

Environmental Protection Agency

Tuesday
October 16, 1979

**PLAINTIFF'S
EXHIBIT**

KM-383

Part III

Environmental Protection Agency

Reproposal of Toxic Substances Control
Act (TSCA) Premanufacture Notice (PMN)
Forms and Provisions of Rules

KMX 01178

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[FRL-1314-1; OTS-050002E]

Reproposal of Premanufacture Notice Form and Provisions of Rules

AGENCY: Environmental Protection Agency (EPA), Office of Toxic Substances.

ACTION: Reproposal of Toxic Substances Control Act (TSCA) Premanufacture Notice (PMN) forms and provisions of rules; request for public comment.

SUMMARY: On January 10, 1979, EPA proposed rules and notice forms to govern premanufacture notification for new chemical substances in accordance with section 5(a)(1)(A) of TSCA. In response to numerous comments, EPA is reproposing the following: (1) Briefer notice forms for domestic manufacturers, importers, and exporters that require submitters to provide significantly less detailed information, and (2) certain provisions of the rules concerning confidentiality and supplemental reporting.

DATES: Written comments must be submitted by November 30, 1979. EPA will meet with interested members of the public who wish to discuss and comment on this reproposal from October 16, 1979 to November 30, 1979. Following the 45-day period, the Agency will hold at least one public meeting to discuss the comments. Persons who want to meet with Agency representatives either during or after the comment period should refer to the section of this notice entitled "Comments and Public Meetings".

ADDRESS: All comments should bear the identifying notation OTS-050002E and be addressed to Document Control Officer, Office of Toxic Substances (TS-793), EPA, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Mr. John B. Ritch, Director, Industry Assistance Office (TS-799), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460; 800-424-9065 toll free; in Washington, D.C., please call 554-1404.

SUPPLEMENTARY INFORMATION: EPA proposed the Premanufacture Notification Requirements and Review Procedures (40 CFR Part 720) on January 10, 1979 (44 FR 2242). Section 5(a)(1)(A) of TSCA requires each person who

intends to manufacture or import a new chemical substance for a commercial purpose to submit a PMN to EPA at least 90 days before he commences such manufacture or importation. A "new" chemical substance is one that is not included on the TSCA section 8(b) Inventory of Chemical Substances. At the end of the notification period, the person may manufacture or import the substance unless EPA has taken action to ban or otherwise regulate the substance. The requirement to submit PMN's took effect on July 1, 1979, 30 days after EPA first published the TSCA Inventory (44 FR 28558 May 15, 1979). Thirty days after the Agency publishes the Revised Inventory [see 44 FR 28558, 28561-64] the premanufacture requirements will apply to importers of new chemical substances as a part of mixtures. On May 15, 1979, EPA published a Statement of Interim Policy (44 FR 28564) to govern the submittal and review of premanufacture notices prior to promulgation of the final rules and forms. Under the Interim Policy, a PMN must satisfy the requirements of section 5 of TSCA.

Following is an index to the remainder of this preamble and the major elements of this reproposal.

Preamble

I. The Premanufacture Notice Form

A. January 10 Proposed Form

1. General Approach
2. Summary of Public Comments
- B. Revised PMN Form
1. General Approach
2. Optional Part
3. Forms for Importers and Exporters
4. Estimated Costs
- C. Related Issues

1. Customer Information
2. Form for Low Volume Substances
3. Followup Reporting

D. Section-by-Section Review

1. Manufacturer Identification
2. Production and Marketing Data
3. Federal Register Notice
4. Risk Assessment Data
5. Worker Exposure
6. Environmental Release
7. Byproducts, Co-products, Feedstocks and Intermediates
8. Transport
9. Process Flow Description
10. Consumer and Commercial Exposure

II. Confidentiality

- A. Issues Addressed in this Proposal
- B. Asserting and Substantiating Claims of Confidentiality

1. January 10 Proposal
2. Summary of Comments on January 10 Proposal
3. Revised Approach for Asserting and Substantiating Claims of Confidentiality
- C. Submittal of Generic Information if Certain Information is Claimed Confidential

1. January 10 Proposal

2. Summary of Comments on January 10 Proposal

3. Revised Approach

III. Supplemental Reporting

A. January 10 Proposal

B. Summary of Comments on January 10 Proposal

C. Revisions to Proposed § 720.50

D. Revisions to Proposed § 720.51

IV. Costs and Economic Impact Issues

A. January 10 Proposal

B. Summary of Comments on January 10 Proposal

C. Revised Analysis

V. Comments and Public Meetings

IV. Public Record

Reproposed Premanufacture Rules

I. Confidentiality: 40 CFR 720.40-45

II. Supplemental Reporting: 40 CFR 720.50 and 720.51

Revised PMN Forms

I. General Premanufacture Notice Form (Form for Domestic Manufacturers)

Appendix A.—Instructions for Asserting and Substantiating Claims of Confidentiality

Appendix B.—Examples of Asserting and Substantiating Claims of Confidentiality

Appendix C.—Examples of Process Descriptions

II. Importers Form

III. Exporters Form

I. The Premanufacture Notice Form

A. January 10 Proposed Form

1. *General Approach.* The January proposal included the following four separate notice forms that were similar in scope and content but designed for different purposes: (1) Domestic manufacturers, (2) importers, (3) processors, and (4) foreign manufacturers/suppliers.

The form for domestic manufacturers and importers contained mandatory and optional parts. The mandatory parts primarily required information on the identity of the manufacturer or importer, the specific identity of the new chemical substance; and production, use, and human and environmental exposure. Submitters were required to provide the information requested in the mandatory parts to the extent it was "known to or reasonably ascertainable by" them. The optional parts identified information concerning engineering and industrial hygiene safeguards, economics, and the assessment of the sufficiency of data submitted on health and environmental effects. If a submitter believed that additional information, other than that requested in the form, would significantly affect EPA's assessment of risk, he could provide it voluntarily. EPA intended for the notice submitter to consider the properties of the new chemical substance, the nature of the business venture, and the costs of completing the optional section(s) when

deciding if it is in his best interest to submit the information contained in the optional part.

2. Summary of Comments on January 10 Proposal. Public interest organizations, other federal agencies, and organized labor generally supported the January 10 proposed forms. Individual companies and trade associations commented that the information requirements of the proposed forms were excessive both in scope and level of detail. Industry commenters primarily were concerned about the specific estimates required in the worker exposure and environmental release sections (e.g., estimates of the concentration of the new chemical substance in effluent streams). The commenters stated that much of these data would not be available at the time a PMN was submitted and that estimates based on pilot-plant operations would be unreliable because transfer of production from pilot-plant operation to full-scale operation usually results in a change of almost every equipment parameter. In addition, they stated that the cost of generating such data would impose unreasonable burdens upon submitters. A large number of industry commenters stated that EPA lacks statutory authority to require much of the information in the January 10 proposal.

Several industry commenters submitted alternative forms with their comments. Generally, these forms were based upon a narrower interpretation of EPA's statutory authority and data needs than that taken by the Agency. The Chemical Manufacturers Association (CMA—formerly the Manufacturing Chemists Association) submitted a form that would reduce both the scope and the level of detail of the information EPA would receive. For example, questions concerning the transport of the new chemical substance and estimates of workplace concentrations would be optional in the CMA form. Many commenters endorsed the CMA form; some submitted forms with even further data deletions, requiring in some instances little more than the name of the submitter and the chemical identity.

Consistent with this narrow interpretation of the premanufacture notification requirements, several industry commenters stated that the level of detail of the proposed forms indicated that EPA's program objectives went far beyond the intent of Congress. They stated that Congress intended the information requirements of a PMN to be modest in scope and that the time and effort required to submit it should

be minimal. They also commented that the Agency's proposed form seemed more appropriate for a registration or certification program (similar to the program for registering pesticides under the Federal Insecticide, Fungicide and Rodenticide Act), instead of a more limited notification program. They stated that EPA's proposed approach would significantly impede innovation in the chemical industry.

Finally, some in industry commented that because EPA did not provide specific guidance as to what is meant by the phrase "known to or reasonably ascertainable," it was unclear how much effort EPA expected submitters to expend to gather and format certain types of data.

B. Revised PMN Form

Sections 5(d)(1)(A), (B) and (C) of the Act authorize EPA to require the data specified in both the January 10 proposal and the current reproposal. EPA does not agree with industry's narrow interpretation of the Agency's statutory authority; therefore, the reduced data requirements of the current reproposal do not reflect a determination by EPA that it lacks statutory authority to require additional information. Based on the comments EPA received on this reproposal, the Agency may expand the data requirements when it promulgates the final rules and forms.

EPA has two major objectives in revising the January 10 proposed notice form: (1) To obtain adequate information to permit at least a preliminary assessment of the risks associated with the manufacture, processing, distribution in commerce, use, and disposal of new chemical substances; and (2) to achieve this objective at a minimum cost to persons submitting notices. In revising the notice form, EPA considered the minimum information and level of detail necessary for such a preliminary assessment, the likely availability of such information, and the associated costs.

Since January EPA has further defined key phases of its process for reviewing PMNs, including information needed for each phase. The Agency faces both time and resource limitations on its ability to review notices. Also, EPA assumes that although some new substances may present risks to health or the environment, most will not require regulatory attention by the Agency. Thus at the beginning of the review process, EPA will review each PMN in an Initial Screen, to identify a small number of chemicals that will be the subject of more detailed assessments and possible regulatory actions. At this time we believe that the information

required by the revised form, plus information available to the Agency through quick literature searches, will be adequate to perform this screening function.

In particular, the revised form is designed to provide EPA information to make the following decisions at the end of the screening phase: (1) Select some substances for more detailed evaluation and for which additional exposure or toxicological data are needed; (2) Identify some that will be subject to requirements for followup reporting concerning their commercial development; (3) Eliminate others from further consideration; and (4) Select a limited number for immediate regulatory attention. When EPA needs additional exposure information, the Agency intends to obtain it from submitters during the notice review period, either voluntarily or by using the authorities of sections 8(a) and 11(c) of TSCA. (Also see Section III, Supplemental Reporting.) For followup reporting, EPA will issue requirements under sections 8 and 5(a)(2). (See Section I-C-3, Related Issues—Followup Reporting.) This approach eliminates the need for companies to submit a considerable amount of information that is not related to EPA's decisionmaking.

Finally, EPA believes that this approach is more cost effective than the one proposed in January. The revised form requests all of the major types of information contained in the January proposal, but at a significantly reduced level of detail. EPA will impose additional reporting burdens only when warranted, based on the contents of PMNs and other information available to the Agency. This will considerably reduce industry's costs of compiling and reporting information on new substances, as demonstrated by the revised cost estimates described below. (See Section I-B-4, Estimated Costs.)

EPA welcomes comments on whether the objectives discussed above could be accomplished by less burdensome, alternative strategies. Specifically, the Agency encourages representatives of public interest organizations and small businesses to comment.

1. General Approach. The revised forms maintain the mandatory and optional approach of the forms proposed in January. The notice submitter must provide the information in the mandatory parts of the revised forms to the extent it is known to or reasonably ascertainable by him. This includes all information in the submitter's possession or control as well as information that he could obtain without unreasonable burden or cost.

Many in industry have expressed difficulty in determining what information EPA considers to be "reasonably ascertainable". Specifically, they are uncertain about the effort EPA expects them to make in obtaining certain types of information. This is particularly true for information concerning exposure levels, byproducts, and impurities. EPA has considered defining, for each item of information requested in the form, what the Agency considers to be "reasonably ascertainable". However, what would be a reasonable effort for one company under a certain set of circumstances could be extremely burdensome and costly for the same company under different circumstances (e.g., producing a different chemical substance) or for another company in the same situation. Therefore, a specific definition of "reasonably ascertainable" may result in inequitable treatment of notice submitters. Under the regulations proposed in January, the notice submitter would be responsible for deciding whether and how to obtain the required data, and when information requested in the form is not reasonably ascertainable. In most instances, data generation activities that are so costly as to preclude commercialization of a new substance would not be reasonable. EPA is continuing to evaluate this issue as part of the rulemaking.

2. *Optional Part.* To simplify this reproposal, EPA has not published the optional part of the revised form in this notice. EPA intends to revise the optional part of the form, to include most of the information that the Agency deleted from the mandatory part of the form.

Specifically, EPA would make optional some of the information included in Part II, Section B, questions 1-5 of the January proposal. Such information includes: (1) Detailed descriptions and estimates of the magnitude, duration, and frequency of worker exposure to the new chemical substance; (2) explanations of how worker exposure estimates are derived; (3) descriptions of analytical sampling methods and capabilities; (4) site-specific data, including stack parameters and water effluent and air emission concentrations; (5) explanations of how environmental release estimates are derived; (6) estimates of the efficiency of disposal methods; (7) descriptions of worker exposure during normal disposal operations; (8) descriptions of worker exposure to byproduct materials; (9) estimates of the concentration and flow rate of byproduct materials in water

effluent and air emission streams; (10) descriptions of potential hazards to transport operators during normal operations and in the event of spills; (11) descriptions of safeguards taken to limit risks during transport; (12) detailed descriptions of the magnitude, duration and frequency of consumer exposure to the new chemical substance; and (13) descriptions of how consumer exposure estimates are derived. The optional section also would include questions concerning these data as they relate to processing operations.

As with the January form, at their discretion, manufacturers may submit any section(s) of the optional part with the revised notice form. This optional information would not be required, and a PMN would be complete and satisfy the statutory requirements if only the mandatory part of the form is completed. EPA is considering providing guidance in the instructions manual to the final forms, to aid submitters in deciding whether to submit any of the optional information. EPA would not require manufacturers to submit any of the optional information; rather, it would identify particular situations when the Agency would be most interested in obtaining the optional information. The Agency welcomes comments on the necessity and feasibility of such guidance.

EPA received comments that companies should be able to submit optional information in any reasonable format. For example, it was suggested that notice submitters be permitted to submit portions of documents which they previously developed, such as standard industrial manuals in lieu of completing the optional industrial hygiene section. EPA agrees with this approach to obtaining information on a voluntary basis. Although the approach undoubtedly will increase EPA's burden in reviewing PMN's, it could significantly reduce the costs of submitting optional information.

3. *Forms for Importers and Exporters.* EPA also is proposing separate notice forms for importers and exporters. (The January 10 proposal did not include a separate form for exporters.) These forms closely parallel the revised form for domestic manufacturers and are consistent with that form in scope and level of detail. Under the rules proposed in January, importers and exporters would not be required to report information concerning commercial activities outside the United States. However, importers and exporters would be required to report information concerning domestic operations.

Only submitters who are manufacturing or processing a new

chemical substance solely for export would use the export form. Moreover to use the form, any processing would have to be conducted at sites under the control of the manufacturer. If the new chemical substances were transferred to any other person for processing, the submitter would be required to complete the domestic notice form.

If EPA promulgates an exporters' form the PMN regulations will explicitly state the conditions under which the form would be used. EPA specifically invites comments on the utility of the proposed exporters' form and the proposed conditions under which it should be used.

Section 720.21(c) of the proposed rules required the importer of a new chemical substance to contact the manufacturer and the person who supplies the substance to the importer and to request such persons to complete a form for foreign manufacturers and suppliers. At this time, EPA is considering whether it should retain this provision in the final rules. If the provision is retained the Agency will promulgate a separate Foreign Manufacturers/Suppliers Form that will be modified to be consistent with the revised form for domestic manufacturers.

4. *Estimated Costs*

Introduction. As part of an effort to evaluate the economic effects of PMN requirements, EPA had an economic contractor prepare unit costs for the revised PMN form (EPA Contract No. 68-01-4717). The contractor's estimated costs include the costs of preparing the revised notice form and the attachments (except for voluntary attachments), but do not include the costs of responding to supplemental reporting requirements that may be incurred for some PMN submissions. The report of the contractor's findings, entitled "Estimated Costs of Preparation and Submission of Reproposed Premanufacture Notice Form", is a part of the record for this rulemaking and is available from EPA's Industry Assistance Office. This section summarizes the findings of that study and presents EPA's interpretation of them.

The estimated cost range for the mandatory portion of the revised form, not including the costs of asserting and substantiating claims of confidentiality, is \$1,200 to \$8,900 per chemical substance. EPA believes this cost range will apply to most substances submitted for premanufacture review; however, it is conceivable that certain chemicals, for example very low or high volume substances, will fall below or above the range. Thus, the cost range should not

be regarded as reflecting the absolute cost limits for PMN submissions.

The costs of asserting and substantiating claims of confidentiality, if claims are made, are estimated to range from \$900 to \$8,400. EPA does not regard the \$900 figure as an absolute lower limit and expects that many companies will be able to comply with the requirements for much less. Thus, including confidentiality costs, the total cost of PMN form submissions are estimated to range from \$1,200 to \$15,300.

The costs of asserting and substantiating claims of confidentiality are presented separate from the costs of the revised form because to a certain extent they are not affected by the form *per se*. Rather, they are determined largely by provisions in TSCA itself, the Freedom of Information Act (FOIA), and EPA's general rules regarding the treatment of confidential information (40 CFR Part 2). In addition, the importance of confidentiality to each company's product development strategy will be a major determinant of the costs incurred in asserting and substantiating claims of confidentiality. The contractor did not estimate the proportion of the costs of confidentiality that is attributable to the revised form *per se*, but EPA believes that it is insignificant, as discussed later in this section.

The major cost elements in making a PMN submission, in addition to asserting and substantiating confidentiality claims, appear to be the requirements to retrieve, organize, and submit health and safety data and the requirement to submit a process flow diagram. These requirements and their associated costs are discussed in more detail later in this section.

Variables Influencing Costs of PMN Submissions. The cost ranges for the revised form necessarily are wide, reflecting the extreme variations in the types of companies and chemicals which are subject to PMN requirements. In developing the unit cost estimates, the contractor assumed that the range of notification costs is a function of the following variables:

Company-Related Variables

Company size
Degree of diversification
Organizational style
Level of technical resources
Importance of confidentiality to company's new product development strategy

Chemical Substance-Related Variables

Apparent toxicity
Anticipated distribution, use, exposure
Complexity of production process
Complexity of composition of chemical substance
Importance of confidentiality for the substance in question.

Thus, in the contractor's estimation, the lowest costs of submitting PMN's should apply to substances submitted by small, closely held or private companies with limited technical resources; substances that do not cause significant health or environmental effects; substances for which exposure will be limited; substances that have limited distribution and use, substances for which confidentiality concerns are minimal; and substances that are simple in composition or are synthesized by simple production processes. Conversely, the highest costs of submitting PMN's should apply to substances submitted by large, publicly owned, and diversified companies with extensive technical resources or research arms; substances that may cause significant health or environmental effects; substances for which exposure will be significant; substances that have extensive distribution and use; substances for which confidentiality concerns are an important factor; and substances that are complex compositions or are synthesized in complex production processes.

Breakdown of PMN Form Costs.

Following is a detailed breakdown of the contractor's estimated costs.

Total Cost Estimates for Completion of Revised PMN Form

(EPA contractor estimates)

Component	Cost
Part I: General information	\$275-\$2,125
Part II: Human exposure and environmental release:	
Section A: Industrial sites controlled by submitter	275- 2,100
Section B: Industrial sites controlled by others	0- 1,200
Section C: Consumer exposure	0- 800
Total	275- 4,100
Part III: List of Attachments:	
a. Physical/chemical properties	150- 600
b. Health and environmental effects data	300- 1,400
c. Notice attachments ¹	
d. Confidentiality attachments ¹	
Total	450- 2,000
Part IV: FEDERAL REGISTER Notice	75- 300
Clerical costs—all sections	80- 400
Subtotal ²	1,155- 8,925
Confidentiality costs—all sections	0- 6,400
Grand total	1,155-15,325

¹The costs of listing attachments in part III-C are negligible.

²The costs of providing confidentiality attachments are included in the line item entitled "Confidentiality Costs—all sections".

³Because confidentiality costs were not included in the cost estimates for the form proposed in January, the range of subtotal costs (\$1,155-\$8,925), and not the range of total costs (\$1,155-\$15,325), should be compared with the January cost estimates.

The economic contractor's report on this repurchase contains more detail on these costs and on the methodology and assumptions used to derive them.

Comparison of January 10 PMN Form and Revised Form. The cost range estimated for the revised PMN form reflects approximately a 50%-60% reduction in costs over the January 10 proposed PMN form. The \$1,200 to \$8,900 range for the mandatory portion of the revised PMN form compares with the \$2,500 to \$22,200 range estimated for the mandatory sections of the January 10 form. The difference in costs between the January 10 form and the revised form is due primarily to the reduction in the level of detail of the questions, particularly those dealing with exposure from industrial manufacturing and processing operations.

Economic Impact Conclusions—Caveats. At this time, EPA has not completed an economic impact analysis based on the change in reporting burden introduced by the revised PMN form.

This is because the Agency lacks sufficient data on specific new chemicals to determine which types of new ventures would be subject to which levels of reporting costs. Initial findings of the economic contractor from a small, non-random sample of chemical companies indicate that most substances may be subject to the low end of the cost range, but the Agency is hesitant to draw conclusions from these data. EPA is preparing an economic impact analysis, based on additional data on new chemicals, and will publish this analysis for public comment prior to promulgation of the premanufacture rules and notice forms. This analysis is discussed in more detail in *Section IV—Cost and Economic Impact Issues*. The cost ranges are based on the assumption that one new substance will be submitted per PMN. EPA realizes that there will be cases where new products or process will be developed that entail multiple new substances, related either in a common process or chemical product. EPA believes that the costs of submitting PMN's for multiple-substance products or processes will not simply be multiples of the cost range estimated by the contractor, because there will be many commonalities among substances submitted in this manner. For example, a PMN for four new chemical intermediates to be used in the same process would cost less than four times the cost of submitting a PMN for one intermediate. This is because the information on production process, use, production volume, marketing estimates, and chemical structure probably will be largely the same for all four substances.

Contractor's Methodology for Estimating Costs. For the purpose of developing unit cost estimates for the revised PMN form, the contractor used the same methodology that it used to derive the cost estimates for the January 10 form. That methodology consisted of the following steps:

- Identification of specific information elements required by the forms;
- Design of worksheets based on these information elements to obtain estimates of time requirements;
- Completion of worksheets by contractor personnel with experience in chemical marketing, chemical and environmental engineering, chemistry, data analysis, and toxicology;
- Assimilation of information from worksheets to develop estimated ranges of time required to complete the forms;
- Multiplication of time estimates by estimated labor rates, to obtain total direct labor costs;
- Interviews with selected chemical companies to obtain their time and cost estimates for completing the forms; and
- Comparison of the chemical companies' estimates for time and costs with the contractor's estimates.

Costs of PMN Forms for Importers and Persons Manufacturing Solely for Export. EPA did not prepare separate estimates of the costs that would be incurred by importers and persons who manufacture new substances solely for export. The Agency will develop estimates as part of its economic impact analysis of the premanufacture rules and notice forms. However, it is possible at this time to discuss several factors that will influence the level of direct costs that may be incurred.

The major distinction between the importers' and exporters' forms, and the form for domestic manufacturers, is that importers and exporters would not be required to provide information on human and environmental exposures resulting from manufacturing, processing, distribution in commerce, use, and disposal which occur outside the United States.

An importer would not need to submit information on exposure at the foreign facility or facilities where the substance was manufactured or processed. Thus the importer would not incur some and perhaps most of the costs attributed to completing Part II, Section A of the revised form for domestic manufacturers. However, because of the way the contractor prepared the cost estimates for this section of the

domestic form, it is not possible to make reliable estimates of the proportion of the costs attributed to this section (\$275 to \$2,100) that importers would not incur.

Similar cost reductions might be experienced by persons who manufacture solely for export. They would be required to submit exposure information only concerning operations within the United States. They would be required to submit information concerning foreign processing sites, under either their own or others' control, or information concerning commercial and consumer exposures, that would occur exclusively outside this country. Therefore exporters would not be subject to the costs (\$0 to \$800) attributed to completion of Section II-C, Consumer Exposure, of the domestic form. In addition, exporters may not incur some or most of the costs attributed to Section II-A (\$275 to \$2,100) or Section II-B (\$0 to \$1,200) of the domestic form, although again it is impossible to give a more definitive range for the likely cost reductions. Overall, the costs of completing the form should be significantly less for persons who manufacture solely for export than for those who manufacture for further processing or use within the United States.

A second factor that may influence the costs of completing the revised import and export forms is the degree to which information is known to or reasonably ascertainable by the submitter. This factor may influence overall costs in two ways. A submitter that does not possess information called for in a section of the form may state that the information is "not available". This submitter would not be subject to the costs of completing that section of the form. On the other hand, although a person may lack certain information, he may incur costs to obtain it because it is reasonably ascertainable to him.

The significance of these factors to importers will depend on the type of importer that submits the PMN. In some cases the importer may be a multinational corporation that manufactures the substance outside the United States and processes or uses it in this country. In other cases, the importer may be an intermediary/broker or a domestic processor or user of the substance, who is not involved in manufacturing the substance. The first importer probably would have considerable information available.

However, the latter may lack basic information on the substance he imports and would need to contact his foreign supplier for much of the information requested in Parts I and IV of the form, including specific chemical identity, production data, physical and chemical properties, and health and safety studies. Such contacts undoubtedly would add some costs to completing the PMN.

The impact of an importer's lack of information about "downstream" activities involving the chemical substance is less clear. A broker-type importer may not possess much information about the processing and use of a substance. This lack of knowledge could reduce the costs of completing the form if he enters "not available" in response to questions about processing and use. On the other hand, EPA assumes that importers who do not possess this basic information will make reasonable efforts to obtain it and may incur some costs in doing so. Taking both of these considerations in account, a broker-importer's costs in completing the processing and use sections of the form may not be distinguishable from costs incurred by a small domestic manufacturer who has limited knowledge about how his customers will process or use a substance.

These factors discussed above concerning the availability of information do not provide a basis for differentiating between exporters and domestic manufacturers. In general, exporters will "know" or find "reasonably ascertainable" the same amount of information concerning chemical identity, manufacturing process, production estimates, physical and chemical properties, and health and safety studies, as would be known to or reasonably ascertainable by a person who manufactures for domestic consumption. Therefore all other things being equal, there is no reason to conclude that an exporter will state that either more or less information is "not available" or that an exporter will incur any different costs in obtaining relevant information from companies.

On the basis of this analysis, EPA believes that many persons manufacturing solely for export may incur direct costs that are somewhat less than those incurred by domestic manufacturers. The conclusions are less certain for importers. Some factors would result in lower costs while others

(e.g., contact with foreign suppliers) may lead to higher costs. EPA will further study the costs and economic impacts of the premanufacture requirements on exporters and importers. The Agency requests comments on the factors it should consider in comparing costs likely to be experienced by manufacturers for domestic consumption, manufacturers solely for export, and importers. In addition, information developed by particular exporters and importers on the costs they would incur in completing the forms for particular chemical substances, and breakdowns of how those costs are derived, would be very useful to EPA in refining its cost estimates.

Significant Cost Components of the Revised PMN Form. Three potentially significant cost components the PMN form merit special attention: (1) The procedures for asserting and substantiating claims of confidentiality; (2) The requirement to provide a process flow description in the PMN form; and (3) The requirement in the form to retrieve, organize, and submit health and safety data.

EPA's contractor estimated that the costs of asserting and substantiating claims of confidentiality would range from \$0 to \$8,400. The costs will vary from substance to substance depending upon the submitter's perceived needs for confidentiality and the amount of resources (legal and technical) he is able and willing to commit to asserting and substantiating claims of confidentiality. In general, EPA believes that larger companies will spend the most of claims of confidentiality and that smaller companies rarely will spend more than \$2,000 per PMN. The Agency assumes that both large and small companies may claim the same items confidential because they have the same needs for confidentiality. However, because of their greater legal and technical resources, larger companies will go to greater lengths to identify and substantiate claims of confidentiality. In addition, larger companies probably will encounter greater costs in organizing and coordinating information to substantiate their claims.

The contractor did not estimate the incremental costs or burdens of confidentiality introduced by the revised PMN form. However, it would be erroneous to attribute the full amount of the estimated costs to the revised form, because the requirements to assert and substantiate claims of confidentiality in some manner exists regardless of the form that EPA proposes. These requirements are contained in Section 14

of TSCA, the Freedom of Information Act, and EPA's business confidentiality regulations (40 CFR Part 2). Thus, the proportion of the total costs of confidentiality that are attributable to EPA's requirements for asserting and substantiating confidentiality claims may be slight.

