completed, send this notice to:

Document Control Officer
Office of Toxic Substances
TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

CONFIDENTIALITY INSTRUCTIONS: If you are asserting a claim of confidentiality for any data or information contained in this notice you should place a check in the box in the left hand margin immediately adjacent to the data or information entry. If you do not assert a claim of confidentiality on this form at the time of submission of the information, EPA may make the information public without further notice to you. Claims of confidentiality must be made in accordance with 40 CFR 720, Subpart E. Confidentiality claims related to chemical identity or health and safety data must be substantiated in accordance with 40 CFR 720.40(c).

FOR EPA USE ONLY

Date of receipt _____

GENERAL INSTRUCTIONS

These instructions are intended to assist the submitter of a premanufacture notice in the use of the following forms:

Premanufacture Notice Form for Importers
Foreign Manufacturer/Supplier Form
Processing and Consumer Use Form

The submitter must complete the mandatory parts of the Premanufacture Notice Form to the extent the information required is known to or reasonably ascertainable by him. In addition, the submitter must contact certain other persons and request them to complete the Foreign Manufacturer/Supplier Form and the Processing and Consumer Use Form as discussed below.

Premanufacture Notice Form for Importers

The Premanufacture Notice Form consists of the three parts listed below. Each part consists of two or more sections.

Part I - General Information

Part II - Risk Assessment Data

Part III - Risk Analysis and Optional Data

All sections of Parts I and II must be completed by the submitter as appropriate in accordance with Section 720.20 of the Premanufacture Notification Rules. The submitter must complete Section B of Part II for each site where he will process the new chemical substance in the United States and Section C of Part II if he intends to produce consumer products that contain the new chemical substance. In addition, the submitter must complete Section B of Part II for processing operations which will be conducted by other persons and Section C of Part II if other persons will produce consumer products that contain the new chemical substance.

The Premanufacture Notice Rules do not require the submission of Part III. This part, or selected sections, may be completed at the discretion of the submitter.

In completing Parts I and II, the submitter must provide all of the information and data requested that are known to or reasonably ascertainable by him. Thus he must answer all questions to the best of his ability, including reasonable estimates where he does not know with factual certainty the answers to particular questions. In cases where the submitter cannot provide a reasonable estimate (i.e., the information is unknown and is not reasonably ascertainable), he should enter NA (not available).

Foreign Manufacturer/Supplier Form

In accordance with 40 CFR 720.21(c) the submitter must contact the foreign manufacturer(s) and supplier(s) of the new chemical substance, and request them to provide all test data in their possession or control which are related to the effects of the substance on health or the environment (in accordance with 40 CFR 720.23) and complete the Foreign Manufacturer/Supplier Form. The submitter must send them copies of this form and state that the recipient is not under a legal obligation to provide the requested information. He must also offer them the option either to provide the requested information to him for inclusion in his notice, or to provide the information directly to EPA. The submitter must certify below his compliance with these procedures, and provide a summary of those whom he contacted and the disposition of their responses.

For further information on these procedures see 40 CFR 720.21(c).

CERTIFICATION

I hereby certify that I have contacted the persons listed below and requested them to complete the Foreign Manufacturer/Supplier Form in accordance with the requirements of 40 CFR 720.21.

Signature of Authorized Official _____

List those persons you have contacted (if appropriate) and check if you have attached their responses to this notice, if you expect them to send information directly to EPA or if you do not know whether the information will be supplied.

Name	Address	Response Attached	Response To Be Sent To EPA	Response Unknown
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]

Processing and Consumer Use Form

In accordance with 40 CFR 720.20(d) the submitter must contact certain other persons and request them to complete the Processing and Consumer Use Form concerning their own processing and use of the new chemical substance. He must send them copies of this form and state that the recipient is not under a legal obligation to provide the requested information. He must also offer them the option either to provide the requested information to him for inclusion in his notice, or to provide the information directly to EPA. The submitter must certify below his compliance with these procedures, and provide a summary of those whom he contacted and the disposition of their responses.

For further information on these procedures, including the persons that must be contacted and exceptions to these requirements, see 40 CFR 720.20(e).

CERTIFICATION

I hereby certify that I have contacted the persons listed below and requested them to complete the Processing and Consumer Use Form in accordance with the requirements of 40 CFR 720.20(e). If no persons were contacted or if a representative sample of persons was contacted I have attached an explanation in accordance with the provisions of 40 CFR 720.20(e).

Signature of Authorized Official _____

List those persons you have contacted (if appropriate) and check if you have attached their responses to this notice, if you expect them to send information directly to EPA or if you do not know whether the information will be supplied.

Name	Address	Response Attached	Response To Be Sent To EPA	Response Unknown
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]
_____	_____	[ ]	[ ]	[ ]

Part 1

GENERAL INFORMATION

All data requested in this Part must be provided insofar as they are known to or reasonably ascertainable by the submitter. A notice is not valid unless the chemical identity is reported. In cases where the requested data are unknown and not reasonably ascertainable enter NA (not available).

Section A Importer Identification

1. Person Filing Notice

[ ] Name of Authorized Official _____

[ ] Title _____

[ ] Organization _____

[ ] Mailing Address _____

_____

_____

_____

[ ] 2. Incorporation Information

Legal Title of Organization _____

_____

Place of Incorporation

Street _____

City _____

State _____

[ ] 3. Principal Place of Business

Street _____

City _____

State _____

4. Technical Contact

[ ] Name/Title _____

[ ] Address _____

[ ] Telephone Number _____

5. Related Companies

a. Other Persons Authorized to Import Chemical

(i) Identify any other persons who may import the chemical substance to the U.S. within five years after you commence import, by virtue of an existing or planned business arrangement (e.g., contract, license, or other form of legal permission) between you and the person.

	Name	Address	Business Arrangement	Anticipated Date of Import
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____

(ii) If such a business arrangement exists or is planned, do the responses on this form include import volume, uses, and exposure information concerning the activities of these persons?

Yes [ ] No [ ]

If no, estimate the import volume expected during the first 5 years after you commence import of the chemical substance.

[ ] b. Parent Company

Name _____

Address _____

_____

_____

[ ] 6. Intended date of commencement of import (date of entry) to the U.S. for commercial purposes.

Month _____ Year _____

If the intended date of commencement of import is more than 3 years after the date of this notice, submit evidence of intent to manufacture in accordance with 40 CFR 720 Subpart C and 720.21(a).

Port of entry _____

Section B Chemical Identity

If chemical identity will be reported by the foreign manufacturer/supplier complete the certification statement below and do not complete the remainder of Section B.

CERTIFICATION STATEMENT: I hereby certify that the chemical identity of the chemical substance for which this notice is submitted will be reported by the foreign manufacturer/supplier designated below.

Name of foreign manufacturer/supplier _____

Signature of Authorized Official _____

Date _____

Complete either 1, 2 or 3 as appropriate. Complete 4. If chemical identity is claimed confidential, complete 5.

1. Class 1 chemical substance (other than polymers).

[ ] a. CAS Registry No. (if known) _____

[ ] b. Specific Chemical Name _____

[ ] c. Molecular Formula _____

[ ] d. Synonyms _____

[ ] e. Trademarks _____

[ ] f. Structural Diagram

2. Class II chemical substance.

[ ] a. CAS Registry No. (if known) _____

[ ] b. Specific Chemical Name _____

[ ] c. Synonyms _____

[ ] d. Trademarks _____

[ ] e. List the immediate precursor substance(s) and/or reactants with their respective CAS Registry Number(s) and the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

3. Polymers

a. (1) Provide the specific chemical name and the CAS Registry Number of those monomers and other reactants used at greater than two percent (by weight) in the manufacture of the polymer. Monomers used at two percent (by weight) or less need not be listed as part of the polymer description; (2) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). Calculate the percent based on the composition of the polymer formed. If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition; (3) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

	(1) Monomers and CAS Registry #	(2) Range of Composition	(3) Maximum Residual (Weight Percent)
[ ]			
[ ]			
[ ]			

[ ] b. List any monomer used at 2% (by weight) or less in the manufacture of the polymer which is not listed in 3(a) above. For each such monomer indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

c. Indicate the minimum molecular weight, compositional restrictions or other restrictions of the polymeric compositions to which this notice applies.

