INSTRUCTION MANUAL FOR REPORTING UNDER THE TSCA §5 NEW CHEMICALS PROGRAM

Contents

A. GENERAL INSTRUCTIONS FOR REPORTING UNDER THE TSCA §5 NEW CHEMICALS PROGRAM

1. Substances which must Be Reported ("New" Chemicals)

a. General

You are responsible for determining whether a substance you intend to manufacture is a "new" chemical substance as defined by the Toxic Substances Control Act (TSCA, the Act) and 40 Code of Federal Regulations (CFR) §720.3. You must submit a notice under §5 of TSCA (i.e., a premanufacture notice (PMN), Low Volume Exemption (LVE), Low Release, Low Exposure Exemption (LoREX), Test Marketing Exemption Application (TMEA) or Significant New Use Notice (SNUN)) if you intend to manufacture (import is considered manufacture) any new chemical substance which is not on the TSCA Inventory or otherwise excluded from notification, as discussed below. Section B of this report is a guide to filling out and submitting this electronic form, EPA form 7710-25.

b. Bona fide request for a TSCA Inventory search

The specific identities of some chemical substances on the Inventory are confidential and therefore do not appear on the Inventory available to the public. Such substances are described by generic names in the Appendix to the Inventory. If a substance you intend to manufacture is not on the published Inventory but you think it may be in commerce based on a confidential Inventory listing, you may request that EPA search the Inventory's confidential file. EPA will search the confidential file only if you can demonstrate a bona fide intent to manufacture the substance. This policy is to ensure that this search procedure cannot be used for, essentially, industrial espionage.

The procedure for demonstrating such a bona fide intent is codified at 40 CFR 720.25 for PMNs and at 40 CFR 725.15 for MCANs. Certain information must be submitted with a bona fide request: an infrared spectrum must be supplied unless this analysis is not suitable for the particular substance, in which case a spectrum or instrument readout from a more appropriate method must be submitted; a currently correct Chemical Abstracts (CA) Index name or CA preferred name, whichever is appropriate; a currently correct Chemical Abstracts Service (CAS) register number (CASRN) (if the substance already has a CASRN assigned to it); molecular formula and a complete or partial chemical structure diagram if known or reasonably ascertainable; a description of R&D activities that have already been conducted (include, for example, years research conducted, end use application, toxicity data, etc.); the most probable manufacturing site; "major intended application or use" of the substance; and the approximate date when the submitter would be likely to submit a §5 notice for the

substance if it is not found in the Inventory. If the substance is being imported, a statement should include: a) how long the substance has been used outside of the U.S., b) name of the country(ies) in which the substance is being used, and c) whether the substance has been used outside the U.S. for the same use as that intended after proposed importation. No specific form is required to be used. Please refer to 40 CFR 720.25 and 40 CFR 721 for instructions on how to submit the statement of bona fide intent.

After conducting its search, EPA will tell you if the substance is included on the Inventory and therefore not subject to premanufacture notification or if you must submit a PMN or an exemption application. If the chemical substance is on the Inventory, EPA will also tell you if there are restrictions on the material; for example, if there is a Significant New Use Rule (SNUR) in effect for the substance, you may need to submit a SNUN.

2. Who Must Submit A PMN

If you intend to manufacture a new chemical substance for a commercial purpose, you must submit a PMN or an exemption application to EPA. You must submit a notice if you intend to import a new substance in bulk form or as part of a mixture, but not if you intend to import the substance only as part of an article. The use of the term "manufacture" in this manual includes both manufacture and import. Importers must fully comply with the information requirements outlined at 40 CFR 720. However, importers are not required, under 40 CFR 720.50(d)(3), to submit any data which relates solely to exposure to humans or the environment outside the United States. Importers must submit non-exposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics and (on sites under their control within the United States) exposure information.

"Article" is defined at 40 CFR 720.3 as a manufactured item which: (1) is formed to a specific shape or design during manufacture; (2) has an end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) either has no change of chemical composition during its end-use or only those changes in composition which have no commercial purpose separate from the article of which it is a part and that may occur as described in 40 CFR 710.4(d)(5) and 40 CFR 720.30(h)(5). Articles are excluded from PMN requirements. Fluids and particles do not meet the definition of an article and are therefore not excluded from inventory reporting requirements. Therefore, all particles or fluids must be reported for the purposes of TSCA unless they can be considered mixtures. Also, OPPT will consider items being

imported to be "articles" only if they are manufactured in a specific shape or design for a particular end use application, and this design is maintained as an essential feature in the finished product.

PMNs for imported new chemical substances should be submitted by the principal importer. "Principal importer" is defined at 40 CFR 720.3(z). It is not necessarily the same as "Importer of Record" under customs regulations.

Generally, when you contract with another person to manufacture a new chemical substance, that person must submit the notice. However, if you request another person to manufacture a new chemical substance, and if you specify the identity and total amount of the substance to be manufactured and the basic technology and controls under which the substance will be produced, and if that person manufactures the substance exclusively for you, that person is considered a "toll manufacturer", and you must submit the notice. Information regarding human exposure and environmental release should be submitted on EPA form 7710.25 in Part II, Section A, Industrial Sites Controlled by the Submitter. EPA recognizes that in this and similar instances, the other manufacturer may have information useful to the Agency's review of the new chemical. Therefore, EPA strongly encourages a letter of support, or a joint submission in these situations.

This manual does not discuss biotechnology submission information requirements for new intergeneric microorganisms subject to section 5 of TSCA. For specific information on submitting notices for biotechnology products please see 40 CFR 725 and EPA's web site at: http://www.epa.gov/oppt/biotech.

For additional information on who must submit a notice, see 40 CFR 720.22 or consult a Prenotice Coordinator. Prenotice Coordinators (see Contact List, Appendix B) are staff in the New Chemicals Program who specialize in assisting with status questions and questions on how to properly complete the notifications.

3. Substances Excluded from Notification

a. Statutorily Excluded Categories

Section 3(b) of TSCA excludes certain substances from premanufacture notification. These include mixtures (individual substances comprising the mixtures are NOT exempted), substances manufactured solely for use as pesticides, food, food additives, drugs, or cosmetics; tobacco and tobacco products; nuclear source materials; firearms and ammunition; impurities; byproducts which have no commercial use; non-isolated

intermediates; and new chemical substances manufactured solely for export. Statutory exclusions are covered also at 40 CFR 720.3(e) and (u) and through criteria at 40 CFR 720.30(h)(3)-(h)(7).

b. Research and Development (R&D) Exemption

R&D includes synthesis of new chemical substances for analysis, experimentation, or research on new or existing chemical substances, including product development activities. R&D may include tests of the physical, chemical, production, and performance characteristics of a substance.

You do not have to submit a notice for a new substance manufactured in small quantities solely for research and development as specified in 40 CFR 720.36. "Small quantities" are those not greater than reasonably necessary for research and development purposes. The quantity which is reasonable may vary depending on the nature of the research and development activities. It is your responsibility to determine what is reasonable in your situation. You do not have to apply for this exemption. However, you must submit a PMN 90 days before you intend to manufacture the substance for a purpose other than research and development undertaken in compliance with 720.36. For additional information on R&D requirements see The New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing available at http://www.epa.gov/oppt/newchems/pubs/tmeranddbulletin.pdf or contact the TSCA Assistance Information Service (TAIS, TSCA Hotline) (see Contact List, Appendix B).

c. Test-marketing Exemption Applications (TMEA)

You may apply for an exemption from premanufacture notification if you plan to manufacture a new chemical substance for test-marketing. Test-marketing involves the distribution of a predetermined limited amount of a chemical substance, or of a mixture or article containing the chemical substance, to specified number of customers to explore market acceptability before general distribution. The submitter needs to show that the intended activity is not commercial production and is not appropriately considered to be research and development.

To approve a test-marketing exemption application, the Agency must make an affirmative finding that the new chemical substance will not present an unreasonable risk to health or the environment during the test-marketing activities. 40 CFR 720.38 identifies the type of information you should submit with a test-marketing exemption application. EPA must approve or deny the application within 45 days. If you do not

provide sufficient information for EPA to make its determination, the Agency will deny the request. For additional information on test-marketing requirements, see The New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing available at http://www.epa.gov/oppt/newchems/pubs/tmeranddbulletin.pdf or contact the TSCA Assistance Information Service (TAIS, TSCA Hotline) (see Contact List, Appendix B).

d. TSCA Section 5(h)(4) Exemptions

Under section 5(h)(4) of TSCA, you may apply to EPA for an exemption from some or all premanufacture notification requirements. EPA may grant an exemption if it makes an affirmative finding that the manufacture, processing, distribution in commerce, use, or disposal of the new substance will not present an unreasonable risk to health or the environment. Unlike other exemptions, such as test marketing, EPA may only grant a section 5(h)(4) exemption by rule. In the rulemaking proceeding, the applicant should provide information sufficient to show that the chemical substance will not present an unreasonable risk to health or the environment. The following exemptions have been promulgated under section 5(h)(4):

i. Low Volume Exemption (LVE)

Requirements for a LVE application are found at 40 CFR 723.50. This exemption is available for substances manufactured in quantities of 10,000 kg or less per year. Multiple LVEs can be issued if there are several manufacturers of a single substance; however, second and subsequent applications will be evaluated in the context of existing permitted exposures. Low volume substances are not added to the TSCA Inventory. The notice must include the site of manufacture and proposed use of the new chemical substance; these are legally binding upon the company. The manufacturer may also provide information on exposure controls. If provided, any controls specified in the notice are binding throughout the period of the exemption. EPA will grant the LVE if it determines that the substance will not present an unreasonable risk of injury. The review period for an LVE is 30 days, which can be extended if more information is required.

Companies must notify the Agency within 30 days of a change of the site of manufacture or application. Manufacturers must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. Manufacturers must also notify processors and users of any exposure controls. An LVE submitter is required (per 40 CFR 723.50(k)) to notify its processors and industrial users of the limits on use and required controls for the LVE material, and the Agency can

require a letter exchange between the manufacturer and its customers demonstrating that customers have agreed to these terms. When exposures/risks of potential concern are associated with second-level customers, however, Agency policy encourages submission of a PMN in lieu of an LVE. PMN submission allows control through Significant New Use Rules (SNURs) and consent orders rather than by letter exchange. Submitters whose materials have characteristics which may lead to Agency concerns, and which are expected to go to a second-level customer before being reacted or consumed, should contact a Prenotice Coordinator to discuss whether a LVE or PMN submission is more appropriate.

Recordkeeping requirements are discussed at Section A.13, Recordkeeping.

ii. Polymer Exemption

Requirements for a Polymer Exemption can be found at 40 CFR 723.250. The exemption was first published at 49 Federal Register (FR) 46066. It was subsequently amended on March 29, 1995 (60 FR 16316) and again on January 27, 2010 (75 FR 4295) and there are useful discussions in the Preamble to those publications. This exemption is available for certain classes of polymers which are not chemically active or bioavailable. The manufacturers are not required to submit a polymer exemption notice to EPA prior to manufacture, but must notify the Agency by 31 January of each year for new materials first manufactured in the preceding calendar year. Recordkeeping requirements are discussed at Section A.13, Recordkeeping.

iii. Low Release and Exposure (LoREX) Exemption

Eligibility for this exemption category is independent of production volume. Performance standards for this exemption are set out in 40 CFR 723.50 (c) and include both absolute criteria (e.g., an upper limit on surface water releases) and goals (e.g., no worker exposure). The notice must include the site of manufacture and proposed use of the new chemical substance which are legally binding on the company. The applicant's exemption notice must describe how exposures and releases of the new chemical substance compare to the criteria of 40 CFR 723.50(c). If the exemption is granted the applicant is responsible for complying with the standards and with any controls or limitations specified in this exemption notice. These requirements must be followed throughout the period of exemption. LoREX exemption notices are subject to 30-day review periods by the Agency. Recordkeeping requirements are discussed at Section A.13, Recordkeeping.

4. When to Submit a Notice

You must submit a PMN or SNUN at least 90 days before you begin to manufacture a new chemical substance for a commercial purpose. You are required to submit a notice for LVE or LoREX exemptions 30 days before you begin to manufacture a new chemical substance, and 45 days before manufacture under a TME. If information additional to that provided with the application is needed, these periods can be extended through suspension requests. If your application is not denied, you will be able to initiate manufacture at the end of these review periods. It is prudent for submitters who think their substances may be required to submit additional testing during PMN review to confer with the Agency before submitting and to submit further in advance of their hoped-for start dates than the minimum number of days for review, as additional testing will extend the Agency review period for the PMN. To initiate this process contact a Prenotice Coordinator (see Appendix B).

5. Filling Out and Submitting the Form

a. e-PMN software

The Agency has established TSCA section 5 electronic reporting regulations at 40 CFR Parts 700, 720, 721, 723 and 725. These electronic reporting regulations established standards and requirements for use of EPA's Central Data Exchange (CDX) to electronically submit premanufacture notices (PMNs and exemption applications), other TSCA section 5 notices such as Notices of Commencement (NOCs), Bona Fide Notices of Intent to Manufacture and support documents to the Agency. The documents which are not to be submitted electronically to EPA include section 5(e) Consent Orders, Polymer Exemptions, and Prenotice Communications.

The e-PMN software provides an efficient way to complete and submit TSCA section 5 notification forms and associated data. The e-PMN software is a module within the Chemical Information Submission System (CISS). The CISS was developed by EPA as a web-based reporting tool for use in submitting data for all sections of TSCA electronically to the Agency.