Even if the required format results in some additional confidentiality costs, the revised approach introduces only a minimal incremental cost or burden over the approach proposed in January. First, the January 10 proposal also required manufacturers to assert claims of confidentiality at the time they submit PMN's, and it required them to substantiate their claims for chemical identity and health and safety studies. These two items appear to be the most burdensome to substantiate in both the January 10 and revised approaches, and probably account for much of the total costs of confidentiality claims. Second, under the January 10 proposal EPA would require manufacturers to substantiate claims for other categories of information in the PMN, such as use and manufacturer's identity, whenever the Agency received FOIA requests for the information. EPA expects to receive FOIA requests for a high percentage of PMN's. If this happens under the January approach, manufacturers would have been required to substantiate many of the items claimed confidential in the PMN's but not substantiated at the time the PMN's were submitted.

Finally, the level of effort expended by companies in response to PMN confidentiality provisions will be more a function of company strategy and perceived need for confidentiality than of the precise form and instructions set forth by EPA, and the timing of substantiation. Companies will incur a major proportion of the costs of confidentiality when they develop their PMN strategies on a case-by-case basis. This development of strategy most likely will occur prior to the initial submission of each PMN, and is likely to include the identification of confidential items and linkages and the construction of the rationale for claiming those items. Once a confidentiality strategy has been developed, the incremental cost of preparing specific responses to the substantiation questions, whether done in the initial PMN submission or in later submissions, probably will be slight.

In sum, EPA does not believe that a significant incremental burden has been introduced by the revised approach to confidentiality. EPA requests comments on the findings presented here and specifically encourages companies to

provide estimates of the time and costs that they actually will spend.

The estimated costs for completing the process information portion of the revised PMN form (Part II, Section A-1) are \$100 to \$800. The costs of reporting process information will be influenced by a number of factors, including the number of steps in the process, the complexity of the process, the number of manufacturing sites, and the final disposition of products and byproducts. Further, the company's degree of sophistication in process engineering and design is largely correlated with the company's size, and will influence the time and costs to complete the process information section.

The estimated costs for the retrieval, organization and attachment of health and safety data range from \$300 to \$1,400, making it a potentially significant cost component. This range reflects differences among companies in the amount of data routinely developed on new chemicals and their ability to retrieve information in the open scientific literature. It also reflects differences among chemicals in the amount of data that are available and must be submitted. For substances with multiple impurities and byproducts that are not on the Inventory and for which data exist, the costs will be the high end of the range. Similarly, PMN's may be more costly for highly toxic chemicals that have more data associated with them.

It is important to stress that the revised form has not changed in any way the basic requirement in section 5(d)(1)(B) of TSCA that the manufacturer must submit all health and safety data that are in his possession or control. It also does not specify formatting requirements for the submittal of test data. The costs of retrieval, organization, and attachment of health and safety data will be largely unaffected by the PMN form because this statutory requirement exists regardless of the PMN form that submitters must use.

A more detailed discussion of the estimated PMN costs, including a section-by-section explanation of the cost estimates, is contained in the separate document entitled "Estimated Costs for Preparation and Submission of Reproposed PMN Form." This is available from EPA's Industry Assistance Office. An appendix to this report includes cost estimates for the PMN form submitted by the Chemical Manufacturers Association during the public comment period on the January proposal. EPA invites comments on all cost estimates presented in the report, as well as on the methodology and

assumptions utilized in developing the costs. Commenters are especially encouraged to provide their own estimates of the time and effort necessary to complete the revised PMN form, using chemicals they manufacture.

As mentioned previously, although the data do not exist currently with which to determine with confidence the economic impacts of the revised PMN form, EPA intends to gather additional data and to conduct an impact analysis prior to the promulgation of the premanufacturer rules and notice forms. This analysis will attempt to determine the proportion of new chemicals that will be subject to various levels of PMN costs and will estimate the corresponding effect on the rate of introduction of new chemicals. Also, the analysis will address the costs and impacts of the proposed premanufacturer requirements in their entirety, including the effects of the initial PMN submission requirements, the proposed Section 8(a) supplemental reporting requirements, and various provisions in the proposed rules (e.g., such as those pertaining to confidentiality, invalid notices, and importers and exporters). This analysis, and EPA's plans for public review and comment, is discussed in more detail in *Section IV—Costs and Economic Impacts*.

C. Related Issues

1. *Customer Information.* The January proposal would have required the notice submitter to contact persons whom he had reason to believe would purchase the new chemical substance (Part 720, Subpart C, § 720.20(e)). He would be required to request them to provide information (either to him or directly to EPA) about worker exposure and environmental release associated with their processing operations, and their intended uses of the substance. The January proposal contained a separate customer contact form that requested this information. Submitters also would have been required to include in their PMNs the names and addresses of those customers contacted.

EPA received numerous comments from industry concerning this "customer contact" provision. Most questioned EPA's statutory authority to require customer contact. They also claimed it would impose excessive administrative burdens, adversely impact innovation, create possible anti-trust violations, and alter the competitive marketplace. Several stated that any customer contact provision should be limited to persons who had made a firm commitment to purchase the substance. EPA has not decided whether to include

the mandatory customer contact provision in the final rules and is still considering the customer contact form proposed in January. EPA is actively considering the following alternatives to the January 10 proposal for customer contact and invites comment on their practicality.

First, to determine the extent of each submitter's knowledge of customer use, the revised form would require the submitter to indicate the number of customers who have made a firm commitment to purchase the substance for a category of use unknown to him (Part I, Section D, question 5). In addition, the submitter would be required to indicate the percent of the estimated production volume of the new substance that such customers will purchase during the first three years of production. This would give EPA an understanding of how complete the use information is in the premanufacturer notice, and would be less burdensome on the industry than the customer contact provision proposed in January.

In combination with other requirements in the revised form, this information would help EPA decide whether to obtain additional use information from the submitter's prospective customers. If EPA determines that it needs additional use information, the Agency can contact the submitter and ask him to voluntarily provide the names and addresses of the relevant customers. EPA also could require the submitter to provide this information under the supplemental reporting provision (see re-proposed Part 720, Subpart F, § 720.50).

Second, EPA is considering the alternative of requiring the submitter to provide a list of the names and addresses of customers who have made a firm commitment to purchase the new chemical substance. This alternative would allow EPA to contact prospective customers directly in cases where use data or other customer information submitted in the PMN is inadequate to assess potential exposures. One advantage to this alternative is that it would eliminate the need for EPA to contact the notice submitter (for customer identities) each time the Agency needs to obtain information from customers. Conversely, it would require all submitters to provide information that the Agency may not use in every case. Further, EPA recognizes the customers lists often are highly confidential, particularly during research and development.

EPA is considering each of these alternatives, or a combination of these alternatives. EPA invites comments on the feasibility of these alternative

approaches. It is not necessary to repeat comments previously submitted on the customer contact provisions proposed in January. EPA will consider them when it develops the final rules.

2. *Form for Low Volume Substances.* Based on comments on the January proposal, EPA has considered developing a special PMN form for extremely low volume chemical substances (e.g., substances manufactured in quantities of less than one metric ton per year). Such a form could require even less detailed information than the re-proposed form. If necessary, after submittal of the form EPA could obtain additional data on the substance during the notice review period. More often EPA would require follow-up reporting on the substance under section 8(a) or section 5(a)(2) (see discussion below).

At this time, EPA is not proposing a form for low volume substances. The revised form would significantly reduce the reporting burden and, therefore, be appropriate even for very low volume chemical substances. EPA specifically welcomes comments on this issue. Commenters should focus on the need for a separate form for low volume substances, considering the reduced level of detail required in the revised form.

3. *Follow-up Reporting.* EPA intends to require follow-up reporting on selected new chemical substances to obtain information not readily available at the time a premanufacture notice is submitted, since manufacturers will be able to report more reliable production, use, and exposure data on new substances after they have been commercially developed. At this time, it also will be feasible to perform more extensive health and environmental effects tests.

EPA currently is developing a follow-up reporting scheme that would employ a combination of TSCA section 8 reporting rules and section 5(a)(2) significant new use rules to track the development of many new chemical substances. Under this scheme, the Agency would require reporting of certain data over a specific period of time after premanufacture notification, or when specific reporting "triggers" are met (e.g., production of a certain number of kilograms of the substance). Comments from industry on the January proposal suggested such a scheme. Any action the Agency takes concerning the followup of new chemical substances will involve separate rulemakings in which EPA would propose one or more schemes and allow public comment on them.

D. Section-by-Section Review

Following is a section-by-section discussion of the information requirements that have been deleted from the forms proposed in January and of other modifications contained in the revised form for domestic manufacturers. EPA invites comments on these changes and the rationales presented below.

1. Manufacturer Identification.

Several questions have been deleted from the manufacturer identification section of the January forms. These questions concerned (1) the principal place of business of the submitter, (2) subsidiary companies, and (3) other persons who the submitter authorizes to manufacture the new substance. EPA may need this information if it considers regulating the new substance, however, it is not warranted for all new chemical substances. When necessary, EPA can obtain this information through supplemental reporting during the notice review period. The revised form still would require submitters to include in their production estimates the production volume of others who are authorized to manufacture the new substance. The deletion of these information requirements should not affect the Agency's assessment of the risks presented by new substances.

2. Production and Marketing Data.

The January forms required sales volume estimates and an indication of the basis upon which production estimates were reported (i.e., firm order, forecasts, or speculation). Through reporting about sales volume, EPA sought an indication of the distribution of a new substance to other persons. In addition, the "basis of the production estimates" would have demonstrated the uncertainty associated with these estimates. EPA has deleted these requirements from the revised form.

The revised form would require production volume estimates to be reported. EPA has deleted estimates of sales volume because it can obtain information about distribution of the substance from other questions in the form (e.g., category of use). The questions concerning the "basis of production estimates" were deleted because EPA will base its exposure assessments for screening purposes on estimates of the maximum production volume. The Agency also will perform market analyses for particular substances of concern and obtain further information from manufacturers on a case-by-case basis.

The January 10 proposed form also required estimates of prior production volume and information concerning

prior government actions, litigation, or voluntary control of the PMN substance. EPA has deleted these requirements to reduce the reporting burden. The Agency expects to obtain information on prior government actions through a routine search of its own data bases. Therefore, the Agency's risk assessment capabilities will not be diminished significantly.

Finally, EPA has deleted the ranges it had provided for reporting production volume. Rather than impose specific ranges, the revised form would permit a submitter to report production volume estimates in any range he considers appropriate. This approach will provide the Agency with a much clearer estimate of potential production volume and adds no additional reporting burden. When EPA performs exposure assessments, it will focus on the upper end of the range.

3. *Federal Register Notice.* Under section 5(d)(2) of the Act, EPA is required, subject to section 14, to publish a Federal Register notice when a PMN is submitted. This notice must identify the chemical substance, list its uses, and describe certain test data submitted with the PMN. In addition, the Agency is authorized to provide public access to non-confidential data. On January 10, EPA proposed that in addition to the information explicitly listed in section 5(d)(2) of the statute, the Federal Register notice would contain information to further characterize exposure to the substance and its potential effects. This information included estimates of populations exposed and the magnitude and duration of such exposures. Some industry commenters argued that EPA lacked statutory authority to include this additional information in the section 5(d)(2) notice.

The revised form proposes a more limited approach to this notice. First, EPA has retained a provision from January that requires the Agency to publish the specific chemical identity unless it is claimed confidential. If it is claimed confidential, the Agency will publish a generic name chosen from three generic names that must be submitted with the PMN. Second, if the manufacturer claims the use confidential, he must report using a generic use scheme that conveys information to interested parties concerning the exposures resulting from the use. Questions proposed in January concerning exposure and release are deleted and replaced with more general indicators of these factors. EPA's generic use scheme is discussed in

Section II below, "Generic Use Information".

Third, the revised form would require submitters to abstract only those data that directly concern the new chemical substance, for publication in the *Federal Register* notice. EPA also would publish a list of all test data submitted with the PMN concerning both the PMN substance and other related chemicals. This approach is consistent with the Agency's intent to reduce reporting burdens and focus reporting requirements on the new chemical substance itself.

4. *Risk Assessment Data.* The January 10 proposed form contained several risk assessment questions and a table for submitters to check off the types of test data submitted. The risk assessment questions were included in the proposed form to highlight EPA's determination that risk assessment data are part of "health and safety data" and, thus, must be submitted. In some instances, this led to the misconceptions that TSCA requires submitters to perform risk assessments on their new substances. The revised form clarifies this distinction, and deletes the specific questions contained in Part II, Section A, of the January 10 form. This change should not result in the submittal of substantially different information than would happen under the January proposal, and simplifies the notice form.

EPA included the health effects table in the January proposed form for use by the Agency in organizing data in PMNs. Because this led to the misconception that these data must be developed, EPA has deleted the table from the revised form. Instead, the revised form would require submitters to provide their own list of the data that they have included in the PMN.

5. *Worker Exposure.* The January 10 proposed form required specific estimates of the magnitude, duration and frequency of worker exposure to the new chemical substance. While these specific estimates would be extremely useful to EPA in assessing worker exposure to new substances, these requirements may be too detailed and burdensome to be imposed on all notice submitters. In cases where the data are available, significant uncertainties also would be inherent in such specific estimates. To mitigate the reporting burden, the revised form requires significantly less detailed estimates and provides ranges for reporting expected workplace concentration levels.

Reducing the detail of workplace estimates requires EPA to use other information in the PMN and to make assumptions concerning potential exposure. However, this other

information and assumptions should be sufficient for the Agency's initial screening of all new substances. Detailed assessments of priority substances will require more specific information, which will necessitate supplemental reporting by submitters and others on a case-by-case basis.

EPA also has eliminated the requirement that the submitter explain how he derived estimates of workplace exposure. This is in keeping with the Agency's general effort to avoid questions requiring potentially burdensome, narrative responses. If the submitter's estimates do not appear reasonable to EPA, the Agency may contact the submitter to learn how the estimates were derived. However, at this time EPA does not think it is appropriate to require this information in all PMNs.

Similarly, the revised form would not require specific information about analytical methods that have been developed. The submitter merely must indicate whether a method exists for detecting and quantifying the presence of the new chemical substance in various media. This approach will require increased supplemental reporting in cases where exact knowledge of available techniques is necessary for surveillance and monitoring purposes.

6. Environmental Release. The January 10 proposed form required specific estimates of environmental release data including stack parameters, concentrations, and daily and hourly discharge rates. This information would enable the Agency to perform detailed modeling to assess the environmental impact of new chemical substances. These requirements are not included in the revised form because commenters indicated that they were too burdensome and that in cases where the estimates were reported, significant uncertainties might render them useless for purposes of performing risk assessments. Given these comments, EPA does not believe that the requirement should be imposed on all notice submitters.

The revised form requires only total release estimates of the new chemical substance. The Agency will make conservative ("reasonable worst case") assumptions concerning release conditions based on standard production practices and other information reported in the PMN. In cases where this approach does not allow an adequate assessment of risk, the Agency intends to require supplemental reporting to obtain more specific estimates if they are known or reasonably ascertainable.

Finally, EPA has deleted a general question concerning data on environmental degradation products. The Agency intends to clarify in the final rules that these data are considered to be "Health and Safety Data", and they must be submitted under proposed § 720.23.

7. Byproducts, Co-products, Feedstocks and Intermediates. The January 10 proposal required the submitter to provide estimates of concentration, flow rates, and the number of persons exposed to byproducts, co-products, feedstocks and intermediates. Because EPA's initial review of PMN's will focus on the new chemical substances themselves, and to minimize the burden on submitters, the Agency has reduced the level of detail concerning environmental release and exposure to such byproduct materials. In the revised form submitters would be required to report the identity of these related substances, and the Agency would obtain further information concerning these substances from other sections of the form (e.g., the process description). This would enable the Agency to identify particular substances of concern while reducing the reporting burden on industry. In some cases, EPA may regulate a substance based on this information. As with other sections of the form where information requirements have been reduced, the Agency may require supplemental reporting by submitters on a case-by-case basis.

8. Transport. The January 10 proposed form required submitters to describe the potential risks presented by transport of the new chemical substance. They also were required to discuss intended safeguards to prevent or reduce those risks. EPA has deleted this information from the revised forms because the Agency believes it may be too burdensome to provide and, in most cases, is unavailable. The Agency will make basic assumptions about the potential risks presented by transport of new chemical substances. When these assumptions are combined with the information required by the revised form (hazard class designation and mode of transport), and with EPA's evaluation of the toxicity of substances, the Agency will be able to focus its assessment on a smaller and better defined group of new chemical substances.

9. Process Flow Description. The January 10 proposed form required the submitter to provide a detailed schematic flow diagram. This information on the manufacturing and processing operations and the resultant environmental releases is critical for

EPA's exposure assessments. This information also supplemented and clarified other data requirements in the January 10 form. However, in an effort to simplify the form and reduce the reporting burden, EPA has deleted several specific requirements from the process description. The revised form does not require description of the type of process equipment, the components of each process stream, and process parameters. Rather, it requires a simplified block diagram that will provide a basic understanding of the manufacturing process necessary to identify the potential exposures. (See sample block diagram provided in Appendix C). EPA welcomes comments on the reduced scope of the process flow requirement. Commenters are encouraged to propose other more appropriate ways to obtain the information required.

10. Exposure to Consumers and Commercial Users. The January 10 proposed form required the submitter to estimate the magnitude, duration and frequency of consumer exposure to the new chemical substance. This information would enable EPA to assess the potential exposure to consumers in the general population who use or otherwise come in contact with the new chemical substance. The consumer exposure section of the revised form has been modified only slightly from the January 10 proposed form. It requires less specific estimates of the duration and frequency of consumer exposure to the new chemical substance. In addition, the revised form does not require quantitative estimates of the magnitude of consumer exposure unless the submitter already has developed them. EPA will rely upon qualitative data for screening purposes. For detailed assessments, the Agency will seek more specific data from submitters, or will make assumptions about the magnitude of exposure.

II. Confidentiality

A. Issues Addressed in This Proposal

In the January 10, 1979, proposed premanufacture notification rules, EPA included several sections describing procedures for asserting claims of confidentiality; and procedures for determining whether PMN information was entitled to confidential treatment (Part 720, Subpart E, §§ 720.40-720.44). EPA intended to use these rules in conjunction with the Agency's existing rules concerning confidentiality of business information, 40 CFR Part 2, Subpart B.

EPA is proposing new procedures for asserting and substantiating

confidentiality claims and for providing generic descriptions for certain types of information. If these procedures are adopted, they would replace those proposed in January. However, the Agency is actively considering both alternatives. Any comments concerning asserting and substantiating claims of confidentiality should consider the earlier proposal, the alternatives included in this proposal and any other schemes that would meet the needs of the Agency, industry and the public.

This reproposal does not change the substantive bases for granting confidentiality. Nor does this reproposal discuss the question of confidentiality for information in a health and safety study, or for specific chemical identity as part of health and safety studies. However, EPA has received extensive comment on both subjects in response to the January proposal. EPA will address these issues in the rules on premanufacture notification.

B. Asserting and Substantiating Claims of Confidentiality

1. *January 10 Proposal.* Under the January proposal, submitters could assert a claim of confidentiality for any item on the form by checking a box adjacent to the item of information; claims would be made on an item-by-item basis. Submitters could also claim confidentiality for any information contained in attachments to the PMN form. Submitters were required to submit two copies of those attachments. One copy was to be complete, with confidential items clearly indicated. The other copy was to have all information claimed as confidential deleted so that it may be placed in the public file.

The January proposal required the submitter to provide substantiation at the time the PMN was submitted for any claim of confidentiality asserted with respect to specific chemical identity or information in a health and safety study. Substantiation for other information could be required at a later date. Substantiation was to consist of complete responses to several questions developed by EPA that would provide information to either grant or deny the claim of confidentiality § 720.40(c)).

2. *Summary of Comments on January 10 Proposal.* Few industry representatives commented on the method proposed in the January proposal for asserting claims of confidentiality on the PMN form. In general, industry comments favored the proposed check-off approach. However, two comments suggested that in addition to the check-off, information claimed to be confidential should be stamped "Confidential" as an extra

precaution against inadvertent release by the Agency.

Some comments stated that information on the form is "private property" and should be kept confidential automatically. One comment stated that substantiation should not be required for data protected under section 14(b) of TSCA (i.e. process and mixtures).

However, representatives of public interest groups favored an approach to confidentiality that would require submitters to individually substantiate each item claimed confidential when a PMN is submitted. They also suggested that EPA abbreviate its procedures for reviewing claims of confidentiality so that non-confidential information would be disclosed more quickly to the public.

3. *Revised Approach for Asserting and Substantiating Claims of Confidentiality.* In this notice, EPA is proposing a revised approach for asserting claims of confidentiality for information submitted as part of a premanufacture notice (on the forms or in attachments to it), and for substantiating those claims. In addition, the Agency is modifying and expanding the procedures for providing generic descriptions for certain information which is claimed confidential in PMNs. The proposals are based upon EPA's experience with premanufacture notices submitted to date, comments received on the January 10 proposal, and further reflection upon the various interests of industry, the public, and the Agency concerning how the Agency determines whether to release or withhold PMN information.

There are three key features to the revised approach. First, EPA has identified five categories into which most confidentiality claims will fall. The submitter, instead of just checking off the items claimed confidential, would be required to indicate, by use of a simple letter code based on these five categories, into which category the claim would fall. Submitters would be required in some cases to provide a brief explanation of why they believe a particular type of information belongs in that category.

Second, rather than substantiating claims only for chemical identity and health and safety data when the PMN is submitted, submitters would be required to provide substantiation for every category of information claimed confidential. For the manufacturer's identity category, substantiation would be very simple—the submitter would attest to the truth of a certification statement. Other categories of claims require more complex substantiation, as discussed below. In general, the varying

amounts of substantiation required reflect the Agency's judgment of the type of information needed to determine whether the specific information can be held confidential.

Third, the proposal provides requirements and new guidelines for providing generic information when specific chemical identity, category of use, submitting company's identity and specific data on physical and chemical properties are claimed confidential.

These new proposals for claiming and substantiating confidentiality and providing generic information are discussed in more detail below.

Assertion of Claims. Any item on the form can be claimed confidential. The Agency has identified five categories into which the majority of confidentiality claims will fall. The five categories are—

- A. Manufacturer's (Importer's) Identity
- B. Specific Chemical Identity
- C. Production Volume
- D. Uses of the New Chemical Substance
- E. Process Information

The Agency recognizes that there may be confidential business information on the form which does not fall into these categories. The submitter may claim this information confidential by using category F, "other".

The instructions indicate which items in the form are automatically included or "linked" to any of the five categories. For example, if specific chemical identity is claimed confidential, the CAS number is automatically considered "chemical identity" and is included in the claim. To assert a claim of confidentiality for all the items automatically linked to a category, the submitter is required only to place a check in the box on the form for that category.

To assert a claim of confidentiality for an item that is *not* automatically linked to a category of claim, the submitter must place the *letter* representing the category in the box next to the item and explain how disclosure of this information would reveal the category of information. To do this, the submitter would answer the corresponding linkage question. The submitter may claim that any single item is confidential for several distinct reasons. For example, if an item is claimed confidential because disclosure would reveal both chemical identity and process information, the submitter should place both a "B" and "E" in the box and answer the linkage questions for both categories.

Substantiation of Claims. The revised premanufacture notification procedure employs an incremental approach to substantiation. For example,

manufacturer's identity is substantiated by signing a certification statement similar to the one required to substantiate confidentiality claims on the Inventory reporting form. This is all the substantiation that would be required.

For production volume, use data, and process information, in addition to signing the certification statement, the submitter would be required to answer two questions. The first asks whether the submitter's confidentiality concern will be met if the link between the manufacturer's (or importer's) identity and the item claimed confidential is not disclosed. The second asks whether the submitter's confidentiality concern will be met if the link between the specific chemical identity and the item claimed confidential is not disclosed. The two questions are designed to lessen the need for multiple confidentiality claims.

Finally, to substantiate a claim of confidentiality for chemical identity and for the category of "other" claims, the submitter would respond to a series of questions. Detailed substantiation is required for each item in the category "other" because the information does not fall within one of the five categories identified by EPA. In addition, submitters would be required to explain why disclosure of the specific information would disclose confidential information if the link between the company and the item is not disclosed and if the link between the chemical identity and the item is not disclosed.

In January, EPA proposed in § 720.40(c)(1) that a submitter who asserts a claim of confidentiality for chemical identity or health and safety data must substantiate the claim in his PMN. Under proposed § 720.40(c)(2), if the company does not provide this substantiation, EPA would notify the company and give it ten days to provide the substantiation before the Agency would place the information in the public record. EPA included this latter provision to ensure that submitters who assert claims, but who unintentionally fail to substantiate them, are given an opportunity to correct this error. The Agency did not intend for proposed § 720.40(c)(2) to affect the requirement in § 720.40(c)(1) that companies must substantiate claims for chemical identity and health and safety data at the time they submit their PMN's.

At this time, EPA is not proposing to change section 720.40(c)(2). However, EPA is considering whether it should eliminate this provision in the final rules if the Agency adopts its new scheme for substantiating all claims when PMN's are submitted. A major reason for

requiring substantiation when PMN's are submitted is to eliminate delays in giving the public information which is not entitled to confidential treatment. Proposed § 720.40(c)(2) is not entirely consistent with this goal because it requires EPA to go back to submitters in all cases where claims are made but substantiation is missing. Further, in most cases EPA will not need to go back to submitters because they will have adequate notice of the Agency's substantiation requirements and should be expected to undertake reasonable steps to ensure that their PMN's are complete. EPA requests comments on whether it should retain proposed § 720.40(c)(2) in the final rules if it promulgates the repropoed scheme for substantiating claims of confidentiality.

Health and Safety Studies. The January 10 proposal would require the submitter to respond to a list of questions when substantiating confidentiality claims for information included in health and safety studies. This procedure was proposed because of the Act's special provisions for release of data from health and safety studies. EPA is proposing an alternative to the January 10 proposal which is consistent with the new approach described above. Information within a health and safety study may be claimed confidential by linking the information claimed to any of the categories proposed by the Agency. In addition, because of the specific language of section 14(b) of TSCA, a person may claim an item of data from a health and safety study as confidential because it would reveal confidential information on the portions of the substance in a mixture. This is claimed confidential by identifying the item with an "M".

Because of the Act's special provisions for release of data from health and safety studies, EPA will deny any claim of confidentiality that does not establish that disclosure of the information claimed would reveal the following confidential information:

Specific chemical identity of the chemical substance (only until the commencement of manufacture)

Process information

Portions of a mixture

Other information that is unrelated to the effects of the substance on human health and the environment.

Section 3(6) of the Act defines "health and safety study" to include "studies of occupational exposure." Any exposure information provided on the PMN form derived from a "health and safety study" is subject to the special provisions of section 14(b) of the Act and those described in this section for asserting and substantiating claims of

confidentiality for health and safety studies. In particular, both section A, subsection 3; and section B, subsection 3 of Part II of the form would require reporting about worker exposure to the extent such information is known to or reasonably ascertainable by the submitter.

EPA specifically invites comment on the extent to which exposure information in PMN's is included in the general definition of "health and safety study". As stated in its January 10 proposal (44 FR 2242, 2258, 2264), EPA interprets the term broadly so that much of the information on exposure included in PMN's could be subject to section 14(b). In addition, the Agency solicits comments on how its proposed scheme for asserting and substantiating claims of confidentiality should be explained and applied to health and safety data contained in the forms themselves. *Analysis of the Revised Proposal for Asserting and Substantiating Confidentiality Claims*

EPA's revision of the procedures for asserting and substantiating confidentiality claims is based on a variety of administrative and policy considerations. These include the need to provide non-confidential PMN information to the public, to provide the Agency with information necessary to make judgments under FOIA, and to establish a mechanism for persons to assert claims of confidentiality, with a minimum burden and uncertainty as to the criteria the Agency will use in making its determinations.

EPA's responsibility to provide PMN information to the public is an affirmative one, extending beyond any requirement merely to comply with FOIA. Section 5(d)(1) states explicitly that the PMN must be made available for "examination by interested persons," subject to section 14. Further, section 5(d)(2) requires EPA to publish a Federal Register notice which identifies the chemical substance, lists the uses or intended uses, and describes test data. More generally, TSCA includes a variety of provisions whereby citizens can petition the Agency to take particular actions with respect to premanufacture notices. EPA interprets such provisions as indicating that, while the Agency is to be the primary decisionmaker regarding new chemical substances, strong citizen involvement was intended. Effective participation is impossible if the maximum amount of information is not made available to the public.

The proposed scheme serves to increase public information in several ways. First, by focusing submitters' attention on why items are being claimed confidential and by indicating

the type of substantiation EPA must have to grant a confidentiality claim, the scheme will result in defensible rather than unwarranted claims. Second, by requiring a generic description of certain data which is claimed confidential, the scheme should provide the public with important information on the risks of the new substance without revealing confidential business information.