[ ] 4. Impurities

List the identities and estimate the maximum percent (by weight) of those impurities which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. Consider information developed during R&D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. Check if the concentration of an impurity will be specifically controlled based upon your knowledge of potential adverse health or environmental effects. Estimate the maximum total percent (by weight) of the impurities that may be present.

Total Percent: _____

	Identity	Maximum Percent	Specifically Controlled
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]

5. Chemical Identity Claimed Confidential

a. If claimed for period prior to commencement of import:

Proposed Generic Name: _____

b. If claimed for period following commencement of import:

Proposed Generic Name: _____

Substantiation and other materials required to be submitted with a claim of confidentiality must be attached in accordance with 40 CFR 720.40(c).

Section C Import and Marketing Data

1. Estimate your import volume (see ranges in Support Document)

[ ] a. First year

[ ] b. Third year

[ ] c. Maximum Annual Demand (fifth year or beyond)

2. Basis of Import Estimate

	% of First Year	% of Third Year	% of Maximum Year
[ ] Firm Order			
[ ] Forecast			
[ ] Speculative	_____	_____	_____
	100%	100%	100%

3. Estimate the total amount of the chemical substance that others may import to the United States in the years following the date of entry reported in question 6, Section A of this Part (see ranges in Support Document).

[ ] a. First year

[ ] b. Third year

[ ] c. Maximum Annual Demand (fifth year or beyond)

4. Chemical Use Assumptions Used in Import Estimate

In the following questions, list each use by function, and as specific an application as possible. (Example: function-solvent; application-paint used in automotive finishes.) List partial information if complete information is not known. (Examples: function-solvent; application-unknown). Uses reported elsewhere in this from should also be reported here.

a. List those uses on which your import estimates are based. List uses in descending order of the anticipated import volume devoted to each use.

	Function	Application
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

b. List any other uses that you believe the chemical substance could have.

	Function	Application
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

c. Do you intend or expect the new chemical substance to be used to treat water or drinking water supplies or to be used in coatings, paints, liners, pipes or other products that will come in contact with drinking water?

[ ] Yes [ ] No [ ]

5. Production Information

a. Has the chemical substance been manufactured before?

Yes [ ] No [ ] Don't Know [ ]

If yes, estimate the average annual production and number of years it was produced (see Support Document for ranges).

b. Estimate the total annual production of the chemical substance outside of the United States in the years following the date of entry reported in question 6, Section A of this Part (see ranges in Support Document).

[ ] i. First year

[ ] ii. Third year

[ ] iii. Maximum Annual Demand (fifth year and beyond)

[ ] c. Was production of this chemical banned or restricted because of governmental action, litigation, or voluntarily because of adverse health or environmental effects?

Yes [ ] No [ ] Don't Know [ ]

If yes, cite references or attach information or data.

6. Hazard Warnings

[ ] Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions, technical data sheet, Material Safety Data Sheet and any other information which will be provided to purchasers regarding the safe handling, use, disposal, treatment upon accidental exposure, or recommendations concerning the formulation, construction or labeling of products containing the chemical substance.

Section D Federal Register Notice

Information provided in this section will be published in the Federal Register in accordance with Section 5(d)(2) of the TSCA. Separate sections are provided for presentation of data related to confidential information where appropriate. Do not enter any information in this section which you consider confidential.

1. Chemical Identity - If chemical identity will be reported by a foreign manufacturer/ supplier do not complete this question.

   a. If chemical identity was not claimed confidential in Section B, enter the specific chemical name which you reported in Section B. For polymers enter those monomers which were listed in Section B(3)(a).

   _____

   b. If chemical identity was claimed confidential in Section B, enter the proposed generic name which you reported in Section B(5).

   _____

2. Use Data

   a. If use data were not claimed confidential in Section C, list the proposed uses of the chemical substance by function and as specific an application as known. List industrial uses and consumer uses separately.

Industrial Uses

Function	Application
_____	_____
_____	_____
_____	_____

Consumer Uses

Function	Application
_____	_____
_____	_____
_____	_____

   b. If use data were claimed confidential in Section C, report a generic description of the proposed industrial and consumer use(s) of the chemical substance. This description should be as specific as possible without revealing confidential information.

Industrial Uses

_____

_____

_____

Consumer Uses

_____

_____

_____

3. Check below the populations that will be exposed to the new chemical substance during processing or use within the U.S., and estimate the maximum number of persons exposed during a one-year period (see Support Document for ranges). Base your estimate on the maximum annual import and use rate anticipated within the first 5 years of import and include all uses and processing operations.

Population	Exposure Yes	Exposure No	Number Exposed
Workers (processing)	[ ]	[ ]	_____
Consumers (through use of a product(s))	[ ]	[ ]	_____
General Population (in vicinity of processing operations)	[ ]	[ ]	_____

4. For each population group listed in question 3, describe the maximum level, duration and frequency of exposures expected.

5. Estimate the percent of the total import volume for the first 5 years of production that will be released to the environment under normal conditions of processing, use and disposal.

Activity	Percent Release
Processing Operations	_____
Industrial Disposal	_____
Consumer Use	_____
Consumer Disposal	_____

6. Test Data

List all data that are being submitted, described or cited as part of this notice in accordance with §720.23 of the Premanufacture Notification Rules. Identify whether the data relate to the new chemical substance or to substances associated with the new chemical substance (e.g., by-products, co-products, feedstocks, intermediates degradation products). For all data that are submitted in accordance with §720.23(a), §720.20(j) and data that are submitted for any other tests you have performed concerning health or the environment, provide a brief abstract of the results.

[ ] Section E Schematic Flow Diagram

For each processing operation you conduct, attach to this notice a schematic flow diagram. This diagram must graphically illustrate (1) each processing step and the type of equipment involved, (2) the major components of the process streams at each step, (3) the points of environmental release to the air, water or land, and (4) the processing steps that account for release of the new chemical substance into the workplace.

Section F

Provide a list of all attachments which are submitted with this form.

Section G Transport

[ ] 1. Indicate the means of transport which will be used for the chemical substance to enter the United States from a foreign country.

Truck [ ]

Railcar [ ]

Pipeline [ ]

Barge/Vessel [ ]

Plane [ ]

Other, specify

For each means of transport:

[ ] 2. Describe the potential hazards to operators exposed to the chemical substance during handling and/or loading operations.

[ ] 3. Describe the potential hazards in the event of a spill or accident. Indicate the magnitude of a potential spill.

[ ] 4. Describe any safeguards taken to prevent or reduce these hazards.

[ ] 5. Indicate the means of transport which will be used for the chemical substance within the United States.

Truck [ ]

Railcar [ ]

Pipeline [ ]

Barge/Vessel [ ]

Plane [ ]

Other, specify

For each means of transport:

[ ] 6. Describe the potential hazards to operators exposed to the chemical substance during handling and/or loading operations.

[ ] 7. Describe the potential hazards in the event of spill or accident. Indicate the maximum amount that may be transported in a single transportation unit (e.g., rail tank car, tank truck, etc.) and estimate the magnitude of a potential spill.

[ ] 8. Describe any safeguards taken to prevent or reduce these hazards.

[ ] 9. Enter the DOT hazard class and shipping name of your chemical substance (if applicable).

[ ] Shipping Name _____

[ ] Hazard Class _____

The DOT criteria for hazardous materials are found in 49 CFR Sections 171.8 and 173. For listing of proper shipping name see 49 CFR 172.101. For more information, call the U.S. Department of Transportation at (202)426-9280.

Part II

RISK ASSESSMENT DATA

All the data requested in this Part must be provided insofar as they are known to or reasonably ascertainable by the submitter. In cases where the requested data are unknown and not reasonably ascertainable enter NA (not available).

Section A Chemical Properties, Environmental Fate Characteristics, and Human and Ecological Effects Data

Under Section 5(d)(1)(B) and (C) of TSCA and 40 CFR 720.23, an importer must submit all test data in his possession and control and a description of any other data which are reasonably ascertainable and are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of the chemical substance on health or the environment. The regulations detail which data must be submitted with the notice and which data may be referenced by a literature citation. In addition, the regulations prescribe formats for data concerning certain effects.