CDX is EPA's electronic system for environmental data exchange to the Agency. The electronic reporting regulations require all persons who will be working online on a submission to register with EPA's CDX and to use the e-PMN module within the CISS to prepare data for submission. CDX registration enables CDX to authenticate the identity of submitters. To submit Section 5 submissions electronically to EPA via CDX, individuals must first register with that system through EPA's web page at

https://cdx.epa.gov/. Limited access of encrypted documents has made it more challenging for companies submitting notices to make changes when employees leave and are replaced. This has been particularly difficult for a few companies whose registered employees have died or been terminated, and whose document passphrases are then not available. We advise companies to think about their succession plans for the individuals who fill these roles.

Since the e-PMN software now exists in the cloud (Thin Client), the role of the Authorized Official (AO) has been expanded. Not only does the AO of the submitting company certify initial notices and submit all types of section 5 documents to EPA via CDX, the role has been broadened to allow non-certifying AOs who work in the submitting company to conduct all section 5 business on behalf of certifying AO; they can do everything except for certifying and submitting initial notices including joint submissions and letters of support. A new role has also been created for Agents and Consultants to conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices including joint submissions and letters of support. Support persons have the ability only to edit information in forms to which they have been granted access by the AO.

All persons preparing a section 5 submission are required to use the e-PMN software. The software guides users through a "hands-on" process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF files or other allowable file types, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. The e-PMN software creates a sanitized version of the data in the EPA Form 7710-25; however, submitters must sanitize their attachments before attaching them to the sanitized e-PMN form.

Further instructions on submitting TSCA section 5 notifications, support documents, and for uploading PDF attachments or other file types are available through EPA's web page at http://www.epa.gov/oppt/newchems/epmn/epmn-index.htm

To submit an amendment to a "valid" notice, the notifier needs to revise the necessary information in the initial notice or a previously modified version of the initial notice and the entire updated notice can then be resubmitted to EPA at this point or saved and resubmitted later. This provides EPA with a complete updated version of the entire submission in one document. The resubmission process will request identification of the changes incorporated into the revised notice in a text field established for this purpose. The notifier must treat "incomplete" or "invalid" notices differently; they cannot be amended as mentioned above. In this instance, the notifier must recreate a

new original notice that includes the corrected information before submitting to the Agency; the submission will receive a new case number and a new day 1.

For Section 5 notices and support documents, there are role designations referred to in registration as “primary” and “secondary” (for both AOs and support persons). “Primary” is the role designation for persons responsible for the original notice submission that is awaiting to be completed by the Secondary joint submitter. “Secondary” is the role designation for persons who will create and submit joint submissions and letters of support.

Submitters should refer to the Users’ Guide for instructions in determining their roles. The Users’ Guide is available through EPA’s web page at http://www.epa.gov/oppt/newchems/epmn/epmn-index.htm

b. General Information

All information provided in a notification must be in English, with the exception that open-literature reports can be submitted in their original languages. If data appears in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume and page numbers. We invite submitters to assist the Agency by providing a photocopy of the article as an electronic attachment to the notice. This is the only exception to the requirement that all information must be submitted in English. Provide all information requested on the notice form to the extent that you know or can reasonably ascertain it. If you do not know or cannot reasonably ascertain the information, enter "NK" ("not known"). Many submitters want to know what is meant by "reasonably ascertainable". In general, the Agency views information in the current literature, held by the submitter or a parent or subsidiary company, or held by a supplier to be reasonably ascertainable.

Some staff members in large corporations have expressed concern for their personal liability on information submission - that there can be information held by their organization which a reasonable search will not uncover. As an example, a branch office of a parent company may have called for a study of a substance and not have retained its results in the ordinary or expected record locations, or a study of a family of substances undertaken for commercialization of one of them may not be found when commercialization of another of those substances is later undertaken. If you think you are in some danger that you might not find all of your company's information about a substance on which you are preparing notification, you should document that you

made a serious search for information, which should have yielded all reasonably ascertainable information, and keep a record of your search with your records of the submission. You should be able to make available to an EPA inspector records showing: that you identified where in your corporate organization (or your suppliers) the information might be, that you sent requests for information to each site where you think the information might be kept, and that you followed up with any non-responding site until you got a response. You should review all applicable information on the substance, such as the Safety Data Sheet (SDS) or Material Safety Data Sheet (MSDS) for the existence of testing on the new chemical substance. It is helpful if there is a corporate information policy to ensure that this sort of information is available to a responsible PMN submitter.

Form 7710-25 is used for several different types of submissions (i.e., PMNs, LVEs, LoREXes, SNUNs, modifications to LVEs and LoREXes, and TMEAs). Notices of Commencement (NOCs) must be submitted electronically, as well, on Form 7710-56.

c. TSCA User Fee

A user fee must be remtted for PMN, MCAN and SNUN Section 5 notices in accordance with 40 CFR 700.45. You must create a unique alpha-numeric identification number ("TS-number") to identify and link your notice with the remittance fee. This six digit number must be placed on the first page of the form in the boxes that have been provided. This number must also be placed on your fee remittance. EPA uses a private bank in St. Louis to receive checks, money orders and bank drafts; they should be made payable either to 'USEPA' or 'US Treasury'. After the bank has processed the payment, the TS Number is sent to EPA Headquarters with certification that payment has been made. EPA Headquarters then verifies that the appropriate remittance with a TS identification number corresponds to a user fee identification number on a PMN and further processing of the notice commences. However, if a problem arises in the payment procedure, (i.e., insufficient funds, improper usage of the TS-number), the notice will be given incomplete notice status in accordance with 40 CFR 720.65(c). The EPA will inform the submitter in writing if this action is taken.

i. What is the fee for submitting?

The fee for most PMN submissions is $2,500.00. The fee is reduced under certain conditions: (1) if your company qualifies as a small business (sales, including those of subsidiary/parent companies, are less than $40 million/year), the fee is $100.00; (2) if a **PMN for an intermediate substance** is submitted with a final product PMN, the fee for

the intermediate substance is $1,000.00; and (3) if a **consolidated PMN**, as approved by a Prenotice, is filed for multiple chemicals (no more than six) that are related, the total fee is $2,500, except that for a small business it is $100.00.

When several product PMNs have been consolidated, the Agency will consider consolidation for intermediates used in their syntheses where those intermediates are used at parallel stages in their syntheses.

For information about PMN fees see 40 CFR Section 700, or contact the TSCA (Toxic Substances Control Act) Assistance Information Service (tsca-hotline@epa.gov).

ii. How do you submit PMN fees?

Fees can be submitted by check or paid by credit card.

To send checks:

The bank that for a number of years provided "lock box" services accepting TSCA section 5 Premanufacture Notice user fees (Mellon Bank, Pittsburgh, PA) has been changed; we are now using US Bank in St Louis Missouri. User fees sent to the Pittsburgh post office box address formerly listed for PMN payments are no longer being forwarded to the St. Louis lock box service at the address below. Please use the address below for user fee payments.

US Mail:
U.S. Environmental Protection Agency
Washington Finance Center
Toxic Substances Control Act User Fees
P.O. Box 979073
St. Louis, MO 63197-9000

Courier services:
U.S. Environmental Protection Agency
Washington Finance Center
Toxic Substances Control Act User Fees
Lockbox 979073 - US Bank
1005 Convention Plaza
St Louis, MO 63101

The telephone number for US Bank staff, which the courier service can use, is: 314-418-1618

To pay by credit card, using the US Treasury Pay.gov program:
The New Chemicals program can accept payments made through the Pay.gov program of the US Treasury. Pay.gov can be a mechanism for paying using a credit card. Pay.gov has generated a form for paying TSCA fees. The form can be found on the Agency List at the Pay.gov homepage, as well.

d. Incomplete Notices

40 CFR 720.65 specifies administrative procedures applicable to incomplete notices in general. The most frequent reason for a submission to be incomplete is a name which is not in conformance with the current CA Index of Chemical Abstracts nomenclature rules and conventions (this definitive guide to CA nomenclature has been used since 1972.) If the notice is declared incomplete, the submission becomes invalid. The review period begins again when a complete notice is refiled. Also, if one chemical in a consolidated set is declared incomplete due to chemical identity, the entire set is declared incomplete. If the notice is declared incomplete, the review period has not begun no matter when in the initial review period the notice is declared incomplete. Therefore, the default review period begins again at day one when a complete notice is received. EPA can, however, choose to restart the clock on the day the notice was declared incomplete if it determines that its review can be completed within the remaining period. This decision is made case-by-case. [See 40 CFR 720.65(c)]

6. Binding Boxes

Control measures instituted by the submitter to reduce exposures and/or releases of the substance may have a direct bearing on the Agency's conclusions regarding risk. Therefore, you may wish to indicate your willingness to be bound to certain submitted information on the form which is related to the issue of potential risk such as use, production volume, protective equipment, engineering controls, and/or process description. In order to make your willingness known to EPA, mark in the "Binding Option" box on EPA Form 7710-25 located to the right of the appropriate information.

In the case of PMNs, if Agency reviewers think binding control measures for your PMN can enable us to approve your application, a Program Manager will contact you. Indicating a willingness to be bound by the terms of your PMN notice does not by itself prohibit the submitter from deviating after the end of the review from the information (except chemical identity) which had been reported in EPA Form 7710-25 (unless the

submitter and the Agency enter into a binding TSCA section 5(e) Consent Order), but it does provide a starting point for discussions between EPA and the submitter.

A checked box can help EPA and the PMN submitter negotiate efficiently in the development of 5(e) consent orders and help the Agency promulgate Significant New Use Rules (SNURs) for those new chemical substances that the Agency determines may present an unreasonable risk if certain control actions are not implemented. The purpose of the binding box is to reduce delays that can slow the development of consent orders absent such prior agreement.

In the case of exemption applications (i.e., TMEs, LVEs and LoREXes), however, use, protective equipment, engineering controls, and process description are binding on the submitter when the Agency approves the exemption applications whether or not the binding boxes are checked. Production volume can be binding when so identified by the Agency during review, and in no case can go over 10,000 kg/yr in the case of a LVE application.

7. Test Data and Other Data

You are required to provide any test data on the health and environmental effects of the new chemical substance, including data on physical/chemical properties, in your possession or control, and a description of any other health and environmental effects data on the substance known to or reasonably ascertainable by you. Data in the possession or control of either a parent company or an affiliated subsidiary located outside the U.S. are considered by the Agency to be data that should be known to or reasonably ascertainable by a submitter (see section A.5.b, above).

Data must be submitted in English. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (not summaries) must be submitted if they do not appear in the open literature. Incomplete reports (e.g., from ongoing studies) are exempt from full reporting. However, you must describe the nature and objective of any incomplete study, report, or test, the name and address of any laboratory developing the data; progress to date; type of data collected; significant preliminary results; and an anticipated completion date. If significant preliminary results or final results are obtained prior to the completion of the notice review period or any other additional information significant to the review of the notice becomes available to you, you must submit this information within 10 days of receipt, but no later than 5 days before the end of the review period. If information becomes available during the last 5 days of the review period, you must immediately inform EPA by telephone.

Examples of the types of test data you must submit are provided in Appendix A of this manual. In addition, a Physical and Chemical Properties Worksheet appears on the last page of EPA Form 7710-25. For additional information on health and safety studies and on submitting test data, see 40 CFR 720.3 and 40 CFR 720.50. Attach test data to EPA Form 7710-25 and it will be referenced in Part III, List of Attachments.

You are not required to submit any data previously submitted to EPA with no claims of confidentiality if you identify in your submission the office or person to whom you submitted the data, the date it was submitted, and, if appropriate, a standard literature citation. If, however, you submitted data with claims of confidentiality, you must resubmit the data with the notice and any claim of confidentiality under 40 CFR 720.80. You also are not required to submit data related solely to product efficacy. This exception does not apply to information required in the notice, test data, or other data.

8. Confidentiality

a. Asserting claims

You may assert a claim of confidentiality for any information submitted to EPA. To assert confidentiality for specific information on the form (e.g., submitter identity, chemical identity, or use information), mark in the "Confidential" or Confidential Business Information (CBI) box on EPA Form 7710-25 located to the right of the information. As well, the box at the bottom of PMN Page 1 of the form is checked if any information in the notice was claimed as confidential in the form.

To assert confidentiality claims for information in attachments to the form, provide a complete copy of the attachment that clearly indicates (e.g., by circling, bracketing or boxing) the information you wish to claim as confidential. Bracket only the specific information you claim as confidential. For example, if you submit a study which contains a physical or chemical property and it is only that property which you wish to claim as confidential, bracket only that property. You must also provide a redacted version for the public file. As well, you must also clearly and specifically identify any confidentiality claims you wish to make for information or correspondence subsequently submitted to EPA about your notification, and it is prudent to provide a redacted version for the public file.

If you claim the identity of the new chemical substance or its category of use as confidential, you must provide a generic description of this information, as indicated in

the appropriate sections of the form. Guidance on developing generic names is given in Section B.2.b of this instruction manual.

This version ("sanitized", "redacted") will be placed in the public file. It must contain all non-confidential information, including health and safety studies. A health and safety study means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under TSCA. If you later provide amendments/additional information, you must also provide a redacted version for the public file.