In addition to these TSCA-specific responsibilities, EPA has responsibilities under FOIA. Under FOIA, any person may request disclosure of any information submitted in a PMN. When such a request is made, EPA, in accordance with the procedures of 40 CFR Part 2, Subpart B, must review any information claimed confidential to determine whether it is entitled to confidential treatment. If EPA does not disclose information because it determines the information is confidential business information, the requester may bring an action in Federal court to review EPA's decision.

In any case, to determine whether information claimed confidential is, in fact, entitled to confidential treatment, EPA requires the submitter of the information to substantiate his claim. Under the January 10 proposal, if substantiation of claims of confidentiality are not included with the PMN, EPA must contact the submitter to request a substantiation of claims. After the person provides this information EPA reviews it and makes a final determination. Under TSCA, EPA provides 30 days notice to the submitter before disclosing the information. It would not be unusual for the full 90-day PMN review period to expire before EPA could release information in response to an FOIA request—even if the original confidentiality claim was totally without legal merit.

EPA's proposed alternative would provide the Agency with all the information it needs to make confidentiality determinations upon receipt of the PMN. Thus, if EPA wished to make a determination of confidentiality (either on its own, or in response to an FOIA request) there would be a significant savings in time, and an increase in the likelihood that information claimed confidential which is not entitled to such treatment could be made available to the public during the 90-day notice period.

Both TSCA and current government policy make it clear that in administration of the Act, unnecessary burdens on industry are to be avoided. EPA believes that the proposed approach provides additional information to the public without

substantially increasing the burdens placed on the notice submitter.

The earlier proposal would have required submitters to assert a claim of confidentiality at the time of submission and to provide substantiation for two classes of claims—specific chemical identity and health and safety studies. However, if other items were claimed confidential, and EPA received an FOIA request, under its business confidentiality rules, the Agency would contact the submitter and require submission of detailed substantiation for this other data within fifteen business days. EPA is currently using a long letter to explain the information required to substantiate claims of confidentiality in PMN's. Included in this letter is a request that the submitter answer detailed questions to show why confidential treatment should be granted for all information claimed confidential in the PMN. Thus, under the January 10 rules, the burdens of substantiating a claim of confidentiality were divided into two phases—those associated with the filing of the notice itself, and those resulting from the requirement to provide additional substantiation at a later date in response to an EPA request.

Under EPA's business confidentiality rules, the submitter must file his substantiation within 15 business days. This deadline is necessary for the Agency to respond to FOIA requests in a timely fashion. Under EPA's January, 1979 proposal this follow-up substantiation procedure would be the rule rather than the exception, because public interest groups have indicated that they intend to submit FOIA requests on all PMNs.

While the January 10 proposal and the scheme proposed here impose similar burdens on the notice submitter, the scheme proposed here offers substantially increased certainty about the criteria the Agency will use in making its confidentiality decisions. For each item of information on the form, the submitter would state what type of information an item will reveal, explain why an item reveals that type of information, and substantiate the claim that the information in that category is entitled to confidential treatment. If a submitter makes a reasonable effort to understand the logic of the factors that entitle information to confidential treatment, and if, with this understanding, he signs the certification and in good faith provides the appropriate answers to all questions, he would have provided the information which the Agency needs to determine whether to release or withhold PMN information. Of course, EPA's

determinations are subject to judicial review.

Additional Proposal for Substantiating Claims of Confidentiality. In addition to the January proposal and this revised scheme, EPA is considering a third approach that combines elements of the first two. The Agency would require substantiation of claims of confidentiality for specific chemical identity, use and test data at the time the PMN is submitted. For other types of information, submitters would have the option of either providing substantiation with their PMN's, or providing substantiation only if EPA specifically requested them to do so, perhaps as a result of an FOIA request. This would allow the Agency to review confidentiality claims for the type of information required to be published in the Federal Register notices under section 5(d)(2) of the Act while deferring substantiation of all other information claimed confidential until the receipt of an FOIA request.

There are at least two problems with this approach. First, although the particular information required to be published by section 5(d)(2) notice is significant for public review, as discussed above, all information in a PMN notice is subject to FOIA requests. Because EPA expects to receive FOIA request for most PMN's, the Agency would be required to request additional substantiation from submitters with the attendant time and resource burdens for both parties.

Second, this approach reduces the benefits provided by the revised approach presented in this reproposal. As discussed above, the revised approach provides a scheme which allows the submitter to understand the relationship among his confidentiality claims, and, therefore, not make claims which may be difficult to defend. This third approach, by requiring substantiation of confidentiality claims in two phases, makes it more difficult for the submitter, as well as the Agency, to evaluate the bases for confidentiality claims.

The Agency specifically solicits comments on this approach as well as other approaches to providing substantiation of confidentiality claims.

C. Submittal of Generic Information if Certain Information is Claimed Confidential

1. *January 10 Proposal.* In the January proposal, persons claiming the specific chemical identity of a new substance confidential would be required to provide a generic name. This name was to be "only as generic as necessary to

protect the confidential identity of the particular chemical substance" and to reveal, to the maximum extent possible, toxicologically significant aspects of the molecular structure. Submitters were to utilize EPA guidelines in constructing generic names (§ 720.41).

EPA also proposed that submitters who claimed confidentiality for information on uses of the new chemical substance provide a generic (i.e., less specific) use description and supplement this information with a characterization of likely exposure to humans or the environment (§ 720.42). This procedure would provide the public with information useful in assessing notices and protect the submitter's confidentiality rights.

No other provisions concerning generic information were included in the January 10 proposal.

2. Summary of Comments on January 10 Proposal. EPA received several comments from industry and trade associations concerning the generic name requirements. The major concern was that the proposed generic name guidelines would not permit the degree of masking necessary to adequately conceal the specific chemical identity. Commenters also stated that the requirement to reveal toxicologically significant aspects of the molecular structure is not realistic given the limited understanding of the relationship between structure and biological activity.

Some commenters also stated that a submitter of a premanufacture notice who claims specific chemical identity confidential will also need to claim some of the physical and chemical property data confidential to prevent disclosure of the specific chemical identity.

3. Revised Approach. In response to these comments and in an effort to provide the public with meaningful information which can be used in assessing a new chemical substance, the Agency has modified its January 10 proposal. Certain data submitted on the form or attachments would have particular significance in aiding the public in assessing a new chemical substance; however, the Agency recognizes that much of this information may be subject to a claim of confidentiality. Therefore, the Agency has identified four classes of information for which EPA would require the submitter to either provide generic (less specific) information if certain items are claimed confidential, or explain why this less specific information cannot be provided. The classes of information are (1) manufacturer's identity, (2) specific

chemical identity, (3) use data, and (4) physical and chemical properties data.

EPA is proposing the following procedures. If specific chemical identity is claimed confidential and the Agency determines that all of the three generic names proposed by the submitter are more generic than necessary to protect the confidential identity, the Agency will propose in writing (to the submitter) an alternative generic name. If the EPA proposed name is not acceptable to the submitter, the submitter must explain why disclosure of the generic name would reveal confidential business information and propose another generic name. If the submitter's proposed generic name is acceptable, it will be published in an amended Federal Register notice under § 720.32. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of its choice and publish the chosen generic name in an amended Federal Register notice thirty days after this notification.

For manufacturer's identity, use and physical and chemical properties, the procedures for developing acceptable generic descriptions would be modified. If the submitter proposed a generic description that was not developed in accordance with the reporting instructions, he must explain why disclosure of such a generic description would reveal confidential business information. If the submitter does not provide a generic description or if EPA determines the generic description provided is more generic than necessary to protect confidential business information, the Agency will develop a generic description and notify the submitter. Thirty days after this notification, the generic information will be disclosed to the public.

The Agency specifically solicits comments on the guidelines for developing acceptable generic descriptions. Comments should address the procedures for notifying submitters that descriptions reported are more generic than necessary to protect confidential business information, and for requiring the submitter to provide additional generic descriptions if the descriptions they have submitted are not acceptable to the Agency.

Chemical Identity. The January 10 proposal required persons claiming the specific chemical identity of a new chemical substance confidential to provide a generic name. Before submitting a premanufacture notice, the submitter was advised to seek an advance determination by EPA of an appropriate generic name. The advantages of this procedure are that the Agency would not need to publish

an amended notice under § 720.32(c), uncertainty about EPA's choice of a generic name would be resolved prior to submission of the notice, and the public would receive useful information. If the prenotice communication procedure is not used by the submitter, the Agency is proposing the following modification to the January 10 proposal for providing generic names.

The revised form requires that the manufacturer provide three different generic names, each masked in a different manner in order to give the Agency a choice in determining which name to publish in the Federal Register. (The names not selected by EPA would be kept confidential if their disclosure in conjunction with other information which is disclosed would reveal confidential information.) This approach is being proposed because of two major considerations. First, section 5(d)(2) of TSCA requires the Agency to publish in the Federal Register a generic description of the new substance within five days of receipt of the notice. This does not allow EPA enough time to resolve problems with respect to the generic name. The Agency believes that the submission of three names will enable it to utilize its own expertise in choosing the most toxicologically descriptive name and will increase the likelihood that an acceptable name can be published in the Federal Register notice.

The second consideration is the limited ability of the Agency to amend a name once it is published in the Federal Register. Once EPA publishes a generic name, any subsequent amendment of that name, taken in conjunction with the one that was originally published, could reveal confidential information. Consequently, EPA's ability to provide the public with an amended name would be seriously impaired.

The requirement to submit three names would not apply to individuals who have developed an acceptable generic name through prenotice communication with EPA.

Generic Use Information. EPA is proposing a modification of its January 10 proposal regarding generic use descriptions for new chemical substances. The objective of the revised approach is to provide information to the public about use data without compromising the submitter's confidential information. The proposal establishes a framework for submitters to describe generic use for the chemical substance when the specific categories of use are confidential.

The proposed approach would require persons who claim the chemical use confidential to provide a use description

based on several lists of use characteristics provided by the Agency. (See Appendix A.) The categories are—

1. Degree of Containment
2. Level of Environmental Release
3. Type of Population Exposed
4. Type of Environmental Release
5. Type of Human Contact
6. Average Frequency of Human Contact

Each category includes several characteristics, which describe an aspect of the use of the chemical. The submitter would select the characteristic(s) within each list that describe the use of the chemical. If more than one characteristic on each list describes the use which is claimed confidential, the submitter would select all the characteristics that describe the use. If use has been claimed confidential, the generic characteristics selected will be published in the Federal Register notice in the narrative format proposed in the Appendix. Publication of this generic description of use in the Federal Register notice provides the public with useful information, while avoiding negative effects on innovation and marketing which could result from disclosure of more specific use information. A detailed description of this system is included in *Appendix A, Section III*.

In general, if a submitter adheres to the proposed system of use characterization, a "generic" description of use and exposure should be developed which eliminates the need for any further explanation. If the submitter did not use the scheme developed by the Agency, then the submitter would be required to explain, in an attachment to the premanufacture notice, why use of the scheme would disclose confidential business information.

The Agency invites comments on cases in which the lists of characteristics may not provide an accurate description of use from which EPA can develop generic use descriptions. EPA would expect those descriptions to provide information on the level, duration and frequency of exposure as well as characteristics of the population that will be exposed to the new chemical substance. The Agency specifically solicits comments on its generic use classification system. Comments should also address alternative ways to provide sufficient instruction to the submitter for development of generic use descriptions which are only as generic as necessary to protect confidential business information while providing use information to the public as required by Section 5(d)(2) of the Act.

Ranges for Physical and Chemical Properties. EPA is proposing a

requirement whereby submitters would report physical and chemical properties in ranges if disclosure of the specific value of the property would reveal confidential business information. EPA is proposing ranges for the following properties: vapor pressure, density, solubility, melting point and boiling point/sublimation point. (See *Appendix A, Section III*.) Submitters would provide their own ranges for other properties if additional specific physical and chemical properties are claimed confidential. EPA will also place these ranges in the public file. If the submitter does not use the proposed ranges, he would be required to explain, in an attachment to the form, why use of the ranges would disclose confidential business information and provide alternative generic information.

EPA is proposing this approach for several reasons. First, the Agency agrees with comments that exact physical and chemical property data, when combined with some generic chemical identity information, may reveal the specific chemical identity of the substance. On the other hand, as indicated in the January 10 proposal, EPA believes that physical and chemical property data are health and safety data and that this data would disclose information on the potential effects of a substance, especially with regard to exposure levels. EPA believes that the use of ranges, as proposed, would address both concerns to a significant extent. EPA intends the ranges to be broad enough to conceal confidential information and narrow enough to provide the public useful information about the new substance.

The Agency specifically solicits comments on the concept of using ranges to disclose physical and chemical property data. Comments are also solicited on whether or not the proposed ranges are too broad to provide useful information to the public or if they are too narrow to conceal confidential information.

Manufacturer's Identification. EPA also is proposing that the submitter of a PMN who asserts that the fact that *his company* has submitted a PMN is confidential, must provide a generic description of the company for inclusion in the section 5(d)(2) Federal Register notice. The objective of this requirement is to provide information to the public about the company without disclosing the submitter's confidential identity. The proposal would require persons who claim manufacturer's identity confidential to provide a description based on three categories of characteristics: (1) General geographic

location of the company, (2) size of the company in total annual sales, and (3) type of company by Standard Industrial Classification (SIC) Code. (See *Appendix A, Section III*.) EPA would publish the characteristics in the section 5(d)(2) notice, in a narrative format.

In particular, the manufacturer would be required to identify the region of the country (as used by the Bureau of Census in its annual Statistical Abstract of the United States) in which the intended site of manufacture is located, and the total annual sales of the company (in ranges). The manufacturer also must provide the three-digit SIC code for the manufacturing site. However, if this code will reveal the company's identity when taken together with the information on geographic location and annual sales, the manufacturer should provide a two-digit code and a brief explanation of why a three-digit code is too specific. If the submitter does not know the intended site of manufacture, he should identify the region in which the company's headquarters is located and the primary SIC code for the entire company.

EPA invites comments on alternative ways to provide information about the manufacturer or importer to the public without compromising the submitter's legitimate interests in maintaining confidentiality. EPA especially invites comments on whether this will provide useful information to the public about importers of new chemical substances. Comments also should address the characteristics EPA has provided to describe manufacturers and whether the subcategories are only as broad as necessary to protect confidential business information while providing useful information to the public.

III. Supplemental Reporting

A. January 10 Proposal

On January 10, 1979, EPA proposed in the Federal Register (44 FR 2242) as part of its Premanufacture Notification Requirements and Review Procedures under Section 5 of TSCA, rules governing supplemental reporting requirements under sections 8(a) and 5 of the Act. The proposed rules provide that EPA may require in writing that certain persons report supplemental information concerning a new chemical substance for which EPA receives a premanufacture notice if it is known to or reasonably ascertainable by them. Small manufacturers (total annual sales less than \$1,000,000) would have been exempt from these reporting requirements, except with respect to information which supplements,

provides further detail on, or clarifies that included on the PMN form.

The supplemental reporting rules as first proposed would have required certain additional information about the new chemical substance. First, under § 720.50(b) EPA could require the manufacturer or importer of a reactant of unknown composition to report the identity or composition of the reactant to EPA under the following circumstances: (1) If a person submitted a PMN for a substance which was a product of a reaction which includes that reactant, and if the submitter has attempted unsuccessfully to obtain the information; and (2) EPA could require a person who submits a premanufacture notice § 720.50(c), or a person who intends to process a substance for which a premanufacture notice has been submitted (§ 720.50(d)), to provide the following: (1) Information designated "optional" on the notice form; (2) information supplementing, detailing, or clarifying information submitted on the notice form; (3) information concerning the benefits of the substance and the economic consequences of any specified regulation under TSCA; and, (4) in addition, EPA could require such intended processors to provide information concerning categories of use, amounts processed, manner and methods of disposal, and any resulting human and environmental exposure that may occur. Such information could be required if it would be relevant to a determination of whether the substance should be tested under section 4 of the Act, controlled under section 5 or section 6, or followed up under sections 5 or 8.

Paragraph (e) of § 720.50 specified the procedures EPA would follow in requiring the submittal of supplemental information. EPA would provide a written notice to any person subject to a reporting requirement. The notice was to include a copy of § 720.50, a detailed description of the information to be submitted, the name and address of the person to whom the information was to be submitted, and the date by which submittal was required. This date was to be no sooner than 15 days after receipt of the notification. The preamble stated that only the Assistant Administrator for Toxic Substances, or one of his Deputy Assistant Administrators, could issue a § 720.50 supplemental reporting requirement.

An analogous provision to § 720.50, proposed § 720.51, stated that EPA could require any person who has possession of a health and safety study to submit that study to EPA, if EPA found that the study will assist in evaluating the health

or environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the substance. The reporting procedures were to be identical to those in § 720.50.

B. Summary of Comments on the January 10 proposal

EPA received a number of comments in response to the January 10 supplemental reporting proposal. Although all comments were reviewed and considered by the Agency in developing the present reproposal, EPA will discuss in this notice only those comments addressing parts of the proposed rule which are being repropounded. EPA will respond to comments concerning other aspects of the January 10 supplemental reporting proposal when the rule is published in final form.

The comments focused on three issues: (1) EPA's authority to require information through letter-writing; (2) the lack of specific criteria indicating when information would be required; and (3) the lack of any procedure for clarifying or objecting to a supplemental reporting requirement.

Some commenters questioned EPA's letter-writing authority and thus objected to the issuance of a general reporting rule providing for such procedures. The commenters strongly suggested that rulemaking on a case-by-case basis would be more consistent with TSCA.

The January 10 regulations were seen by some commenters as overly broad and vague, giving the EPA or any of its employees total discretion as to the types of information which could be required. To remedy this perceived deficiency, commenters suggested that EPA should promulgate self-executing regulations that outline clear criteria that would enable submitters and processors to better predict when supplemental information might be required.

Commenters also suggested that there should be procedures for clarifying or objecting to a supplemental reporting requirement. They stated that without such a procedure, administrative review of each request for information would be precluded and regulatees would be deprived of notice and opportunity to be heard.

C. Revisions to Proposed § 720.50

After an initial review of the comments received on the January 10 proposal, EPA is still convinced that the reporting approach contained in § 720.50—implementing information requirements by letter rather than by case-by-case rulemaking procedures,

with notice in the Federal Register—is valid and necessary. EPA's key concern, as indicated in the January 10 proposal, is time. It would be difficult to promulgate section 8(a) reporting rules on a case-by-case basis and still receive the needed information within the section 5 review period. Also, it is not clear that full rulemaking procedures are necessary since the supplemental requirement would apply to a single individual who will receive actual notice of the requirement and be given an opportunity to comment.

The need for supplemental reporting authority is made more acute by EPA's repropounded PMN form. Except in a very limited number of cases, the information contained in a PMN should be adequate to identify substances and exposures of concern; it may, however, be inadequate to determine how or if such new substances should be regulated. Use of supplemental reporting authority to gather additional information for further evaluation of substances of concern is an integral part of the Agency's proposal to reduce the PMN requirements, and if EPA lacks a mechanism for obtaining such information on an expedited basis, one of EPA's major justifications for streamlining the PMN form will be removed.

While EPA is not proposing a modification of the principle of imposing reporting requirements under section 8(a) by letter, the Agency is repropounding this section of the regulations to alleviate some of the chief concerns expressed in the comments. EPA's major effort has been to develop more detailed criteria indicating when EPA may require additional information, and specifying the types of information that the Agency may require if the criteria are met. A second significant change has been to add to the paragraph on "Procedures For Reporting" (former § 720.50(e)) a mechanism by which the person subject to a proposed reporting requirement can file a request for modification or clarification of the requirement. These major revisions, along with others of a less significant nature, are discussed in detail below.

Subsection (a)(1) of proposed § 720.50 has been modified to clarify the applicability of the proposed rule. First, it states that the supplemental reporting requirement may pertain to chemical substances for which a premanufacture notification has been received and related substances. Related substances include impurities, byproducts, coproducts, degradation products, and unintended reaction products. Thus, EPA will be able to obtain complete information on exposure related to the

manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance. Second, the revised paragraph (a) provides that EPA would issue supplemental reporting requirements under § 720.50 only during the premanufacture review period (including any extensions under section 5(c) of the Act). This limitation was not contained in the January 10 proposal. After the PMN review period EPA would rely on general section 8(a) reporting rules now being developed.

Paragraph (a)(2) contains the proposed small business definition for the purposes of § 720.50. The definition is the same as that proposed in January 1979. EPA has received many comments on this proposed definition and is still evaluating them; the Agency is not proposing any modification. Persons may wish to supplement their comments in the context of the revised reporting requirements.

EPA is also proposing, in paragraph (a)(2), that the provisions requiring small manufacturers to submit additional information explaining that the PMN be retained. Small business is generally exempt from reporting under section 8(a) of TSCA; it is not exempt from section 5 requirements. Therefore, EPA believes small business can be required under the authority of section 5 to submit information that could have been required in the PMN but was not. The Agency is proposing to modify significantly the scope of the information small business could be required to report. The exclusion would now be limited to information which explains or clarifies information the person was required to submit in a premanufacture notice. EPA has deleted the provision that information which "supplements" that submitted in the PMN could also be required because the Agency recognizes that the term "supplements" is broad enough to cover the information the Agency would require under § 720.50. The terms "explains" and "clarifies" may be somewhat ambiguous, and EPA solicits comments on how the regulations might more clearly define the boundary between information which could be required under section 5 and other information the Agency will obtain under the authority of section 8(a). Finally, the revised proposal for paragraph (a)(2) specifically recognizes that section 8(a)(3)(ii) authorizes EPA to require small business to report information in specified circumstances; EPA intends to maintain this authority in § 720.50.

Proposed paragraph (b) provided that if EPA received a PMN for a new

substance which was the product of an unknown reactant, the Agency could require the manufacturer or the importer to report concerning the composition of the reactant. EPA is not proposing any modification of this provision in this notice. However, EPA will, in the future, be proposing a rule under section 8(a) to require reporting by manufacturers and importers of unknown reactants. Paragraph (b) may be modified or deleted when such a rule becomes effective.

Sections 720.50(c) and (d) of the January proposal, which contained supplemental reporting requirements for notice submitters and intended processors, have been replaced by paragraphs (c)–(g) in this proposal. Paragraph (c) of this proposal would require reporting by notice submitters concerning direct human exposure, and paragraph (d) would require reporting by notice submitters concerning environmental release or indirect human exposure. Analogous reporting requirements for persons who intend to process the new substance are contained in paragraphs (e) and (f). Paragraph (g), which would apply to both notice submitters and processors, prescribes information EPA may require to identify the submitter and its customers, and prescribes information to determine the economic significance of the new substance and the impact of possible regulatory actions. The general structure of each paragraph (c) through (f) is as follows. First, EPA details the finding the Agency would make before requiring any supplemental reporting; then the rule spells out the types of information EPA may require.

Each paragraph sets out the two basic findings which must be made before EPA could require supplemental reporting. The first alternative finding applies to a substance of suspected toxicity. If this determination is made, EPA must also find that the physical and chemical properties of the substance (or chemical fate information, where reporting of environmental release data is concerned) and information on release indicate a potential for human or environmental exposure.

As an alternative, EPA may apply a reporting requirement if the Agency determines that it lacks sufficient data to determine the potential hazard from the substance. In this situation, EPA would also have to find that physical and chemical properties (or chemical fate data) indicate a potential for significant human or environmental exposure. In general, exposure could be "significant" if it is widespread at any level of concentration, or if there is high

exposure to any number of persons or ecological populations. Thus, if EPA lacks data indicating toxicity, the Agency would need to meet a more rigorous exposure test before requiring supplemental reporting during the PMN review period.

Once one of the findings set out above is made, EPA, under the revised proposal, would require reporting of specific information only if the Agency found that exposure might occur at a particular stage of a substance's life cycle. These stages include manufacturing, processing and industrial use, distribution in commerce, disposal, and end use. The last part of each paragraph sets forth the information which may be required for each stage in a substance's life cycle. For example, if under § 720.50(c) EPA found that the criteria of paragraphs (c)(2) or (c)(3) were met and that exposure might occur upon end use of a substance, the Agency could require reporting of information on packaging and labeling, use specifications and recommendations, and other similar information.

A reporting requirement under paragraph (g) may be issued on the basis of any of the findings under paragraphs (c) through (f). If such findings are made, EPA may need to identify potential customers. Furthermore, any substance for which such findings are made is a candidate for regulatory action by EPA. For most regulatory actions under TSCA, EPA will consider available data on economic consequences of the action. In addition, if EPA intends to seek judicial action under sections 5(e) or 5(f), specific identifying information for the company may be required. (This Federal Register notice proposes deleting the requirement that submitters provide such information in the PMN.)

Finally, in paragraph (h) of § 720.50, EPA is proposing a modification of the procedures for imposing a supplemental reporting requirement. As in the January 10 proposal, the requirement will be initiated by a written notice to the person for whom information is required. The regulation specifies that the notice will be signed by the Assistant Administrator or a Deputy Assistant Administrator in the Office of Toxic Substances. This makes clear that these reporting requirements will not be issued by lower-level staff members within OTS.

Under the proposed approach, the first notice to the company will be a proposed reporting requirement. The contents of this notice will be expanded from those previously proposed. EPA is proposing to include a statement of the findings made under this section to

require supplemental reporting; in addition, the notice will describe the appeal procedures EPA has established.

The proposed appeal procedures, set forth in § 720.50(h)(2), were developed in response to comments that persons subject to the rule should be given an individual opportunity to comment. The person subject to the requirement would be required to file any formal objections within ten days after his receipt of the reporting notice. This short time period is necessitated by the statutory time limits on PMN review. An objection may include a request for modification or further explanation of the requirement, or a request for an extension of the time period within which to report. In any case, the company would be required to state which specific part of the requirement it is seeking to modify, and to provide a detailed explanation of the grounds for this objection. Provisions for which no objections or requests have been received within the ten-day filing period will become final at the end of the ten day period.

EPA would consider all objections or requests regarding the supplemental reporting requirements, and in every case would respond in writing to the objections. EPA could either revoke the proposed requirement, or finally adopt it. The reporting requirement would become final and effective as soon as it was received by the submitter or other person subject to the requirement.

Alternatives Considered. In formulating this reproposal, EPA considered two alternative approaches for establishing criteria for imposition of a supplemental reporting requirement. The first alternative was to maintain very general criteria similar or identical to those in the proposal of January 10. These criteria were very broad. This alternative would be attractive to EPA because, by setting out more specific criteria, the Agency will inevitably find that in at least some cases information would not be available during the PMN review period. However, EPA recognizes that this approach would not allow industry to anticipate the circumstances under which information would be required.

A second alternative considered by EPA was to develop very precise criteria, which would link the presence or absence of specific information on the form to specific categories of information which could be required by EPA. Although this approach would be more responsive to the request for more concrete reporting criteria, EPA has concluded that development of such criteria at this time would be extremely difficult. The state of the art concerning analysis of the risk potential of new

chemical substances does not allow for the development of simple equations to determine if a substance presents a risk, and to indicate what if any additional data are necessary to make a responsible evaluation. It would be nearly impossible, for example, to prescribe a specific range of results concerning the activity of analogue substances that could be relied upon, in combination with exposure data, to indicate the Agency's informational needs efficiently and effectively. Intending to avoid both extremes, EPA with this notice is reproposing the rule to clarify and specify when reporting may be required, without creating a criteria system so complex that it is burdensome and inefficient to administer.

D. Revisions to § 720.51

EPA is not proposing any revision in the criteria to exercise the Agency's authority to require submission of health and safety studies. The criteria for reporting are simple. First, EPA must have some indication that the person possesses a study concerning a particular substance. Second, the study must be such as to assist EPA in evaluating potential health and environmental effects of a substance. Generally, this second finding should not be controversial, because for many new substances (and related substances) there will be little testing available, and each study will have a significant incremental value in understanding potential hazards.

EPA has revised § 720.51(b) to reflect the new reporting procedures developed for § 720.50. While the possible objections to a requirement to provide a particular health and safety study or studies are less complex, and the full procedures of § 720.50(h) may not often be necessary to resolve any conflict, this distinction does not justify the maintenance of different reporting procedures under §§ 720.50 and 720.51.

Section IV—Cost and Economic Impact Issues

A. January 10 Proposal

In January 1979 EPA published an economic report entitled "Impact of TSCA Proposed Premanufacturing Notification Requirements" (EPA Contract No. 68-01-4717), which accompanied the proposed premanufacture rules and notice forms. The report was a preliminary attempt to characterize the chemical industry, particularly to estimate the effect that the proposed PMN requirements might have on the development of new chemicals in this country.