Table 1 lists what EPA considers to be the most important basic physical and chemical properties and potential effects that should be considered in an assessment of risk. This section of the form requires additional information concerning the relationship of the test data and information submitted with this form to the properties and effects listed in Table 1.

[ ] 1. Using Table 1, check the property(ies), characteristic(s) or effect(s) for which you have submitted: (1) data, (2) a description of data and/or (3) a literature citation. Enter the name of the specific technique or methodology of those tests for which you have submitted data next to the property(ies), characteristic(s) or effect(s) to which each pertains. (A given test may be pertinent to two or more properties, characteristics or effects.)

[ ] 2. Discuss any conclusions, evaluations or assessments which you have made concerning the implications of the test data results or descriptions of other data you have submitted for each particular property, characteristic or effect.

[ ] 3. Have you evaluated the health or environmental risks associated with the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 4. Have you evaluated the health or environmental risks presented by substances associated with the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance (e.g., byproducts, co-products, feedstocks, intermediates, degradation products)?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 5. Have you evaluated whether the data you have submitted are sufficient to assess the risk associated with the property(ies), characteristic(s) or effect(s) to which they pertain?

Yes [ ] No [ ]

If yes, explain your evaluations. Provide references to any factors discussed in other sections of this notice.

If you have not reported any information for a particular property or effect listed in Table 1 because you believe that such information is either unnecessary or impractical, or if data you are submitting may indicate adverse health or environmental effects, you may wish to provide additional information or explanation to EPA. Section A of Part III is an optional section which provides a format for the presentation of such information.

Table 1

CONFIDENTIALITY: The information that is required to be entered in this table is limited to the identification of: (1) the physical/chemical properties and health and environmental effects for which data or a description of data has been submitted with this notice and (2) the specific technique or methodology used to develop such data. If you are asserting a claim of confidentiality for any of these data you must mark the attached document(s) which contains the data in accordance with Section 720.40(b) of the Premanufacture Notification Rules.

PHYSICAL/CHEMICAL PROPERTIES

(1) data submitted
(2) description submitted
(3) literature citation

Property	(1)	(2)	(3)	Test Methodology or Technique
Spectra (ultraviolet, visible, infrared)	[ ]	[ ]	[ ]	_____
Density	[ ]	[ ]	[ ]	_____
Solubility in water	[ ]	[ ]	[ ]	_____
Melting point	[ ]	[ ]	[ ]	_____
Boiling point	[ ]	[ ]	[ ]	_____
Sublimation point	[ ]	[ ]	[ ]	_____
Vapor pressure	[ ]	[ ]	[ ]	_____
Dissociation constant	[ ]	[ ]	[ ]	_____
Particle size distribution	[ ]	[ ]	[ ]	_____
pH	[ ]	[ ]	[ ]	_____
Other physical/chemical or fate characteristics tests (specify)	[ ]	[ ]	[ ]	_____
Chemical Reactivity:				
Photochemical degradation	[ ]	[ ]	[ ]	_____

Table 1 (continued)

Property	(1)	(2)	(3)	Test Methodology or Technique
Hydrolysis	[ ]	[ ]	[ ]	
Chemical oxidation	[ ]	[ ]	[ ]	
Chemical reduction	[ ]	[ ]	[ ]	
Chemical incompatibility	[ ]	[ ]	[ ]	
Flammability	[ ]	[ ]	[ ]	
Explodability	[ ]	[ ]	[ ]	
Other	[ ]	[ ]	[ ]	
Biodegradation	[ ]	[ ]	[ ]	
Adsorption/desorption characteristics	[ ]	[ ]	[ ]	
Formation of persistent transformation products	[ ]	[ ]	[ ]	

HEALTH AND ENVIRONMENTAL EFFECTS DATA

(1) data submitted
(2) description submitted
(3) literature citation

Property	(1)	(2)	(3)	Test Methodology or Technique
Acute animal effects	[ ]	[ ]	[ ]	
Genetic effects	[ ]	[ ]	[ ]	
Subchronic	[ ]	[ ]	[ ]	
Teratogenicity	[ ]	[ ]	[ ]	
Reproductive effects	[ ]	[ ]	[ ]	
Oncogenicity	[ ]	[ ]	[ ]	
Other health effects (chronic or latent animal effects)	[ ]	[ ]	[ ]	
Microbial effects	[ ]	[ ]	[ ]	

Effect	(1)	(2)	(3)	Test Methodology or Technique
Aquatic invertebrate effects	[ ]	[ ]	[ ]	
Plant effects	[ ]	[ ]	[ ]	
Fish effects	[ ]	[ ]	[ ]	
Bioconcentration	[ ]	[ ]	[ ]	
Community or ecosystem level effects	[ ]	[ ]	[ ]	
Other environmental effects* (specify)	[ ]	[ ]	[ ]	

*"Other environmental effects" refers to any direct or indirect effect on any environmental entity, process, function, or amenity not specifically included in another category. Example: weather modification, stratospheric ozone depletion, property damage, agricultural or silvicultural damage, or aesthetic effects.

Section B Exposure From Processing Operations

This section must be completed by the submitter for each site where the submitter or certain other persons (as specified in Section 720.20(e) of the Premanufacture Notification Rules) intend to process the new chemical substance within the United States. If more than one processing site will be used, attach supplementary sections.

[ ] Site Name _____

[ ] Address _____

_____

_____

[ ] Technical Contact _____

The information in this section is for:

[ ] submitter's processing site [ ]

[ ] other person's processing site [ ]

1. Worker Exposure

a. Check the routes of exposure to the new chemical substance that may occur at the processing site during normal operations. For each route checked, estimate the maximum number of workers exposed to the new chemical substance during a one-year time period in the first 5 years (see Support Document for ranges).

	Exposure Route	Maximum Number Exposed
[ ]	Inhalation	[ ]
[ ]	Ingestion	[ ]
[ ]	Skin contact	[ ]

b. Describe the magnitude, duration and frequency of the exposures that may occur through ingestion, or skin contact. Include a description of inhalation exposures if the information in question b is not known and not reasonably ascertainable.

c. State the maximum levels of the new chemical substance in the workplace air that workers are expected to be exposed to during normal operations at the processing site during the first 5 years. If appropriate, include levels for the following types of exposure situations: (1) direct exposure that occurs in close proximity to processing equipment and/or from direct handling of the chemical substance and (2) exposure to ambient workplace concentrations that may be experienced by any worker normally in the general vicinity of a processing operation.

Levels

			Direct	Ambient Workplace Air
[ ]	1.	Time-weighted average concentration in air for an 8-hour day, 40-hour work week schedule ([ ] ppm or [ ] mg/m^3)		
[ ]	2.	Peak concentration in air for 15 minutes ([ ] ppm or [ ] mg/m^3)		

[ ] c. Explain how the workplace exposure estimates in question a and b were derived.

[ ] d. Based on your analytical and instrument capabilities enter the minimum level of the new chemical substance you can detect in the workplace air. Describe the analytical and sampling techniques on which you have based the minimum detectable level.

[ ] e. Estimate the maximum number of workers exposed to the levels of the new chemical substance in the workplace air reported in question b during a one-year time period in the first 5 years as listed below (see Support Document for ranges). Estimate the maximum number of days per year and hours per day that any person may be exposed to the chemical substance.

	Exposure	Maximum Number Exposed	Maximum Hours/day	Maximum Days/year
[ ]	Direct			
[ ]	Ambient workplace			

f. Describe the use(s) of the new chemical substance at this site by function and application and estimate the amount devoted to each use.

Uses

	Function	Application	Amount
[ ]			
[ ]			
[ ]			

g. Describe any products produced by your processing operations which intentionally contain the chemical substance and are intended for use at industrial sites only.

2. Environmental Release

[ ] a. Indicate, as required in Table 2, the maximum amount of the new chemical substance intended to be processed at the site (kg/yr), the hours of operation, and the estimated average and maximum environmental release rates and concentrations of the chemical substance at the processing site during normal operation. Enter the minimum level of the new chemical substance that you have analytical and sampling capability to detect in air emission streams and water effluent streams and describe your method of detection. Enter the specified stack parameters for each air process emission point listed. Place the following letters in the appropriate range estimates to indicate the range of the maximum and average release rates or concentrations expected. Base your estimates on the year of maximum release during the first 5 years.