Information from health and safety studies which can be claimed confidential is quite limited - this is discussed at 40 CFR 720.90. Chemical identity is assumed to be part of a health and safety study. 40 CFR 720.90(b)(2) discusses the claims which must be made and substantiated for chemical identity in a health study to be confidential: that disclosure would reveal manufacturing or processing information, that it would disclose the fraction of a mixture which the substance comprises, that the study could be interpreted without knowing the identity of the substance, and that disclosure would have harmful competitive effects on the submitter.

Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. In sum, any data that bear on the effects of a chemical substance on health or the environment would be included.

b. Substantiating claims

You are not required to provide substantiation of any confidentiality claim when you submit your notice. However, you must substantiate your claim of confidentiality for chemical identity at the time you submit a Notice of Commencement of Manufacture (NOC), if you want EPA to maintain your confidentiality claim after you begin manufacture. (NOC requirements are described in 40 CFR 720.102 and in Section A.12 of this manual.) To substantiate that claim, you must provide EPA with detailed answers to questions which appear in 40 CFR 720.85(b)(3)(iv).

This substantiation must accompany your NOC. You may be required to substantiate other confidentiality claims if EPA receives a Freedom of Information Act (FOIA) request on that information.

9. Consolidated Notices; One-Pot Mixtures

If you are manufacturing two or more, but no more than six, structurally similar new substances, you may contact a Prenotice Coordinator (see Appendix B) to obtain approval to submit a single consolidated PMN notice. A consolidated notice is suitable for chemical substances of similar structure with the same or similar uses and which share similar test data and other information. A consolidated notice must identify each new substance individually; you may not submit a consolidated notice for an open-ended category. A separate chemical identity page must be provided for each substance. A distinct Agency "PMN" number is assigned to each chemical. It will be unusual if the Agency approves a request to consolidate a series of intermediates and a final product as they generally will not share common uses, test data, and other information. Consolidations are not given for LVEs, LoREXs and TMEA applications.

EPA encourages you to submit consolidated notices when appropriate. You may submit a consolidated notice only after you have received prior approval from a Prenotice Coordinator. This request should concisely describe the chemical identity of each substance to be included in your consolidated notice (note: you need not use names from the Inventory Expert Service of the CAS to request approval for a consolidation). You need only to describe the chemical substances well enough that EPA personnel can determine whether they are similar enough for combined review. You must, however, use separately obtained Method I names for each substance in a consolidation when PMN is submitted. Many requestors provide this information using the chemical identity pages of the form or in a one page table format. Remember to enter your prenotice communications number given to you by the Prenotice Coordinator in Part I, Section A(3) (PMN Page 3) of the form.

If you are submitting on two or more materials made in the same synthetic operation and for which you do not intend separation, the Agency considers this to be a ‘one-pot mixture’. These materials can be submitted in the same application, and the submitter does not need to get approval from a Prenotice Coordinator for this. The chemical identities are given on a single page, rather than one identity per page as is the practice for consolidated submissions. These materials need not be chemically nor toxicologically similar. As well, LVE, LoREX, and TMEA applications, which are not eligible for consolidations, are appropriate for one-pot single submissions. Please identify the submission as a one-pot mixture in a cover letter, to ensure it is treated appropriately at our pre-screen phase.

10. Submission of Information by Others

a. Submission by an agent

For information on submissions by agents, see 40 CFR 720.40(e).

b. Letter of support/ Joint submissions

You may also prepare and submit a PMN with another person. A letter of support or joint submission may be useful where different persons have information required in the notice, including a situation when another person has information fundamental to the notice, but wishes to keep it confidential to the other party. For example, you may have information on the identity and the physical and chemical properties of the new substance and another person may know its manufacturing process and its intended use.

Because signatures are required by each party of a joint/Letter of Support submission, each party will need to complete its own sections of information and submit as two separate notices (note: this requires both parties of the joint submission to register to submit to EPA via CDX). The TS number should be the same for each notice. The person sending in the document should be listed in section 1a and the joint submitter will be listed in section 1c; the Letter of Support submitter will be listed on a continuation page. Each submission (primary submission as well as the joint/Letter of Support submissions) should have a cover letter in which the primary submitter for the chemical is identified and the secondary submitter(s) is also identified; also, in the cover letter enter comments regarding what information will be supplied in this secondary submission.

Due to validation requirements, each joint submitter may need to enter "see joint submitter" in required text fields, add an attachment which says "see joint submitter" for required structure fields, and enter "1" for any required number fields like production volume (and they can attach the "see joint submitter" attachment to the section as an explanation).

To create a secondary submission, log into CDX and select Secondary Authorized Official as your user role. Launch the "TSCA Section 5 Notices and Supports – ePMN" program and from the Forms screen, select to "Start New Form". The Authorized Official of the primary submission should send an email to the secondary party(ies) which contains a system generated unique identifier. The secondary Authorized Official enters the unique identifier to create the second party submission.

Each joint submitter must sign the certification on the form. Each person must also assert all confidentiality claims as described in 40 CFR 720.80 and in Section A.1 of this manual. However, you are not relieved of statutory notice requirements by arranging a joint submission. You are required to complete all mandatory sections of the form to the extent that you know or can reasonably ascertain the information, even if another person also submits information for a certain section.

If you submit a joint notice, the review period will not begin until EPA has received all required parts of the notice. You should identify the joint submitter in your notice and identify the section(s) which the person is submitting. See 40 CFR 720.40(e) for additional information on joint submissions.

11. Consultation with EPA Concerning the Premanufacture Notice

a. Before notice submission

i. General inquiries

General inquiries concerning the premanufacture notification program which are not related to a specific chemical or notice should be directed to the TSCA hotline (see Contact List, Appendix B). Copies of the TSCA section 5 rules, this Instruction Manual, and other materials relating to the TSCA Section 5 New Chemicals Program are available on the New Chemicals web site, http://www.epa.gov/oppt/newchems/.

ii. Specific inquiries

Specific inquiries concerning the TSCA section 5 notification requirements, confidentiality, joint submissions, consolidated notices, etc., should be directed to the Prenotice Coordinator. You can contact the Prenotice Coordinator by telephone, facsimile, or email (see Contact List, Appendix B).

b. During notice review

Upon receipt of the notice by the OPPT Document Control Officer (DCO), the Agency will make an initial determination whether the notice is complete. The initial determination looks to see that the notice contains all the items required on PMN Pages 4 through 8 of the form and for apparent chemical identity problems. If no problems are

seen, your form is initially determined to be "complete", goes on for further review, and Day 1 of the 90-day review period is assigned as the date of receipt by the DCO. A more detailed review can, however, discover other additional information that has not been provided, and you can be contacted to provide additional information at any time during the review period.

You will receive written notification if your notice is declared "incomplete" as described at 40 CFR 720.65. If your notice is initially considered complete, you will receive an acknowledgment letter telling you your notice number and the Day 1 for the review period. The Inventory is searched to ensure that the substance for which the notice is submitted is not already included on the TSCA Chemical Substance Inventory. If your chemical substance is on the Inventory, you will be notified that your substance is not subject to premanufacture notification, and that you are free to begin manufacture immediately, subject to any conditions which may have been established for the material. If the substance is not on the Inventory, and if the substance is not dropped from further review at the Agency's initial review meeting ("Focus Meeting", which takes place at approximately Day 20), a Program Manager will be assigned to coordinate the review of the notice and to be your official contact with the Agency throughout the remainder of the review period. Based on decisions made at the Focus Meeting, it is possible that EPA may declare the PMN to be "incomplete." Also during the review period, the Program Manager may contact you for clarification of information you have provided in the notice or if the Agency identifies issues of concern. If you are not contacted prior to the expiration of the review period, you are free to commence manufacture of the substance identified in your notice after the review period has expired. You can check the status of your submission at the New Chemicals Internet site (http://www.epa.gov/oppt/newchems/tools/status1.htm) after approximately day 30.

The Program Manager will also notify you before the review period expires if he/she will extend the review period under TSCA §5(c) or if regulatory action is being considered on the new substance under TSCA §5(a), §5(e) or 5(f). TSCA §5(e) Consent Orders are typically issued with a follow-up TSCA §5(a) SNUR subsequently promulgated. In addition, a Program Manager will contact you if the Agency plans to develop a non-§5(e) SNUR (a case in which a 5(e) Consent Order does not precede the development of a SNUR) on the chemical substance identified in your notice.

12. Notice of Commencement (NOC) of Manufacture (or Import)

If EPA has not taken any action to regulate the new chemical substance during the review period, you may begin manufacturing the new chemical substance upon

expiration of the review period. For a PMN, EPA requires that you notify the Agency by using EPA electronic form 7710-56, no later than 30 calendar days after the first day of such domestic manufacture or import for non-exempt commercial purposes (for import, Day 1 is the date the material clears US Customs) (see 40 CFR 720.102).

Your NOC must be submitted electronically by CDX to EPA even if it is a NOC for a PMN filed before the CDX enabled electronic submissions. In your NOC, you must provide the specific chemical identity of the substance, its PMN number, the site of first domestic manufacture or import, and the date when domestic manufacture or import began. You must also substantiate a confidentiality claim for chemical identity in your letter if you want EPA to maintain the claim after you begin domestic manufacture or import, by answering the questions shown below:

> (A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?
>
> (B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?
>
> (C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?
>
> (D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?
>
> (E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g., in technical journals or other publications; in libraries; or in State, local or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product; in an effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in 40 CFR 720.90(b)(2). **(Persons must answer this question if a health and safety study was provided at any time in the new chemical process.)**

See 40 CFR 720.85(b) for further information on substantiating confidentiality claims.

13. Recordkeeping

Recordkeeping requirements for submissions under §5 of TSCA are found in several different sections of the CFR.

a. PMN or SNUN

40 CFR 720.78(a) requires that you retain documentation of information for a PMN or SNUN for five years from the date of commencement of manufacture. You are not required to develop information solely for recordkeeping purposes, but only to retain information you have obtained or developed in the course of completing your submission.

The records you must retain include (1) information supporting the information supplied on the notice form, (2) other data, as defined in 40 CFR 720.50(b), in your possession or control, (3) production volume for the first three years of domestic production or import, and documentation to support your stated production volume, and (4) date of commencement of manufacture, and documentation to support your stated date.

b. Research and Development

40 CFR 720.78(b) requires that if you manufacture a new chemical substance under the exemption for substances manufactured solely for research and development, you must retain documentation of compliance with the exemption until five years after they are developed.

c. Test-Marketing Exemption

40 CFR 720.78(c) requires that, if you manufacture under a test-marketing exemption under TSCA, you must retain documentation of information in the application and documentation of your compliance with any restrictions imposed by EPA when it granted the application until five years after the final date of manufacture under the exemption.

d. LVE or LoREX

40 CFR 723.50(n) requires that each manufacturer of a new substance reported under the terms of a LVE or LoREX exemption must maintain records of (1) the annual production volume of the new chemical substance under the exemption, and (2) documentation of information in the exemption notice in compliance with the terms of the exemption. Records must be retained for five years after date of their preparation.

e. Polymer Exemption

40 CFR 723.250(j) requires that a manufacturer of a polymer made under the terms of the polymer exemption must maintain records for five years from the date of commencement of manufacture for: the production volume for the first three years of manufacture, the date of commencement of manufacture, documentation of the information provided above, documentation of any other information provided in the

notice, such as information that demonstrates that the new polymer is not specifically excluded from the exemption and the polymer meets the exemption criteria.

14. Recognition of Pollution Prevention and Recycling Benefits

During the course of its review, the Agency will be considering whether the activities surrounding the manufacture, processing, distribution in commerce, use, or disposal of the substance identified in the notice may present an unreasonable risk of injury to human health or the environment.

It is also important that EPA be provided with any information regarding technological, risk reduction, or environmental benefits which may be realized if the new chemical being notified is introduced into commerce in the United States. By submitting information describing the positive pollution prevention aspects of your PMN substance, you may achieve two possible benefits: first, the pollution prevention information may enable EPA to regulate the substance less stringently than it would have absent the information, and second, the pollution prevention information may be chosen by the Agency for affirmative recognition as part of the EPA New Chemicals Pollution Prevention Recognition Project. Therefore, PMN submitters are encouraged to complete and provide the optional information on pollution prevention on PMN Page 11 of form 7710-25.

In the Agency's EPA New Chemicals Pollution Prevention Recognition Project, EPA seeks to promote safer new chemicals and processes, providing several forms of recognition, including a letter from the Director of OPPT, inclusion in a listing of recognized chemical substances on the OPPT Internet Homepage, and other positive publicity. If you want the Agency to consider your PMN substance for this recognition, you must explicitly request to be considered in your response on the (OPTIONAL) POLLUTION PREVENTION AND RECYCLING INFORMATION page of the PMN form and identify the pollution prevention merits of your PMN substance. To the extent that you think it helpful for Agency consideration, EPA strongly encourages you to (1) submit actual test data on the PMN substance to substantiate any pollution prevention claims you assert and (2) minimize claims of confidentiality claims to facilitate publicity regarding the PMN substance.

For example, the EPA will consider any information on methods used to minimize potential risks associated with the new substance through source reduction or recycling. Some of the benefits for which information may be provided are a reduction in the volume manufactured, a reduction in the generation of waste materials, a reduction in exposure and/or environmental release or increased performance and/or operation

efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications. Recycling activities include reclamation of useful chemical components from wastes that would otherwise be released as air emissions, water discharges or land releases during manufacture, process or use. All descriptions may be quantitative or qualitative.