Although the data and time available to complete the study were limited, the study did provide EPA with the following:

(1) A characterization of the chemical industry in terms of products and markets, output, growth, foreign trade, employment, and market structure;

(2) A characterization of new chemical development practices;

(3) An estimate of the range of unit costs possible under the proposed PMN forms;

(4) An assessment of the impact of premanufacture notice costs on the rate of introduction of new chemicals; and

(5) An estimate of the total industry costs as a result of the proposed PMN forms.

EPA acknowledges that the study was limited in scope, because it only addressed the notice form itself. The study did not consider the costs and perceived risks to new product introduction presented by other provisions, such as those dealing with confidentiality, invalid notices, "customer contact", and importers and exporters. Similarly, the study was limited in that it only addressed one measure of impact, the impact on the numbers and types of chemicals introduced for commercial purposes.

The conclusions of the study, as interpreted by EPA, were that PMN costs would range from about \$2,500 to \$22,200 per substance for the mandatory portion of the form, and from about \$8,000 to \$41,400 for the combined mandatory and optional parts. EPA agreed with the contractor's findings that, in general, the lowest costs of premanufacture notification would apply to substances (1) that are submitted by smaller companies, (2) that are not expected to have significant health/environmental effects or exposure, (3) for which most data are readily available, and (4) for which there is limited distribution and use. EPA similarly agreed with the contractor's findings that the highest costs of premanufacture notification would apply to substances (1) that are submitted by larger companies, (2) that might have significant health/environmental effects or exposure, (3) for which the existing data would require extensive retrieval and formatting efforts, and (4) for which there is extensive distribution and use.

Given this range of costs, the report concluded that one result of PMN requirements could be that the rate of introduction of chemical substances could be reduced from 10% (if the \$2,500 figure were incurred for all submissions) to 90% (if the \$41,400 figure were incurred for all submissions).

The costs and impacts derived in the study may have been overestimated because the study did not adequately take into account the approach that small companies would take to completing the PMN form. Due to the limited technical and legal resources of small companies, and because the answer to many of the questions in the form would be "not available", EPA concluded that the unit costs of notification and, hence, the impacts for many companies would be much lower than these ranges.

In addition, EPA believed that the data on which the analysis was based were insufficient to characterize new chemicals and their development process with an adequate degree of certainty, for purposes of projecting the impacts of the premanufacture requirements. Because inadequate data existed with which to characterize the uses, production processes, and toxicity of the chemicals sampled in the study, no attempt could be made to determine which chemicals in the sample would have been subject to which levels of cost. Further, the contractor had to make assumptions concerning the ability of manufacturers to pass forward the costs of premanufacture notification to consumers; the maximum portion of profit that manufacturers might be willing to divert to regulatory costs; and the average length of product life. These assumptions had direct bearing on the outcome of the impact analysis and, in the opinion of EPA, should be subject to closer scrutiny before determining the economic impact of the premanufacture requirements.

B. Public Comments

During the public comment period following the January 10 proposal, EPA received a number of comments concerning the costs and economic impacts of the proposal. With few exceptions there was general consensus from the industry that the unit costs estimated by the contractor were accurate and reasonable and that, given those costs, the conclusions concerning the effect on the rate of introduction of new chemicals were accurate. In light of the contractor's conclusions, industry commenters stated that the burden of the proposed requirements would be onerous, a deterrent to innovation, and a threat to the economic viability of the chemical industry.

Although most commenters did not provide much information about their new chemical development practices or about how the PMN requirements would actually affect them, the following common areas of concern were identifiable:

(1) **Proposed Notice Form—Comments** concerning the notice form indicated that the costs of completing the form would be excessive relative to the profits of many new substances. Several companies commented that the scope of the form was too broad and that many companies do not possess the types of expertise identified by the economic contractor as being required to complete the form.

(2) **Invalid Notice Provisions—**Comments on the invalid notice provisions (proposed § 720.34) indicated a concern by many companies that there could be lengthy delays in the notice review process that would erode the commercial attractiveness of certain new ventures (particularly small volume specialty chemicals). This in turn would discourage companies from initiating those types of ventures. However, some companies stated that the possibility for dialogue with EPA in case of ambiguity or error would alleviate some of the uncertainty associated with this provision and, hence, some of the barriers to innovation.

(3) **Confidentiality Provisions—**Comments concerning the confidentiality provisions indicated that the provisions could be a major deterrent to innovation, depending upon how EPA implemented them. The risks posed by untimely disclosure of chemical identity, company name, or marketing data could create disincentives to develop new chemicals because disclosure would erode a company's competitive advantage in new ventures as well as its ability to secure patents.

(4) **"Customer Contact" Provisions—**Industry comments on the proposed "customer contact" provisions (proposed § 720.20(e)) indicated that the procedures for mandatory notification of potential customers would dissuade many potential customers from sampling, testing, and purchasing new substances and would thus create disincentives to the development of new chemicals.

(5) **Import Provisions—**Comments on the provisions for imported substances (proposed § 720.21) indicated a number of distinct concerns:

a. Commenters stated that notification requirements appeared to be less stringent for importers than for domestic manufacturers (due to the omission of workplace exposure questions in the importers form), and that importers, therefore, would have a cost advantage in bringing new chemical substances to the American market.

b. Commenters stated that the import provisions would give a competitive advantage to importers or foreign

manufacturers by virtue of their ability more freely to test market abroad and screen out commercially unsuccessful substances prior to submitting PMN's.

c. Commenters stated that the import provisions would create a non-tariff trade barrier to importation of chemicals due to the requirement for "upstream" commercial contact (proposed § 720.21(e)). Because some importers (e.g. brokers, intermediaries) do not know very much about the chemicals they import, they would have to rely on foreign manufacturers to provide most of the information to EPA. Because these types of importers also typically do not have direct access to their foreign manufacturers, there was concern that there would be difficulties getting the necessary data to EPA in a timely fashion, possibly leading to frequent findings of invalid notice, supplemental reporting requirements, and Section 5(e) actions.

(6) **Impact on Research and Development (R&D) Expenditures and Activities—**Several industry commenters indicated that the premanufacture requirements would force changes in the R&D expenditure policies of companies. Some companies commented that the increased costs of product development would lower the profitability of basic research, resulting in a cutback in funding for basic research and increased emphasis on development and modification of existing chemicals.

(7) **Macroeconomic Impacts of PMN requirements—**Several commenters stated that the proposed PMN requirements would have far-reaching effects on the economy as a whole. The importance of innovation in chemical technology to all facets of the American economy, and the reliance on chemical innovation by many other industries for their own competitive advantage in world markets, were said to be a basis for the proposed requirements to have significant effects on gross national product, the balance of trade, prices, employment, and other macroeconomic indicators.

(8) **Impact on Small Business—**Several commenters expressed concern that small businesses would be disadvantageously affected by the proposed requirements. The reasons stated generally were that small companies would not be able to absorb the increases in R&D costs as readily as larger companies and would be forced to cutback R&D expenditures or to discontinue R&D altogether. It was stated that this would result in a greater concentration of R&D activities and sales among the larger companies.

C. EPA's Response to Comments—The Revised Analysis

EPA currently is conducting a more in-depth study of the proposed premanufacture requirements to respond to the issues raised in the public comment period and to determine with a greater degree of confidence the nature of the results costs and economic impacts. The main purpose of this analysis is to account for the costs and impacts of the initial reporting program in its entirety. EPA will attempt to access the costs and economic implications of the following rules provisions, in addition to the costs and impacts of the notice form itself:

Confidentiality
Invalid Notice
Imports and Exports
"Customer Contact"
Supplemental Reporting
Notice of Continuing Review
Extension of Notice Period
Exemptions for Small Quantities for Research and Development
Exemptions for Test Marketing

Although these assessments are likely to be qualitative EPA believes they will help answer the questions of which, if any, types of companies or ventures will be adversely affected by the rulemaking and how they would be affected.

A second purpose of the revised analysis is to attempt to extend the previous analysis by examining more closely the secondary impacts of the premanufacture requirements. The proposed economic analysis examined the impact of the requirements on the rate of introduction of new chemicals. To the extent possible, this revised analysis will assess the effects that changes in the numbers and types of chemicals will have on policies for R&D allocation and expenditure and on industry sales, growth, profitability, and structure. Due to the complexity of the chemical industry, it is not likely that this analysis will yield quantitative conclusions. However, it may give some indication of the direction and types of change that might occur if EPA promulgates the proposed requirements.

The revised analysis will use a methodology similar to that used in the previous economic analysis, but will benefit from an improved data base. Data will be collected on chemicals recently introduced by as many as 30 companies. This should provide information from which to determine the types of chemicals and companies that may be affected adversely by the premanufacture requirements, and why they would be so affected.

At this time EPA believes that the premanufacture requirements will not

adversely effect most manufacturers, due to the reduced costs of the revised PMN form. However, EPA is aware that even minimal notification requirements and time delays may impose special burdens on, and threaten the existence of, certain enterprises. Through its data gathering effort, EPA intends to characterize those companies and chemicals that may be adversely affected.

D. Public Review and Comment

This new analysis will focus on the economic costs and impacts of major provisions in the proposed premanufacture rules and forms, and will be based upon an expanded data base. Therefore, before the Agency promulgates the rules and notice forms, it will publish for public comment a report that includes the new data plus the cost and impact analyses. Notice of the availability of this report will be published in the *Federal Register*. During the public comment period EPA will solicit input concerning these data and analyses, including the assumptions and methodologies used and conclusions reached.

In general, EPA will not ask the public to provide comments on the technical, legal, and policy aspects of the proposed rules and notice forms—those comments must have been submitted during the public comment period accompanying the January proposal and this current reproposal. However, comments on the economics report may address policy and other non-economic aspects of the rulemaking insofar as decisions on the latter should be influenced by the economic findings and conclusions. EPA will carefully review and use the report and comments received on it in making decisions concerning the contents of the final rules and notice forms.

V. Comments and Public Meetings

EPA invites comments on all issues raised in this notice. Comments on the revised notice forms should focus on EPA's general approach, the Agency's need for the information, the availability of requested information to notice submitters, and the burden of obtaining the information and completing the forms. Do not resubmit comments on the January 10 proposed rules and forms. They will continue to be a part of the official record of this rulemaking. When EPA promulgates the final rules and forms, the comments on the January proposal, as well as the comments on this notice, will be evaluated.

During the 45-day comment period, beginning on the publication date of this notice, EPA personnel will be available to meet with interested persons from

individual companies, trade associations, organized labor, and public interest organizations to discuss the revised notice form and other issues raised in this notice. EPA will provide the facilities and make other necessary arrangements for such meetings. The Agency will prepare transcripts or summaries of the meetings for inclusion in the official public record.

The meetings will be open to all members of the public, but active participation will be limited to those persons who request the meetings and EPA participants. Persons should call EPA's Industry Assistance Office at the number listed below for more information (i.e. dates, times, places, participants, topics).

Most meetings will be held in Washington, D.C. However, EPA is very interested in obtaining input directly from small companies, local labor officials, and regional public interest organizations. For this reason, the Agency will hold a limited number of meetings outside of Washington where there is a demonstrated interest in and need for such meetings. For example, EPA officials will agree to meet with a number of small companies at a central location if it is clear that the Agency cannot otherwise receive input from such persons.

Persons who wish to meet with EPA representatives should contact the Industry Assistance Office at 800-424-9065; in Washington, D.C. please call 554-1404. This office will arrange times and places for the meetings and, as noted above, will provide such information to the public.

After the public comment period closes, EPA will evaluate the comments received and will hold at least one general public meeting to discuss the comments with interested persons (particularly those who submitted them); the meeting is scheduled as follows:

Date: Dec. 12, 1979

Time: 9:00-4:00

Location: Health Education and Welfare Auditorium, 4th & Independence Ave. SW., Washington, D.C.

During the comment period, if EPA determines that it should hold more than one of these general meetings, the Agency will announce them in the *Federal Register*. In general, any such meetings will be organized around a series of key topics, and will include a panel of EPA officials in dialogue with persons who submitted written comments. The Agency will prepare transcripts of such meetings for inclusion in the public record. Active participation will be limited in these meetings to persons who submit written

comments during the 45-day comment period. The Agency does *not* intend to reopen the comment period for submittal of written comments following these meetings.

EPA welcomes suggestions concerning these meetings—(number, formats, and so forth). Address specific comments on this issue to:

*Director, Industry Assistance Office,
Environmental Protection Agency, 401 M
Street, SW., Wash. DC 20460*

VI. Public Record

EPA has established a public record for this rulemaking (docket number OTS 050002) that is available for inspection in the OTS Reading Room from 9:00 a.m. to 5:00 p.m., on working days (Room 447E, 401 M Street, S.W., Washington, D.C. 20460). This record includes all of 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 all of the categories of information listed in the January 10, 1979, Notice of Proposed Rulemaking (44 FR 2263). In particular, the record has been supplemented for the purposes of this reproposal with the following documents:

(1) USEPA—OTS. "Reproposal of Premanufacture Notice Forms and Provisions of Rules: Notice of Proposed Rulemaking."

(2) USEPA—OTS. (Impact of TSCA Proposed Premanufacturing Notification Requirements; contract No. 68-01-4717.)

(3) Working drafts of the proposed Premanufacture Notice forms dated June 28, 1979, July 23, 1979, and August 7, 1979.

(4) EPA documents distributed at the meetings (and transcripts) of the Administrator's Toxic Substances Advisory Committee (ATSAC), August 14, 1979, and September 25, 1979.

(5) EPA materials on the planned reproposal of the premanufacture notice forms distributed at the Embassy Officials Briefing, September 11, 1979.

The docket of the record that details its specific contents to date is available in the OTS Reading Room. EPA welcomes comments 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 section 19(a)(3).

Note.—Under Executive Order 12044, Improving Government Regulations, EPA must determine whether a proposed regulation is "significant" and therefore subject to the requirements of the order. On May 29, 1979, EPA published a report on how it will implement the order (44 FR 30988).

Consistent with the order and EPA's report, the Agency has reviewed the proposed Premanufacture Notification Requirements and Review Procedures (44 FR 2242), January 10, 1979, and the forms and rules that are repropounded in this Federal Register notice. EPA has determined that they are "major significant" regulations, as that term is defined in the Agency's report (44 FR 30989-90). EPA will issue them in accordance with the requirements of the report concerning internal Agency development and review, public participation, economic analysis, and consideration of other regulatory impacts and alternatives. In particular, see Section I.B.4 above for a discussion of the economic costs of this reproposal and Section IV for a description of other economic analyses that EPA has under way.

(Secs. 5, 8, and 14 of the Toxic Substances Control Act (15 U.S.C. 1604, 2607, and 2613.))

Dated: October 1, 1979.

*Douglas M. Costle,
Administrator.*

40 CFR 720.40, 720.41, 720.42 and 720.43 are repropounded to read as follows: Section 720.44 is redesignated as § 720.45, and a new § 720.44 is added.

§ 720.40 General provisions.

(c)(1) At the time a person submits the information to EPA, he must substantiate all claims of confidentiality. The person must provide substantiation in the manner specified in the reporting instructions.

§ 720.41 Specific chemical identity.

(a) * * *

(i)(A) Submit the specific chemical identity of the substance; and either (B) Report the generic name which was accepted by EPA in the prenotice consultation under paragraph (a)(2) of this section or

(C) Provide three generic names, each masking the chemical identity in a different manner, and each only as generic as necessary to protect the confidential identity of the particular chemical substance. These names should reveal to the maximum extent possible toxicologically significant aspects of the molecular structure. Before proposing generic names to meet these criteria, the submitter should consult the guidelines for Creating Proposed Generic Names, published as Appendix II to these rules. The submitter shall explain why a more specific name would reveal confidential business information.

(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 in the Federal

Register notice under § 720.32 either the generic name agreed upon by EPA or one of the generic names proposed by the submitter.

(iv)(A) If at any time EPA determines that the generic names proposed by the submitter are more generic than necessary to protect the confidential identity, the Agency will propose in writing, for review by the submitter, an alternative generic name that will reveal to the maximum extent possible toxicologically significant aspects of the molecular structure.

(B) If the EPA proposed generic name is acceptable to the submitter, EPA will publish the generic name in an amended Federal Register notice under § 720.32.

(C) If the EPA proposed generic name is not acceptable to the submitter, the submitter must explain in detail why disclosure of the generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect this confidential information. If EPA does not receive a response from the submitter within 30 days after the person receives this notice, the Agency will publish its chosen generic name in an amended Federal Register notice under § 720.32 without further notice. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish the generic name in an amended Federal Register notice under § 720.32. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of its choice of a generic name. Thirty days after this notification, EPA will publish the chosen generic name in an amended Federal Register notice under § 720.32.

(b) * * *

(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 propose in writing for review by the submitter an alternative generic name that will reveal to the maximum extent possible toxicologically significant aspects of the molecular structure.

(iii) If the EPA proposed generic name is acceptable to the submitter, EPA will place the generic name in an appendix to the inventory.

(iv) If the EPA proposed generic name is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name

which is only as generic as necessary to protect the confidential identity. If EPA does not receive a response from the submitter within 30 days after he receives this notice, the Agency will place its chosen generic name in an appendix to the inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish the generic name in an appendix to the inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of its choice of a generic name. 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.

(b) * * *

(2) Provide, in non-confidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. Before proposing a generic description of the uses to meet these criteria, the submitter should consult EPA's reporting instructions. The generic use description will be included in the Federal Register notice under § 720.32.

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

(d)(1) If the submitter reports a generic use description other than in accordance with the reporting instructions, he must explain in an attachment to the form why disclosure of a generic use description developed in accordance with the reporting instructions would reveal confidential business information.

(2) If the submitter does not provide a generic use description, or if EPA determines that the use description provided is more generic than necessary to protect the confidential uses, the Agency will develop a generic use description and notify the submitter. Thirty days after this notification, EPA will publish its chosen generic use description in an amended Federal Register notice under § 720.32.

§ 720.43 Data from health and safety studies.

(e) *Ranges for physical and chemical properties.* (1) If a submitter has claimed specific chemical properties of the substance confidential, he must report the specific data to EPA and also provide the data for these properties in

ranges that are only as generic as necessary to protect the confidential data. These ranges will be placed in the public docket of the premanufacture notice. Before proposing the ranges, the submitter should consult EPA's reporting instructions.

(2) The submitter must provide a detailed written substantiation of the claim, as specified in the reporting instructions.

(3) If the submitter does not provide this data in the ranges specified by EPA, he must explain in an attachment to the form why disclosure of the data in the specified ranges would reveal confidential business information.

(4) If the submitter does not provide ranges for the chemical properties or if EPA determines that the ranges provided are more generic than necessary to protect the confidential data, EPA will assign a range to the data and notify the submitter. Thirty days after this notification, EPA will place the ranges for the data in the public docket.

§ 720.44 Manufacturer's identity.

(a) If the submitter claims his identity confidential, he must provide a description of the company which is only as generic as necessary to protect the confidential identity. This generic description will be included in the Federal Register notice under § 720.32. Before preparing the description, the submitter should consult EPA's reporting instructions.

(b) The submitter must provide substantiation of the claim, as specified in the reporting instructions.

(c)(1) If the submitter does not follow the reporting instructions for developing a generic manufacturer identity, he must explain in an attachment to the form why disclosure of the generic identity developed in accordance with the reporting instructions would reveal confidential business information.

(2) If the submitter does not submit a generic description for manufacturer's identity, or if EPA determines that the description provided is more generic than necessary to protect the confidential identity, the Agency will develop a generic description of the manufacturer's identity and notify the submitter. Thirty days after this notification, EPA will publish the chosen generic manufacturer identity description in an amended Federal Register notice under § 720.32.

§ 720.45 Public files. [Redesignated from § 720.44.]

2. 40 CFR 720.50 and 720.51 are reported to read as follows:

§ 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 (h) of this section to require persons to report supplemental information during the premanufacture review period. EPA may request information with respect to the manufacture, import, processing, distribution in commerce, use, or disposal of a new chemical substance or related substances for which the Agency receives a premanufacture notice. Related substances include impurities, by-products, coproducts, degradation products, and unintended reaction products. Except as provided in paragraph (a)(2) of this section, paragraphs (b), (c), (d), (e), (f), and (g) of this section prescribe the persons who may be subject to these reporting requirements. Information must be submitted if it is known to or reasonably ascertainable by the submitter or processor.

(2) 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, except for information which explains or clarifies any information which the person was required to submit in his premanufacture notice, or information with respect to a substance for which section 8(a)(3)(ii) of the Act is applicable. In the case of a company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

(b) * * *

(c) *Notice submitters' requirement to report information concerning potential risk resulting from direct human exposure.*—(1) *General.* If EPA makes the findings in paragraphs (c)(2) or (c)(3) of this section, and if EPA finds that there may be exposure in the manufacture, processing, distribution in commerce, use, or disposal stages of a chemical substance's life cycle, the Agency may require the submitter of a premanufacture notice to report any of the information specified in paragraph (c)(4) of this section, pertaining to that stage of a substance's life cycle.

(2) *Finding with respect to substances of suspected toxicity.* A finding under this paragraph (c)(2) may be made if all of the following criteria are met with respect to a new chemical substance or a related substance:

(i) Information on toxicity submitted with the premanufacture notice or otherwise obtained by EPA indicates the

substance may present a significant hazard to humans. The following will be considered: Results of in vitro tests, results of in vivo tests, data on analogues, epidemiological data, and other similar data;

(ii) Information on physical/chemical properties indicates a potential for release resulting in human exposure. Properties to be considered include: Physical state, vapor pressure, viscosity, particle size distribution, surface tension, solubility, vapor emission rate, and other similar data; and

(iii) Information on release submitted in the notice form and any other information obtained by EPA indicates a potential for release resulting in human exposure.

(3) *Finding with respect to substances of unknown toxicity.* A finding under this paragraph (c)(3) may be made if all the following criteria are met:

(i) Sufficient data on toxicity have not been submitted with the premanufacture notice nor have other data been obtained by EPA (including data on analogues) that are sufficient to determine whether the substance may be harmful to humans;

(ii) Physical/chemical properties, including those listed in paragraph (c)(2)(ii) of this section, indicate a potential for release resulting in significant human exposure; and

(iii) Information on release submitted with the premanufacture notice or any other information obtained by EPA indicates a potential for release resulting in significant human exposure.

(4) *Information which may be required.* EPA may require the following information with respect to the stage of the substance's life cycle for which appropriate findings are made:

(i) With respect to the manufacture, processing, or industrial use of a substance, EPA may require information concerning: an explanation of any information presented in the form, equipment specifications, engineering safeguards, operating procedures, industrial hygiene practices, maintenance, cleaning, and preparation procedures, process chemistry, use, and other similar information.

(ii) With respect to distribution in commerce, EPA may require the following types of information about the substance, and mixtures and articles containing the substance: Packaging and labeling information, potential for and magnitude of a spill, transport safeguards and handling procedures, and other similar information.

(iii) With respect to disposal, EPA may require the following types of information about the substance, and mixtures and articles containing the

substance: Waste handling procedures, identity of disposal site, information on method of disposal, and other similar information.

(iv) With respect to end use, EPA may require the following types of information about the substance, and mixtures and articles containing the substance: Formulation or construction of the product, packaging and labeling information, use specifications and recommendations, and other similar information.

(d) *Notice submitters' requirement to report information concerning potential risk to human health or the environment resulting from environmental release.*—

(1) *General.* If EPA makes the findings in paragraphs (d)(2) or (d)(3) of this section, and if EPA finds that there may be environmental release in the manufacture, processing, distribution in commerce, use, or disposal stages of a chemical substance's life cycle, the Agency may require the submitter of a premanufacture notice to report any of the information specified in paragraph (d)(4) of this section pertaining to that stage of a substance's life cycle.

(2) *Finding with respect to substances of suspected toxicity.* A finding under this paragraph (d)(2) may be made if all of the following criteria are met with respect to a new chemical substance or a related substance:

(i) Information on toxicity, including data listed in paragraph (c)(2)(i) of this section, submitted with the premanufacture notice or otherwise obtained by EPA, indicates that the substance or mixtures or articles containing the substance may present a significant hazard to human health or the environment;

(ii) Information on chemical fate submitted with the premanufacture notice or other information obtained by EPA, including information on potential for environmental transport, potential for or nature of transformation in the environment, and potential for bioaccumulation indicates that human or environmental exposure might occur; and

(iii) Information on release submitted with the premanufacture notice and any other information obtained by EPA indicates a potential for release resulting in human or environmental exposure.

(3) *Finding with respect to substances of unknown toxicity.* A finding under this paragraph (d)(3) may be made if all the following criteria are met:

(i) Sufficient data on toxicity have not been submitted with the premanufacture notice nor have other data been obtained by EPA (including data on analogues) which are sufficient to

determine whether the substance may be harmful to humans or the environment;

(ii) Information on chemical fate submitted with the premanufacture notice and other information obtained by EPA, including data on properties listed in paragraph (d)(2)(ii) of this section, indicates that significant human or environmental exposure might occur; and

(iii) Information on release submitted with the premanufacture notice and other information obtained by EPA indicates a potential for significant release resulting in human or environmental exposure.

(4) *Information which may be required.* EPA may require the following information with respect to the stage of the substance's life cycle for which appropriate findings are made:

(i) With respect to the manufacture, processing, or industrial use of the substance, EPA may require information concerning: pollution control equipment, existing treatment of the substance, specific aspects of the manufacturing or processing operation, uses of the substance, and other similar information.

(ii) With respect to distribution in commerce, EPA may require the types of information concerning the substance, and mixtures and articles containing the substance, that are listed in paragraph (c)(4)(ii) of this section.

(iii) With respect to disposal, EPA may require the types of information concerning the substance, and mixtures and articles containing the substance, that are listed in paragraph (c)(4)(iii) of this section.

(iv) With respect to end use, EPA may require the types of information concerning the substance, and mixtures and articles containing the substance, that are listed in paragraph (c)(4)(iv) of this section.

(e) *Processors' requirement to report information concerning potential risk resulting from direct human exposure.*—

(1) *General.* If EPA makes the findings set forth in paragraphs (c)(2) or (c)(3) of this section, and if EPA finds that there may be exposure in the processing, distribution in commerce, use, or disposal stages of a chemical substance's life cycle, the Agency may require any person who intends to process a substance for which a premanufacture notice was submitted to report the information specified in paragraph (e)(2) of this section, pertaining to that stage of a substance's life cycle.

(2) *Information which may be required.* EPA may require submittal of the types of information listed in

paragraph (c)(4) of this section, with respect to the stage of the substance's life cycle for which appropriate findings have been made. EPA will not require information concerning the manufacturing or import of the chemical substance under this paragraph.

(f) *Processors' requirement to report information concerning potential hazard to health or the environment resulting from environmental release.*—(1)

General. If EPA makes the findings in paragraphs (d)(2) or (d)(3) of this section, and if EPA finds that there may be exposure in the processing, distribution in commerce, use, or disposal stages of a chemical substance's life cycle, the Agency may require any person who intends to process a substance for which a premanufacture notice was submitted to report the information specified in paragraph (f)(2) of this section pertaining to that stage of a substance's life cycle.

(2) *Information which may be required.* EPA may require submittal of the types of information listed in paragraph (d)(4) of this section, with respect to the stage of the substance's life cycle for which appropriate findings have been made. EPA will not require information concerning the manufacturing or import of the chemical substance under this paragraph.

(g) *Person's requirements to submit other types of information, including information concerning the benefits of the substance and the economic consequences of any specified regulation.* If the finding in paragraphs (c)(2), (c)(3), (d)(2) or (d)(3) of this section is made, EPA may require the following information from submitters of premanufacture notices or persons intending to process the new chemical substance, as appropriate:

(1) Information concerning the identity of the submitter of the premanufacture notice, including information on place of incorporation and principal place of business;

(2) Information concerning other companies which are involved with the substance, including subsidiaries associated in commercialization activities, or other persons who may manufacture the substance in the U.S., or import the substance into the U.S. by virtue of an existing or planned business arrangement.

(3) Information concerning the identity of any persons who have either contracted to purchase, submitted a purchase order or made any other firm commitment to purchase the new chemical substance or related substances for processing, distribution in commerce, industrial or end use;

(4) Information concerning the benefits of the substance for various uses resulting from either the manufacture or the processing of the substance, and the availability of substitutes for those uses; and

(5) Information concerning the reasonably ascertainable economic consequences of any specified control measure under the Act, including impact on the national economy, small business, technological innovation, the environment, and public health.

(h) *Procedures for imposing a reporting requirement.*—(1) *Written notification from EPA.* If EPA makes the findings required by paragraphs (b)—(g) of this section, EPA will propose a supplemental reporting requirement. EPA will notify in writing any person who would be subject to a proposed reporting requirement under this section. The proposed requirement will be signed by the Assistant Administrator, or a Deputy Assistant Administrator, for Toxic Substances. The notification will be sent by certified mail, with return receipt requested. The written notification will include:

(i) A copy of this § 720.50;

(ii) A statement of the findings made by EPA under this section with respect to the Agency's need for the specified information;

(iii) A detailed description of the information which would be required, with a citation to the paragraph of this section under which the information would be required;

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

(v) The date by which the information would be submitted, which shall be no sooner than 15 days after the 10-day period for filing objections under paragraph (h)(2) of this section has ended; and,

(vi) Information on procedures under paragraph (h)(2) of this section for filing objections to the proposed reporting requirement.