A - average discharge rate or average hourly concentration in air emission streams, average daily concentration in water effluent streams.

M - maximum discharge rate or concentration.

TABLE 2

ENVIRONMENTAL RELEASE FROM PROCESS SITES

Amount Manufactured kg/yr _____ Hours of Operation/Yr. _____
Hours/day _____

Type of Level		Range				
Air						
[ ] a.	estimated discharge to the air from an entire site (kg/hr)	<.1 [ ]	.1-1 [ ]	1-10 [ ]	10-100 [ ]	>100 [ ]
[ ] b.	hourly concentration in process emission streams [ ] ppm [ ] mg/m^3	10	10-100	100-1,000	1,000-10,000	10,000-100,000

	Stack	Stack Dia.	Stack height	Velocity	Temp					
[ ]	1.	_____	_____	_____	____	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	2.	_____	_____	_____	____	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	3.	_____	_____	_____	____	[ ]	[ ]	[ ]	[ ]	[ ]

[ ] c. minimum detectable level in process emission streams [ ] ppm [ ] mg/m^3 _____ Method of Detection: _____

WATER [ ] POTW[1] [ ] Navigable Waterway or Tributary [ ] Other

[ ] a.	estimated discharge rate in effluent streams (kg/day)	<1 [ ]	1-10 [ ]	10-100 [ ]	100-1000 [ ]	>1000 [ ]
[ ] b.	daily concentration in effluent streams [ ] ppm [ ] ppb	<1	1-10	10-100	100-1000	>1000
[ ]	1. _____ flow rate [ ] GPD[2]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	2. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	3. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]

[ ] c. minimum detectable level in effluent streams [ ] ppm [ ] ppb _____ Method of Detection: _____

1-POTW - Publicly Owned Treatment Works
2-GPD - gallons per day

[ ] b. Enter the name of the receiving water body(ies) or name and location of the POTW listed in Table 2 to which you will be discharging.

[ ] c. If the concentration levels listed in Table 2 result from treatment of the wastewater stream or use of air pollution control equipment, describe the type of control equipment, identify the air emission stream or water effluent stream it serves, and state the expected efficiency of the equipment (i.e., the percent of emission or effluent reduction).

[ ] d. Explain how the environmental release estimates in Table 2 were derived.

3. Disposal

[ ] a. Describe any materials associated with the processing operation that contain the new chemical substance and require disposal. Estimate the maximum amount of each material to be disposed of in a one-year period during the first 5 years (see Support Document for ranges), the percent of the new chemical substance contained in the materials requiring disposal and enter the anticipated method of disposal. Also enter the name of the commercial disposer (if applicable) and the location of the site of disposal if known.

	Material Requiring Disposal	Amount (kg/yr)	Percent of New Chemical Substance	Anticipated Method of Disposal	Name and Site Location
[ ]					
[ ]					
[ ]					

[ ] b. If substances containing the new chemical substance that require disposal are incinerated or otherwise treated to destroy or remove the chemical substance indicate the efficiency of this removal.

[ ] c. Attach to this notice a copy or reasonable facsimile of any warning statement, labels, labeling or instructions that will be provided by you to persons who may dispose of the new chemical substance in order to inform them of disposal procedures you recommend.

[ ] d. Estimate the maximum number of workers that may be exposed to the new chemical substance during normal disposal operations and characterize the magnitude, duration, and frequency of such exposures (see Support Document for ranges).

Section C Exposure From Consumer Use

Complete this section if you or certain other persons (as specified in 40 CFR 720.20(e)) will manufacture a product(s) that contains the new chemical substance and that will be distributed for use by the general population or for use in products to which the general population may be exposed. A separate section should be completed for products intended to be produced by the submitter and products the submitter believes other persons intend to produce.

The information in this section is for:

products produced by the submitter [ ]

products produced by other persons [ ]

[ ] 1. Using Table 3, list the anticipated products by function and application and the total amount of the new chemical substance devoted to each product to one significant figure. Estimate the consumer market population which will be exposed to the product (see Support Document for ranges), the route of exposure and the frequency and duration of exposure based on each use. For products which are mixtures indicate the maximum percent by weight of the chemical substance in the product. Check those products which are constructed or formulated so as to limit potential exposure.

[ ] 2. Describe the level of human exposure that may occur through use of products that contain the new chemical substance. Where possible provide quantitative estimates of exposure levels such as the maximum concentration of the substance in air during normal use.

[ ] 3. Describe how the estimates in question 2 were derived.

[ ] 4. For each article checked in Table 3 explain those aspects of its construction or formulation which will affect the potential for exposure to the new chemical substance.

[ ] 5. Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions which will be provided with each product regarding the prevention of adverse health and/or environmental effects upon use or disposal.

TABLE 3

CONSUMER EXPOSURE

	Product Function/ Application	Amount For each Use	Consumer Market Population for each use	Frequency of Exposure	Duration of Exposure	Exposure Route Through Use			% in formulated Mixture	Controlled Exposure Construction
						Inhal.	Ingest.	Derm.		
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]

Part III

Risk Analysis and Optional Data

(Optional)

A reasonable evaluation of the health and environmental effects of a chemical substance requires basic data relating to the primary factors of health effects, ecological effects, chemical properties (transport and persistence), and exposure. Information on such factors is required in Part II of this form.

Other factors can affect the magnitude of human and environmental risk from chemicals or influence the analysis of risk. These additional factors include structure/activity relationships, engineered safeguards, industrial hygiene programs, and consideration of intended restrictions on chemical use. This part of the form (Part III) is optional and provides the form and manner in which data and information pertaining to these factors can be submitted to EPA. The submitter may complete any section or portion of a section in this Part. In addition to this part the submitter may attach any information which he believes EPA should consider in assessing this notice.

Section A Risk Analysis

[ ] 1. Describe your overall testing/evaluation scheme and discuss the scientific rationale underlying your scheme.

[ ] 2. If no data are submitted concerning a particular effect or property listed in Table 1 (pages 16 through 18 of Part II) explain why the development of additional data concerning such properties or effects is unnecessary for the chemical substance. In the absence of such data explain why you believe the information which you have submitted allows a reasoned evaluation of the health and environmental effects of the new chemical substance. Provide references to any mitigating factors discussed in the other sections of this notice (e.g., structure/activity relationships, safeguards, etc.).

[ ] 3. For each of the properties, characteristics, or effects listed in Table 1 (pages 16 through 18 of Part II), if any of the applicable data indicate a potential for adverse health or environmental risk, alone or in combination with other data, discuss any information which you feel mitigates such risk.

[ ] 4. If testing for any effect or property listed in Table 1 was not done because of economic impracticality, explain why you reached such a conclusion.

[ ] 5. One common approach utilized in risk assessment methodology consists of identifying conditions of maximum exposure or susceptible segments of the population in order to identify maximum potential for risk. You may assist EPA by providing estimates of maximum exposure (considering or speculating upon new uses, expanded production, accidental exposure, misuse of the chemical, etc.) or identifying those uses that affect the most susceptible segments of the population (e.g., children, the infirm, etc.). Further, you may wish to provide EPA with your own analysis of risk under these same conditions.

Section B Structure/Activity Relationships

[ ] 1. Have you attached a description of any data or information to this notice concerning properties or effects of chemical substances or classes of substances that are related to the new chemical substance on the basis of structural similarity, chemical reactivity or other characteristics and that relate to an evaluation of the risks posed by the new chemical substance?
[ ] Yes [ ] No

If yes, identify the related chemical(s) and explain what makes these related chemicals similar (e.g., functional group characteristic chemical reactivity, other chemical or physical property).

[ ] 2. Explain why you concluded that this similarity presents a valid basis for evaluating the activity of the new chemical substance.

[ ] 3. Explain how properties or effects of these related chemical substances affect the risk associated with the new chemical substance.

[ ] 4. Are there other structurally related chemical substances which you have not discussed here?
[ ] Yes [ ] No

If yes, explain why.