The "Optional Pollution Prevention Information" page of the PMN requests optional information that will be used in the evaluation of the new chemical substance and to compare the relative risks and benefits of the substance as a substitute for substances with similar uses currently on the market. PMN submitters are encouraged to report any and all relevant information not reported elsewhere in the PMN which they believe to be important to a thorough regulatory decision. The page provides submitters with the opportunity to describe pollution prevention and risk reduction options considered by the company in regard to the submission. A useful format for presenting such information is provided Part B, Section 4 of this Manual. Providing this pollution prevention information to EPA may benefit PMN submitters by reducing regulatory controls and/or testing requirements, if the pollution prevention information sufficiently mitigates EPA's concerns for the toxicity, human exposure, or environmental releases of the PMN substance. EPA considers this information in line with the strictures of the Pollution Prevention Act of 1990.

Under the Pollution Prevention Act of 1990 (PPA), Congress established a national policy that: (a) pollution should be prevented or reduced at the source whenever feasible, (b) pollution that cannot be prevented should be recycled in an environmentally safe manner whenever feasible, and, (c) disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.

EPA defines "pollution prevention" to mean "source reduction," as defined under the PPA, and other practices that reduce or eliminate the creation of pollutants through; (a) increased efficiency in the use of raw materials, energy, water, or other resources, or, (b) protection of natural resources by conservation.

The PPA defines "source reduction" to mean any practice which: (a) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal, and, (b) reduces the hazards to workers, public health, and the environment associated with the release of such substances, pollutants, or contaminants.

The term includes: equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control. The term "...does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process which itself is not integral to and necessary for the production of a product or the providing of a service" (Sec. 3(5)(B)). Thus, end of pipeline controls, such as thermal oxidizers, incinerators, or waste water treatment systems are not defined as "source reduction".

EPA is interested in information on how improved processes for handling individual new chemical substances may reduce potential exposures and releases of specific PMN substances. Submitters may include a discussion of Pollution Prevention/Risk Reduction measures actually selected for implementation and the rationale for the selection. Submitters are encouraged to consider and include information comparing the releases and exposures for various process options considered but not selected, anticipated reductions in releases and exposures which can be expected in the production of the PMN substance as compared to an existing chemical substance, and how the PMN substance and/or the product in which it is used may compare favorably with existing chemicals in terms of pollution prevention. Submitters may also describe other pollution prevention-related advantages, such as process modifications, increases in product life or durability, or decreased energy consumption, etc. A set of questions to address these concerns is put forward in Section II of this Manual.

EPA is also interested in information describing possible reductions in toxicity, and human exposure, as well as environmental release of a new chemical substance, as compared to those of already commercialized chemical substances for which the new substance may substitute. Such information may demonstrate that the new chemical substance is a viable safer substitute for an existing chemical substance.

Voluntary submission of pollution prevention information is not intended to negatively affect the outcome of EPA's review of the Premanufacture Notification. When risk reductions are documented, the information will be carefully considered during EPA's review of the PMN.

Useful reference material on pollution prevention are available on EPA’s P2 website at: http://www.epa.gov/p2/.

B. PAGE-BY-PAGE INSTRUCTIONS FOR COMPLETING THE TSCA §5 NEW CHEMICALS PROGRAM PREMANUFACTURE NOTICE (PMN) FORM 7710-25

1. Administrative Information

a. Identify Type of Notice, Your Submission (PMN Page 1)

Total pages: In order for the e-PMN software to calculate number of pages, you must provide the total number of pages for each attachment.

TS-number: The submitter chooses this number. It is used by the bank which receives money for EPA ("drop-box service") when it notifies the Agency that the fee has been received, and also to enable EPA to assemble the parts of a submission when additional communications (letters of support, joint submissions, and corrections) are sent before a tracking number (e.g., a PMN or LVE number) has been assigned by EPA to the notification. There are six spaces in the TS-number block on Form 7710-25. We have actually had duplication of TS-numbers, and these instructions have been revised to add some new requirements to make duplication less likely in future: your TS-number must be a 6-character alphanumeric. It should include 2, 3, or 4 letters. One or more numerals must be interposed between two letters (that is, LLNNLL, LNNNLL, NNLLNL, NLNLNL are okay, LLLNNN, NNNNLL are not). We recommend against company names, recognizable words and numerical series (ROY01X, X01DOW are not good ideas). The TS-number should be unique to this submission from your company, do not give this number to a subsequent submission.

Confidentiality Claims: Check this box if ANY information in the form is claimed confidential.

Test and Other Data: Indicate which types of data are included with the notice by checking the appropriate boxes.

Type of Notice: Please identify the type of notice being submitted by checking the appropriate box.

Check "**PMN**" if the application is for a standard, new chemical substance for placement on the TSCA Inventory. Also check "**PMN**" if this notice is for a chemical substance which is an intermediate used in the direct production of another chemical intermediate or a final product for which a separate notice is submitted simultaneously, and for

which the submitter has no intention of making a non-intermediate use. In addition, the intermediate PMN must identify the final product. Separate user fee identification numbers must be generated for and appear on each notice; although a single check may be remitted bearing all user fee identification numbers for a sequence of intermediate(s) and final product. "Certification", below, discusses fees paid by small manufacturers. For further information on "intermediate PMNs" see 40 CFR 700.43 and 40 CFR 700.45(b)(2)(ii).

The "**Significant New Use Notice**" (SNUN) box should be marked for any notice that is submitted in accordance with a SNUR.

The "**Test Marketing Exemption Application**" (TMEA) box should be marked for any notice submitted in accordance with the criteria listed in 40 CFR 720.38. You are now required to use form 7710-25 to submit a TMEA; however you may provide the information in a cover letter or attachment**.**

Boxes are also provided to identify your submission as an application for either a "**Low Volume Exemption**" (LVE) [see 40 CFR 723.50(c)(1)] or a "**Low Release/ Low Exposure Exemption**" (LoREX) [see 40 CFR 723.50(c)(2)]. These exemptions must be requested through use of the PMN form. Modifications for earlier approved requests for either of these exemptions are requested by checking the modification box on the first page of the PMN form.

For an application to modify an LVE or LoREX exemption, a submitter is not required to provide again information which was submitted in a previously approved exemption. Each data element for which information has changed, must be provided. Any application to modify an LVE for a substance which had been the subject of an LVE which had been submitted before the amendments of March 29, 1995, however, is a new application and the full notice must be submitted.

Consolidated PMN: If this notice is for a consolidated PMN, the number of chemicals (two or more, but no more than six) included in the notice should be entered on page one in the space provided. A separate PMN number is assigned by EPA to each chemical substance identified in a consolidated notice. Approval for a consolidated PMN notice must have been obtained from the Prenotice Coordinator prior to submission. You are required to identify the Prenotice Communication number you were given when your consolidation was approved on PMN Page 3, question 3 of the form. Further information on submitting a consolidated notice is provided at Section I, Part I of this manual.

b. Certification (PMN Page 2)

The official named in Part I, Section A of the form as the person submitting the notice must select the certification statements on PMN Page 2 of the notice form. This official is responsible for the truth and accuracy of each statement in the certification, and signs electronically.

In addition, the submitter must check certain "user fee" certification statements as appropriate as required at 40 CFR 700, Subpart C. For a PMN, consolidated PMN or SNUN, a fee is required. If the submitter is a small business, it must remit the fee identified in 40 CFR 700.45(b)(1) (small business concerns remit a fee of $100). If the submitter is not a small business, it must remit the fee identified at 40 CFR 700.45(b)(2) (all non-"small" submitters remit a fee of $2,500 for final products, $1,000 if the submission is for an intermediate and is submitted with the application for the final product).

A small business concern is one whose total annual sales (include all sites, including those owned or controlled by a foreign or domestic parent company) are below $40 million for the fiscal year preceding the date of the submission of the applicable §5 notice (see 40 CFR 700.43).

When using the PMN form to submit a LVE or LOREX application in accordance with 40 CFR 723.50, all three of the corresponding certification statement boxes must be checked to acknowledge that you will manufacture under the terms of the exemption. In addition, a submitter of an LVE application must certify that the manufacturer intends to commence manufacture of the proposed exempted substance for commercial purposes within 1 year of the date of expiration of the 30 day review period. There is no fee for an LVE or LOREX.

2. GENERAL INFORMATION-- (Part I)

a. Submitter Identification (Section A, PMN Page 3)

(1a). **Person Submitting Notice** - This information will populate from your e-PMN registration.

(1b). **Agent** - Complete only if you authorize an agent to assist you in preparing this notice.

If you mark the "Confidential" box next to items 1a or b, all information in the item will be treated as confidential.

(1c). **Joint Submitter** - Mark the box if your submission is a joint submission. Identify in Part I, Section A (1)(c) the name of the joint submitter who is authorized by the U.S. submitter to provide some of the information required in the notice. For additional information on joint submissions, see Section A.10 of this Manual. A notice will not be considered complete until all information is received by the Agency. If information from multiple parties will not be sent to the Agency in the same package, use your TS user identification number to link multiple notices. You can generate a TS-number solely to link submissions, even for a no-fee exemption.

Mark the "Confidential" box next to item 1c if you wish this information to be treated as confidential.

If you authorize another person (e.g., a foreign manufacturer or supplier) to provide information directly to EPA, such as confidentially held trade name chemical substance identification, indicate which information will be supplied by the other person. Identify that person by name, company, and address in a continuation sheet. That person's identity may be claimed as confidential. Review period for a notice will not begin until this information is provided. Use your TS-User Identification Number to link this information.

(2). **Technical Contact** - Identify a person who can provide EPA with additional information on the new chemical substance during the notice review period. The technical contact identified should be located in the United States and be available to be reached by telephone during normal business hours. If you mark the "Confidential" box next to this subsection, all information in it will be treated as confidential.

(3)**. Prenotice communication number** Provide any prenotice communication number assigned to your prenotice inquiry. In addition, see Section A.9 of this Manual for further information on submission of a consolidated PMN that requires a prenotice consultation.

(4). **Previous exemption application** Provide the exemption number assigned for any previous exemption application submitted for the chemical substance covered by this notice. It is especially important for an exemption modification request that you provide the EPA assigned exemption number from your original exemption application. Also, provide a previously assigned PMN number, if any, for the chemical substance.

(5). **Previous Submission of Statement of Bona Fide Intent to Manufacture**. Self-explanatory.

(6). **Manufacture or import** Mark to indicate whether you intend to domestically manufacture or import the new chemical substance or both domestically manufacture and import. Use the optional binding box to indicate your willingness to be bound to either import or domestic manufacture only.

b. Chemical Identity Information (Section B, PMN Pages 4-6)

Submitters of PMN and exemption notices are required to provide the currently correct Chemical Abstract (CA) name for the substance(s) identified in the notice based on the current CA Index of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. EPA must receive complete and unambiguous identification of the new chemical substance. If the substance is not adequately identified, the submission will not meet statutory requirements and the notice review period will not begin. If a principal importer does not know the specific identity of the new substance, the submitter must contact the foreign manufacturer or supplier and have the specific chemical identity information required in the PMN provided directly to EPA. In this way, foreign manufacturers can protect confidential business information. The same holds true for U.S. manufacturers reporting chemical substances using a generic or trade name to identify a component of the new chemical substance. The submitter of the new chemical substance must have the supplier provide chemical identity information directly to EPA before the notice can be considered complete. This information may be provided in a letter of support from the supplier or as a joint submission between the two companies. A letter of support should be provided on the supplier company's letterhead. See Section A.10 of this manual on how and when to file a joint submission. Since a letter of support or a joint submission may be received separately by the Agency, an identification number such as a TS-user fee number should be used to link a PMN with information from a supplier or foreign manufacturer. The TS- number should appear on both pieces of correspondence submitted to EPA; otherwise, there can be a delay in processing the PMN.

The type of chemical identity information required in the notice depends on whether the substance is a Class 1 or Class 2 substance or a polymer. A **Class 1 chemical substance** is a substance whose composition, except for impurities, can be represented by a definite chemical structural diagram. For Class 1 substances, a name that is consistent with the nomenclature rules and conventions of the current Index of the Chemical Abstracts Service (CAS) and with current TSCA Inventory listings must be

provided. Examples of such substances are 1,3- butadiene, benzene, and sodium chloride.

A **Class 2 chemical substance** is a substance whose composition **cannot** be easily represented by a definite chemical structural diagram. Such a substance is generally derived from natural sources or complex reactions. Its composition may be complex, difficult to characterize, and variable. For Class 2 substances and polymers, a CA Index Name or CA Preferred Name must be provided. In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Trade names or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names. Unacceptable names would include, *e.g.*, "chlorinated naphthalene", "glycerol monoester of hydrogenated cottonseed oil acids", or a "reaction product of x, y, z".

A **polymer** is a substance composed of molecules characterized by the regular or irregular repetition of one or more types of identical monomeric units. In most cases, the number of monomeric units is quite large and not precisely known.

If the substance is clearly a Class 1 or 2 substance, then items a-d of Question 1 on PMN Page 4 must be properly completed. If the substance has been named as a polymer (whether the Exemption Rule requirements are met, or not), then items a-c of Question 2 on PMN Page 5 must be addressed and answered completely. If you are uncertain whether the chemical substance is a Class 1 or 2 substance or a polymer, contact the Prenotice Coordinator for further assistance. If the variability of the composition of a reaction product is too complex to be described as distinct individual components, then reaction product nomenclature is employed. If, however, components of a reaction product can be readily identified and will always be present in the reaction product, then the components should be specifically identified and may be listed individually on the TSCA Inventory. All reaction products may be reported as Class 2 substances. Submitters may obtain the correct chemical identity of the PMN substance through the Chemical Abstracts Service (CAS) Inventory Expert Service (so-called Method 1) or from any other source (so-called Method 2). Consolidations MUST be submitted with Method 1 names. A notice submitter must identify in the chemical identity section which method they used to report the substance's identity. For Method 1, a copy of the CAS report must be attached to the notice.