(2) *Submitter's or processor's objections.* (i) Within 10 days after a submitter or processor receives the notice of a proposed reporting requirement, he may file written objections, requesting modification or explanation of the requirement or a change in the reporting schedule. Any such objections must specify that part of the proposed requirement which the submitter or processor seeks to modify and the basis for the objection. Any provisions of the reporting requirement concerning which no objections are received within the 10-day filing period will become final at the expiration of the 10-day period.

(ii) EPA will consider the objections filed, and the Assistant Administrator or Deputy Assistant Administrator for Toxic Substances will either revoke the proposed reporting requirement or promulgate a final requirement. EPA will notify the person who would be subject to the reporting requirement, by letter (certified mail, return receipt requested), of the Agency's response to the objection. The reporting rule will be final and effective upon receipt by the person subject to the reporting rule.

§ 720.51 Requirements for Submittal of Health and Safety Studies under section 8(d) of the Act

(a) * * *

(b) *Procedures.* (1) EPA will notify in writing any person who would be subject to a proposed reporting requirement under this section. The proposed requirement will be signed by the Assistant Administrator, or a Deputy Assistant Administrator, for Toxic Substances. The notification will be sent by certified mail, with return receipt requested. The written notification will include:

(i) A copy of this § 720.51;

(ii) A statement of the findings made by EPA under paragraph (a) of this section;

(iii) A description of the requested study;

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

(v) The date by which the information would be submitted, which shall be no sooner than 15 days after the 10-day period for filing objections under paragraph (b)(2) of this section has ended; and,

(vi) Information on procedures under paragraph (b)(2) of this section for filing objections to the proposed reporting requirement.

(2) *Submitter's or processor's objections or requests for modification.*

(i) Within 10 days after a person receives the notice of a proposed reporting requirement, he may file written objections, requesting modification or explanation of the requirement or a change in the reporting schedule. Any such objections must specify that part of the proposed requirement which the person seeks to modify and the basis for the objection. Any provisions of the reporting requirement concerning which no objections are received within the 10-day filing period will become final at the expiration of the 10-day period.

(ii) EPA will consider the objections filed, and the Assistant Administrator or Deputy Assistant Administrator for Toxic Substances will either revoke the

proposed reporting requirement or promulgate a final requirement. EPA will notify the person who would be subject to the reporting requirement, by letter (certified mail, return receipt requested), of the Agency's response to the objection. The reporting rule will be final and effective upon receipt by the person subject to the reporting rule.

BILLING CODE 6560-01-M

PROPOSED FORM



United States
Environmental Protection
Agency

PREMANUFACTURE NOTICE

DOMESTIC MANUFACTURERS

When completed send this form to:

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

EPA USE ONLY

Date of receipt

GENERAL INFORMATION

The Premanufacture Notice form for domestic manufacturers is divided into the following parts:

- Part I - General Information
- Part II - Human Exposure and Environmental Release
- Part III - List of Attachments
- Part IV - Federal Register Notice
- Part V - Optional Data

The optional part (part V) is not included in this package. All data requested in the mandatory parts (parts I, II, III, and IV) must be reported to the extent they are known to or reasonably ascertainable by the submitter. This means that the submitter is expected to answer all questions to the best of his/her ability, including making reasonable estimates in cases where complete factual information is not available. If the submitter is unable to make a reasonable estimate (i.e., the data is not known and is not reasonably ascertainable), he/she should enter "NA" (not available).

In part I, the submitter is required to report the specific chemical identity of the new substance, regardless of whether the information is claimed as confidential. In accordance with proposed §720.20(f), the submitter may authorize another person to report the specific chemical identity in his/her behalf. The notice will not be valid until the specific chemical identity is received by EPA.

If the space on the form is not sufficient to adequately answer a question, the submitter may attach additional sheets. Identify any continuation by part, section, subsection, and item.

ASSERTING AND SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Read Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality, for information on how to claim and substantiate confidential business information included in this form or in attachments to the form. Claims of confidentiality must be made in accordance with sections I and II of these instructions. In addition, substantiation of all claims of confidentiality

must be made in accordance with section IV of these instructions. If you claim any item in any attachment to this form confidential, see SPECIAL INSTRUCTIONS for attachments, Appendix A, Section II, Appendix B "Examples," provides additional guidance for asserting and substantiating claims of confidentiality.

In accordance with sections I and II of the confidentiality instructions, claims of confidentiality must be made by using the following six categories:

A. MANUFACTURER'S IDENTITY

A claim of confidentiality for Category A, Manufacturer's identity, automatically includes items 1, 2, and 3 in part I, section A.

B. SPECIFIC CHEMICAL IDENTITY

A claim of confidentiality for category B, Specific Chemical Identity, automatically includes items 1, 2, and 3 in part I, section B.

C. PRODUCTION VOLUME

A claim of confidentiality for category C, Production Volume automatically includes item 1 in part I, section D. These items do not need to be individually claimed.

D. USE DATA

A claim of confidentiality for category D, Use Data, automatically includes item 2 in part I, section D. These items do not need to be individually claimed.

E. PROCESS INFORMATION

A claim of confidentiality for category E, Process information, automatically includes items in part II, section A, subsection 2. These items do not need to be individually claimed.

F. OTHER INFORMATION

No items on the form are automatically included in this category. Thus all claims for this category must specify category F.

GENERAL CERTIFICATION

I hereby certify to the best of my knowledge and belief, that:

- a. The company named in section A, item 1, intends 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);
- b. All information entered on this Premanufacture Notice form is complete and truthful as of the date of submittal; and
- c. 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 also 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

CONFIDENTIALITY CERTIFICATION

I hereby certify to the truth and accuracy of the following four statements concerning all information which is claimed confidential.

- a. My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- b. The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without the company's consent;

- c. The information is not publicly available elsewhere; and
- d. Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

Signature of authorized official

Date

Part I - GENERAL INFORMATION

Section A - MANUFACTURER IDENTIFICATION

If you claim Manufacturer's identity confidential, mark (X) the box at the right. ☐
 The answers to items 1, 2, and 3 will be included in this claim.

If you claim the answers to items 4 or 5 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

		Confidential code	
1. Person Filing Notice	Name of authorized official	Title	
	Organization		
	Mailing address (Number and street)		
	City, State, ZIP code		
2. Technical Contact	Name	Title	
	Mailing address (Number and street)		
	City, State, ZIP code	Telephone	Area code Number
3. Parent Company	Name		
	Mailing address (Number and street)		
	City, State, ZIP code		
4. Enter the intended date of commencement of manufacture for commercial purposes. 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). ☐ Mark this box if you attach evidence.		Month	Year
5. If you have had a Prenotice Communication (PC) concerning this notice and EPA assigned a PC number to this notice, enter PC Number		Mark (X) if none ☐	

CONTINUE WITH SECTION B ON PAGE 3

Section B - CHEMICAL IDENTITY		Confidential code
If you claim Chemical Identity confidential, mark (X) the box at the right. ☐ The answers to items 1, 2, and 3 will be included in this claim. If you claim Chemical Identity confidential, is this claim limited to the period prior to manufacture? 1 ☐ Yes 2 ☐ No If you claim the answer to item 4 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E. Complete either 1, 2, or 3 as appropriate. Complete 4.		
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	
☐ Mark this box if you attach a continuation sheet.		
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 reactants with their respective CAS Registry Number(s) and describe the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.	
☐ Mark this box if you attach a continuation sheet.		

3. Polymers

- a. (1) Provide the specific chemical names and the CAS Registry Number of those monomers and other reactants used in the manufacture of the polymer. (2) Mark (X) the identity column if you wish monomers used at two percent (by weight) or less to be listed as part of the polymer description on the inventory. (3) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (4) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

Monomers and CAS Registry No. (1)	Identity Mark (X) (2)	Range of composition (3)	Maximum amount (weight percent) (4)	Confiden- tial code (5)
			%	
			%	
			%	
			%	

- b. Indicate the minimum average molecular weight or the minimum degree of polymerization of the polymeric compositions to which this notice applies.

☐ Mark this box if you attach a continuation sheet.

4. Impurities

- (a) List each impurity, including CAS Registry Number, which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. (b) Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R & D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. (c) Mark (X) if the concentration of an impurity will be specifically controlled because of your concern about potential adverse health or environmental effects. (d) Estimate the maximum total percent (by weight) of the impurities that may be present.

Impurity and CAS Registry number (a)	Maximum percent present (b)	Mark if to be specifically controlled (c)	Confiden- tial code
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
d. Total percent →	%		

☐ Mark this box if you attach a continuation sheet.

Section C - GENERIC NAMES

Complete this section only if Specific Chemical Identity is claimed confidential.

For instructions on how to develop generic names, see appendix II, 40 CFR 720 (44 FR 2278), Proposed Premanufacture Notification Requirements and Review Procedures.

1. Enter the generic name agreed on by EPA in Prenotice Communication or provide 3 generic names.

Section D - PRODUCTION AND MARKETING DATA

If you claim Production Volume confidential, mark (X) the box at the right. ☐
 The answers to item 1 will be included in this claim.

1. Estimate the minimum and maximum annual production volume for the first three years of production. Include in your estimates production by others with whom you have contracted to manufacture the new chemical substance.

Production year (1)	Production (Kg/yr)		Confidential code
	Minimum (2)	Maximum (3)	
a. First year			
b. Second year			
c. Third year			

2. Category of use

If you claim Use Data confidential, mark (X) the box at the right. ☐
 The answers to item 2 will be included in the claim.

- a. List the category(ies) of use on which you have based your production estimates. (Example: solvent used in automotive paint.) List partial information if complete information is not known. (Example: solvent.) Mark (X) the categories of use as site limited, industrial, commercial, or consumer. Estimate the percent of total production for the first 3 years devoted to each category of use.

Category of use (1)	Production percent (2)	Mark (X) appropriate column(s)				Confidential code
		Site limited (3)	Industrial (4)	Commercial (5)	Consumer (6)	
	%					
	%					
	%					

☐ Mark this box if you attach a continuation sheet.

- b. List any other category(ies) of use that you have actively explored

☐ Mark this box if you attach a continuation sheet.

- c. Do you intend or expect the new chemical substance to be used to treat drinking water supplies or to be used in products (e.g., paints or coatings) that will come in contact with drinking water?

1 ☐ Yes 2 ☐ No 3 ☐ Don't know

NOTE - If you claim the answers to items 3 or 5 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

3. Has the chemical substance been manufactured before?

1 ☐ Yes 2 ☐ No 3 ☐ Don't know

4. Hazard warnings

Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the new chemical substance.

☐ Mark this box if you attach a hazard warning.

5. Enter the number of customers who have either contracted to purchase, submitted a purchase order, or made any other firm commitment to purchase the new chemical substance from you for a category of use unknown to you. Estimate the percentage of your production volume that will be purchased by such customers during the first 3 years of production.

Number of customers	Percentage production volume	Confidential code

Section E - TRANSPORT

Complete this section if you intend to ship the new chemical substance from its site of manufacture.

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A-F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).

Confiden-
tial code

a. Shipping name

b. Hazard class

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance.

1 ☐ Truck

5 ☐ Plane

2 ☐ Railcar

6 ☐ Other - Specify

3 ☐ Barge, vessel

4 ☐ Pipeline

Section F - RISK ASSESSMENT

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

If you have evaluated the health or environmental risks which may be presented by the manufacture, processing distribution in commerce, use, or disposal of the new chemical substance attach your evaluation.

☐ Mark this box if you attach a risk assessment.

Section G - DETECTION METHODS

If you claim the answers to item 1 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

1. Is an analytical method available to identify and quantify the presence of the new chemical substance -

Confiden-
tial code

Identify			Quantify		
a. In workplace air?			e. In workplace air?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
b. In effluent streams?			f. In effluent streams?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
c. In materials requiring disposal?			g. In materials requiring disposal?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
d. In end products for which the new substance is an intermediate?			h. In end products for which the new substance is an intermediate?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know

Part II - HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A - INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

If you claim Process Information confidential, mark (X) the box at the right. ☐
 The answer to subsection 2 will be included in this claim.

If you claim the answers to items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E. If you claim the answers to items 3.3, 4.3, or 4.4 in subsections 3 or 4, or any items submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

Complete a separate subsection 1 and subsection 2 sheet for each site where you will manufacture, process or use the new chemical substance.

Subsection 1 - PROCESS INFORMATION

Confidential code

1.1 Identity of site	Name					
	Physical location address (Number and street)					
	City, County, State, ZIP code					
1.2 Type of site	1 ☐ Manufacturing	2 ☐ Processing	3 ☐ Use	4 ☐ Continuous	5 ☐ Batch	
1.3 Hours of operation	Days per year		Hours per day			
1.4 Amount manufactured, processed, or used	Minimum Kg/yr.		Maximum Kg/yr.			

Subsection 2 - BLOCK DIAGRAM

2.1 Provide a block diagram identifying the major unit operations and chemical conversions. Also include:

- For each chemical conversion in the block diagram identify the major chemical reactions and the major side reactions.
- Provide the approximate mass of all feed materials, byproduct materials, and products which are entering and leaving each major unit operation and chemical conversion. Indicate the method of transfer of these materials and whether the operation is open or closed to the workplace environment.
- Identify those points in the block diagram from which there will be releases of the new chemical substance or byproduct materials into the air, land, or water environment.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 - OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each site at which you will manufacture, process, use, or dispose of the new chemical substance. Indicate the anticipated route(s) of exposure to the new chemical substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A—Average or P—Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on maximum annual production, processing, or use during the first 3 years of manufacture under normal operating conditions with all engineering safeguards in place.

Confiden-
tial code3.1 Identity
of site

Name

Physical location address (Number and street)

City, County, State, ZIP code

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4)		Concentration (5)									
			Unit of measure	Mark (X) appropriate column A – Average P – Peak										
				0–1		1–10		10–100		> 100				
				A	P	A	P	A	P	A	P			
a. Manufacture					1 ☐ ppm 2 ☐ mg/m ³									
b. Processing					1 ☐ ppm 2 ☐ mg./m ³									
c. Use					1 ☐ ppm 2 ☐ mg./m ³									
d. Disposal					1 ☐ ppm 2 ☐ mg./m ³									

3.3 Describe those operations in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other — Specify2 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ LiquidConfiden-
tial code

3.5 For each site of manufacture, list any other substances (e.g., byproducts, co-products, feedstocks and intermediates) associated with the manufacture of the new chemical substance that may reasonably be anticipated to be present in the workplace and to which workers may be exposed. Provide the CAS Registry Number.

Substance (1)	CAS Registry Number (2)	Confiden- tial code

☐ Mark this box if you attach a continuation sheet.

► Subsection 4 – ENVIRONMENTAL RELEASE AND DISPOSAL Complete a separate subsection 4 for each site where you intend to manufacture, process, use or dispose of the new chemical substance.								Confidential code
4.1 Identity of site	Name _____ Physical location address (Number and street) _____ City, County, State, ZIP code _____							
4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.								
Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)					
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10–100 (5)	100–1000 (6)	1000–10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								
1 ☐ POTW (Publicly Owned Treatment Works) 2 ☐ Navigable waterway 3 ☐ Other			} Enter name _____					
d. Effluent stream flow rate _____ Gallons per day								
4.3 For each release point indicated in the block diagram, characterize the composition of the release materials.								
☐ Mark this box if you attach a continuation sheet.								
4.4 Describe pollution control equipment and disposal operations (e.g., scrubber, baghouse, landfill, incinerator, activated sludge, carbon absorption, etc.) used to treat individual or combined releases indicated in the block diagram(s) of manufacturing, processing, and use operations.								
☐ Mark this box if you attach a continuation sheet.								

Section B - INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete this section using your own forecasts, any information already obtained from other persons who may process, use, dispose of, or manufacture (under contract) the new chemical substance or any other information that is reasonably ascertainable. Complete a separate subsection 1 and subsection 2 for each site where you expect other persons to manufacture (under contract), process, use, or dispose of the new chemical substance.

If you claim the answers to the items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

If you claim the answers to items in subsection 2, or item 3.3 in subsection 3 confidential, see SPECIAL INSTRUCTIONS in appendix A, section II, part B.

► Subsection 1 - PROCESS INFORMATIONConfiden-
tial code1.1 Identity
of site
(Optional)

Name

Physical location address (Number and street)

City, State, ZIP code

County

► Subsection 2 - PROCESS DESCRIPTION

Briefly describe processing, use, or manufacturing operations conducted by others.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each industrial site where you expect other persons to process, use, dispose of, or manufacture the new chemical substance. Indicate the anticipated routes of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A–Average or P–Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on the maximum amount anticipated to be manufactured, processed, used, or disposed during the first 3 years of operation under normal conditions with all engineering safeguards in place.

Confidential code

3.1 Identity of site (optional)

Name

Physical location address (Number and street)

City, State, ZIP code

County

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4)		Concentration (5)									
					Unit of measure	Mark (X) appropriate column A – Average P – Peak								
						0–1		1–10		10–100		> 100		
			A	P		A	P	A	P	A	P			
a. Manufacture			Hrs./day	Days/yr.	1 ☐ ppm 2 ☐ mg/m ³									
b. Processing					1 ☐ ppm 2 ☐ mg/m ³									
c. Use					1 ☐ ppm 2 ☐ mg/m ³									
d. Disposal					1 ☐ ppm 2 ☐ mg/m ³									

3.3 Describe those activities in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other – Specify 2 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ Liquid

Confidential code

► Subsection 4 - ENVIRONMENTAL RELEASE AND DISPOSAL

Complete a separate subsection 4 for each site where other persons intend to manufacture, (under contract) process, use, or dispose of, the new chemical substance.

Confidential code

4.1 Identity of site (Optional)

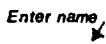
Name

Physical location address (Number and street)

City, State, ZIP code

County

4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.

Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)					Confidential code
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10-100 (5)	100-1000 (6)	1000-10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								
1 ☐ POTW (Publicly Owned Treatment Works) 2 ☐ Navigable waterway 3 ☐ Other								
Enter name 								
d. Effluent stream flow rate  Gallons per day								

4.3 (1) List any byproduct materials containing the new chemical substance that are generated during manufacturing, use, and processing operations and which are disposed of (e.g., landfill, incineration, or other physical/chemical treatment). Water effluent and air emission streams should not be listed here. Estimates of release of the new chemical substance contained in such streams are required to be reported in item 4.2. (2) Indicate the method of disposal. (3) Estimate the amount of each material generated (Kg/Kg of the new chemical substance), and (4) estimate the percent (by weight) of the new chemical substance.

Material requiring disposal (1)	Anticipated method of disposal (2)	Amount (Kg/Kg) (3)	Percent of new chemical substance (4)	Confidential code

☐ Mark this box if you attach a continuation sheet.

Section C - CONSUMER AND COMMERCIAL USER EXPOSURE

Complete this section for all consumer and commercial categories of use which involve use of a product that intentionally contains the new chemical substance. Provide the information based on your own forecasts, information already obtained from other persons, or any other information that is reasonably ascertainable.

If you claim the answers to Item 1 confidential, enter letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

If you claim the answers to items 2, 3, or 4 confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

1. Complete the table below. For each consumer and commercial use category reported in section D, Item 2, mark (X) if the product will be manufactured by the submitter or by other persons. Indicate the maximum number of consumers or commercial users expected to be exposed, the expected routes of human exposure and the frequency of exposure.

Category of use from part III, section D (1)	Use category (2)		Manufactured by - (3)		Exposure route(s) (4)	Maximum number exposed (5)	Frequency of exposure (6)				Confiden- tial code
	Consumer	Commercial	Submitter	Other			Daily	Weekly	Monthly	Yearly	

2. Attach any estimates that have been developed of potential exposure levels for each category of use.

☐ Mark this box if you attach any estimates.

3. For each product containing the new chemical substance, explain any aspect of its construction or formulation which you believe will limit the potential for exposure to the new chemical substance. For mixtures, indicate the maximum percent by weight of the chemical substance in the product.

☐ Mark this box if you attach a continuation sheet.

4. Identify any byproducts which are formed as a result of each category of use described in this section.

☐ Mark this box if you attach a continuation sheet.

Part III - LIST OF ATTACHMENTS

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 that are known to or reasonably ascertainable by him/her concerning the effect of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance on health or the environment. The regulations specify which data must be submitted with the notice and which data may be referenced by literature citations. Using the categories provided, identify (1) attachments containing test data, descriptions of data, or literature citations in accordance with 720.23; (2) other attachments required to be submitted with this notice; (3) confidentiality substantiations and (4) attachments which contain information voluntarily submitted. All attachments should be clearly identified and numbered.

To assert and substantiate a claim of confidentiality for any information included in the following attachments, follow the instructions in Appendix A, section II, part B. Note - Special directions for test data or other "Health and Safety" studies included in section III, part C.

The instructions provide that you must also submit a "sanitized" copy of the attachment with all information that you are claiming confidential deleted. EPA will place this copy in the public docket.

Attachment name		Attachment number		
a. Physical and chemical properties data				
b. Health and environmental effects data				
c. Notice attachments	Part	Section/Subsection	Item	
d. Confidentiality attachments				
e. Voluntary attachments				

☐ Mark this box if you attach a continuation sheet.

Part IV – FEDERAL REGISTER NOTICE

Information provided in this part will be published in the Federal Register in accordance with section 5(d)(2) of TSCA. Do not enter any information in this part for which you have asserted a claim of confidentiality.

Section A – CHEMICAL IDENTITY

Enter the specific chemical name of the substance if it is not claimed confidential. If the chemical identity is claimed confidential, enter the name agreed to by EPA in Prenotice Communication or EPA will enter one of the three proposed generic names in part I, section C.

Section B – MANUFACTURER IDENTIFICATION

Enter the legal title of the organization filing this notice if it is not claimed confidential. If the legal title of the organization is claimed confidential, provide a description of the organization in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

Section C – USE DATA

1. If use data were not claimed confidential in section D, list the category(ies) of use that you reported in section D, item 2a. Mark (X) if the use category(ies) is site limited, industrial, commercial, or consumer.

Category of use (1)	Mark (X) appropriate box			
	Site limited (2)	Industrial (3)	Commercial (4)	Consumer (5)

2. If use data were claimed confidential, provide a description of the category of use(s) of the chemical substance in accordance with section II, Appendix A, Instructions for Asserting and Substantiating Confidentiality. This description should be as specific as possible without revealing confidential information.

Section D – TEST DATA

List all test data concerning health and environmental effects of the manufacture, processing, distribution, in commerce, use, or disposal of the new chemical substance that are being submitted, described, or cited as part of this notice. Provide a brief abstract of all test data on the new chemical substance that are submitted in accordance with 720.23(a) and 720.20(j). If physical-chemical properties are claimed confidential, provide a generic description of these properties in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

☐ Mark this box if you attach a continuation sheet.

APPENDIX AINSTRUCTIONS FOR ASSERTING AND SUBSTANTIATINGCLAIMS OF CONFIDENTIALITYINTRODUCTION

These are the instructions for asserting and substantiating claims of confidentiality for any information you submit in a premanufacture notice (PMN). You may request confidential treatment for any item of information you submit in a PMN, whether it is entered on the PMN form or in attachments to the form.

To make this request, you must follow the procedures set out in these instructions. More specifically:

1. You must assert a claim of confidentiality, identifying

the information that you claim to be confidential. You must do this in accordance with these instructions, at the time you submit the PMN. Any information you do not claim as confidential will be included in the PMN public record without further notice to you.

2. You must substantiate your claims of confidentiality. You must do this in accordance with these instructions, at the time you submit the PMN. Otherwise, EPA may determine that you have waived your claims, and may then release the information in question, in accordance with section 720.40(c)(2).

3. For some of the items contained in the PMN, you must provide a non-confidential, generic (i.e. less specific) substitute for the information you claim to be confidential. In providing generic substitutes you must follow the instructions in this Appendix. Otherwise, EPA will develop its own generic substitutes, which it will publish after giving you notice. This third requirement applies to:

- The identity of the company submitting the notice;
- The specific chemical identity of the new chemical substance;
- The proposed categories of use of the substance; and
- Certain physical and chemical properties of the substance.

If you assert a claim of confidentiality and you substantiate that claim, EPA will disclose the information only as provided in the Agency's confidentiality regulations which appear in 40 CFR Part 2. Those regulations include provisions stating that, with specific exceptions, EPA will maintain the confidentiality of information claimed as confidential until the EPA General Counsels Office makes a final determination that certain information is not entitled to confidential treatment; and that if confidentiality is denied, the submitter will receive written notice 30 days before the date EPA will make the information available to the public.

ORGANIZATION OF THESE INSTRUCTIONS

These instructions are organized as follows:

- Section I describes six "categories" of confidentiality claims. The categories will apply to all claims, both those for items on the form and those for any information submitted separately as attachments.
- Section II - A explains how to assert a claim of confidentiality for information on the PMN form, and describes the steps you must take to "link" individual claims to the appropriate categories described in Section I.
- Section II - B explains how to assert a claim of confidentiality for information in attachments to the PMN form, and includes special instructions for asserting a claim for information in health and safety studies.
- Section III identifies the items in the PMN for which you must develop generic substitutes, and provides a method for creating these substitutes.
- Section IV describes how to provide the required substantiation for each of the five specific categories of information in which you have asserted a claim of confidentiality and for each piece of information that is claimed confidential which is not "linked" to the five specific categories.
- Section V describes the format for answering linkage and substantiation questions, and for justifying generic substitutes which are not developed in accordance with the instructions provided in Section III.

I. CATEGORIES OF CLAIMS

EPA has identified five categories of information into which most confidentiality claims will fall:

Category A: Manufacturer's (Importer's) Identity

Category B: Specific Chemical Identity

Category C: Production Volume

Category D: Uses of the New Chemical Substance

Category E: Process Information

You may wish to claim confidential treatment for information that does not fall under any of the categories A-E. These claims will be referred to in these instructions as "Category F" claims.

The instructions that follow explain how these six categories are to be used.

II. ASSERTING CONFIDENTIALITY CLAIMS

A. Use of the Categories to Assert Claims of Confidentiality for Information on the Premanufacture Notice Form

There are two ways to assert claims of confidentiality on the form. The first may be used for items that EPA has "linked" to one of the categories A-E. The second way must

be used for items that you have to link to one of these categories, or that you claim as a "category F" item. The instructions for each of these two ways of asserting claims follow.

(1) Linkages Identified by EPA

To assert a claim of confidentiality for any item on the PMN form in Column 2 (below) you must mark the box on the form next to that item. (EPA has already determined the category linkages for these items, as indicated under Column 1.) However, if the basis of your claim of confidentiality for any of the items listed in Column 2 does not correspond with the linkages given in Column 1, then you must use the procedures in the following section, "Linkages that You Must Indicate and Establish", to assert your claim.

Column 1

Column 2

Category

Identified

Linkages

A: Manufacturer's (Importer's) Identity	Part I, Section A, items 1,2, & 3
B: Chemical Identity	Part I, Section B, items 1,2, & 3
C: Production Volume	Part I, Section D, item 1
D: Use Data	Part I, Section D, item 2
E: Process Information	Part II, Section A

Subsection 2

F: Other

NONE

(2) Linkages that You Must Indicate and Establish

If you wish to claim confidentiality for any information not listed in Column 2 above, first you must indicate the category of information -- that is, in which of the categories A-F the item falls. To do this you must place the appropriate category letter(s) in the box next to the information you claim to be confidential. By doing this, you indicate the basis of your confidentiality claim.

Second, if you assert a claim by linking an item to one of the categories A-E, you must explain why the item would reveal information in that category. You must do this for each item, by answering the appropriate "linkage" questions below. If you assert a confidentiality claim in category F because disclosure would reveal other confidential information that is not in any of the categories A-E, you do not have to answer any linkage questions.

Linkage Questions

A: Manufacturer's (Importer's) Identity

For every item that you have marked with an "A", answer the following question:

How would disclosing this item reveal your company's identity?

B: Specific Chemical Identity

For every item that you have marked with a "B", answer the following question:

How would disclosing this item reveal the specific chemical identity?

C: Production Volume

For every item that you have marked with a "C", answer the following question:

How would disclosing this item reveal production volume?

D: Use Data

For every item that you have marked with a "D", answer the following question:

How would disclosing this item reveal the use(s) of the new chemical substance?

E. Process Information

For every item that you have marked with an "E", answer the following question:

How would disclosing this item reveal process information?