Section C Non-Risk Factors: Economic and Non-Economic Benefits

The economic significance and benefits associated with a chemical substance are relevant to determining if the risks associated with the importation, processing, use, or disposal of the chemical substance are unreasonable. This section assists the importer in providing his assessment of certain economic and benefit factors which he believes EPA should consider when evaluating the chemical's risks and benefits.

1. Economic changes resulting from importation of the new chemical.

[ ] a. Estimate the total five-year projected gross market value of the new chemical.

b. What effect will importation of the new chemical have on the price of any domestically produced feedstocks, intermediates, end products or non-chemical products? Identify any affected products and indicate by means of the appropriate price change symbol.

		Affected Product	Price Change	Current Price
[ ]	1.		[ ]	[ ]
[ ]	2.		[ ]	[ ]
[ ]	3.		[ ]	[ ]

Key:
1 = Decrease in excess of 25%
2 = Decrease between 10% and 25%
3 = Some decrease but less than 10%
4 = No change
5 = Some increase but less than 10%
6 = Increase between 10% and 25%
7 = Increase in excess of 25%

c. What effect will importation of the new chemical have on the volume of production of any domestically produced feedstocks, intermediates, end products or non-chemical products? Identify any affected products and indicate by means of the appropriate production change symbol.

	Affected Product	Production Change
[ ]	1.	[ ]
[ ]	2.	[ ]
[ ]	3.	[ ]

Key:
1 = Decrease in excess of 50,000 pounds
2 = Decrease between 10,000 and 50,000 pounds
3 = Some decrease but less than 10,000 pounds
4 = No change
5 = Some increase but less than 10,000 pounds
6 = Increase between 10,000 and 50,000 pounds
7 = Increase in excess of 50,000 pounds

d. What employment effects will result from importation of the new chemical? Indicate the source and magnitude of any employment change below, using the appropriate symbol.

	Affected Product	Employment Change
[ ]	A. Importation of the chemical itself	[ ]
	B. Domestic production of any feedstock, intermediates, end products or non-chemical products (Identify below)	
[ ]	_____	[ ]
[ ]	_____	[ ]
[ ]	_____	[ ]

Key:
1 = Decrease in excess of 25 people
2 = Decrease between 10 and 25 people
3 = Some decrease but less than 10 people
4 = No change
5 = Increase but less than 10 people
6 = Increase between 10 and 25 people
7 = Increase in excess of 25 people

[ ] e. Describe any significant regional or community effects resulting from importation of the new chemical, such as a significant reduction in the rate of unemployment.

f. What effects on the balance of trade will result from importation of the new chemical? Indicate the source and magnitude of export and import changes by the appropriate symbol.

Source	Changes in Exports	Changes in Imports
[ ] A. Importation of the new chemical itself	[ ]	[ ]
[ ] B. Domestic production of any feedstocks, intermediates, end products or non-chemical products (Identify below)	[ ]	[ ]

Key:
1 = Decrease in excess of $25 million annually
2 = Decrease between $10 million and $25 million annually
3 = Some decrease but less than $10 million annually
4 = No change
5 = Some increase but less than $10 million annually
6 = Increase between $10 million and $25 million annually
7 = Increase in excess of $25 million annually

[ ] g. Are any plant and equipment outlays planned in conjunction with importation of the new chemical? Describe the nature of the investment, the timing, and the amount of the investment.

Investment		
Year	Amount	Production Capacity Created

[ ] h. What are the (unique) properties of this chemical that will be the basis of its value in the marketplace? (Include such factors as contribution to reliability or durability of intermediates or end products, increases in productivity, convenience factors, and aesthetic factors).

[ ] i. What existing substitute products or processes (if any) have any of the properties listed in 1(h)? In what ways do the properties of the new chemical exceed those of existing substitutes?

2. Non-economic benefits resulting from production of the new chemical.

[ ] a. Are there any uses for the new chemical which contribute directly or indirectly to human health or safety?

[ ] b. What existing substitute products or processes (if any) have any of the uses listed in 2(a)? In what ways do the use properties of the new chemical exceed those of existing substitutes?

[ ] c. Are there any uses for the new chemical which result in environmental benefits or conservation of energy or natural resources?

[ ] d. What existing substitute products or processes (if any) have any of the uses listed in 2(c)? In what ways do the use properties of the new chemical exceed those of existing substitutes?

FOREIGN MANUFACTURERS/SUPPLIERS FORM

CERTIFICATION STATEMENT: I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and truthful as of the date of submittal.

Signature of Authorized Official _____

Date _____

GENERAL INSTRUCTIONS

Section 720.21(c) of the rules for Premanufacture Notification for New Chemical Substances requires an importer of a new chemical substance submitting a premanufacture notice to request the manufacturer and supplier of the substance to complete this form. You have been selected because an importer has indicated that you intend to manufacture or supply the substance(s) for which premanufacture notification has been or will be submitted. If you do not intend to manufacture or supply this substance, you should not complete this form. If you do intend to manufacture or supply the substance, you are requested to complete this form, but you are not under a legal obligation to do so. However, if you have been authorized to report the chemical identity on behalf of the importer, failure to do so will invalidate the importer's notice.

If this form is completed, it may be returned to the person who sent it to you, or sent directly to EPA at the following address:

Document Control Officer
Office of Toxic Substances
TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

CONFIDENTIALITY INSTRUCTIONS: You may assert a claim of confidentiality with respect to any data or information submitted on this form. If you are asserting such a claim, you should place a check in the box in the left hand margin immediately adjacent to the data or information entry. If you do not assert a claim of confidentiality on this form at the time of submission of the information, EPA may make the information public without further notice to you. Claims of confidentiality must be made in accordance with 40 CFR 720, Subpart E, and EPA's Public Information provisions in 40 CFR Part 2. Information submitted to EPA, and subject to a claim of confidentiality, will be treated in accordance with 40 CFR 720, Subpart E, and 40 CFR Part 2.

Part 1

GENERAL INFORMATION

Section A Manufacturer Identification

[ ] 1. Person Completing Form

Name of Authorized Official _____

Title _____

Organization _____

Address _____

2. Incorporation Information

Legal Title of Organization _____

_____

Place of Incorporation

Street _____

City _____

State _____

[ ] 3. Principal Place of Business

Street _____

City _____

State _____

[ ] 4. Technical Contact

Name/Title _____

Address _____

Telephone Number _____

5. Related Companies

a. Other Persons Authorized to Manufacture and Export Chemical to U.S.

1) Identify any other persons that may manufacture or export this chemical substance to the United States by virtue of an existing or planned business arrangement (e.g., contract, license, or other form of legal permission) between you and the person.

	Name	Address	Business Arrangement	Anticipated Date of Export
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____
[ ]	_____	_____	_____	_____

[ ] 2) If such a business arrangement exists will the responses on this form include export volume and use information resulting from the activities of these other persons?

Yes [ ] No [ ]

[ ] If no, provide export volumes expected for the next five years.

[ ] b. Parent Company

Name _____

Address _____

_____

_____

Section B Chemical Identity

If chemical identity will be reported by the importer who sent you this form, check this box and do not complete the remainder of this section [ ]. If you have been authorized to report the chemical identity for the importer, failure to do so will invalidate the importer's notice.

Complete either 1, 2, or 3 as appropriate. Complete 4. If chemical identity is claimed confidential also complete 5.

1. Class 1 chemical substance (other than polymers).

[ ] a. CAS Registry No. (if known) _____

[ ] b. Specific Chemical Name _____

[ ] c. Molecular Formula _____

[ ] d. Synonyms _____

[ ] e. Trademarks _____

[ ] f. Structural Diagram

2. Class 2 chemical substance.

[ ] a. CAS Registry No. (if known) _____

[ ] b. Specific Chemical Name _____

[ ] c. Syncnyms _____

[ ] d. Trademarks _____

[ ] e. List the immediate precursor substance(s) and/or reactants with their respective CAS Registry Number(s) and the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

3. Polymers

a. (1) Provide the specific chemical name and the CAS Registry Number of those monomers and other reactants used at greater than two percent (by weight) in the manufacture of the polymer. Monomers used at two percent (by weight) or less need not be listed as part of the polymer description; (2) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). Calculate the percent based on the composition of the polymer formed. If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition; (3) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

	(1) Monomers and CAS Registry #	(2) Range of Composition	(3) Maximum Residual (Weight Percent)
[ ]			
[ ]			
[ ]			

b. List any monomers used at 2% (by weight) or less in the manufacture of the polymer which are not listed in 3(a) above. For each such monomer indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

c. Indicate the minimum molecular weight, compositional restrictions or other restrictions of the polymeric compositions to which this notice applies.