Submitters who choose to develop their own chemical identity are cautioned that the Agency will consider submissions incomplete and thus delay their review if incorrect nomenclature is received from a source other than CAS. If the Inventory Expert Service

has been used and all identity information was properly supplied to CAS, the Agency will work with the IES to agree on a name, and the review period will not be affected. Use of CAS services other than the Inventory Expert Service, including CAS' Registry Service or CAS Client Services, will also be considered Method 2. In all cases, each chemical substance in a consolidated submission must be identified by Method 1 except in cases where third party identity information has been confidentially provided to the Agency.

i. Class 1 or Class 2 chemical substances (PMN Page 4)

a. Mark the appropriate class.

b. Enter the specific chemical name of the new chemical substance.

For a Class 1 substance, the name must be a clear description of a unique substance. In describing the chemical substance, the EPA requires Chemical Abstracts Service (CAS) chemical nomenclature be used for identification purposes when it is available. There is a separate box in question one, item c on PMN Page 4 for entry of the CAS number. You are required to enter the CAS registry number, if one has been assigned to the substance. The Agency encourages submitters to have contact with CAS prior to submission in order to obtain concise chemical identity information. Use the CAS standard rules of chemical nomenclature to identify the new substance. Identify the positions of attachment of chemical groups or of unsaturation, if any, by using locants. The chemical name should contain all of the information known about the details of the structure and should permit the drawing of an unambiguous chemical structural diagram.

The chemical name of a Class 2 substance must describe the chemical substance as completely as possible. In some cases, the name may be similar to the names used to describe Class 1 compounds, but it should indicate the substance's multiple components. For example, "polychlorinated biphenyl" indicates a composition that has multiple components varying both in the number and the placement of the substituent chlorine atoms. In other cases, the best possible name may only identify the substance as a reaction product of specified reactants, for example, "anhydrosorbitol monoester of hydrogenated castor oil acids".

c. Provide a molecular formula that gives the identity and number of atoms of each element contained in the molecule. For example, C6H6 is the molecular formula for benzene. When the substance is not molecular or when the exact number of atoms in

the molecule is indefinite, such as the infinite crystal sodium chloride, give the relative numbers of each element's atoms.

d. For a Class 1 substance, provide a structural diagram. The diagram should clearly indicate the identity of the atoms and the nature of bonds joining the atoms. Any ionic charges or stereochemistry should be shown clearly. In the description of the nature of the reaction or process, as much specific detail as possible should be provided on the reaction conditions, (i.e. temperature, time, etc.) and on the relative amounts of reactants. All known stereochemical details should be provided. Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown. Where applicable, specify the proportions of isomers or tautomeric forms, degree of neutralization, etc.

For a Class 2 substance:

(1) List the immediate precursor substances by chemical name and CAS Registry Number (if known).

(2) For substances prepared by chemical reaction, describe the nature of the reaction or process. A description should appear in the form of a reaction scheme:

A + B ---------> C

The nature of the reaction must be described as specifically as possible (e.g., acetylation, alkaline hydrolysis, diazotization). For substances that have been produced without chemical reaction (e.g., by chemical extraction from a natural source), specify the source, the production process, and the nature of the product.

(3) If you intend to manufacture a Class 2 chemical substance within a limited range of possible compositions, report the range. For example, a manufacturer filing a notice for chlorinated naphthalene might specify a compositional range of 20-40 percent chlorine by weight. In determining the range, you may have to consider the reaction conditions, the catalyst, or the purification process that may be used to produce the substance, and other factors. You should provide the range of composition in weight percent for each specific component or class of components that you intend to manufacture for commercial purposes. Indicate the typical composition or any actual values for samples.

(4) Provide as complete a structural diagram as possible. The diagram should indicate the characteristic structure or variable compositional elements of the substance.

ii. Polymers (PMN Page 5)

Submitters should be aware of the PMN filing exemption applicable to some polymers and useful to some manufacturers. The regulations for this exemption are at 40 CFR 723.250. Persons intending to manufacture polymers, and who have determined that their polymers do not meet the requirements of the exemption should file a PMN or LVE/LoREX. Persons intending to manufacture polymers, and who have determined that, for business reasons, an Inventory listing for their substance is desirable, should file a PMN.

a. Indicate the lowest number-average molecular weight of any composition of the polymer you intend to manufacture. Identify the method you used to make this determination (e.g., vapor pressure osmometry or other colligative property determinations, gel-permeation chromatography, light scattering, or various correlative techniques). If you have not determined number-average molecular weight by analytical methods, briefly explain the basis for your estimate. Indicate the **maximum** weight percent of low molecular weight species below 500 and below 1,000 absolute molecular weight. Include the weight of oligomeric reaction products (including molecules formed that are not polymer molecules) in your determination but do not include the weight of residual monomers or other reactants. Attach test data supporting your estimate. If you do not have actual test data, provide an estimate and describe the basis for the estimate. NOTE: The lowest number-average molecular weight is NOT the lowest MW of any component of the polymer mixture, but the lowest number average of several samples of the same polymer, run over time.

b. Column (1) - Monomer or other reactant and CAS Registry Number You are required to provide the chemical name and CAS Registry Number of each reactant used in the manufacture of the polymer or incorporated into the polymer, including those used or incorporated at 2 weight percent or less. Trade names are not acceptable if the chemical identity is known by the submitter. Reactants include monomers, free radical initiators, and cross-linking, chain transfer, and other reactive agents that are used intentionally to become chemically a part of the polymer composition. If a prepolymer is used in the manufacture of the polymer, list the prepolymer and its CASRN as charged into the reaction vessel. If prepolymer compositional information is available to the submitter, identify by bracketing or another method the monomers which are components of the prepolymer. If compositional information of the prepolymer is not available to the submitter or if the prepolymer is represented for purposes of TSCA by a structural repeating unit (SRU) name (examples include silicones and polyethoxylated and –propoxylated substances), you should identify the prepolymer as it is listed in the

TSCA Inventory. Solvents, emulsifiers, and non-reacting components should not be listed.

Column (2) - CBI claim.

Column (3) - % of reactant, typical composition: For each reactant (including monomers), indicate its typical weight percent in the polymer. The weight percent can be determined in one of two ways: according to the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. For the first method, the weight percent of a reactant is the weight of the reactant charged to the reactor divided by the weight of the polymeric chemical manufactured (times 100). Thus, the weight percent of reactant A of a polymer manufactured from reactants A, B, and C is the weight of A charged to the reactor divided by the dry weight of the polymer A-B-C (times 100). For the second method, the weight percent of the reactant using the "incorporated method" is determined using theoretical calculations of the minimum weight of monomer or other reactant necessary to account for the polymer's actual weight. Manufacturers must maintain analytical data or theoretical calculations to demonstrate their determination.

Please note that a zero percent value is NEVER an acceptable value of percent composition for a monomer or other reactant that is to be part of the polymer chemical identity. To report a polymeric substance as including, for example, "0 – 30%" of a given monomer or other reactant will only result in the PMN being declared incomplete due to an uncertain chemical identity. If you are reporting a polymer for which a given monomer or other reactant will vary at very low levels, you can enter, for example, ">0 – 5%", "trace – 5%", or some range having a known, finite lower limit, such as "0.1 – 5%", without causing a chemical identity uncertainty with respect to that monomer/reactant that would occur if you reported it at "0 - 5%." Note, however, that a zero-containing range, such as "0 – 1.5%" would be acceptable for a monomer or other reactant that is <u>not</u> to be part of the polymer's chemical identity because of your application of the so-called "two percent rule." On the other hand, if you have a certain monomer or other reactant which you intend to sometimes include at over 2% and at other times omit or include at less than or equal to 2%, this would likely be an appropriate circumstance for a consolidated PMN.

Please note that ranges are not allowed in the table for PMN page 5; please enter the typical composition value and the maximum residual value in the reactant table and include an attachment with range information if necessary.

If you use a prepolymer in the manufacture of the polymer, you must determine the weight percent of its component reactants. For example, the weight percent of E used in the manufacture of a polymer (using the "amount charged" method) from reactants A, B, and C and prepolymer D-E is the total weight of monomer E in the prepolymer D-E used divided by the weight of the polymer A-B-C-D-E manufactured (times 100). You must provide the identity and typical weight percent of each monomer and other reactant used in the manufacture of the polymer regardless of the weight percent at which it is used. If you will typically manufacture the polymer using a reactant in a range of weight composition, you may indicate the range of weight percent instead of the typical weight percent.

Column (4) - Identity Mark: Reactants used or incorporated at greater than 2 weight percent in the manufacture of the polymer are included as part of the description of the polymer listed on the TSCA Chemical Substance Inventory. However, you can choose to include a reactant used or incorporated at 2 weight percent or less in the Inventory description of the polymer by marking this column. Mark the identity column if you want a reactant present or incorporated at 2 weight percent or less to be included in the description of the polymer which is added to the Inventory.

Column (5) - CBI claim.

Column (6) - maximum weight percent present: Indicate the **maximum** weight percent of each reactant that may be present as a residual (unreacted material) in the polymer as manufactured for commercial purposes.

Column (7) - CBI claim.

Note that you must make separate confidentiality claims for reactant identity, composition information, and residual reactant information.

c. Identify which method you used to develop or obtain the specified chemical identity - Method 1, CAS Inventory Expert Service (a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to the notice), or Method 2, other than CAS Inventory Expert Service.

d. Correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.

e. Provide a simple, representative structural diagram that illustrates what you know or can reasonably ascertain concerning the key structural features of the polymer

molecules. For example, you could identify the linkages formed during polymerization, the functional groups present, the range and typical values for the number of repeating structural units, and the relative molar ratios of the precursors. Indicate if the repeating substructures are arranged in a nonrandom order such as in graft or block arrangements. For example:

$HO\text{-}R(=O)\text{-}O\text{-}(C(=O)\text{-}R'\text{-}C\text{-}O\text{-}R\text{-}O)_n\text{-}H$

$3<n<10$, where R may be either

$\text{-}CH_2CH_2\text{-}$ or $\text{-}CH_2CH\text{-}CH_3$

and R' may be either a 1,4-substituted benzene ring or $\text{-}(CH_2)_4\text{-}$

Provide approximate relative mole ratios of precursors, *e.g.*:

diethyl terephthalate: 2.0
adipic acid 1.5
ethylene glycol 1.0
propylene glycol 3.0

iii. Impurities (PMN Page 6)

Identify each impurity you reasonably anticipate will be present in the substance as manufactured for commercial purposes. An impurity is any chemical substance that is unintentionally present in the new chemical substance. List all impurities (regardless of weight percent). If the substance contains some unidentified impurities, also enter "unidentified" in column (a). Do not include any substances that are mixed with the new substance after manufacture.

In addition to impurities, list in this section other chemical substances, such as solvents, inhibitors, etc., that also may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes.

You should consider the following in identifying impurities:

(1) Chemical and instrumental analyses - often performed on the chemical substance during research and development to characterize the substance before it undergoes health effects or environmental effects testing, to optimize product performance, or to understand process chemistry and optimize output.

(2) Manufacturing process chemistry - including feedstocks, feedstock impurities, byproducts, and intermediates both from the major reaction pathway and from significant side reactions.

(3) Quality control operations - operations which determine the nature and level of impurities that may be present in the chemical substance.

a. Identify **impurities** as specifically as possible. You should provide the following information:

- the specific chemical name; or
- a class or range of structures (e.g., C_6 - C_{18} fatty acid salts or polychlorinated cyclic and acyclic hydrocarbons in the range C_5 - C_{12}); or
- the source (e.g., pyrolysis products of cellulose or coal tar residues).

Include the CAS Registry Number if available.

b. Enter the **maximum** weight percent of each impurity in the new chemical substance in column (b). If the substance contains unidentified impurities, enter the total weight percent of unidentified impurities in column (b).

c. **confidentiality claim**: must be made separately for each impurity.

iv. Synonyms (PMN Page 6)

Enter common chemical names by which the new chemical substance may be identified in the scientific or technical literature, including the names or codes used to identify the new chemical in test data or other data which are attached to the notice.

v. Trade Identification (PMN Page 6)

Enter any trade name under which the new substance has been or will be marketed. Report all trade names or brand names, even if they are not registered.

vi. Generic chemical name (PMN Page 6)

If the new substance's identity is claimed as confidential, enter a generic chemical name. This name should be only as generic as is necessary to protect the confidential chemical

identity, and should reveal the chemical identity of the substance to the maximum extent possible. The generic name will be published in the Federal Register notice on the new substance. EPA will review the adequacy of the generic chemical name when the NOC for the substance is submitted. If the name seems more generic than necessary, EPA will contact you to develop an adequate name.