B. Asserting Claims of Confidentiality for Information in
Attachments to the PMN Form

To assert a claim of confidentiality for information in attachments to the PMN form, you must:

- Provide a complete copy of the attachment which (i) clearly indicates (e.g., by circling, underlining, bracketing) the information you wish to claim confidential, and (ii) identifies with a letter A-F the category on which your claim is based. (You should make clear to what information a particular letter refers.)
- Answer the appropriate linkage questions for each item claimed confidential in categories A-E.
- Submit a sanitized copy, deleting all the information that you claim as confidential on the original document. The sanitized version will be placed in the public docket.

C. Special Directions for Attachments Containing Test Data
or Other "Health & Safety Studies"

In general, you must assert a claim of confidentiality for information in health and safety studies in the same manner as for other attachments. However, when identifying the category on which a claim is based, you may find it necessary to claim an item confidential because it reveals confidential information on the portions of chemical substances in a mixture. For purposes of Health and Safety studies only, you should identify this information with an

"M". Each time you indicate this reason for asserting confidentiality, you must answer the following linkage question:

How would disclosing this information reveal the portion of any chemical substance in the mixture?

You may claim any data included in test data or health and safety studies confidential for any reason. However, in accordance with EPA's interpretation of section 14(b) of the Act, the Agency will deny confidentiality claims for any item not shown to reveal information in one of the following categories:

- specific chemical identity of the chemical substance (a claim on this basis alone will be upheld only until manufacture of the substance begins)
- process information
- portion of a mixture comprised by any of the chemical substances in the mixture
- other items of information such as manufacturer's identity, cost or financial data, marketing plans, only if they are unrelated to the health and safety effects of the substances. (Information on the methodology of the test and its results does not fall within this exception.)

III. PROVIDING GENERIC SUBSTITUTES FOR CERTAIN
INFORMATION ASSERTED TO BE CONFIDENTIAL

Certain information submitted on the form or in

attachments is particularly important for public participation in the assessment of new chemical substances. However, much of this information may be subject to claims of confidentiality. To balance these interests, EPA requires you to either provide generic (i.e. less specific) substitutes for certain items you claim confidential, or to explain why nonconfidential generic information cannot be developed. EPA will review the generic substitute or the explanation and notify you of its decision. After notifying you, EPA will make public the chosen non-confidential generic description. Note: You must provide EPA the specific information requested on the form. The generic substitute is for public disclosure. It should not be used as a substitute for any of the items on the form. Generic substitutes are for the following:

- If you assert a claim of confidentiality for specific chemical identity (Part I, section B of the form) you must provide three generic names in Part I, section C in accordance with the EPA Guidelines for Creating Proposed Generic Names for Confidential Chemical Substance Identities for Premanufacture Notification. EPA will select one generic name to publish in the FEDERAL REGISTER notice.
- If you assert a claim of confidentiality for category of use (Part I, section D of the form), you must provide generic use information for Part

III of the form in accordance with these instructions. EPA will publish the generic information in the FEDERAL REGISTER notice.

- If you submit (in an attachment) data on the new substance's vapor pressure, density, solubility, melting point, or boiling point/sublimation point, and if you assert a claim of confidentiality for such data, you must provide the data in the ranges specified in these instructions. These ranges will be placed in the public docket.
- If you assert a claim of confidentiality for manufacturer's identity (Part I, section A of the form) you must develop a description of the manufacturer for Part III of the form in accordance with these instructions to be published in the FEDERAL REGISTER notice.

The instructions for developing these four kinds of generic information follow.

A. Instructions for Generic Chemical Identity

Names

If (but only if) you claim specific chemical identity confidential and you have not agreed with EPA on a generic name during prenotice communication, you must provide three generic names to be included in the FEDERAL REGISTER notice, Part III, Section A, of the PMN form. These names must be provided in accordance with the Guidelines for Creating Proposed Generic Names for Confidential Chemical Substance

Identities for Premanufacture Notification.

B. Instructions for Generic Descriptions
of Manufacturer's Identity

If you have claimed your company's identity confidential, use the following scheme to develop a generic description of the company identity for inclusion in the FEDERAL REGISTER notice, Part III, section B of the PMN form.

Instructions for Selection of Characteristics

Select from List 1, Geographic Location of the Company, the region of the country in which the intended site of manufacture is located. If you do not know the site, identify the region in which your company's headquarters is located.

Select from List 2, Size of Company in Total Annual Sales, the category in which your company's total annual sales figure fall. This figure should be based on the company's latest complete fiscal year and should reflect the entire corporate entity.

Identify the three-digit Standard Industrial Classification (SIC) Code for the manufacturing site. If you do not know the site, identify the primary SIC code for the entire company. If the three-digit code will reveal the company's identity taken together with the information on geographic location and annual sales, provide a two-digit code and a brief explanation of why a three-digit code is

Once you have selected the appropriate characteristics, you may use them to write a generic manufacturer identity description. Alternatively, you may select the characteristics and enter them in the spaces provided on the form. In this case, EPA will compose the generic manufacturer identity based upon the selected descriptors. The following example is provided as a suggested format for composing generic manufacturer identity descriptions. If the Agency composes any descriptions, it will follow this format.

Example: ABC Chemicals Company has corporate headquarters in Chicago, Illinois, with total annual sales of \$87,500,000. It intends to produce the new substance at its plant in Los Angeles, California, which has SIC code 2861. The company's general description would read as follows: "The submitter has total annual sales of between \$10,000,000 and \$99,999,999, and intends to produce the new chemical substance at a plant in the Pacific region of the country whose three-digit Standard Industrial Classification code is 286, "Industrial Organic Chemicals".

List of CharacteristicsList 1 Geographic Location of the CompanyRegion

Northeast: Connecticut, Maine, Massachusetts,

New Hampshire, Rhode Island, Vermont

Middle Atlantic: New Jersey, New York, Pennsylvania

East North Central: Illinois, Indiana, Michigan, Ohio,
Wisconsin

West North Central: Iowa, Kansas, Minnesota, Missouri,
Nebraska, North Dakota, South
Dakota

South Atlantic: Delaware, District of Columbia,
Florida, Georgia, Maryland, North
Carolina, South Carolina, Virginia,
West Virginia

East South Central: Alabama, Kentucky, Mississippi,
Tennessee

West South Central: Arkansas, Louisiana, Oklahoma,
Texas

Mountain: Arizona, Colorado, Idaho, Montana, Nevada,
New Mexico, Utah, Wyoming

Pacific: Alaska, California, Hawaii, Oregon, Washington

List 2 Size of Company

- a) under \$1,000,000
- b) \$1,000,000 to \$9,999,999
- c) \$10,000,000 to \$99,999,999
- d) \$100,000,000 to \$499,999,999
- e) \$500,000,000 and up

C. Instructions for Generic Use Information

If (but only if) you claim the categories of use or intended uses of the substance confidential, you must use the following method to develop generic use information to be included in the section 5(d)(2) FEDERAL REGISTER notice, Part III, section C, of the PMN form.

Select from List 1, Degree of Containment, the characteristics which describe the degree of containment of the substance. Some examples are included in List 1, to help explain the meaning of the terms. Most industrial uses of chemicals will fall in the "open use" or "dispersive use" categories. Most consumer uses will be classified as "highly dispersive". If no characteristic is appropriate, provide an appropriate term on the line marked "other".

Select from List 2, Level of Environmental Release, one characteristic to represent the total loss to the environment due to the use. Total loss includes losses from commercial and industrial waste streams and fugitive emissions, consumer end use, and final consumer disposal as solid waste.

Select from List 3, Type of Population Exposed, the characteristic which describe each type of population that may be exposed to the substance due to its use. Many uses will involve some commercial or industrial exposure as well as some consumer exposure. In the case of some printing inks, for example, the press operators are exposed to them

as are the consumers who handle the printed material. In these cases, more than one type of population characteristic should be chosen for each category of use or intended use.

Select from List 4, Environmental Release, the necessary descriptors for each type of release to the environment due to the use. Only identify the releases that give information about the use of the substance. For example, using an industrial coating on furniture production may involve some release of spent lacquers to a landfill. However, during the use of the substance, release would result from the evaporation of solvents from the coatings. In this case, you would report the releases as an industrial or commercial loss or waste stream to the air, but not a release to a landfill. Some releases, particularly some industrial releases, may not give any information about the use. In these cases you should choose descriptor (e).

For each type of population identified above, select as many descriptors as appropriate from List 5, Type of Human Contact.

For each type of population identified above select one descriptor from List 6, Frequency of Use or Human Contact. Most consumer uses will imply an average frequency of use. For example, dishwashing detergents may be used an average of five times per week. Industrial and commercial uses may differ, since discrete occurrences of use are replaced by frequent or perhaps continuous exposure to substances which are used daily. Either type of use can be classified by the

descriptors in List 6. Group the descriptors from List 5 and 6 according to the exposed populations identified.

Once you have selected the appropriate characteristics, you may use them to write narrative generic substitutes for the use information you claim confidential. Alternatively, you may select the characteristics and enter them in the space provided on the form. In this case, EPA will compose the narrative generic substitute based upon the selected descriptors. The following example is provided as a suggested format for composing narrative generic substitutes for use information. If the Agency composes any generic substitutes, it will follow this format.

Example: The premanufacture notice indicates that the substance will be used in an open use that will release more than 50 kilograms but less than 5,000 kilograms of the substance to the environment per year. The manufacturer states that the use will involve exposure to non-chemical industry employees more than five times per week with intended skin contact and a potential for eye contact. The use will also involve exposure for consumers as part of an article with an average exposure frequency of once a month or less and a potential for skin and eye contact. There will be release to the environment as an industrial loss to the air and in an industrial waste stream to a Publicly Owned Treatment Works (POTW) as well as release to the air from a consumer end use.

LIST OF CHARACTERISTICSList 1 Degree of Containment

- | | |
|---------------------------|--|
| a) destructive use | (e.g., fuels, fuel additives, chemical intermediates) |
| b) contained use | (e.g., closed processes, fluids sealed in products) |
| c) open use | (cases somewhere in between dispersive uses and contained uses) |
| d) dispersive use | (e.g., some textile dyes, automobile tire rubber, friction devices) |
| e) highly dispersive use | (e.g., pesticides, fertilizers, salt for snow removal, paint solvents) |
| f) other, please describe | _____ |

List 2 Level of Environmental Release

- a) less than 50 kg/year
- b) more than 50 kg/year but less than 5,000 kg/year
- c) more than 5,000 kg/year but less than 50,000 kg/year
- d) more than 50,000 kg/year

List 3 Type of Population Exposed

- a) industrial employees - chemical
- b) industrial employees - non-chemical
- c) commercial employees - maintenance, services and retail sales
- d) consumers - formulated products (e.g., mixtures)
- e) consumers - part of an article

List 4 Environmental Release

As an industrial or commercial loss or waste stream

- a) - to air
- b) - to water
- c) - to a Publicly Owned Treatment Works (POTW)
- d) - to a landfill
- e) - other, please describe

Consumer end use

- f) - to air
- g) - to navigable waters
- h) - to a Publicly Owned Treatment Works (POTW)
- j) - final consumer disposal as solid waste

List 5 Type of Human Contact

- a) - very low potential for contact
- b) - potential skin contact
- c) - potential eye contact
- d) - potential oral contact
- e) - potential inhalation
- f) - potential ingestion
- g) - intended skin contact
- h) - other, please describe

List 6 Average Frequency of Human Contact

- a) - once a year or less
- b) - once a month or less
- c) - once a week or less
- d) - more than once per week
- e) - five times per week
- f) - continuous or very frequent exposure during
working hours
- g) - other, please describe

D. Instructions for Providing Generic Physical and
Chemical Properties

You must use the ranges provided below for vapor pressure, density, solubility, melting point and boiling point/sublimation point if you claim these physical and chemical properties confidential because disclosing the "specific" value for any of them would

reveal confidential business information. If you do not use these ranges, provide a range of your own and explain why such an expanded or different range is necessary to protect the confidential business information. If you claim any other specific physical and chemical properties confidential, provide a range of your own choosing. This nonconfidential information will be placed in the public docket.

Ranges for Reporting Physical and Chemical Properties

Vapor Pressure

Temperature _____	☐ 0 - 10 ⁻²	
	☐ 10 ⁻² - 1	torr
	☐ 1 - 10	torr
	☐ 10 - 100	torr
	☐ 100 - 1000	torr
	☐ >1000	torr

Density (Liquid or Solid)

☐ <.9	gm/cc
☐ .9 - 1.1	gm/cc
☐ >1.1	gm/cc

Solubility

Temp _____	☐ <10 ⁻⁶	gm/l
Solvent _____	☐ 10 ⁻⁴ - 10 ⁻⁶	gm/l
	☐ 10 ⁻⁴ - 10 ⁻²	gm/l
	☐ 10 ⁻² - 1	gm/l
	☐ 1 - 10	gm/l
	☐ >10	gm/l

Melting Point

☐ <0C°
☐ 0 - 30C°
☐ 30 - 50C°
☐ 50 - 100C°
☐ >100C°

Boiling Point/Sublimation Point

☐ <0C°
☐ 0 - 30C°
☐ 30 - 50C°
☐ 50 - 100C°
☐ 100 - 200C°
☐ >200C°

IV. SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

In addition to asserting a claim as explained in sections I - III of the instructions, notice submitters must do the following to substantiate claims of confidentiality for information on the PMN form or in attachments to the form.

A. GENERAL CERTIFICATION

The person who signs the form must certify the truth and accuracy of the following four statements which apply to all information claimed confidential. (Note: The certification is only to be signed once for the entire form and attachments):

- a. My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- b. The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without my company's consent;
- c. The information is not publicly available elsewhere; and
- d. Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

B. CATEGORY A: Manufacturer's (Importer's) Identity

To substantiate claims for Category A, Manufacturer's Identity, you need only sign the confidentiality certification. You are not required to answer any specific questions for this category.

C. CATEGORY B, C, D, E, and M: SPECIFIC QUESTIONS

In addition to the certification, you must answer the following questions if you claim information confidential in these categories. (Note: for each category, you must answer the questions only once, regardless of the number of times you claim information confidential in that category.)

Category B - Specific Chemical Identity

1. How would disclosing the specific chemical identity substantially harm your competitive position? Be specific about the connection between disclosure and the harm.
2. How long should confidential treatment be given (until a specific date, until the occurrence of a specific event, or permanently)? Why?
3. Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent? If the substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?
4. To what extent has it been revealed to others that this chemical substance is or will be manufactured or imported for a commercial purpose? What precautions

have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

5. Has this particular chemical substance left your site in any form, e.g., as product, effluent, emission? If so, what measures have you taken to guard against discovery of its identity? Before you begin manufacture of this substance will it leave your site in any form? If so, what measures will you take to guard against discovery of its identity?
6. If the chemical substance has left the site in a product that is available to the public or your competitors, can the substance be identified by analysis of the product?
7. Has EPA, another federal agency, or any federal court made any pertinent confidentiality determinations regarding this information? If so, please attach copies of such determinations.
8. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA keeps confidential the link between your company identity and the specific chemical identity, your identity will not be associated in any way with the chemical identity. In this case, what harm to your competitive position would result from disclosing only the specific chemical identity? How could a

competitor use this information? What is the casual relationship between the disclosure and the harm?

Category C - Production Volume

1. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA keeps confidential the link between your company identity and production volume, your identity will not be associated in any way with the production volume. In this case, what harm to your competitive position would result from disclosing the production volume? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?
2. If you have claimed confidentiality for chemical identity (Category B) so that the chemical identity (other than generic name) is not associated in any way with production volume, what harm to your competitive position would result from disclosing the production volume? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

Category D - Use Data

1. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA keeps confidential the link between your company identity and the use data, your identity will not be associated in any way with the use data. In this

case, what harm to your competitive position would result from disclosing the use data? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

2. If you have claimed confidentiality for chemical identity (Category B) so that the chemical identity (other than generic name) is not associated in any way with the use data, what harm to your competitive position would result from disclosing the use data? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

Category E - Process Information

1. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA keeps confidential the link between your company identity and process information, your identity will not be associated in any way with this information. In this case, what harm to your competitive position would result from disclosing the process information? How could a competitor use such information? What is the causal relationship between the disclosure and the harmful effects?
2. If you have claimed confidentiality for chemical identity (Category B) so that the chemical identity (other than generic name) is not associated in any way with the process information, what harm to your

competitive position would result from disclosing the process information? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

Category M: Portions of a Mixture

(Only for use in Health and Safety Studies)

1. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA keeps confidential the link between your company identity and the proportions of the mixture, your identity will not be associated in any way with this information. In this case, what harm to your competitive position would result from disclosing the proportions of the mixture? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?
2. If you have claimed confidentiality for chemical identity (Category B) so that the chemical identity (other than generic name) is not associated in any way with the proportions of the mixture, what harm to your competitive position would result from disclosing the proportions of the mixture? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

D. CATEGORY F - OTHER INFORMATION - SPECIFIC QUESTIONS

For Category F, Other Information, you must answer the following questions each time you claim information confidential for that category:

1. Is the item confidential in and of itself? If so, what is revealed by its disclosure?
2. Is the item confidential because it will reveal some other confidential information, whether or not that other information is reported on this form? If so, what is the information that will be revealed?
3. Is the item confidential because it will reveal other confidential information when the item is disclosed in association with some other item(s) submitted on this form? If so, what are those item(s)?
4. If the answer to 1, 2, or 3 is yes, what harm would disclosing the confidential information cause to your competitive position? How would disclosure lead to this harm?
5. If you have claimed confidentiality for manufacturer's identity (Category A) and EPA maintains the confidentiality of the link between your company identity and this information, your identity will not be associated in any way with the item claimed. In this case what harm to your competitive position would result from disclosing the item? How could a competitor use this information?

What is the causal relationship between the disclosure and the harm?

6. If you have claimed confidentiality for chemical identity (Category B) so that the chemical identity (other than generic name) is not associated in any way with the item claimed, what harm to your competitive position would result from disclosing the item? How could a competitor use this information? What is the causal relationship between the disclosure and the harm?

V. FORMAT FOR RESPONSES TO LINKAGE AND SUBSTANTIATION QUESTIONS AND JUSTIFYING GENERIC SUBSTITUTES

Any attachments to the premanufacture notice form that either (i) establish linkages to the EPA categories of claims, or (ii) substantiate information claimed confidential, or (iii) justify generic substitutes should follow the format described below:

1. The responses for any one category -- whether establishing a linkage, substantiating a claim of confidentiality, or justifying a generic substitute should be grouped together. For example, responses to linkage questions, substantiation questions and any explanation of why the EPA approach to developing generic substitutes was not used (if it was not used), about the information in the use data category should be grouped together.

2. With your responses grouped by category, you should then arrange the groups in the order of the categories themselves, starting with A. For example, if category A (manufacturer's identity) and category D (use data) are claimed confidential, the responses in category D should all follow the responses in category A. An outline of your attachments if you make confidentiality claims in each of the categories might be the following:

I. Category A Claims (Manufacturer's Identity)

A. Answers to linkage questions.

B. Justification of a generic substitute (only if you do not use EPA's guidelines for providing this information.)

(To substantiate a claim of confidentiality for Manufacturer's Identity, sign the Confidentiality Certification statement appearing on the front of the PMN form.)

II. Category B Claims (Specific Chemical Identity)

A. Answers to linkage questions.

B. Justification of generic description (only if you do not use EPA's guidelines for providing this information.)

C. Answers to substantiation questions.

III. Category C Claims (Production Volume)

A. Answers to linkage questions

B. Answers to substantiation questions

- IV. Category D Claims (Use of the New Chemical Substance)
 - A. Answers to linkage questions.
 - B. Justification for generic description (only if you do not use EPA's guidelines for providing this information.)
 - C. Answers to substantiation questions.
- V. Category E Claims (Process Information)
 - A. Answers to linkage questions
 - B. Answers to substantiation questions
- VI. Category F Claims (Other)
 - A. Answers to substantiation questions for each item claimed in this category.

EPA will treat as confidential the information provided to justify confidentiality claims, so long as this information is clearly marked CONFIDENTIAL.

Appendix B

Examples of Asserting and Substantiating Claims of Confidentiality

The following three examples are provided to illustrate how a submitter would assert a claim of confidentiality.

Example 1 - Manufacturer's Identity **(Part I, Section A)**

Absolusol Company has filed a PMN. The company is asserting a claim of confidentiality for the company name because public disclosure of the fact that this company intends to manufacture a new chemical substance would reveal confidential business information. As illustrated on the attachment, a check has been placed in the box to indicate

that the company is asserting this claim. The answers to Questions 1, 2 and 3 of Part I, Section A are automatically included in the claim of confidentiality for manufacturer's identity when this single box is checked.

In accordance with EPA's instructions for claiming confidentiality for manufacturer's identity, Absolusol has provided EPA a generic description in Part III of the form which will be published in the FEDERAL REGISTER notice. (See attached sample page.)

The company is also asserting a claim of confidentiality for the answer to Question 4, intended date of commencement of manufacture for commercial purposes. The company has placed an "A" in the box next to Question 4 because the company is asserting that disclosure of this information will reveal the company identity. The company explains how disclosure of the answer to question 4 will reveal company identity by responding to the linkage question found in the instructions.

To substantiate the claim of confidentiality for all category A claims, Samuel Hunter, President of Absolusol Company, has signed the confidentiality certification statement appearing on the front of PMN form. No other substantiation is required for claims in this category.

PROPOSED FORM



United States
Environmental Protection
Agency

PREMANUFACTURE NOTICE

DOMESTIC MANUFACTURERS

When completed send this form to:

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

EPA USE ONLY
Date of receipt

GENERAL INFORMATION

The Premanufacture Notice form for domestic manufacturers is divided into the following parts:

- Part I - General Information
- Part II - Human Exposure and Environmental Release
- Part III - Use of Attachments
- Part IV - Federal Register Notice
- Part V - Optional Data

The optional part (part V) is not included in this package. All data requested in the mandatory parts (parts I, II, III, and IV) must be reported to the extent they are known to or reasonably ascertainable by the submitter. This means that the submitter is expected to answer all questions to the best of his/her ability, including making reasonable estimates in cases where complete factual information is not available. If the submitter is unable to make a reasonable estimate (i.e., the data is not known and is not reasonably ascertainable), he/she should enter "NA" (not available).

In part I, the submitter is required to report the specific chemical identity of the new substance, regardless of whether the information is claimed as confidential. In accordance with proposed §720.20(f), the submitter may authorize another person to report the specific chemical identity in his/her behalf. The notice will not be valid until the specific chemical identity is received by EPA.

If the space on the form is not sufficient to adequately answer a question, the submitter may attach additional sheets. Identify and continuation by part, section, subsection, and item.

ASSERTING AND SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Read Appendix A, Instructions for Asserting and Substantiating Claims of confidentiality, for information on how to claim and substantiate confidential business information included in this form or in attachments to the form. Claims of confidentiality must be made in accordance with sections I and II of these instructions. In addition, substantiation of all claims of confidentiality

must be made in accordance with section IV of these instructions. If you claim any item in any attachment to this form confidential, see SPECIAL INSTRUCTIONS for attachments, Appendix A, Section II. Appendix B "Examples," provides additional guidance for asserting and substantiating claims of confidentiality.

In accordance with sections I and II of the confidentiality instructions, claims of confidentiality must be made by using the following six categories:

A. MANUFACTURER'S IDENTITY

A claim of confidentiality for Category A, Manufacturer's identity, automatically includes items 1, 2, and 3 in part I, section A.

B. SPECIFIC CHEMICAL IDENTITY

A claim of confidentiality for category B, Specific Chemical identity, automatically includes items 1, 2, and 3 in part I, section B.

C. PRODUCTION VOLUME

A claim of confidentiality for category C, Production Volume automatically includes item 1 in part I, section D. These items do not need to be individually claimed.

D. USE DATA

A claim confidentiality for category D, Use Data, automatically includes item 2 in part I, section D. These items do not need to be individually claimed.

E. PROCESS INFORMATION

A claim of confidentiality for category E, Process Information, automatically includes items in part II, section A, subsection 2. These items do not need to be individually claimed.

F. OTHER INFORMATION

No items on the form are automatically included in this category. Thus all claims for this category must specify category F.

GENERAL CERTIFICATION

I hereby certify to the best of my knowledge and belief, that:

- a. The company named in section A, item 1, intends 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);
- b. All information entered on this Premanufacture Notice form is complete and truthful as of the date of submittal; and
- c. 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 also 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

Samuel Hunter, President

Date

Sept. 15, 1979

CONFIDENTIALITY CERTIFICATION

I hereby certify to the truth and accuracy of the following four statements concerning all information which is claimed confidential.

- a. My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- b. The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without the company's consent;

- c. The information is not publicly available elsewhere; and
- d. Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

Signature of authorized official

Samuel Hunter, President

Date

Sept. 15, 1979

Part I - GENERAL INFORMATION

Section A - MANUFACTURER IDENTIFICATION

If you claim Manufacturer's identity confidential, mark (X) the box at the right. ☒
 The answers to items 1, 2, and 3 will be included in this claim.

If you claim the answers to items 4 or 5 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

					Confiden- tial code	
1. Person Filing Notice	Name of authorized official	Samuel Hunter.				
	Title	President				
	Organization	Absolusol Company				
	Mailing address (Number and street)	1820 State Street				
	City, State, ZIP code	Boston, Mass. 01792				
2. Technical Contact	Name	Sally Murphy, Ph.D.				
	Title	Project Engineer				
	Mailing address (Number and street)	1820 State Street				
	City, State, ZIP code	Boston, Mass. 01792				
	Telephone	607	Area code	992	Number	8666
3. Parent Company	Name	N/A				
	Mailing address (Number and street)					
	City, State, ZIP code					
4. Enter the 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). ☐ Mark this box if you attach evidence.		April 1	1980			
5. If you have had a Prenotice Communication (PC) concerning this notice and EPA assigned a PC number to this notice, enter PC Number		1	Mark (X) if none		☐	

SAMPLE

CONTINUE WITH SECTION B ON PAGE 3

Part IV - FEDERAL REGISTER NOTICE

Information provided in this part will be published in the Federal Register in accordance with section 5(d)(2) of TSCA. Do not enter any information in this part for which you have asserted a claim of confidentiality.

Section A - CHEMICAL IDENTITY

Enter the specific chemical name of the substance if it is not claimed confidential. If the chemical identity is claimed confidential, enter the name agreed to by EPA in Prenotice Communication or EPA will enter one of the three proposed generic names in part I, section C.

This section would be completed in accordance with the instructions.

Section B - MANUFACTURER IDENTIFICATION

Enter the legal title of the organization filing this notice if it is not claimed confidential. If the legal title of the organization is claimed confidential, provide a description of the organization in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

The submitter has total annual sales of between \$1,000,000 and \$9,999,999, and intends to produce the new chemical substance at a plant in the Northeast region of the country whose three digit Standard Industrial Classification code is 307.

Section C - USE DATA This section would be completed in accordance with the instructions.

1. If use data were not claimed confidential in section D, list the category(ies) of use that you reported in section D, item 2a. Mark (X) if the use category(ies) is site limited, industrial, commercial, or consumer.

Category of use (1)	Mark (X) appropriate box			
	Site limited (2)	Industrial (3)	Commercial (4)	Consumer (5)

2. If use data were claimed confidential, provide a description of the category of use(s) of the chemical substance in accordance with section II, Appendix A, Instructions for Asserting and Substantiating Confidentiality. This description should be as specific as possible without revealing confidential information.

Section D - TEST DATA This section would be completed in accordance with the instructions.

List all test data concerning health and environmental effects of the manufacture, processing, distribution, in commerce, use, or disposal of the new chemical substance that are being submitted, described, or cited as part of this notice. Provide a brief abstract of all test data on the new chemical substance that are submitted in accordance with 720.23(a) and 720.20(j). If physical-chemical properties are claimed confidential, provide a generic description of these properties in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

-- ☐ Mark this box if you attach a continuation sheet.

(This information would be provided in an attachment to the form.)

CONFIDENTIAL

Sample

Confidentiality Claims

Category A

Linkage Question

A. Manufacturer's (Importer's) Identity

For every item that you have marked with an "A", answer the following question:

How would disclosing this item reveal your company's identity?

Part I, Section A, Question 4:

"This information in conjunction with the generic information provided for the manufacturer's identity and chemical identity would reveal our company name because we are the only company of our size located in the northeast with the capability of manufacturing a new chemical substance of this type within the next six months. When we introduce our new product it will be clear that our company submitted the premanufacture notice."