4. Impurities

List the identity and estimate the maximum percent (by weight) of those impurities which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. Consider information developed during R&D activities,

your knowledge of manufacturing process chemistry and anticipated quality control operations. Check if the concentration of an impurity will be specifically controlled based upon your knowledge of potential adverse health or environmental effects. Estimate the maximum total percent (by weight) of the impurities that may be present. Total percent _____.

	Identity	Maximum Percent	Specifically Controlled
[ ]			[ ]
[ ]			[ ]
[ ]			[ ]

5. Chemical Identity Claimed Confidential

a. If claimed for period prior to commencement of export to the U.S.:

Proposed Generic Name _____

b. If claimed for period following commencement of export to the U.S.:

Proposed Generic Name: _____

Substantiation and other materials required to be submitted with a claim of confidentiality must be attached in accordance with 40 CFR 720.40(c).

Section C Production and Marketing Data

1. Estimate your past total annual production of the new chemical substance for the following years (see ranges in Support Document).

[ ] a. One year ago

[ ] b. Three years ago

[ ] c. Five years ago

2. Estimate the past total annual production of the new chemical substance by others for the following years (see ranges in Support Document).

[ ] a. One year ago

[ ] b. Three years ago

[ ] c. Five years ago

3. Has the chemical substance been manufactured more than five years ago?

Yes [ ] No [ ] Don't Know [ ]

If yes, estimate the average annual production and the number of years it was produced (see ranges in Support Document).

4. Estimate your total annual production volume for the years following submittal of this notice (see ranges in Support Document).

[ ] a. First year

[ ] b. Third year

[ ] c. Maximum annual demand (fifth year or beyond)

5. Export Volumes

a. Estimate the total amount of the chemical substance that you will sell for export to the United States for the following years (see ranges in Support Document).

[ ] (i) First year

[ ] (ii) Third year

[ ] (iii) Maximum annual sales (fifth year or beyond)

6. Basis of Export Estimate

	% of First Year	% of Third Year	% of Maximum Annual Demand
[ ] Firm Orders			
[ ] Forecast			
[ ] Speculative	_____	_____	_____
	%100	%100	%100

7. Chemical Use Assumptions Used in Production Estimate

In the following questions, list each use by function, and as specific an application as possible. (Example: function-solvent; application-paint used in automotive finishes.) List partial information if complete information is not known. (Examples: function-solvent; application-unknown.) Uses reported elsewhere in this form should also be reported here.

a. List those uses on which your export estimates are based. List uses in descending order of the anticipated production volumes devoted to each use.

	Function	Application
[ ]	_____	_____
[ ]	_____	_____
[ ]	_____	_____

b. List any other uses that you believe the chemical substance could have. Identify those uses for which the chemical substance was manufactured prior to the date of this notice.

	Function	Application	Prior Use
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]
[ ]	_____	_____	[ ]

c. Do you intend or expect the new chemical substance to be used within the United States to treat water or to be used in drinking water supplies or to be used in coatings, paints, liners, pipes or other products that will come in contact with drinking water?

[ ] Yes [ ] No [ ]

[ ] 8. Was production of this chemical banned or restricted because of governmental action, litigation, or voluntarily because of adverse health or environmental effects?

Yes [ ] No [ ] Don't Know [ ]

If yes, cite references or attach information or data.

9. Hazard Warnings

Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions, technical data sheet, Material Safety Data Sheet and any other information which will be provided to purchasers regarding the safe handling, use, disposal, treatment upon accidental exposure, or recommendations concerning the formulation, construction or labeling of products containing the chemical substance.

Section D Federal Register Notice

Information provided in this section will be published in the Federal Register in accordance with Section 5(d)(2) of the TSCA. Separate sections are provided for presentation of data related to confidential information where appropriate. Do not enter any information in this section which you consider confidential.

1. Chemical Identity - If chemical identity will be reported by the importer who sent you this form do not complete this question.

a. If chemical identity was not claimed confidential in Section B, enter the specific chemical name which you reported in Section B. For polymers enter those monomers which were listed in Section B(3)(a).

_____

b. If chemical identity was claimed confidential in Section B, enter the proposed generic name which you reported in Section B(5).

_____

2. Use Data

a. If use data were not claimed confidential in Section C, list the proposed uses of the chemical substance in the United States by function and as specific an application as known. List industrial uses and consumer uses separately.

Industrial Uses

Function	Application

Consumer Uses

Function	Application

b. If use data were claimed confidential in Section C, report a generic description of the proposed industrial and consumer use(s) of the chemical substance in the United States. This description should be as specific as possible without revealing confidential information.

Industrial Uses

_____

_____

_____

Consumer Uses

_____

_____

_____

Part II

RISK ASSESSMENT DATA

Section A Chemical Properties, Environmental Fate Characteristics, and Human and Ecological Effects Data

Under Section 5(d)(1)(B) and (C) of TSCA and 40 CFR 720.23, a manufacturer within the United States must report all test data in his possession or control and a description of any other data which is reasonably ascertainable related to the effect of any manufacture, processing, distribution in commerce, use or disposal of the chemical substance. The regulations detail which data must be submitted with the notice and which data may be referenced by a literature citation. In addition, the regulations prescribe a format for data on certain effects.

Foreign manufacturers/suppliers are not under a legal obligation to report any test data in their possession or control, or a description of any other data. However, the submission of such data or a description of data will aid EPA in assessing the risk associated with the chemical substance. In addition, in some cases (such as when significant human exposure to the chemical substance is expected and the importer possesses little or no data), voluntary reporting of health or environmental effects data by you may reduce the chance of a delay in importation of the chemical substance due to inadequate data.

Table 1 lists what EPA considers to be the most important basic chemical properties and potential effects that should be considered in an assessment of risk. You are urged to attach to this notice all health and environmental effects and physical/chemical properties data concerning the effects and properties listed in this Table. This section of the form requires additional information concerning the relationship of the test data and information submitted with this form to the properties and effects listed in Table 1. If such data are reported, you are also requested to complete this section.

[ ] 1. Using Table 1, check those property(ies), characteristic(s) or effect(s) for which you have submitted: (1) data, (2) a description of data and/or (3) a literature citation. Enter the name of the specific technique or methodology of those tests for which you have submitted data next to the property(ies), characteristic(s) or effect(s) to which each pertains. (A given test may be pertinent to two or more properties, characteristics or effects.)

[ ] 2. Discuss any conclusions, evaluations or assessments which you have made concerning the implications of the test data results or descriptions of other data you have submitted for each particular property, characteristic or effect.

[ ] 3. Have you evaluated the health or environmental risks associated with the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 4. Have you evaluated the health or environmental risks presented by substances associated with the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance (e.g., by-products, co-products, feedstocks, intermediates, degradation products)?

Yes [ ] No [ ]

If yes, explain your evaluations.

[ ] 5. Have you evaluated whether the data you have submitted are sufficient to assess the risk associated with the property(ies), characteristic(s) or effect(s) to which they pertain?

Yes [ ] No [ ]

If yes, explain your evaluations. Provide references to any factors discussed in other sections of this notice.

If you have not reported any information for a particular property or effect listed in Table 1 because you believe that such information is either unnecessary or impractical, or if data you are submitting may indicate adverse health or environmental effects, you may wish to provide additional information or explanation to EPA. Section C provides a format for the presentation of such information.

Table 1

CONFIDENTIALITY: The information that is required to be entered in this table is limited to the identification of (1) the physical/chemical properties and health and environmental effects for which data or a description of data has been submitted with this notice and (2) the specific technique or methodology used to develop such data. If you are asserting a claim of confidentiality for any of this data you must mark the attached document(s) which contain the data in accordance with Section 720.40(b) of the Premanufacture Notification Rules.