Generic chemical names are created for Class 1 chemical substances by masking structurally descriptive parts of their specific chemical names. Masking can be accomplished by substituting non-descriptive terms (e.g., "substituted") for descriptive parts of the name. Here is an example with the oil source masked: hydrogenated palm-oil fatty acids, esters with D-mannitol, ethoxylated, could become: hydrogenated fatty acids, esters with hexahydroxyalkane, ethoxylated. Guidelines for developing a generic name were provided in Appendix B of the TSCA Chemical Substance Inventory, Volume 1, 1985, and this document is available at http://www.epa.gov/oppt/newchems/pubs/genericnames.pdf.

vii. Byproducts (PMN Page 6)

List the byproducts that you reasonably anticipate will result from the manufacture, processing, use, and disposal of the new chemical substance at sites you control. Identify the byproducts as specifically as possible by name and CAS Registry Number (if available). You should give the following information:

- the specific chemical name; or
- a class or range of structures (e.g., C_6 - C_{18} fatty acid salts or polychlorinated cyclic and acyclic hydrocarbons in the range C_5 - C_{12}); or
- the source (e.g., pyrolysis products of cellulose or coal tar residues). If there are no byproducts, enter "None."

c. Production, Import, & Use Information (Section C, PMN Page 7)

i. Production volume

Estimate the production volume for the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first 3 years of manufacture. Provide your estimates in kilograms. Maximum production volume is the maximum amount of the new chemical substance on a 100% basis. Report the amount of pure new chemical substance, not including solvents or other

components if the new chemical substance is in a mixture that you expect to produce during any 12-month period (*e.g.*, June 2015 through May 2016). Include in this total amounts produced by persons under contract to you. If part of the amount manufactured is for export, include this amount in your estimates. (You are not allowed to exclude exports from LVE quantity limits after any of the substance is manufactured for domestic use) If you submit a consolidated PMN, make your production volume estimates on a per chemical basis.

For an LVE, the Agency will generally perform the risk assessment under the exemption as if the total amount permissible under the exemption (10,000 kg) were being produced. However, submitters wishing their exemption to be based upon annual production volumes lower than 10,000 kg may so indicate in their exemption notice by marking the binding box adjacent to the production volume space on the form. Submitters who so elect are bound by their election, and if they subsequently wish to increase their maximum production volume under the exemption must submit a new exemption notice cross-referencing the original exemption number on the cover of the notice. If the new exemption is granted, it will supersede the previous exemption.

ii. Use information

a. Table Columns

Column (1) category of use: Identify the intended category of use of the new chemical substance by describing its function and application. "Function" is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, ultraviolet absorber). "Application" refers to the use of the substance in particular processes or products (e.g., a degreaser may be used for cleaning of fabricated metal parts).

Following are some examples of appropriate categories of use:

- a disperse dye carrier for finishing polyester fibers
- a cross-linking agent for epoxy-type coatings for metal surfaces
- a flame retardant for surface application on cotton apparel, textile home furnishings, and exterior canvas products
- a surfactant in automobile spray wax
- a colorant for paper and other cellulosics
- fiber-reactive dye for nylon carpeting and upholstery
- an antioxidant in fuels oils and lubricants

Column (2) CBI claim.

Column (3) Binding option for category of use (binding option is described at I-F).

Column (4) Estimate the percent of the total production volume that you anticipate will be manufactured for each category of use.

Column (5) CBI claim.

Column (6) Estimate the weight percent of the new chemical substance that will be contained in any formulated mixture, suspension, emulsion, solution, or gel associated with each category of use as manufactured for commercial purposes at sites under your control. Where the substance is distributed from your site in a pure state, enter 100%.

In the example below, a PMN substance will be used for several different uses, including a crosslinking agent where the substance is distributed in a pure state and as a surfactant where the substance is manufactured, then formulated at a weight percent of 4%. Eighty percent of the production volume goes to the first use and twenty percent of the production volume will be used for the second use.

Category of use	**CBI**	**Binding Option**	**% of Production**	**CBI**	**% in Formulation**	**CBI**
Cross-linking Agent	X	X	80	X	100	X
Surfactant in Automobile Spray Wax	X	X	20	X	4	X

Column (7) CBI claim.

Column (8) Mark to indicate if the category of use is site-limited or, if the substance is intended for industrial, commercial, and/or consumer use, as defined below, estimate the percent of the production volume expected for each category.

> **Site-limited** - The substance will be used only on the contiguous property unit where it is manufactured and not intentionally distributed outside that site except for waste disposal. This includes all factories, storage places, and warehouses at the site. In most cases, this would be an intermediate which is further reacted on-site. If the substance is transported across a public road which bisects a site, it can still be site-limited.
>
> **Consumer** - The new chemical substance **or products containing the substance** will be used by private individuals in or around a residence, or during recreation, or for any other personal use or enjoyment, e.g., automotive polish, dyed wearing apparel, household cleaners, hunting lure, etc. If a consumer use is

identified, then the EPA requests the following information to be provided on an attached continuation sheet: a detailed description of the use of the new chemical substance expected in consumer products and any reactions that occur causing the substance to lose its identity in the consumer product. This section does not apply to situations where the PMN substance has clearly reacted away and lost its identity before the final article is used by consumers (e.g., coatings).

Industrial - The new chemical substance **or products containing the substance** will be used at the site of other manufacturers or processors, e.g., textile dyeing, paint formulation, use of a curable resin to manufacture an article.

Commercial - The new chemical substance **or products containing the substance** will be used by a commercial enterprise providing a consumer service, e.g., use by commercial dry cleaning establishments, use by painting contractors, or use by roofers in commercial building construction.

Mark all boxes, as appropriate. For example, a surfactant in an automobile wax may have a consumer use in liquid wax, a commercial use in auto washes, and an industrial use by automobile manufacturers. Mark the binding option statement where applicable.

Note: You must make separate confidentiality claims for the description of the category of use, the percent of production devoted to each category, the percent in formulation, and category of use information.

The information in this section is used to evaluate potential exposure and release of the new substance. If you wish to provide any additional information which would assist in this analysis, it may be submitted as optional information. You should be aware that the Agency uses conservative default assumptions to estimate exposure in the absence of specific information.

b. Generic use description - includes degree of containment

For each category of use description which is claimed as confidential, provide a generic description of the category. If such a generic description does not provide a sufficient indication of potential exposure, the description can also describe the degree of containment of the new chemical substance, as shown in the list below; however, a generic use description that solely describes the degree of containment such as "open, non-dispersive use" is not acceptable.

Identify the category of use to which the generic description applies. The generic use should reveal the intended category of use to the maximum extent possible. For example, the specific use of a new substance as an antioxidant in a lubricant could be described generically as a lubricant additive; a fiber-reactive dye for nylon carpeting could be described generically as a dye for fibers.

Degree of Containment

(a) destructive use	(e.g., fuels, fuel additives, chemical intermediates)
(b) contained use	(e.g., catalysts used in closed processes, certain photographic chemicals, capacitor fluids)
(c) open, non-dispersive use	(e.g., printing inks, textiles, dyes, plasticizers, adhesives, liquid paints, resins)
(d) dispersive use	(e.g., cutting fluids, fabric softeners, automobile tire rubber)
(e) highly dispersive use	(e.g., fertilizers, salt for de-icing, paint solvents, spray paints)
(f) other	(describe)

iii. Hazard information

Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet (MSDS), safety data sheet (SDS) or other information which will be provided to any person regarding protective equipment, engineering controls, or practices for the safe transport, use, or disposal of the new chemical substance. If hazard warning information is not yet prepared, describe the statement you intend to provide, if any. If you do not provide an MSDS or SDS with your application we may ask you to develop one during the review period. Identify copies of hazard warning statements or other hazard information that you attach in Part III, List of Attachments.

3. HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE (Part II, PMN Pages 8-10)

In sections A and B, you must provide information on manufacturing, processing, and use operations involving the new chemical substance or products containing the new

substance. Preparing a chemical for an end use application typically involves several production steps, or operations, where potential human exposure and environmental release could occur. Use section A to provide information on operations that occur at industrial sites you control. This will include operations taking place at toll manufacturers with whom you have contracted. Typically, this will involve manufacturing and processing operations. Use section B to describe operations that occur at industrial sites controlled by others. Typically, this will involve processing and end use applications, e.g., dyeing of nylon carpeting, paint spraying of automobiles.

As an example, for a solvent used in automotive paint for automobile manufacture, there are solvent manufacture, paint manufacture, and industrial paint spraying operations. Paint manufacture may occur at a site you control or at a site you do not control. If paint manufacture occurs at a site you control, describe that operation in section A. If paint manufacture occurs at a site you do not control, describe that operation in section B. If processing or end use operations occur at industrial sites you control, they should be described in section A.

In most cases, you will have more specific information on sites you control than sites you do not control. If you do not have specific information on sites controlled by others, describe a typical operation involving the particular processing or end use application based on information available to you and on your experience with similar chemicals. Provide all information requested to the extent to which it is known to or reasonably ascertainable by you. Where EPA has available only limited information on worker exposure and environmental release, its evaluation will be based on reasonable worst case assumptions.

Note that if you are an importer, although you do not have to complete section A or B for operations outside the United States, you may still have to report information in these sections. If there are further industrial processing or use operations after import of the substance, you must describe these operations in section A or B as appropriate.

Because EPA assesses the potential domestic manufacture and processing of imported chemicals, you may choose to complete section A or B for operations outside the United States to assist EPA with this assessment. Providing this information is optional and is not required.

a. Industrial Sites Controlled by the Submitter (Section A, PMN Pages 8-9)

Complete a separate section A for each type of manufacturing, processing, or use operation involving the new chemical substance at sites you control. If the same

operation is performed at more than one site, you are not required to complete a separate section A for each operation, but simply describe the typical operation common to these sites. However, if operations or production rates vary substantially among the different sites, you must provide a separate section A for each different operation.

i. Operation Description

a. Identity - Identify the site which the section describes. If this section describes more than one site, provide additional site identities on a continuation sheet. Indicate the total number of sites at which the operation this section describes will occur. If you mark the confidential box next to this item, all information in it will be treated as confidential.

b. Type - Mark the appropriate box.

c. Amount and duration - Estimate the maximum amount of the new substance (on a 100% new chemical substance (i.e. pure) basis) manufactured, processed, or used in the operation and the duration of the operation. Provide information per batch for batch operations and per day for continuous operations. Base the estimates on the maximum 12 month production provided on PMN Page 7 of the PMN form.

d. Process description - Provide a process flow diagram which describes the manufacturing, processing, or use operation involving the new chemical substance.

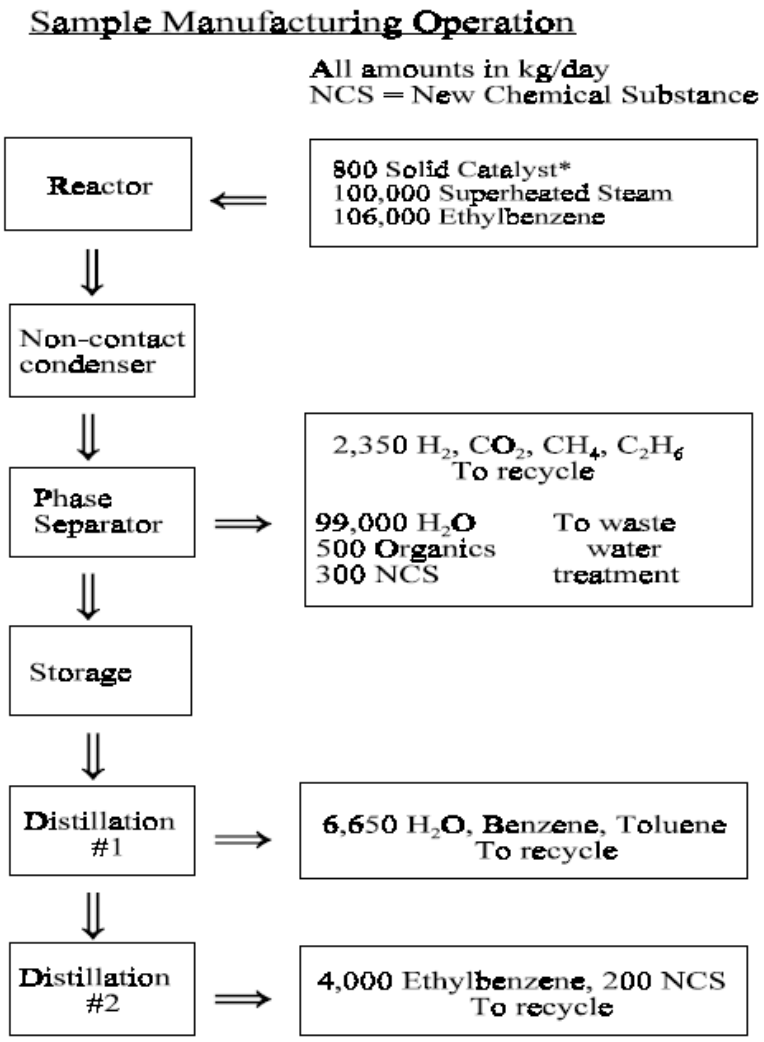
(1) Identify the major unit operation steps and chemical conversions, including secondary operations involving the new chemical substance, such as interim storage and shipping containers. "Unit operation" means a functional step in a manufacturing, processing, or use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the new substance is formulated into gels, mixtures, suspensions, solutions, etc. Specify the shipping containers, including expected capacities (e.g. 5 gallon pails, 55 gallon drums, 5,000 gallon tank trucks, 20,000 gallon rail cars).