Example 2 - Chemical Identity

(Part II, Section B)

Beeswax Incorporated has filed a PMN. The company is asserting a claim of confidentiality for information in category B, specific chemical identity. As illustrated on the form, a check has been placed in the box to indicate that the company is asserting this claim. The answers to items 1, 2, and 3 are automatically included in the claim of confidentiality. In accordance with EPA's instructions for claiming confidentiality for specific chemical identity the company has provided three generic name(s) from which EPA will choose a single name for publication in the FEDERAL REGISTER notice along with other information in Part III of the form.

The company is also asserting a claim of confidentiality for information on impurities provided in response to question 4. Because the answer to question 4 is not automatically linked to the claim of confidentiality for category B, specific chemical identity, Beeswax must place a "B" in the box next to question 4, and answer the following linkage question in Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality:

B: Specific Chemical Identity

For every item that you have marked with a "B", answer the following question:

How would disclosing this item reveal the specific chemical identity?

The answers to the linkage question and the answer to the substantiation questions for category B, chemical identity, were attached to the form by the company.

Section B - CHEMICAL IDENTITY

If you claim Chemical Identity confidential, mark (X) the box at the right. ☒
The answers to items 1, 2, and 3 will be included in this claim.

If you claim Chemical Identity confidential, is this claim limited to the period prior to manufacture? 1 ☒ Yes 2 ☐ No

If you claim the answer to item 4 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

Complete either 1, 2, or 3 as appropriate. Complete 4.

Confidential code

1. Class 1
Chemical
Substance
(other than
polymers)

a. CAS Registry No. (if known)
103-88-8

b. Specific chemical name

N-(4-bromophenyl) acetamide

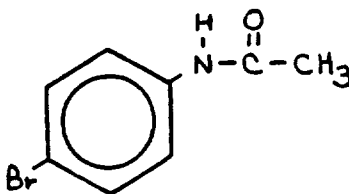
c. Molecular formula
C₈H₈ONBr

d. Synonyms
4-bromo acetanilide, p-bromo acetanilide

e. Trademarks

N/A

f. Structural diagram



☐ Mark this box if you attach a continuation sheet.

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 reactants with their respective CAS Registry Number(s) and describe the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

☐ Mark this box if you attach a continuation sheet.

3. Polymers

a. (1) Provide the specific chemical names and the CAS Registry Number of those monomers and other reactants used in the manufacture of the polymer. (2) Mark (X) the identity column if you wish monomers used at two percent (by weight) or less to be listed as part of the polymer description on the inventory. (3) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (4) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

Monomers and CAS Registry No. (1)	Identity Mark (X) (2)	Range of composition (3)	Maximum amount (weight percent) (4)	Confiden- tial code (5)
			%	
			%	
			%	
			%	

b. Indicate the minimum average molecular weight or the minimum degree of polymerization of the polymeric compositions to which this notice applies.

☐ Mark this box if you attach a continuation sheet.

SAMPLE

4. Impurities

(a) List each impurity, including CAS Registry Number, which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. (b) Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R & D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. (c) Mark (X) if the concentration of an impurity will be specifically controlled because of your concern about potential adverse health or environmental effects. (d) Estimate the maximum total percent (by weight) of the impurities that may be present.

Impurity and CAS Registry number (a)	Maximum percent present (b)	Mark if to be specifically controlled (c)	Confiden- tial code
2,4-dibromo acetanilide (23373-04-8)	.5 %		B
N,N-diacetylaniline (NA)	.01 %		B
acetanilide (103-84-4)	.1 %		B
	%		
	%		
	%		
	%		
	%		
	%		
4. Total percent →	.7 %		

☐ Mark this box if you attach a continuation sheet.

Section C - GENERIC NAMES

Complete this section only if Specific Chemical Identity is claimed confidential.

For instructions on how to develop generic names, see appendix II, 40 CFR 720 (44 FR 2278), Proposed Premanufacture Notification Requirements and Review Procedures.

1. Enter the generic name agreed on by EPA in Prenotice Communication or provide 3 generic names.

4-substituted acetanilide

4-substituted bromobenzene

N-(bromo carbomonocycle) acetamide

SAMPLE

SAMPLE

(Submitter's Attachment to the Form)

Confidentiality Claims

Category B

CONFIDENTIAL

1. Linkage Question for Question 4 of Part I, Section B:

Disclosure of the information that one of the impurities is 2,4-dibromo acetanilide in conjunction with the generic name "4-substituted acetanilide" clearly reveals that the masked substituent in the generic name is bromine.

In addition disclosure of the information that N,N-diacetylaniline and acetanilide are minor impurities in conjunction with generic names 2 or 3 reveals that the masked portion of the molecular structure is an acetamide derivative. Therefore, the information in question 4 plus the generic names would disclose the specific chemical identity which we claim is confidential business information.

2. Substantiation for All Claims in Category B:

(Beeswax Incorporated's answers to the substantiation questions would begin here.)

Example 3 - Health and Safety Study

(Attachment)

This example illustrates how a submitter would assert a claim of confidentiality for information in a health and safety study. Examples of substantiation for this information are not provided.

Pinnacle Chemical Company filed a PMN and submitted a health and safety study as an attachment to the PMN form. It claimed confidentiality for information in the health and safety study under Category A, Manufacturer's Identity, and Category B, Specific Chemical Identity. Pinnacle identified these confidential items in the health and safety study by circling them where they appear in the study and by writing the appropriate category letter (A or B, in this case) in the margin next to the circled information. (In addition to the claims illustrated in this example, Pinnacle made the claims on the PMN form itself in accordance with EPA's reporting instructions. The company also adhered to the guidelines for developing a generic manufacturer's identity and three generic chemical names in Part III of the form, for publication in the Section 5(d)(2) FEDERAL REGISTER notice).

Pinnacle answered the linkage questions for Categories A & B that are found in Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality. The company also submitted an explanation establishing that its identity is unrelated to the health and safety effects of the substance, as explained in Section II C of the Instructions.

SAMPLE

(Submitter's Attachment to the Form)

Confidentiality Claims

Category A

SAMPLE

CONFIDENTIAL

Linkage Question for Items in Our Health and Safety Study:

How would disclosing this item reveal your company's identity?

Answer: These items are our company's identity.

[NOTE: If other items on the form or in the attachment are claimed confidential and linked to Category A, Manufacturer's Identity, the answers to the linkage questions for each item claimed in Category A would be included in this attachment.]

SAMPLE

(Submitter's Attachment to the Form)

Explanation of Irrelevance of Manufacturer's Identity
to Health and Safety Study

SAMPLE

CONFIDENTIAL

Our company's identity is totally irrelevant to the health and safety effects of this substance. It is not necessary to know the name of our company to interpret and assess this health and safety study. Knowledge of our company's identity would not provide any information regarding the appropriateness, the validity, the methodology or the accuracy of this study. Thus keeping our identity confidential will have no bearing on using the attached study to assess the risks that this chemical may or may not present to health and the environment.

SAMPLE

(Submitter's Attachment to the Form)

Confidentiality Claims

Category B

Linkage Question for Items in Our Health and Safety Study:

How would disclosing this item reveal the specific chemical identity?

Answer: $\text{CH}_2\text{F CH}_2\text{OCH}_2\text{H}_2\text{F}$ is the molecular formula of the substance and is equivalent to specific chemical identity.

Explanation: Chlorsake is the common name of this chemical and has been manufactured previously. It has been referenced in the chemical literature and the name Chlorsake is tied to the molecular structure in this literature. Therefore any competitor who would see Chlorsake appearing in conjunction with the generic names we have submitted, and who knows that Chlorsake is being used with reference to a new chemical substance, would have enough information to know the specific chemical identity.

[NOTE: If other items on the form or in the attachments are claimed confidential and linked to Category B, Specific Chemical Identity, the answers to the linkage questions for each item claimed in category B would be included in this attachment.]

NOTE: (The tradename, molecular formula, and test results used in this example are for illustrative purposes only and do not reflect actual test results. Only the executive summary has been included in this example. The company would have submitted the entire report).

HEALTH AND SAFETY STUDY

EXECUTIVE SUMMARY

SAMPLE

CONFIDENTIAL

SAMPLE

1. Identity:

[B]

Chemical Substance: [Chlorsake] [(CH₂F)
CH₂OCH₂CH₂F)]

2. Summary of Adverse Effects and Possible Risks:

[B]

Previous testing has shown that [Chlorsake] was not mutagenic to bacteria in the Ames test. In teratogenicity studies involving rats, the compound is fetotoxic at exposure levels of 500 ppm., but no effects were seen at exposure levels of 50 ppm.

CONFIDENTIAL

The following effects have been noted in two dominant lethal studies using mice. The studies were designed to look for possible sperm effects in male animals. In the first study, two groups of male mice were exposed in inhalation chambers for six hours per day to levels of 100 and 1000 ppm for five days and a third group was exposed to 2000 ppm for two days followed by 500 ppm for three days (necessary because of the toxic effects of 2000 ppm on the mice). Each of the mice was mated weekly with two virgin females for eight-nine weeks to cover all stages of spermatogenesis. The number of successful fertilizations was reduced at the 1000 and 2000 ppm levels, but unaffected the 100 ppm level when compared with an unexposed control group. It was not possible to determine whether the reduction in fertilizations was due to reduced food intake, to loss of libido, or to a true sperm effect.

The second study, while not statistically analyzed, has confirmed the reduced fertility observed in the first study and demonstrated a true sperm effect. The reduced fertility occurred in both exposed groups (1000 and 250 ppm) and was accompanied by high cumulative mortality (34% and 27% at the high and low dosages respectively), reduced testicular

weight, a low sperm count, and a slight increase in the percentage of abnormal sperm. Histological examination of the testes revealed direct toxic effects on the germinal epithelium in which most damage occurred by weeks two, three and four with recovery of tubules and spermatogenesis from week five onwards.

- [B] The present commercial usage of [Chlorsake] is as an intermediate ingredient. In contrast to the levels of exposure in the above animal tests, normal exposure levels of [Chlorsake] measured in our facility are less than four ppm and average less than two ppm personal exposure. We therefore do not believe, on the evidence that we have, that there will be an effect on the employees from the very low exposure levels found in the workplace.

Submitted by:

[A]

[Pinnacle Chemical Company
Niagara Falls, N.Y.]

Sincerely yours,

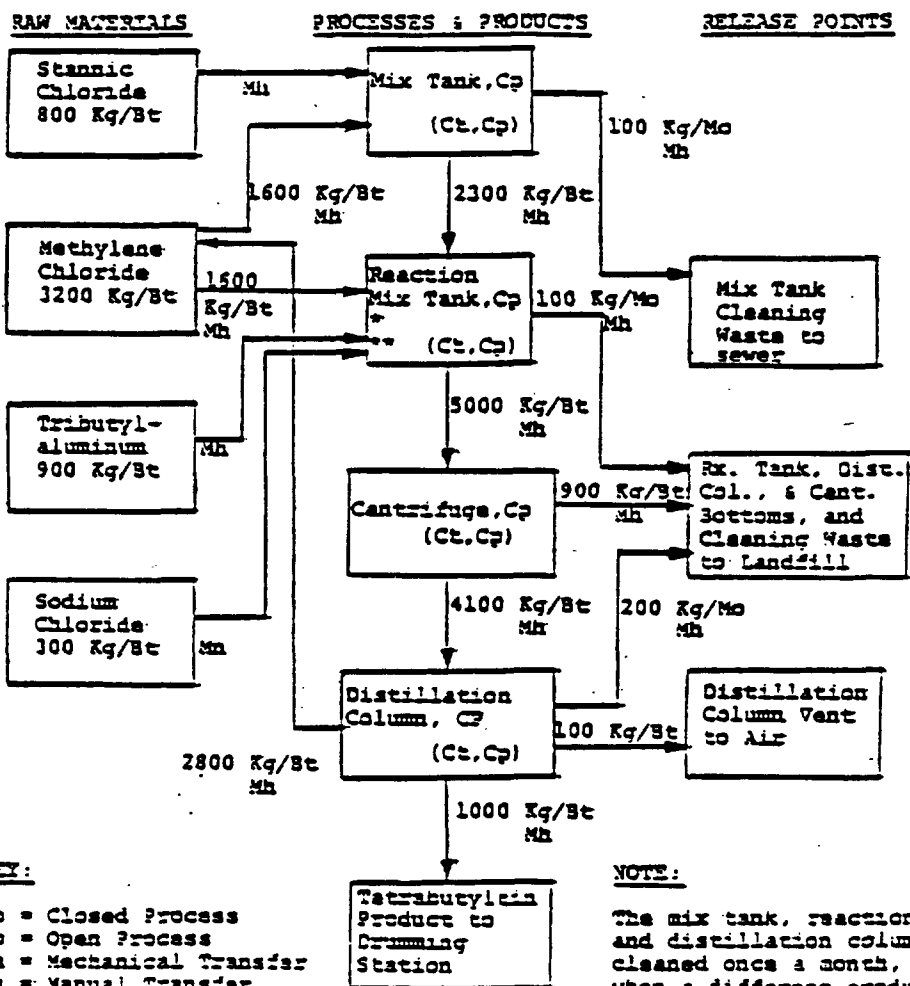
[A]

[T. M. I. Babylon
Director
Safety/Environmental Affairs
Pinnacle Chemical Company
Hoboken, N.J.]

APPENDIX C

Attached are two sample block diagrams (A, manufacturing operation; B, processing operation) that illustrate the type of response that should be provided in completing Part II, Section A, Subsection 2, of the Premanufacture Notice Form for domestic manufacturers. The level of detail of an individual submitter's response may vary depending upon the extent to which the information is "known to or reasonably ascertainable."

Attachment A

PROCESS INFORMATION
TETRABUTYLEN BATCH PRODUCTION

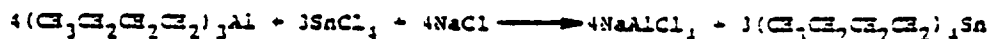
KEY:

Cp = Closed Process
Op = Open Process
Mh = Mechanical Transfer
Mn = Manual Transfer
Bt = Batch
Mo = Month
Ct = Cleaning Operation

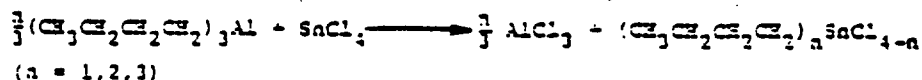
NOTE:

The mix tank, reaction tank, and distillation column are cleaned once a month, or when a different product is manufactured. The mix tank is purged with water when cleaned. The wastewater is then discharged to sewer. The reaction tank, centrifuge, and distillation column are purged with methylene chloride, or other suitable solvent depending upon product to be manufactured. These wastes are distilled to recover solvent and product. The bottoms are drummed and sent to a landfill.

*REACTION:

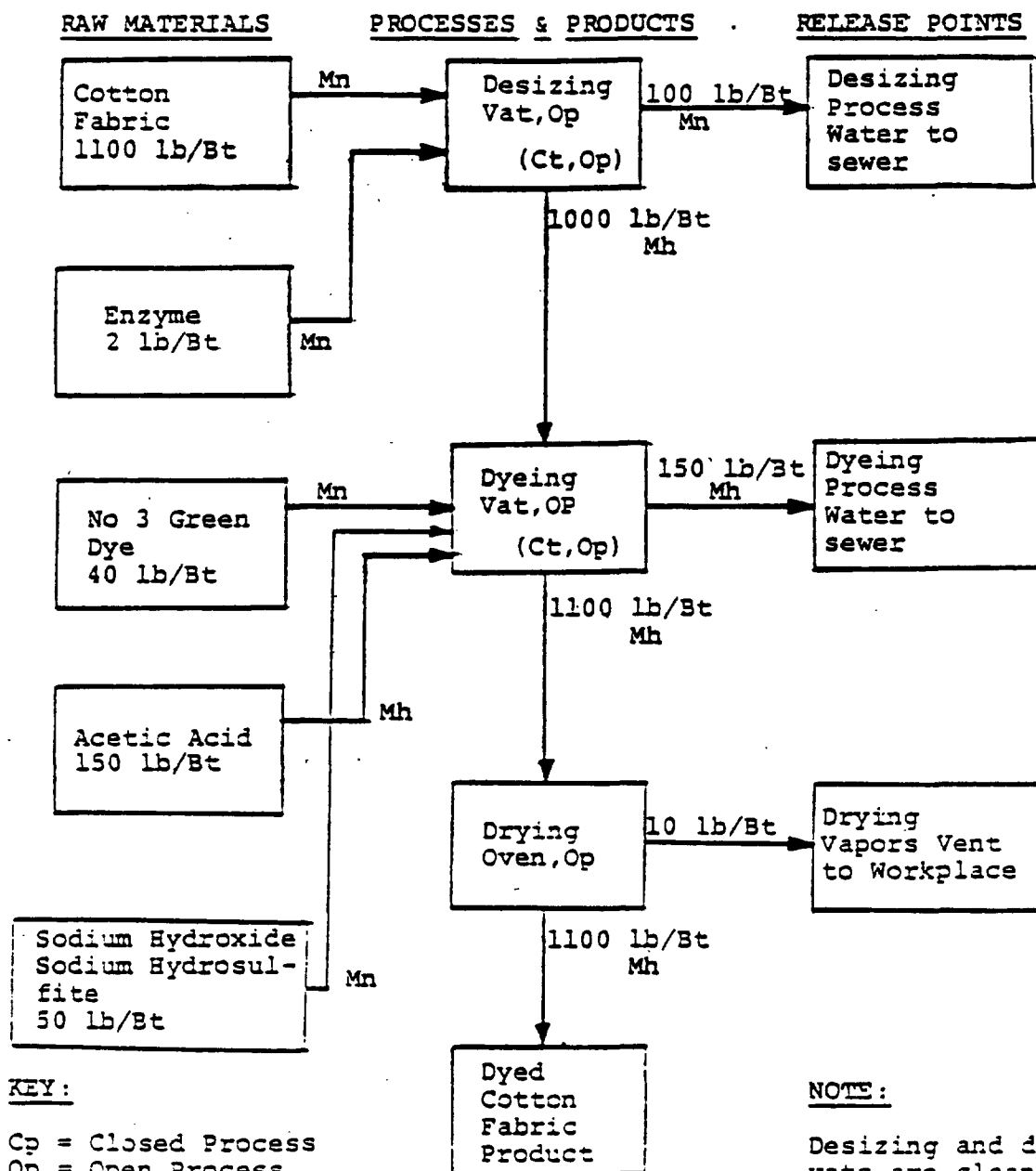


**SIDE REACTION:



Attachment B

**PROCESS INFORMATION
BATCH DYEING PROCESS
USING NUMBER 3 GREEN DYE**

KEY:

Cp = Closed Process
 Op = Open Process
 Mh = Mechanical Transfer
 Mn = Manual Transfer
 Bt = Batch
 Ct = Cleaning Operation

NOTE:

Desizing and dyeing vats are cleaned with caustic (10% NaOH) every two days, or when different fabrics and dyes are used. The caustic wastewater is discharged to sewer.

PROPOSED FORM



United States
Environmental Protection
Agency

PREMANUFACTURE NOTICE

IMPORTERS

When completed send this form to:

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

EPA USE ONLY
Date of receipt

GENERAL INFORMATION

The Premanufacture Notice form for importers is divided into the following parts:

- Part I - General Information
- Part II - Human Exposure and Environmental Release
- Part III - List of Attachments
- Part IV - Federal Register Notice
- Part V - Optional Data

The optional part (part V) is not included in this package. All data requested in the mandatory parts (parts I, II, III, and IV) must be reported to the extent they are known to or reasonably ascertainable by the submitter. This means that the submitter is expected to answer all questions to the best of his/her ability, including making reasonable estimates in cases where complete factual information is not available. If the submitter is unable to make a reasonable estimate (i.e., the data is not known and is not reasonably ascertainable), he/she should enter "NA" (not available).

In part I, the submitter is required to report the specific chemical identity of the new substance, regardless of whether the information is claimed as confidential. In accordance with proposed §720.20(f), the submitter may authorize another person to report the specific chemical identity in his/her behalf. The notice will not be valid until the specific chemical identity is received by EPA.

If the space on the form is not sufficient to adequately answer a question, the submitter may attach additional sheets. Identify any continuation by part, section, subsection, and item.

ASSERTING AND SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Read Appendix A. Instructions for Asserting and Substantiating Claims of Confidentiality, for information on how to claim and substantiate confidential business information included in this form or in attachments to the form. Claims of confidentiality must be made in accordance with sections I and II of these instructions. In addition, substantiation of all claims of confidentiality

must be made in accordance with section IV of these instructions. If you claim any item in any attachment to this form confidential, see **SPECIAL INSTRUCTIONS** for attachments, Appendix A, Section II. Appendix B "Examples," provides additional guidance for asserting and substantiating claims of confidentiality.

In accordance with sections I and II of the confidentiality instructions, claims of confidentiality must be made by using the following six categories:

A. IMPORTER'S IDENTITY

A claim of confidentiality for category A, Importer's identity, automatically includes items 1 and 2 in part I, section A.

B. SPECIFIC CHEMICAL IDENTITY

A claim of confidentiality for category B, Specific Chemical identity, automatically includes items 1, 2, and 3 in part I, section B.

C. IMPORT VOLUME

A claim of confidentiality for category C, Import Volume automatically includes item 1 in part I, section D. These items do not need to be individually claimed.

D. USE DATA

A claim of confidentiality for category D, Use Data, automatically includes item 2 in part I, section D. These items do not need to be individually claimed.

E. PROCESS INFORMATION

A claim of confidentiality for category E, Process Information, automatically includes items in part II, section A, subsection 2. These items do not need to be individually claimed.

F. OTHER INFORMATION

No items on the form are automatically included in this category. Thus all claims for this category must specify category F.

GENERAL CERTIFICATION

I hereby certify to the best of my knowledge and belief, that:

- a. The company named in section A, item 1, intends 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);
- b. All information entered on this Premanufacture Notice form is complete and truthful as of the date of submittal; and
- c. 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 also 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

CONFIDENTIALITY CERTIFICATION

I hereby certify to the truth and accuracy of the following four statements concerning all information which is claimed confidential.

- a. My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- b. The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without the company's consent;

- c. The information is not publicly available elsewhere; and
- d. Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

Signature of authorized official

Date

Part I - GENERAL INFORMATION

Section A - IMPORTER IDENTIFICATION

If you claim importer's identity confidential, mark (X) the box at the right. ☐
The answers to items 1 and 2 will be included in this claim.

If you claim the answers to items 3, 4, 5, or 6 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

Confidential code

1. Person Filing Notice

Name of authorized official

Title

Organization

Mailing address (Number and street)

City, State, ZIP code

2. Technical Contact

Name

Title

Mailing address (Number and street)

City, State, ZIP code

Telephone

Area code

Number

3. Enter the intended date of commencement of import for commercial purposes.

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

☐ Mark this box if you attach evidence.

Month

Year

4. Port of entry - Enter name

5. If you have had a Prenotice Communication (PC) concerning this notice and EPA assigned a PC number to this notice, enter PC Number

Mark (X)
If none

6. Do you intend to manufacture, or contract for the manufacture of the new chemical substance in the United States within 3 years of the intended date of import?

1 ☐ Yes2 ☐ No3 ☐ Don't know

CONTINUE WITH SECTION B ON PAGE 3

Section B - CHEMICAL IDENTITY		
If you claim Chemical Identity confidential, mark (X) the box at the right. The answers to items 1, 2, and 3 will be included in this claim. ☐ If you claim Chemical Identity confidential, is this claim limited to the period prior to manufacture? 1 ☐ Yes 2 ☐ No If you claim the answer to item 4 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E. Complete either 1, 2, or 3 as appropriate. Complete 4. Mark (X) the box at the right if the chemical identity will be reported by the foreign manufacturer or supplier. ☐		Confidential code
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	
☐ Mark this box if you attach a continuation sheet.		
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 reactants with their respective CAS Registry Number(s) and describe the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.	
☐ Mark this box if you attach a continuation sheet.		

3. Polymers

- a. (1) Provide the specific chemical names and the CAS Registry Number of those monomers and other reactants used in the manufacture of the polymer. (2) Mark (X) the identity column if you wish monomers used at two percent (by weight) or less to be listed as part of the polymer description on the inventory. (3) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (4) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

Monomers and CAS Registry No. (1)	Identity Mark (X) (2)	Range of composition (3)	Maximum amount (weight percent) (4)	Confiden- tial code (5)
			%	
			%	
			%	
			%	

- b. Indicate the minimum average molecular weight or the minimum degree of polymerization of the polymeric compositions to which this notice applies.

☐ Mark this box if you attach a continuation sheet.

4. Impurities

- (a) List each impurity, including CAS Registry Number, which may reasonably be anticipated to be present in the chemical substance as it will be imported for commercial purposes. (b) Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R & D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. (c) Mark (X) if the concentration of an impurity will be specifically controlled because of your concern about potential adverse health or environmental effects. (d) Estimate the maximum total percent (by weight) of the impurities that may be present.

Impurity and CAS Registry number (a)	Maximum percent present (b)	Mark if to be specifically controlled (c)	Confiden- tial code
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
d. Total percent	%		

☐ Mark this box if you attach a continuation sheet.

Section C - GENERIC NAMES

Complete this section only if Specific Chemical Identity is claimed confidential.

For instructions on how to develop generic names, see appendix II, 40 CFR 720 (44 FR 2278), Proposed Premanufacture Notification Requirements and Review Procedures.

1. Enter the generic name agreed on by EPA in Prenotice Communication or provide 3 generic names.

Section D - U.S. IMPORT AND MARKETING DATA

If you claim Import Volume confidential, mark (X) the box at the right ☐
The answers to item 1 will be included in this claim.

1. Estimate the minimum and maximum annual import volume for the first three years of import. Include in your estimates import by others with whom you have contracted to import the new chemical substance.

Import year (1)	Import (Kg/yr)		Confiden- tial code
	Minimum (2)	Maximum (3)	
a. First year			
b. Second year			
c. Third year			

2. Category of use

If you claim Use Data confidential, mark (X) the box at the right ☐
The answers to item 2 will be included in the claim.

- a. List the category(ies) of use on which you have based your import estimates. (Example: solvent used in automotive paint.) List partial information if complete information is not known. (Example: solvent.) Mark (X) the categories of use as industrial, commercial, or consumer. Estimate the percent of total import volume for the first 3 years devoted to each category of use.

Category of use (1)	Percentage of import volume (2)	Mark (X) appropriate column(s)			Confiden- tial code
		Industrial (3)	Commercial (4)	Consumer (5)	
	%				
	%				
	%				

☐ Mark this box if you attach a continuation sheet.

- b. List any other category(ies) of use that you have actively explored

☐ Mark this box if you attach a continuation sheet.

- c. Do you intend or expect the new chemical substance to be used to treat drinking water supplies or to be used in products (e.g., paints or coatings) that will come in contact with drinking water?

1 ☐ Yes 2 ☐ No 3 ☐ Don't know

NOTE - If you claim the answers to items 3 or 5 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

3. Has the chemical substance been manufactured before?

1 ☐ Yes 2 ☐ No 3 ☐ Don't know

4. Hazard warnings

Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the chemical substance.

☐ Mark this box if you attach a hazard warning.

5. Enter the number of customers who have either contracted to purchase, submitted a purchase order, or made any other firm commitment to purchase the new chemical substance from you for a category of use unknown to you. Estimate the percentage of your import volume that will be purchased by such customers during the first 3 years of import.

Number of customers	Percentage import volume	Confiden- tial code

Section E - TRANSPORT

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A-F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).

Confiden-
tial code

a. Shipping name

b. Hazard class

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance to enter the U.S. and within the U.S.

a. To enter the United States -

1 ☐ Truck

3 ☐ Barge, vessel

5 ☐ Plane

2 ☐ Railcar

4 ☐ Pipeline

6 ☐ Other - Specify _____

b. Within the United States -

1 ☐ Truck

3 ☐ Barge, vessel

5 ☐ Plane

2 ☐ Railcar

4 ☐ Pipeline

6 ☐ Other - Specify _____

Section F - RISK ASSESSMENT

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

If you have evaluated the health or environmental risks which may be presented by the manufacture, processing distribution in commerce, use, or disposal of the new chemical substance attach your evaluation.

☐ Mark this box if you attach a risk assessment.

Section G - DETECTION METHODS

If you claim the answers to item 1 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

Confiden-
tial code

1. Is an analytical method available to identify and quantify the presence of the new chemical substance -

Identify

Quantify

a. In workplace air?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

e. In workplace air?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

b. In effluent streams?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

f. In effluent streams?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

c. In materials requiring disposal?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

g. In materials requiring disposal?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

d. In end products for which the new substance is an intermediate?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

h. In end products for which the new substance is an intermediate?

1 ☐ Yes

2 ☐ No

3 ☐ Don't know

Part II - HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A - U.S. INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

If you claim Process Information confidential, mark (X) the box at the right. ☐
The answer to subsection 2 will be included in this claim.