PHYSICAL/CHEMICAL PROPERTIES

(1) data submitted
(2) description submitted
(3) literature citation

Property	(1)	(2)	(3)	Test Methodology or Technique
Spectra (ultra-violet, visible, infrared)	[ ]	[ ]	[ ]	_____
Density	[ ]	[ ]	[ ]	_____
Solubility in water	[ ]	[ ]	[ ]	_____
Melting point	[ ]	[ ]	[ ]	_____
Boiling point	[ ]	[ ]	[ ]	_____
Sublimation point	[ ]	[ ]	[ ]	_____
Vapor pressure	[ ]	[ ]	[ ]	_____
Dissociation constant	[ ]	[ ]	[ ]	_____
Particle size distribution	[ ]	[ ]	[ ]	_____
pH	[ ]	[ ]	[ ]	_____
Other physical/ chemical or fate characteristics tests (list)	[ ]	[ ]	[ ]	_____

Table 1 (continued)

Property	(1)	(2)	(3)	Test Methodology or Technique
Chemical Reactivity:				
Photochemical degradation	[ ]	[ ]	[ ]	
Hydrolysis	[ ]	[ ]	[ ]	
Chemical oxidation	[ ]	[ ]	[ ]	
Chemical reduction	[ ]	[ ]	[ ]	
Chemical incompatibility	[ ]	[ ]	[ ]	
Explodability	[ ]	[ ]	[ ]	
Other	[ ]	[ ]	[ ]	
Biodegradation	[ ]	[ ]	[ ]	
Adsorption/desorption characteristics	[ ]	[ ]	[ ]	
Formation of persistent transformation products	[ ]	[ ]	[ ]	

HEALTH AND ENVIRONMENTAL EFFECTS DATA

(1) data submitted
(2) description submitted
(3) literature citation

Effect	(1)	(2)	(3)	Test Methodology or Technique
Acute animal effects	[ ]	[ ]	[ ]	
Genetic effects	[ ]	[ ]	[ ]	
Subchronic	[ ]	[ ]	[ ]	

Table 1 (continued)

Effect	(1)	(2)	(3)	Test Methodology or Technique
Teratogenicity	[ ]	[ ]	[ ]	
Reproductive effects	[ ]	[ ]	[ ]	
Oncogenicity	[ ]	[ ]	[ ]	
Other health effects (chronic or latent animal effects)	[ ]	[ ]	[ ]	
Microbial effects	[ ]	[ ]	[ ]	
Aquatic invertebrate effects	[ ]	[ ]	[ ]	
Plant effects	[ ]	[ ]	[ ]	
Fish effects	[ ]	[ ]	[ ]	
Bioconcentration	[ ]	[ ]	[ ]	
Community or ecosystem level effects	[ ]	[ ]	[ ]	
Other environmental effects* (specify)	[ ]	[ ]	[ ]	

*"Other environmental effects" refers to any direct or indirect effect on any environmental entity, process, function, or amenity not specifically included in another category. Example: weather modification, stratospheric ozone depletion, property damage, agricultural or silvicultural damage, and aesthetic effects.

Section B Risk Analysis

[ ] 1. Describe your overall testing/evaluation scheme and discuss the scientific rationale underlying your scheme.

[ ] 2. If no data are submitted concerning a particular effect or property listed in Table 1 (pages 13 through 15 of Part II) explain why the development of additional data for such properties or effects is unnecessary for your chemical substance. In the absence of such data explain why you believe the information which has been submitted allows a reasoned evaluation of the health and environmental effects of your new chemical substance. Provide references to any mitigating factors discussed in the other sections of this notice (e.g., structure activity relationships, safeguards, etc.).

[ ] 3. For each of the properties, characteristics, or effects listed in Table 1 (pages 13 through 15 of Part II), if any of the applicable data indicate a potential for adverse health or environmental risk, alone or in combination with other data, discuss any information which you feel mitigates such risk.

[ ] 4. If testing for any effect or property listed in Table 1 was not done because of economic impracticality explain why you reached such a conclusion.

[ ] 5. One common approach utilized in risk assessment methodology consists of identifying conditions of maximum exposure or susceptible segments of the population in order to identify maximum potential for risk. You may assist EPA by providing estimates of maximum exposure (considering or speculating upon new uses, expanded production, accidental exposure, misuse of the chemical, etc.) or identifying those uses that affect the most susceptible segments of the population (e.g., children, infirm, etc.). Further, you may wish to provide EPA with your own analysis of risk under these same conditions.

Section C Structure/Activity Relationships

[ ] 1. Have you attached a description of any data or information to this notice concerning properties or effects of chemical substances or classes of substances that are related to the new chemical substance on the basis of structural similarity, chemical reactivity or other characteristics and that relate to an evaluation of the risks posed by your new chemical substance?

Yes [ ] No [ ]

If yes, identify the related chemical(s) and explain what makes these related chemicals similar (e.g., functional group, characteristic chemical reactivity, other chemical or physical property).

[ ] 2. Explain why you concluded that this similarity presents a valid basis for evaluating the activity of the new chemical substance.

[ ] 3. Explain how properties or effects of these related chemical substances affect the risk associated with the new chemical substance.

[ ] 4. Are there other structurally related chemical substances which you have not discussed here?

Yes [ ] No [ ]

If yes, explain why.

PROCESSING AND CONSUMER USE FORM

CERTIFICATION STATEMENT: I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and truthful as of the date of this submittal.

Signature of Authorized Official _____

Date: _____

GENERAL INSTRUCTIONS

Section 720.20(e) of the Premanufacture Notification Rules for New Chemical Substances requires each person who submits a premanufacture notice to request certain other persons to complete this form. You have been selected because of an indication that you may process or use the substance(s) for which a premanufacture notice has been or will be submitted. If you do not intend to process or use this substance, you should not complete this form. If you do intend to process or use the substance, please complete this form. However, you are not under a legal obligation to do so.

If you complete this form, it may be returned to the person who sent it to you, or sent directly to EPA at the following address:

Document Control Officer
Office of Toxic Substances
TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

CONFIDENTIALITY INSTRUCTIONS

You may assert a claim of confidentiality with respect to any data or information submitted on this form. If you are asserting such a claim, you should place a check in the box in the left hand margin immediately adjacent to the data or information entry. If you do not assert a claim of confidentiality at the time of submission of the information, EPA may make the information public without further notice to you. Claims of confidentiality must be made in accordance with 40 CFR 720, Subpart E, and EPA's Public Information provisions, in 40 CFR Part 2.

Information submitted to EPA, and subject to a claim of confidentiality, will be treated in accordance with 40 CFR 720, Subpart E, and 40 CFR Part 2.

Person Completing Form

Name of Authorized Official _____
Title _____
Organization _____
Mailing Address _____

Part I

PROCESSING OPERATIONS

The risk which a chemical substance presents to health or the environment depends upon two factors: effects (toxicity) and exposure. Further, exposure has two aspects: (1) the type and magnitude of exposure to humans and ecological populations and (2) the probability that such exposure will occur. To perform assessments of risks presented by new chemical substances, EPA needs information on both aspects. This section is intended to identify the levels of exposure to workers, the general population, and the environment resulting from processing of the chemical substance.

Sections A, B and C should be completed for each site where you intend to process the new chemical substance. If more than one processing site will be used attach supplementary sections.

[ ] Site Name _____

[ ] Address _____

_____

_____

Section A Worker Exposure

1. Check the routes of exposure to the new chemical substance that may occur at the processing site during normal operations. For each route checked, estimate the maximum number of workers exposed to the new chemical substance during a one-year time period in the first 5 years (see Support Document for ranges).

	Exposure Route	Maximum Number Exposed
[ ]	Inhalation	[ ]
[ ]	Ingestion	[ ]
[ ]	Skin contact	[ ]

Describe the magnitude, duration and frequency of the exposures that may occur through ingestion or skin contact. Include a description of inhalation exposures if the information in Question 2 is unknown and not reasonably ascertainable.