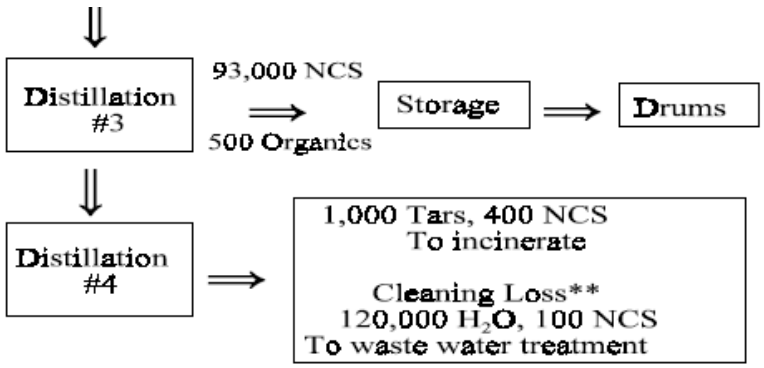
(2) Indicate in your diagram the entry and exit point of all feedstocks (e.g., reactants, solvents, catalysts) used in the operation, products, recycle streams, and wastes. Identify each feedstock and specify its approximate weight (by kg/day for continuous operations or kg/batch for batch operations). Include

cleaning chemicals, and state how often they are used (e.g., every day, every batch, monthly).

(3) Number all points from which the new chemical substance and substances containing the new chemical substance will be released to the environment or to control equipment, including small or intermittent releases (e.g. some cleaning releases, drum residues, etc.) and trace amounts of the new chemical substance. Do not include accidental releases. Including fugitive emissions is optional.

(4) Mark the box if you wish to indicate your willingness to have your process description binding.

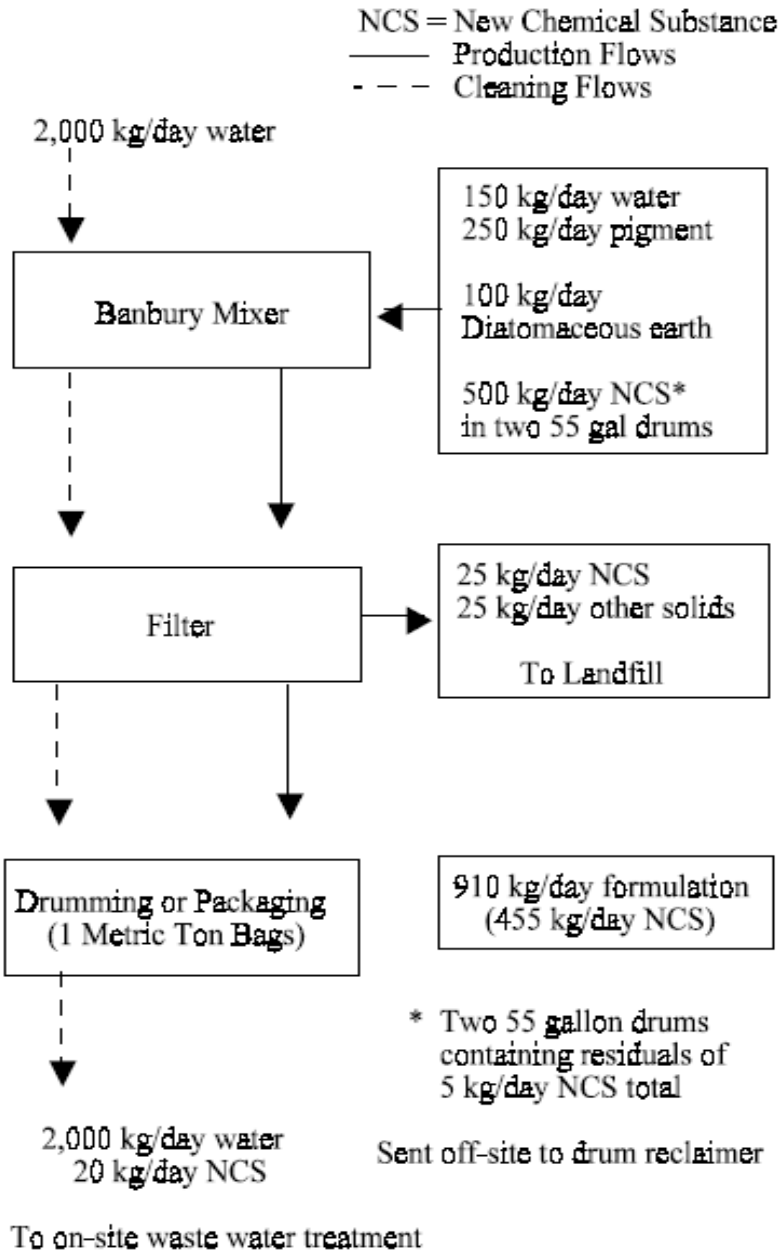




* Mix of Fe_2O_3, Cr_2O_3, and K_2CO_3

**Note: Entire process cleaned once annually with steam and water (120,000 kg total). NCS loss from cleaning is 100 kg.

Sample Processing Operation



ii. Occupational Exposure

Column (1) - worker activity: Describe each specific activity in the operation during which workers may be exposed to the new chemical substance. Such activities may include charging reactor vessels, sampling for quality control, transferring materials from one work area to another, drumming, bulk loading, changing filters, and cleaning equipment, etc. Activities must be described even if workers wear protective equipment. (Material Safety Data Sheets indicating recommended protective equipment should be submitted as part of Hazard Information in Part I, section C, subsection 3 of the notice form.)

Column (2) - CBI claim for worker activity.

Column (3) - protective equipment and engineering controls: provide information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance (i.e., type of gloves, type of goggles, NIOSH-certified 21c respirator, NIOSH-certified 19c respirator, closed containment system, nitrogen blanket, etc.

Column (4) - Binding option for protective equipment and engineering controls.

Column (5) - physical form: Indicate the physical form [e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), wet press cake] of the new substance and its weight percentage (if in a mixture) at the time of exposure, even if workers wear protective equipment.

Column (6) - Binding option for physical forms.

Column (7) - CBI claim for physical form.

Column (8) - maximum number of workers exposed: Estimate the maximum number of workers involved in each specific activity, based on the estimated maximum 12-month production volume.

Column (9) - CBI claim.

Column (10) - maximum duration in hours/day: Enter the maximum duration that any one worker will engage in the activity in hours/day, e.g., 8 hours/day.

Column (11) - maximum duration in days/year: Enter the maximum duration that any one worker will engage in the activity in days/year, e.g., 200 days/year, based on the estimated maximum production volume.

Column (12) - CBI claim.

Note that you must make separate confidentiality claims for the description of worker activity, physical form of the new substance, number of workers exposed, and duration of exposure. (See 2, 7, 9, 12).

iii. Environmental Release and Disposal

Column (1) - release point number: For each release point indicated in the process description (Part II, Section A, subsection 1(d)(3) of the notice form, enter the corresponding number. If you indicated more than 5 release points, make a continuation sheet to cover them.

Column (2) - amount of new chemical released at release point: Estimate the amount of new chemical (in kg/day for continuous operations or kg/batch for batch operations) that will be released from the release point directly into either (a) the environment or (b) into control technology (in kg/day or kg/batch). Base your estimate on the expected maximum twelve-month production volume. EPA is particularly interested in the amounts of chemicals used and frequencies of cleaning of equipment and releases from transport containers, including the location (if different from that of manufacture or processing) of drum recyclers, tank truck cleaning facility, etc.)

Column (3) - CBI claim.

Column (4) - medium of release: Enter the medium [stack air, fugitive air (optional), surface water, on-site or off-site land or incineration, Publicly Owned Treatment Works (POTW), or other (specify)] into which the release stream discharges (whether or not control technology is used). You do not have to identify fugitive air releases, but if EPA reviewers consider that such air releases are likely and estimates are not provided in the submission the reviewers will estimate reasonable worst-case fugitive air releases. In estimating reasonable worst-case releases we generally consider vapor pressure and type of use, including the location if different from that of site manufacture or processing.

Column (5)(a) release / control technology / efficiency: For a release to air or water, describe the type of technology used to control the release of the new chemical and the efficiency of the control technique. Examples of control technologies include carbon filter, scrubber and biological treatment (primary, secondary, etc.). Use the optional binding box to indicate your willingness to be bound to control technology described. Attach optional information such as data and methods of waste treatment or purification efficiency studies.

Column (5)(b) release after control technology: Enter the estimated amount released to the environment after control technology (in kg/day). Enter "none" if no control technology is used and the substance is released directly into the environment.

For disposal on land, describe the landfill site construction (including liners) and handling procedures. Describe landfill containers.

You may wish to optionally attach efficiency data for control technologies used. For example, carbon adsorption removal efficiency of the new chemical substance from an aqueous stream could help EPA estimate release of the new chemical substance from a facility using carbon adsorption treatment.

Column (6) - CBI claim.

Column (7) - destination of water releases: Mark the appropriate box and/or specify other destinations of water releases. [i.e., POTW, navigable waterway or specify other]. Provide the name of the POTW receiving water releases and the NPDES (National Pollutant Discharge Elimination System) number for the POTW, navigable waterway or other direct discharger. This 9-digit number is assigned by EPA or the State under the authority of the Clean Water Act. When appropriate, contact your POTW to obtain its NPDES number.

Note that you must make separate confidentiality claims for each of: release number, amount of new chemical substance released, control technology disposal information, and the destination of the releases to water.

b. Industrial Sites Controlled by Others (Section B, PMN Page 10)

Complete a separate Section B (continuation pages for second and subsequent) for each type of processing or use operation associated with each category of use specified in Part 1, Section C, subsection 2(a) at industrial sites you do not control. If the same

operation is performed at more than one site, then describe the typical operation and enter the number of sites in the space provided.

Describe each typical processing or use operation to the maximum extent possible from information known to or reasonably ascertainable by you. Information may be provided as ranges or estimates as allowed by the software.

i. Operation Description

Generally self-explanatory - the information requested here differs from that requested for Section A Operation Description only by the additional worker activity information requested. EPA is particularly interested in the chemicals used and frequencies of cleaning of equipment and transport containers.

ii. Worker Exposure/Environmental Release

Column (1) - Activity Letter: Provide the letter for each activity from the diagram above and complete columns 2-8 for each worker activity associated with the letter.

Column (2) - maximum number of workers exposed: Estimate the maximum number of workers exposed to the new substance during the activity.

Column (3) - CBI claim.

Column (4)(a) - duration of exposure - hours/day: Estimate the duration of exposure of the new chemical substance per worker in hours per day.

Column (4)(b) - duration of exposure - days/year: Estimate the duration of exposure of the new chemical substance per worker in days per year.

Column (5) - CBI claim.

Column (6) - Physical Form, Protective Eqpt, Eng'g Controls: Provide information on the physical form [e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), wet press cake] of exposure and percent new chemical substance (if in a mixture), and protective equipment and engineering controls employed to safeguard the worker from potential exposure associated with the new chemical substance, i.e., gloves, goggles, respirators, etc..

Column (7) - Percent in the Product Formulation: Estimate the percent in the product formulation of the new chemical substance to which the worker is potentially exposed during the activity.

Column (8) - CBI claim.

Column (9) - release points Enter the number given to each release point in reference to the process diagram above and complete 9-13 for each release point identified (use continuation pages if necessary).

Column (10) - maximum release Provide an estimate for the maximum amount of new chemical substance in kg per year that may be released to the media specified in Column (12) (see below) under typical operating conditions. Provide this information for releases (a) directly to the environment or (b) into control technology to the environment in kg per day for continuous operations or kg per batch for batch operations. EPA is particularly interested in the amounts of chemicals used and frequencies of cleaning of equipment and releases from transport containers.

Column (11) - CBI claim.

Column (12) - medium of release: Describe medium of release [stack air, fugitive air (optional), surface water, on-site or off-site land or incineration, POTW, or other (specify)] and the control technology(ies) used to limit the release of the new substance to the environment to the extent that the information is known to you.

Column (13) - CBI claim.

Column (14) - byproducts: Identify all byproducts resulting from the reaction to the extent that the information is available to you.

Note that you must make separate confidentiality claims for the numbers of workers exposed, the duration of exposure, the percentage of the product in formulation, the amount of new substance released, and the control technology.

4. (OPTIONAL) POLLUTION PREVENTION AND RECYCLING INFORMATION (PMN Page 11)

On the form itself and in Section A.14 of this Manual, we describe the Agency's goals in providing this mechanism for you to inform us of environmental benefits which may be available from your new substance. Below are suggestions for organizing such

information to be most useful to improve the review of your substance: part of the material to provide is about characteristics of the substance and part relates to your process description and calls for a discussion of how a shift to the new chemical substance may enable the use of the more desirable process. If you wish your PMN substance to be considered for the Agency's EPA New Chemicals Pollution Prevention Recognition Project, you should tell us so in this information.

a. Product Information

Will this substance be produced to address an environmental problem or in response to environmental regulation? (One example would be CFC substitutes.) Do you wish your substance to be considered for the Agency's EPA New Chemicals Pollution Prevention Recognition Project?

b. Toxicity Information

EPA is interested in information describing possible reductions in toxicity of a new chemical substance as compared to that of already commercialized chemical substances for which the new substance may substitute. Such information may demonstrate that the new chemical substance may be a viable safer substitute.

c. Technical Information

i. Process Chemistry

Chemical approaches which may minimize waste production include the following:

a. Selection of synthetic method: high yield, minimal side reactions, minimization of coproducts unless they are of commercial value.

b. Choice and purity of feedstocks, reagents, catalysts, solvents, etc. Reduction/ elimination of undesirable feedstocks, solvents (e.g. VOC's), catalysts, etc.

c. Optimization of reaction conditions to minimize side reactions.

d. Optimization of stoichiometry to minimize presence of excess reactants.

e. Product Purification.

f. Use of advanced chemical technology such as shape-selective zeolite catalysts, stereoselective synthesis, and permselective membranes for molecular separations (liquid phase).

ii. Product Substitution/ Source Reduction

a. Perceived advantages related to the use of the new chemical substance compared to existing substances. Comparison of the relative risk of the new chemical to existing chemicals (for example, volumes, releases, exposure, human health effects and ecotoxicity) of the substances. A new chemical that causes less pollution may nonetheless be more toxic than an existing chemical and therefore the risk to health and the environment may be higher.

b. Changes in product composition or physical state.