If you claim the answers to items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E. If you claim the answers to items 3.3, 4.3, or 4.4 in subsections 3 or 4, or any items submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

Complete a separate subsection 1 and subsection 2 sheet for each site where you will process or use the new chemical substance.

► Subsection 1 - PROCESS INFORMATION

Confiden-
tial code

1.1 Identity of site	Name _____ Physical location address (Number and street) _____ City, County, State, ZIP code _____	
1.2 Type of site	1 ☐ Processing 2 ☐ Use 3 ☐ Continuous 4 ☐ Batch	
1.3 Hours of operation _____	Days per year _____	Hours per day _____
1.4 Amount processed or used _____	Minimum Kg./yr. _____	Maximum Kg./yr. _____

► Subsection 2 - BLOCK DIAGRAM

2.1 Provide a block diagram identifying the major unit operations and chemical conversions. Also include:

- a. For each chemical conversion in the block diagram identify the major chemical reactions and the major side reactions.
- b. Provide the approximate mass of all feed materials, byproduct materials, and products which are entering and leaving each major unit operation and chemical conversion. Indicate the method of transfer of these materials and whether the operation is open or closed to the workplace environment.
- c. Identify those points in the block diagram from which there will be releases of the new chemical substance or byproduct materials into the air, land, or water environment.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each site at which you will process, use, or dispose of the new chemical substance. Indicate the anticipated route(s) of exposure to the new chemical substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure, (in days per year and hours per day). In the table below, mark (X) A—Average or P—Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on maximum annual processing, or use during the first 3 years of import under normal operating conditions with all engineering safeguards in place.

Confiden-
tial code3.1 Identity
of site

Name

Physical location address (Number and street)

City, County, State, ZIP code

3.2 Occupational Exposure at Industrial Site

Activity	Exposure route(s)	Maximum number exposed	Maximum duration		Concentration (5)												
			(4)		Unit of measure	Mark (X) appropriate column A – Average P – Peak											
						0-1		1-10		10-100		> 100					
						A	P	A	P	A	P	A	P				
(1)	(2)	(3)	Hr./day	Days/yr.													
a. Processing					1 ☐ ppm												
					2 ☐ mg/m ³												
b. Use					1 ☐ ppm												
					2 ☐ mg/m ³												
c. Disposal					1 ☐ ppm												
					2 ☐ mg/m ³												

3.3 Describe those operations in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other – Specify _____2 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ LiquidConfiden-
tial code

► Subsection 4 - ENVIRONMENTAL RELEASE AND DISPOSAL								Confidential code
Complete a separate subsection 4 for each site where you intend to process, use or dispose of the new chemical substance.								
4.1 Identity of site		Name						
		Physical location address (Number and street)						
		City, County, State, ZIP code						
4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.								
Media		Duration of release		Amount of new chemical substance released (Kg/yr.)				
(1)		Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10-100 (5)	100-1000 (6)	1000-10,000 (7)	More than 10,000 (8)
a. Air								
b. Land								
c. Water								
1 ☐ POTW (Publicly Owned Treatment Works)		Enter name _____						
2 ☐ Navigable waterway								
3 ☐ Other								
d. Effluent stream flow rate		Gallons per day						
4.3 For each release point indicated in the block diagram, characterize the composition of the release materials.								
☐ Mark this box if you attach a continuation sheet.								
4.4 Describe pollution control equipment and disposal operations (e.g., scrubber, baghouse, landfill, incinerator, activated sludge, carbon absorption, etc.) used to treat individual or combined releases indicated in the block diagram(s) of processing and use operations.								
☐ Mark this box if you attach a continuation sheet.								

Section B - U.S. INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete this section using your own forecasts, any information already obtained from other persons who may process, use, or dispose of, the new chemical substance or any other information that is reasonably ascertainable. Complete a separate subsection 1 and subsection 2 for each site where you expect other persons to process, use, or dispose of the new chemical substance.

If you claim the answers to the items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

If you claim the answers to items in subsection 2, or item 3.3 in subsection 3 confidential, see SPECIAL INSTRUCTIONS in appendix A, section II, part B.

► Subsection 1 - PROCESS INFORMATION**Confiden-
tial code****1.1 Identity
of site
(Optional)**

Name

Physical location address (Number and street)

City, State, ZIP code

County

► Subsection 2 - PROCESS DESCRIPTION

Briefly describe processing or use operations conducted by others.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each industrial site where you expect other persons to process, use, or dispose of the new chemical substance. Indicate the anticipated routes of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A–Average or P–Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on the maximum amount anticipated to be processed, used, or disposed of during the first 3 years of operation under normal conditions with all engineering safeguards in place.

Confidential code

3.1 Identity of site (optional)

Name

Physical location address (Number and street)

City, State, ZIP code

County

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4)		Concentration (5)									
					Unit of measure	Mark (X) appropriate column A – Average P – Peak								
						0–1		1–10		10–100		> 100		
			A	P		A	P	A	P	A	P			
a. Processing			Hrs./day	Days/yr.	1 ☐ ppm 2 ☐ mg/m ³									
b. Use					1 ☐ ppm 2 ☐ mg/m ³									
c. Disposal					1 ☐ ppm 2 ☐ mg/m ³									

3.3 Describe those activities in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other – Specify 22 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ Liquid

Confidential code

► Subsection 4 — ENVIRONMENTAL RELEASE AND DISPOSAL

Complete a separate subsection 4 for each site where other persons intend to process, use, or dispose of the new chemical substance.

Confidential code

4.1 Identity of site
(Optional) Name
Physical location address (Number and street)
City, State, ZIP code
County

4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.

Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)					
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10— 100 (5)	100— 1000 (6)	1000— 10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								
1 ☐ POTW (Publicly Owned Treatment Works) 2 ☐ Navigable waterway 3 ☐ Other			Enter name _____					
d. Effluent stream flow rate →			Gallons per day					

4.3 (1) List any byproduct materials containing the new chemical substance that are generated during processing and use operations and which are disposed of (e.g., landfill, incineration, or other physical/chemical treatment). Water effluent and air emission streams should not be listed here. Estimates of release of the new chemical substance contained in such streams are required to be reported in item 4.2. (2) Indicate the method of disposal. (3) Estimate the amount of each material generated (Kg. Kg of the new chemical substance), and (4) estimate the percent (by weight) of the new chemical substance.

Material requiring disposal (1)	Anticipated method of disposal (2)	Amount (Kg/Kg) (3)	Percent of new chemical substance (4)	Confidential code

☐ Mark this box if you attach a continuation sheet.

Section C - U.S. CONSUMER AND COMMERCIAL USER EXPOSURE

Complete this section for all consumer and commercial categories of use which involve use of a product that intentionally contains the new chemical substance. Provide the information based on your own forecasts, information already obtained from other persons, or any other information that is reasonably ascertainable.

If you claim the answers to item 1 confidential, enter letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

If you claim the answers to items 2, 3, or 4 confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

1. Complete the table below. For each consumer and commercial use category reported in section D, item 2, mark (X) if the product will be manufactured by the submitter or by other persons. Indicate the maximum number of consumers or commercial users expected to be exposed, the expected routes of human exposure and the frequency of exposure.

Category of use from part II, section D (1)	Use category (2)		Manufactured by - (3)		Exposure route(s) (4)	Maximum number exposed (5)	Frequency of exposure (6)				Confiden- tial code
	Consumer	Commercial	Submitter	Other			Daily	Weekly	Monthly	Yearly	

2. Attach any estimates that have been developed of potential exposure levels for each category of use.

☐ Mark this box if you attach any estimates.

3. For each product containing the new chemical substance, explain any aspect of its construction or formulation which you believe will limit the potential for exposure to the new chemical substance. For mixtures, indicate the maximum percent by weight of the chemical substance in the product.

☐ Mark this box if you attach a continuation sheet.

4. Identify any byproducts which are formed as a result of each category of use described in this section.

☐ Mark this box if you attach a continuation sheet.

Part III - LIST OF ATTACHMENTS

Under section 5(d)(1)(B) and (C) of TSCA and 40 CFR 720.23, an importer must submit all test data in his/her possession and control, and a description of any other data that are known to or reasonably ascertainable by him/her concerning the effect of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance on health or the environment. The regulations specify which data must be submitted with the notice and which data may be referenced by literature citations. Using the categories provided, identify (1) attachments containing test data, descriptions of data, or literature citations in accordance with 720.23; (2) other attachments required to be submitted with this notice; (3) confidentiality substantiations and (4) attachments which contain information voluntarily submitted. All attachments should be clearly identified and numbered.

To assert and substantiate a claim of confidentiality for any information included in the following attachments, follow the instructions in Appendix A, section II, part B. Note - Special directions for test data or other "Health and Safety" studies included in section III, part C.

The instructions provide that you must also submit a "sanitized" copy of the attachment with all information that you are claiming confidential deleted. EPA will place this copy in the public docket.

Attachment name				Attachment number
a. Physical and chemical properties data				
b. Health and environmental effects data				
c. Notice attachments	Part	Section/Subsection	Item	
d. Confidentiality attachments				
e. Voluntary attachments				

☐ Mark this box if you attach a continuation sheet.

Part IV - FEDERAL REGISTER NOTICE

Information provided in this part will be published in the Federal Register in accordance with section 5(d)(2) of TSCA. Do not enter any information in this part for which you have asserted a claim of confidentiality.

Section A - CHEMICAL IDENTITY

Enter the specific chemical name of the substance if it is not claimed confidential. If the chemical identity is claimed confidential, enter the name agreed to by EPA in Prenotice Communication or EPA will enter one of the three proposed generic names in part I, section C.

Section B - IMPORTER IDENTIFICATION

Enter the legal title of the organization filing this notice if it is not claimed confidential. If the legal title of the organization is claimed confidential, provide a description of the organization in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

Section C - USE DATA

1. If use data were not claimed confidential in section D, list the category(ies) of use that you reported in section D, item 2a. Mark (X) if the use category(ies) is site limited, industrial, commercial, or consumer.

Category of use (1)	Mark (X) appropriate box			
	Site limited (2)	Industrial (3)	Commercial (4)	Consumer (5)

2. If use data were claimed confidential, provide a description of the category of use(s) of the chemical substance in accordance with section II, Appendix A, Instructions for Asserting and Substantiating Confidentiality. This description should be as specific as possible without revealing confidential information.

Section D - TEST DATA

List all test data concerning health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance that are being submitted, described, or cited as part of this notice. Provide a brief abstract of all test data on the new chemical substance that are submitted in accordance with 720.23(a) and 720.20(j). If physical-chemical properties are claimed confidential, provide a generic description of these properties in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

☐

Mark this box if you attach a continuation sheet.

PROPOSED FORM



United States
Environmental Protection
Agency

PREMANUFACTURE NOTICE EXPORTERS

When completed send this form to:

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

EPA USE ONLY
Date of receipt

GENERAL INFORMATION

The Premanufacture Notice form for exporters is divided into the following parts:

- Part I - General Information
- Part II - Human Exposure and Environmental Release
- Part III - List of Attachments
- Part IV - Federal Register Notice
- Part V - Optional Data

The optional part (part V) is not included in this package. All data requested in the mandatory parts (parts I, II, III, and IV) must be reported to the extent they are known to or reasonably ascertainable by the submitter. This means that the submitter is expected to answer all questions to the best of his/her ability, including making reasonable estimates in cases where complete factual information is not available. If the submitter is unable to make a reasonable estimate (i.e., the data is not known and is not reasonably ascertainable), he/she should enter "NA" (not available).

In part I, the submitter is required to report the specific chemical identity of the new substance, regardless of whether the information is claimed as confidential. In accordance with proposed §720.20(f), the submitter may authorize another person to report the specific chemical identity in his/her behalf. The notice will not be valid until the specific chemical identity is received by EPA.

If the space on the form is not sufficient to adequately answer a question, the submitter may attach additional sheets. Identify any continuation by part, section, subsection, and item.

ASSERTING AND SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Read Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality, for information on how to claim and substantiate confidential business information included in this form or in attachments to the form. Claims of confidentiality must be made in accordance with sections I and II of these instructions. In addition, substantiation of all claims of confidentiality

must be made in accordance with section IV of these instructions. If you claim any item in any attachment to this form confidential, see SPECIAL INSTRUCTIONS for attachments, Appendix A, Section II. Appendix B "Examples," provides additional guidance for asserting and substantiating claims of confidentiality.

In accordance with sections I and II of the confidentiality instructions, claims of confidentiality must be made by using the following six categories:

A. MANUFACTURER'S IDENTITY

A claim of confidentiality for Category A, Manufacturer's identity, automatically includes items 1, 2, and 3 in part I, section A.

B. SPECIFIC CHEMICAL IDENTITY

A claim of confidentiality for category B, Specific Chemical identity, automatically includes items 1, 2, and 3 in part I, section B.

C. PRODUCTION VOLUME

A claim of confidentiality for category C, Production Volume automatically includes item 1 in part I, section D. These items do not need to be individually claimed.

D. USE DATA

While use data itself is not required in the exporter's form, a manufacturer may claim information on the form confidential because it reveals confidential use data.

E. PROCESS INFORMATION

A claim of confidentiality for category E, Process Information, automatically includes items in part II, section A, subsection 2. These items do not need to be individually claimed.

F. OTHER INFORMATION

No items on the form are automatically included in this category. Thus all claims for this category must specify category F.

GENERAL CERTIFICATION

I hereby certify to the best of my knowledge and belief, that:

- a. The company named in section A, item 1, intends to manufacture, solely for export, 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);
- b. All information entered on this Premanufacture Notice form is complete and truthful as of the date of submittal; and
- c. 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 also 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

CONFIDENTIALITY CERTIFICATION

I hereby certify to the truth and accuracy of the following four statements concerning all information which is claimed confidential.

- a. My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- b. The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without the company's consent;

- c. The information is not publicly available elsewhere; and
- d. Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

Signature of authorized official

Date

Part I - GENERAL INFORMATION

Section A - MANUFACTURER IDENTIFICATION

If you claim Manufacturer's identity confidential, mark (X) the box at the right. ☐
 The answers to items 1, 2, and 3 will be included in this claim.

If you claim the answers to items 4 or 5 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

Confidential code

1. Person
Filing
Notice

Name of authorized official

Title

Organization

Mailing address (Number and street)

City, State, ZIP code

2. Technical
Contact

Name

Title

Mailing address (Number and street)

City, State, ZIP code -

Telephone

Area code

Number

3. Parent
Company

Name

Mailing address (Number and street)

City, State, ZIP code

4. Enter the intended date of commencement of manufacture for export.

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).

☐ Mark this box if you attach evidence.

5. If you have had a Prenotice Communication (PC) concerning this notice and EPA assigned a PC number to this notice, enter PC Number

Mark (X) ☐
 If none ☐

CONTINUE WITH SECTION B ON PAGE 3

Section B - CHEMICAL IDENTITY

If you claim Chemical Identity confidential, mark (X) the box at the right. ☐
 The answers to items 1, 2, and 3 will be included in this claim.

If you claim Chemical Identity confidential, is this claim limited to the period prior to manufacture? 1 ☐ Yes 2 ☐ No

If you claim the answer to item 4 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

Complete either 1, 2, or 3 as appropriate. Complete 4.

Confidential code

**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

☐ Mark this box if you attach a continuation sheet.

**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 reactants with their respective CAS Registry Number(s) and describe the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

☐ Mark this box if you attach a continuation sheet.

3. Polymers

- a. (1) Provide the specific chemical names and the CAS Registry Number of those monomers and other reactants used in the manufacture of the polymer. (2) Mark (X) the identity column if you wish monomers used at two percent (by weight) or less to be listed as part of the polymer description on the inventory. (3) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (4) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

Monomers and CAS Registry No. (1)	Identity Mark (X) (2)	Range of composition (3)	Maximum amount (weight percent) (4)	Confiden- tial code (5)
			%	
			%	
			%	
			%	

- b. Indicate the minimum average molecular weight or the minimum degree of polymerization of the polymeric compositions to which this notice applies.

☐ Mark this box if you attach a continuation sheet.

4. Impurities

- (a) List each impurity, including CAS Registry Number, which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. (b) Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R & D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. (c) Mark (X) if the concentration of an impurity will be specifically controlled because of your concern about potential adverse health or environmental effects. (d) Estimate the maximum total percent (by weight) of the impurities that may be present.

Impurity and CAS Registry number (a)	Maximum percent present (b)	Mark if to be specifically controlled (c)	Confiden- tial code
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
d. Total percent →	%		

☐ Mark this box if you attach a continuation sheet.

Section C - GENERIC NAMES

Complete this section only if Specific Chemical Identity is claimed confidential.

For instructions on how to develop generic names, see appendix II, 40 CFR 720 (44 FR 2278), Proposed Premanufacture Notification Requirements and Review Procedures.

1. Enter the generic name agreed on by EPA in Prenotice Communication or provide 3 generic names.

Section D - PRODUCTION AND MARKETING DATA

If you claim Production Volume confidential, mark (X) the box at the right. ☐
 The answers to item 1 will be included in this claim.

If you claim the answers to items 2 or 3 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

1. Estimate the minimum and maximum annual production volume for the first three years of production. Include in your estimates production by others with whom you have contracted to manufacture the new chemical substance.

Production year (1)	Production (Kg/yr)		Confidential code
	Minimum (2)	Maximum (3)	
a. First year			
b. Second year			
c. Third year			

2. Reentry into the United States

Will the new chemical substance reenter the United States within the first 3 years of production -

- a. In bulk form? 1 ☐ Yes
 2 ☐ No
 3 ☐ Don't know
- b. As part of a mixture? 1 ☐ Yes
 2 ☐ No
 3 ☐ Don't know
- c. As part of an article? 1 ☐ Yes
 2 ☐ No
 3 ☐ Don't know

3. Has the chemical substance been manufactured before?

- 1 ☐ Yes
 2 ☐ No
 3 ☐ Don't know

4. Hazard warnings

Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the chemical substance.

☐ Mark this box if you attach a hazard warning.

CONTINUE WITH SECTION E ON PAGE 6

Section E - TRANSPORT

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A-F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E.

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).

Confiden-
tial code

a. Shipping name

b. Hazard class

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance -

a. Within the United States

1 ☐ Truck

3 ☐ Barge, vessel

5 ☐ Plane

2 ☐ Railcar

4 ☐ Pipeline

6 ☐ Other - Specify _____

b. From U.S. port of exit to destination

1 ☐ Truck

3 ☐ Barge, vessel

5 ☐ Plane

2 ☐ Railcar

4 ☐ Pipeline

6 ☐ Other - Specify _____

Section F - RISK ASSESSMENT

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

If you have evaluated the health or environmental risks which may be presented by the manufacture, processing distribution in commerce, use, or disposal of the new chemical substance attach your evaluation.

☐ Mark this box if you attach a risk assessment.

Section G - DETECTION METHODS

If you claim the answers to item 1 confidential, place the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

1. Is an analytical method available to identify and quantify the presence of the new chemical substance -

Confiden-
tial code

Identify			Quantify		
a. In workplace air?			e. In workplace air?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
b. In effluent streams?			f. In effluent streams?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
c. In materials requiring disposal?			g. In materials requiring disposal?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know
d. In end products for which the new substance is an intermediate?			h. In end products for which the new substance is an intermediate?		
1 ☐ Yes	2 ☐ No	3 ☐ Don't know	1 ☐ Yes	2 ☐ No	3 ☐ Don't know

Part II - HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A - INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

If you claim Process Information confidential, mark (X) the box at the right. ☐
 The answer to subsection 2 will be included in this claim.

If you claim the answers to items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A-E. If you claim the answers to items 3.3, 4.3, or 4.4 in subsections 3 or 4, or any items submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

Complete a separate subsection 1 and subsection 2 sheet for each site where you will manufacture or process the new chemical substance.

Subsection 1 - PROCESS INFORMATION

Confidential code

1.1 Identity of site

Name

Physical location address (Number and street)

City, County, State, ZIP code

1.2 Type of site

1 ☐ Manufacturing2 ☐ Processing3 ☐ Continuous4 ☐ Batch

1.3 Hours of operation

Days per year

Hours per day

1.4 Amount manufactured or processed

Minimum Kg/yr.

Maximum Kg/yr.

Subsection 2 - BLOCK DIAGRAM

2.1 Provide a block diagram identifying the major unit operations and chemical conversions. Also include:

- For each chemical conversion in the block diagram identify the major chemical reactions and the major side reactions.
- Provide the approximate mass of all feed materials, byproduct materials, and products which are entering and leaving each major unit operation and chemical conversion. Indicate the method of transfer of these materials and whether the operation is open or closed to the workplace environment.
- Identify those points in the block diagram from which there will be releases of the new chemical substance or byproduct materials into the air, land, or water environment.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each site at which you will manufacture, process, or dispose of the new chemical substance. Indicate the anticipated route(s) of exposure to the new chemical substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A—Average or P—Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on maximum annual production or processing during the first 3 years of manufacture under normal operating conditions with all engineering safeguards in place.

Confidential code

3.1 Identity of site

Name

Physical location address (Number and street)

City, County, State, ZIP code

3.2 Occupational Exposure at Industrial Site

Activity	Exposure route(s)	Maximum number exposed	Maximum duration		Concentration (5)												
					Unit of measure	Mark (X) appropriate column A – Average P – Peak											
			(4)			0-1		1-10		10-100		> 100					
						A	P	A	P	A	P	A	P				
(1)	(2)	(3)	Hr./day	Days/yr.													
a. Manufacture					1 ☐ ppm 2 ☐ mg/m ³												
b. Processing					1 ☐ ppm 2 ☐ mg/m ³												
c. Disposal					1 ☐ ppm 2 ☐ mg/m ³												

3.3 Describe those operations in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other – Specify2 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ Liquid

Confidential code

3.5 For each site of manufacture, list any other substances (e.g., byproducts, co-products, feedstocks and intermediates) associated with the manufacture of the new chemical substance that may reasonably be anticipated to be present in the workplace and to which workers may be exposed. Provide the CAS Registry Number.

Substance (1)	CAS Registry Number (2)	Confidential code

☐ Mark this box if you attach a continuation sheet.

► Subsection 4 – ENVIRONMENTAL RELEASE AND DISPOSAL Complete a separate subsection 4 for each site where you intend to manufacture, process, or dispose of the new chemical substance.								Confiden- tial code
4.1 Identity of site Name _____ Physical location address (Number and street) _____ City, County, State, ZIP code _____								
4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.								
Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)					
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10–100 (5)	100– 1000 (6)	1000– 10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								
1 ☐ POTW (Publicly Owned Treatment Works) 2 ☐ Navigable waterway 3 ☐ Other			Enter name _____					
d. Effluent stream flow rate _____ Gallons per day								
4.3 For each release point indicated in the block diagram, characterize the composition of the release materials.								
☐ Mark this box if you attach a continuation sheet.								
4.4 Describe pollution control equipment and disposal operations (e.g., scrubber, baghouse, landfill, incinerator, activated sludge, carbon absorption, etc.) used to treat individual or combined releases indicated in the block diagram(s) of manufacturing and processing operations.								
☐ Mark this box if you attach a continuation sheet.								

Section B - INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete this section using your own forecasts, any information already obtained from other persons who may manufacture (under contract) or dispose of the new chemical substance, or any other information that is reasonably ascertainable. Complete a separate subsection 1 and subsection 2 for each site where you expect other persons to manufacture (under contract), or dispose of the new chemical substance.

If you claim the answers to the items in subsections 1, 3, or 4 confidential, enter the letter(s) A-F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A-E.

If you claim the answers to items in subsection 2, or item 3.3 in subsection 3 confidential, see SPECIAL INSTRUCTIONS in appendix A, section II, part B.

► Subsection 1 - PROCESS INFORMATION**Confiden-
tial code****1.1 Identity
of site**

Name

Physical location address (Number and street)

City, State, ZIP code

County

► Subsection 2 - PROCESS DESCRIPTION

Briefly describe manufacturing operations conducted by others.

☐ Mark this box if you attach a continuation sheet.

► Subsection 3 - OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each industrial site where you expect other persons to manufacture or dispose of the new chemical substance. Indicate the anticipated routes of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A—Average or P—Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on the maximum amount anticipated to be manufactured or disposed during the first 3 years of operation under normal conditions with all engineering safeguards in place.

Confiden-
tial code3.1 Identity
of site

Name

Physical location address (Number and street)

City, State, ZIP code

County

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4) Hrs./day Days/yr.	Unit of measure	Concentration (5) Mark (X) appropriate column A - Average P - Peak							
					0-1		1-10		10-100		> 100	
					A	P	A	P	A	P	A	P
a. Manufacture				1 ☐ ppm 2 ☐ mg/m ³								
b. Disposal				1 ☐ ppm 2 ☐ mg/m ³								

3.3 Describe those activities in which workers will be directly exposed to the new chemical substance.

☐ Mark this box if you attach a continuation sheet.

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

1 ☐ Solid3 ☐ Aerosol5 ☐ Mist7 ☐ Dust9 ☐ Other - Specify2 ☐ Gas4 ☐ Powder6 ☐ Fume8 ☐ LiquidConfiden-
tial code

► Subsection 4 - ENVIRONMENTAL RELEASE AND DISPOSAL

Complete a separate subsection 4 for each site where other persons intend to manufacture (under contract) or dispose of the new chemical substance.

Confiden-
tial code4.1 Identity
of site

Name

Physical location address (Number and street)

City, State, ZIP code

County

4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.

Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)				
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10- 100 (5)	100- 1000 (6)	1000- 10,000 (7)	More than 10,000 (8)
a. Air							
b. Land							
c. Water							

- 1 ☐ POTW (Publicly Owned Treatment Works)
 2 ☐ Navigable waterway
 3 ☐ Other

Enter name

d. Effluent stream flow rate

Gallons per day

4.3 (1) List any byproduct materials containing the new chemical substance that are generated during manufacturing and processing operations and which are disposed of (e.g., landfill, incineration, or other physical/chemical treatment). Water effluent and air emission streams should not be listed here. Estimates of release of the new chemical substance contained in such streams are required to be reported in item 4.2. (2) Indicate the method of disposal. (3) Estimate the amount of each material generated (Kg/Kg of the new chemical substance), and (4) estimate the percent (by weight) of the new chemical substance.

Material requiring disposal (1)	Anticipated method of disposal (2)	Amount (Kg/Kg) (3)	Percent of new chemical substance (4)	Confiden- tial code

☐ Mark this box if you attach a continuation sheet.

Part III - LIST OF ATTACHMENTS

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 that are known to or reasonably ascertainable by him/her concerning the effect of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance on health or the environment. The regulations specify which data must be submitted with the notice and which data may be referenced by literature citations. Using the categories provided, identify (1) attachments containing test data, descriptions of data, or literature citations in accordance with 720.23; (2) other attachments required to be submitted with this notice; (3) confidentiality substantiations and (4) attachments which contain information voluntarily submitted. All attachments should be clearly identified and numbered.

To assert and substantiate a claim of confidentiality for any information included in the following attachments, follow the instructions in Appendix A, section II, part B. Note - Special directions for test data or other "Health and Safety" studies included in section III, part C.

The instructions provide that you must also submit a "sanitized" copy of the attachment with all information that you are claiming confidential deleted. EPA will place this copy in the public docket.

Attachment name		Attachment number		
a. Physical and chemical properties data				
b. Health and environmental effects data				
c. Notice attachments	Part	Section/Subsection	Item	
d. Confidentiality attachments				
e. Voluntary attachments				

☐ Mark this box if you attach a continuation sheet.

Part IV - FEDERAL REGISTER NOTICE

Information provided in this part will be published in the Federal Register in accordance with section 5(d)(2) of TSCA. Do not enter any information in this part for which you have asserted a claim of confidentiality.

Section A - CHEMICAL IDENTITY

Enter the specific chemical name of the substance if it is not claimed confidential. If the chemical identity is claimed confidential, enter the name agreed to by EPA in Prenotice Communication or EPA will enter one of the three proposed generic names in part I, section C.

Section B - MANUFACTURER IDENTIFICATION

Enter the legal title of the organization filing this notice if it is not claimed confidential. If the legal title of the organization is claimed confidential, provide a description of the organization in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

Section C - TEST DATA

List all test data concerning health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance that are being submitted, described, or cited as part of this notice. Provide a brief abstract of all test data on the new chemical substance that are submitted in accordance with 720.23(a) and 720.20(j). If physical-chemical properties are claimed confidential, provide a generic description of these properties in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.



Mark this box if you attach a continuation sheet.

United States
Environmental Protection
Agency

Official Business
Penalty for Private Use
\$300

First-Class Mail
Postage and Fees Paid
EPA
Permit No. G-35

Washington DC 20460

US372C BS
DOUG MERRILL
PACO TEXTURES
987 COMMERCIAL ST
SAN CARLOS
CA 94070