2. State the maximum levels of the new chemical substance in the workplace air that workers are expected to be exposed to during normal operations at the processing site in the first 5 years. If appropriate, include levels for the following types of exposure situations: (1) direct exposure that occurs in close proximity to manufacturing equipment and/or from direct handling of the chemical substance and (2) exposure to ambient workplace concentrations that may be experienced by any worker normally in the general vicinity of a processing operation.

		Levels	
		Direct	Ambient Workplace Air
[ ]	a. Time-weighted average concentration in air for an 8-hour day, 40-hour work week schedule ([ ] ppm or [ ] mg/m3)		
[ ]	b. Peak concentration in air for 15 minutes ([ ] ppm or [ ] mg/m3)		

[ ] 3. Explain how the workplace exposure estimates in Questions 1 and 2 were derived.

[ ] 4. Based on your analytical and instrument capabilities enter the minimum level of the new chemical substance that you can detect in the workplace air. Describe the analytical and sampling techniques on which you have based the minimum detectable level.

[ ] 5. Estimate the maximum number of workers exposed to the levels of the new chemical substance in the workplace air reported in Question 2 during a one-year time period in the first 5 years as listed below (see Support Document for ranges). Estimate the maximum number of days per year and hours per day that any person may be exposed to the chemical substance.

	Exposure	Maximum Number Exposed	Maximum Hours/day	Maximum Days/Year
[ ]	Direct			
[ ]	Ambient workplace			

6. Describe the use(s) of the new chemical substance at this site by function and application and estimate the amount devoted to each use to one significant figure.

	Uses		
	Function	Application	Amount
[ ]	_____	_____	_____
[ ]	_____	_____	_____
[ ]	_____	_____	_____

7. Describe any products produced by your processing operations which intentionally contain the chemical substance and are intended for use at industrial sites only.

Section B Environmental Releases

[ ] 1. Indicate, as required in Table 1, the maximum amount of the new chemical substance intended to be processed at the site to one significant figure (kg/yr), the hours of operation, the estimated average and maximum environmental release rates and concentration of the chemical substance at the processing site during normal operation. Enter the minimum level of the new chemical substance that you have analytical and sampling capability to detect in air emission streams and water effluent streams and describe your method of detection. Enter the specified stack parameters for each air process emission point listed. Place the following letters in the appropriate range estimates to indicate the range of the maximum and average release rates or concentrations expected. Base your estimates on the year of maximum release during the first 5 years.

A - average discharge rate or average hourly concentration in air emission streams, average daily concentration in water effluent streams.

M - maximum discharge or concentration.

[ ] 2. Enter the name of the receiving water body(ies) or name and location of the POTW listed in Table 1 to which you will be discharging.

[ ] 3. If the concentration levels listed in Table 1 result from treatment of the wastewater stream or use of air pollution control equipment, describe the type of control equipment, identify the air emission stream or water effluent stream it serves, and state the expected efficiency of the equipment (i.e., the percent of emission or effluent reduction).

[ ] 4. Explain how the environmental release estimates in Table 1 were derived.

TABLE 1

ENVIRONMENTAL RELEASE FROM PROCESS SITES

Amount Manufactured kg/yr _____ Hours of Operation/Yr. _____
Hours/day _____

Type of Level		Range					
Air							
[ ] a.	estimated discharge to the air from an entire site (kg/hr)	<.1 [ ]	.1-1 [ ]	1-10 [ ]	10-100 [ ]	>100 [ ]	
[ ] b.	hourly concentration in process emission streams [ ] ppm [ ] mg/m^3	10	10-100	100-1,000	1,000-10,000	10,000-100,000	>100,000
Stack	Stack Dia. / Stack height / Velocity / Temp						
[ ] 1.	_____ _____ _____ ____	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] 2.	_____ _____ _____ ____	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] 3.	_____ _____ _____ ____	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ] c.	minimum detectable level in process emission streams [ ] ppm [ ] mg/m^3	_____ Method of Detection: _____.					
WATER	[ ] POTW[1] [ ] Navigable Waterway or Tributary [ ] Other						
[ ] a.	estimated discharge rate in effluent streams (kg/day)	<1 [ ]	1-10 [ ]	10-100 [ ]	100-1000 [ ]	>1000 [ ]	
[ ] b.	daily concentration in effluent streams [ ] ppm [ ] ppb	<1	1-10	10-100	100-1000	>1000	
[ ]	1. _____ flow rate [ ] GPD[2]	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ]	2. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ]	3. _____ flow rate [ ] GPD	[ ]	[ ]	[ ]	[ ]	[ ]	
[ ] c.	minimum detectable level in effluent streams [ ] ppm [ ] ppb	_____ Method of Detection: _____.					

1-POTW - Publicly Owned Treatment Works
2-GPD - gallons per day

Section C Disposal

[ ] 1. Describe any materials associated with the processing operation that contain the new chemical substance and require disposal. Estimate the maximum amount of each material to be disposed of in one year during the first 5 years (see Support Document for ranges), the percent of the new chemical substance contained in the substances requiring disposal and enter the anticipated method of disposal. Also enter the name of the commercial disposer (if applicable) and the location of the site of disposal if known.

	Material Requiring Disposal	Amount (kg/yr)	Percent of New Chemical Substance	Anticipated Method of Disposal	Name and Site Location
[ ]					
[ ]					
[ ]					

[ ] 2. If substances containing the new chemical substance that require disposal are incinerated or otherwise treated to destroy or remove the chemical substance indicate the efficiency of this removal.

[ ] 3. Attach to this notice a copy or reasonable facsimile of any warning statement, labels, labeling or instructions that will be provided by you to persons who may dispose of the new chemical substance in order to inform them of disposal procedures you recommend.

[ ] 4. Estimate the maximum number of workers that may be exposed to the new chemical substance during normal disposal operations and characterize the magnitude, duration, and frequency of such exposures (see Support Document for ranges).

Section D Federal Register Notice

Information provided in this section will be published in the Federal Register in accordance with Section 5(d)(2) of the TSCA. Separate sections are provided for presentation of data related to confidential information where appropriate. Do not enter any information in this section which you consider confidential.

1. If use data were not claimed confidential, list the proposed uses of the chemical substance by function and as specific an application as known. List industrial uses and consumer uses separately.

Industrial Uses

Function	Application

Consumer Uses

Function	Application

2. If use data were claimed confidential provide a generic description of the proposed industrial and consumer use(s) of the chemical substance. This description should be as specific as possible without revealing confidential information.

Industrial Uses

_____

_____

_____

Consumer Uses

_____

_____

_____

Part II

GENERAL POPULATION EXPOSURE/CONSUMER PRODUCTS

Complete this part if you will manufacture a product(s) that intentionally contains the new chemical substance and that will be distributed for use by the general population or for use in products to which the general population may be exposed.

[ ] 1. Using Table 2 list the anticipated products by function and application and the total amount of the new chemical substance devoted to each product to one significant figure. Estimate the consumer market population which will be exposed to the product (see Support Document for ranges), the route of exposure and the frequency and duration of exposure based on each use. For products which are mixtures indicate the maximum percent by weight of the chemical substance in the product. Check those products which are constructed or formulated so as to limit potential exposure.

[ ] 2. Describe the level of human exposure that may occur through use of products that contain the new chemical substance. Where possible provide quantitative estimates of exposure levels such as the maximum concentration of the substance in air during normal use.

[ ] 3. Describe how the estimates in Question 2 were derived.

[ ] 4. For each article checked in Table 2 explain those aspects of its concentration or formulation which will affect the potential for exposure to the new chemical substance.

[ ] 5. Attach to this notice a copy or reasonable facsimile of any hazard warning statement, labels, labeling or instructions, which will be provided with each product regarding the prevention of adverse health and/or environmental effects upon use or disposal.

TABLE 2

CONSUMER EXPOSURE

	Product Function/ Application	Amount For each Use	Consumer Market Population for each use	Frequency of Exposure	Duration of Exposure	Exposure Route Through Use			% in formulated Mixture	Controlled Exposure Construction
						Inhal.	Ingest.	Derm.		
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]
[ ]	_____	_____	_____	_____	_____	[ ]	[ ]	[ ]	_____	[ ]

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