Consider potential changes in product compositions or physical states which may reduce releases and exposures. For example: using a more concentrated product may decrease the amount of release or waste generated; or reformulating a powder into a paste to mitigate inhalation concerns.

c. Enhanced product life or durability.

Improvements which may be expected from enhancements to product life or durability of new chemical substances over existing substances. For example, a more durable product could result in less solid waste going to landfills.

d. Changes in product effectiveness/ Effect of product performance at lower concentrations (significant orders of magnitude).

New chemical substances which may be more effective than existing substances, or if as effective at significantly lower concentrations than an existing chemical may result in reduced releases and exposures.

e. Packaging (transportation, concentration, disposal, life-cycle analysis, weight loss, etc.).

Examples of packaging with pollution prevention in mind may include (A) reusable packaging materials, or (B) making the new chemical substance more concentrated to minimize size or volume of packaging.

iii. Process Modifications

a. Engineering technology changes.

In some cases, existing equipment which may be used to produce new chemicals may not be the best technology from the standpoint of pollution prevention. Consider alternative technologies for the major unit operations (i.e. separation, filtration, etc.) in the process and their potential impacts on releases and exposures. Some examples of alternative technologies include: (A) steam stripping instead of air stripping, (B) pan filter versus rotary drum filter or centrifuge or, (C) flash dryer versus spray dryer.

b. Equipment/piping/ layout changes

Equipment/piping/ layout alternatives can have an effect on releases and exposures. Some examples of these changes include: (A) redesigning equipment and piping to reduce the volume of material drained for batch changes and for cleaning operations, (B) installing bellow-sealed valves versus conventional valves to reduce VOC emissions and worker exposure, or, (C) use of new resources such as by-product steam from another process.

c. Operating Conditions

Optimize operating conditions at major unit operations (including reactors and separation equipment). Available supporting laboratory information (i.e. experimental design data) may be collected and submitted describing reduction of chemical exposure using the new PMN substance, reduced emissions to the workplace or environment, etc. An example might be use of a new surfactant to reduce the amount of solvent needed in cleanup operations.

d. Automation

Potential automation/control steps may have pollution prevention or exposure implications. For example, a batch process can be successfully automated to reduce off-spec. product and spillage, which reduces waste. A manual packaging system can be automated to reduce worker exposures.

e. Closed systems

Reduced exposures, emissions, or elimination of isolated intermediates.

iv. Operating Practices

Examples of operational and administrative changes which could reduce pollution and exposure are:

a. Procedural measures

Increasing drain time from 15 to 20 minutes could reduce leftover material in a tank.

b. Loss prevention

Installing overflow alarms in tanks could reduce overflows or releases.

c. Management practices

Reducing inventories of toxics to minimize the consequences of emergencies.

d. Waste stream segregation

Segregating waste streams to avoid cross-contaminating hazardous and non-hazardous materials could allow recycling of some waste. For example, changing waste segregation to separate organics from an aqueous waste stream.

e. Material handling improvements

Changing from small-volume containers to bulk or reusable containers could reduce releases of residue.

f. Production scheduling

Larger batch sizes can be made, which could reduce number of production runs, cleanup waste, and worker exposure.

g. Safety

Examples would be use of substances which are less explosive, less flammable, or less corrosive. Use of less corrosive substances may also serve to decrease cost and maintenance, as well as increase life, of equipment.

h. Reuse/Recycling/Reclamation

Identify potential reuse/ recycling/ reclamation (both on-site and off-site opportunities) of the waste streams. Some examples of the reuse/ recycling/ reclamation opportunities are:

(1). Use of recycled materials in original process

Returning recovered solids from a filtrate (through the use of a settling tank) to the reactor. Wastes from unrelated processes may be used in feedstock to make new substances.

(2). Recovery and recycling of resources utilized in the process

Installing vapor recovery systems to capture and return vaporous emissions. Feedstock or off-spec. substance previously discarded may be recycled back into the process.

(3). Reuse or processing of by-products/coproducts of the original process for other processes.

The off-acid gas from a reactor could be absorbed with water to convert it into dilute acid and sold as a by-product.

i. Energy Savings

Almost any change in an industrial process will entail some change in the amount and form of energy consumed in that process. How might the new chemical substance result in savings of energy resources in any phases of manufacture, processing, or use?

Energy conservation is a form of pollution prevention. For example, reduced energy use decreases the quantity of fossil fuels burned and the amount of air pollutants generated. Reduced boiler operation also reduces the discharge of waste cooling water blowdown and boiler blowdown. Purification of raw water to produce boiler feedwater by ion exchange or other processes produces wastes such as regeneration chemicals. Reduced boiler operation could also reduce this waste stream. Another example might be shifting from thermal polymerization/ curing to radiation polymerization/ curing.

j. Alternative Treatment Methods

Consider efficiency of alternative treatment methods and the compositions and quantities of the input PMN waste streams and output release streams. For example:

(1). Use of ammonia instead of sodium hydroxide to neutralize a process, allowing the excess to be vacuum stripped and possibly recycled, rather than removal by water washes which create a caustic waste requiring treatment and/or disposal as a hazardous waste.

(2). Replacement of organic solvents with water, eliminating VOC emissions.

v. Alternative Waste Disposal Methods

Compare release media (land, air, water) in light of the PMN waste streams being disposed, including quantity of release, composition of the waste, and applicable regulatory limitations. For example, an aqueous ammonia waste stream may be converted into fertilizer for agricultural use.

5. LIST OF ATTACHMENTS (Part III, PMN Page 12)

Attach any continuation sheets for sections of the form as you fill out the form. Related sections will be identified automatically. Other attachments (e.g., test data and other data (including structure-activity information)), and optional information are entered under Part III, after PMN page 12. Enter the inclusive page numbers of each Part III attachment. The total number of pages in the notice on PMN Page 1 of the form will then be calculated automatically. The software will generate a redacted version of the form you have filled out. You must sanitize and provide with the redacted version sanitized version of any attachment in which you claim information as confidential. Mark the "Confidential" box next to any attachment name you claim as confidential. Read "E" and "H" in Section I of this manual for guidance on how to claim any information in an attachment as confidential.

6. PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET (Optional)

A worksheet which assists EPA's review of the physical/chemical property information you submit is provided on the last page of the form. Providing physical/chemical property information in this format is optional. However, all physical/chemical properties data in your possession or control must be submitted with your notice. If you submit this worksheet, identify it on the List of Attachments.

Appendix A -- EXAMPLES OF TEST DATA

Following is a list of the types of test data which you must attach to the notice form if it is in your possession or control. This list is illustrative, not exhaustive.

Physical and Chemical Properties and Environmental Fate Data

- Chromatograms
- Spectra (ultraviolet, visible, infrared)
- Density / relative density
- Solubility in water
- Melting temperature
- Boiling / sublimation temperature
- Softening point
- Vapor pressure
- Dissociation constant
- Particle size distribution
- Octanol / water partition coefficient
- Henry's law constant
- Volatilization from soil
- pH
- Flammability
- Explodability
- Adsorption / desorption characteristics
- Photochemical degradation
- Viscosity
- Odor
- Hydrolysis
- Thermal analysis
- Chemical analysis

Health Effects Data

- Mutagenicity
- Carcinogenicity
- Teratogenicity
- Neurotoxicity / behavioral effects
- Pharmocological effects
- Mammalian absorption
- Distribution
- Metabolism and excretion
- Cumulative, additive and synergistic effects
- Acute, subchronic and chronic effects
- Structure / activity relationships
- Epidemiology
- Reproductive effects
- Clinical studies
- Dermal toxicity
- Phototoxicity
- Irritation
- Sensitization
- Allergy
- Skin staining

Environmental Effects Data

- Microbial bioassay
- Algal bioassay
- Aquatic macrophyte bioassay
- Seed germination and root elongation
- Seedling growth
- Plant uptake
- Acute toxicity to invertebrates
- Life cycle test on invertebrates
- Acute toxicity to fish
- Early life stage (fish)
- Avian dietary / reproduction
- Bioaccumulation / bioconcentration
- Model ecosystem studies
- Physical environment impairment effects
- Flesh staining of aquatic organisms

- Chemical oxidation
- Chemical reduction
- Biodegradation
- Transformation to persistent or toxic products

Appendix B -- CONTACT LIST: 2015

Routine questions about forms, publications, general policies, etc. are handled by the TSCA Assistance Information Service (TAIS, TSCA Hotline). TAIS can be reached on (voice) (202) 554-1404, (facsimile) (202) 554-5603, (email) tscahotline@epa.gov.

To check on the EPA review status of a particular exemption notice, click on the "Premanufacture Notice Status" link in the left margin of the New Chemicals Program web page: http://www.epa.gov/oppt/newchems/tools/status1.htm.

If you have technical issues or problems regarding the **e-PMN** software or **CDX registration**, please contact the CDX Help Desk at helpdesk@epacdx.net or 888-890-1995. International callers who wish to contact the Help Desk should call 970-494-5500. If you have programmatic questions, please contact Kathryn Schechter at 202-564-8589 or e-mail Schechter.Kathryn@epa.gov, or Anna Coutlakis at 202-564-9207 or e-mail Coutlakis.Anna@epa.gov.

The risk management component of the New Chemicals Program is managed by the **New Chemicals Management Branch (Greg Schweer, Branch Chief, 202/564-8469)** in OPPT's Chemical Control Division. This branch is comprised of three teams: the Pre-Notice and Exemptions Management Team, the Notice and Regulations Management Team #1, and the Notice and Regulations Management Team #2.

The **Pre-Notice and Exemptions Management Team** facilitates all pre-notice communications/activities and assists potential submitters in determining whether their chemical substances require premanufacture notice. This Team is also responsible for outreach, TSCA section 5 policy formulation and interpretation, coordinating the review of all section 5 exemption notices (i.e., low volume (LVE), low releases and low exposures (LoREX), and test marketing (TME)), coordination/outreach with international groups, and various administrative support activities.

For answers to questions about procedural, technical, or regulatory requirements prior to submitting a PMN, or to request consolidation in PMN notice review, submitters can contact one of the following PMN Prenotice Coordinators:

David Schutz, 202/564-9262 (Schutz.David@epa.gov)
Anna Coutlakis, 202/564-9207 (Coutlakis.Anna@epa.gov)
Adella Underdown, 202/564-9364 (Underdown.Adella@epa.gov)
Jesse A. Miller, 202/564-2976 (Miller.Jesse@epa.gov)

The Pre-Notice and Exemptions Management Team is also responsible for this manual. We are eager to hear from our users if they have input on how it can be improved. If you have suggestions, please send to Dave Schutz.

The **Notice and Regulations Management Teams** are charged with managing the process for Premanufacture Notices (PMNs) submitted under TSCA. Submissions which are under active review post-FOCUS meeting are generally the subject of active communication between the EPA Program Manager in one of these Teams and the submitter (The FOCUS meeting is the first meeting where risk management decisions occur, at approximately day 20 of the PMN review process).

The focus of **Notice and Regulations Management Team #1** is the risk management of conventional new chemical (including PFC substitutes) PMNs. The roster of the Notice and Regulations Management Team #1 is:

Rose Allison, Team Leader 202/564-8970
Jeff Bauer, 202/564-9042
Geraldine Hilton, 202/564-8986
Virginia Lee, 202/564-0883

The focus of **Notice and Regulations Management Team #2** is the risk management of new nanomaterials, microorganisms, and Significant New Alternatives Policy (SNAP) chemicals, as well as the development of batch Significant New User Rules and other regulations. The roster of the Notice and Regulations Management Team #2 is:

Ken Moss, Team Leader, 202/564-9232
James Alwood, 202/564-8974
Tracey Klosterman, 202/564-2209
Kristan Markey, 202/564-8716

Written inquiries may be sent by US mail to:

Prenotice Coordinator, New Chemicals Program
Chemical Control Division
Mail Stop 7405M
USEPA, 1200 Pennsylvania Ave., NW
Washington, D.C. 20460

or by facsimile at (202) 564-9490. Persons considering using facsimile to send confidential information to the Agency have to be aware that the 564-9490 telephone line is not a secured line, however the facsimile machine itself is in a secured area. EPA does not regard email as an

appropriate way to transmit confidential information to or from the Agency. If you wish to use email to transmit a non-confidential question, address it to Greg Schweer (Schweer.greg@epa.gov).

Mail inquiries may be sent to:

TSCA Assistance Information Service
Mail Stop 7408M
USEPA, 1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Use the following direct address to send material by courier. (The building guards will need a New Chemicals Program staff contact phone and room number):

U.S. EPA
Office of Pollution Prevention & Toxics (New Chemicals Program)
EPA East Building, Room 4133
1201 Constitution Avenue, NW
Washington, DC 20004-3302.