



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 29 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Annotated PMN Form - Guide to PMN Submitters

Attached is an annotated Premanufacture Notice (PMN) form that was developed by the 3M Company and incorporates comments and suggestion by EPA experts. This collaboration has produced a document that should be useful to PMN submitters, as it can help them better understand the type and quality of data EPA reviewers need to conduct their risk assessment of new chemicals. It is hoped that this in turn can lead to more complete and useful new chemical notifications submitted to the Agency. 3M is making this guide available without charge to requesters, as part of its corporate responsibility, regulatory compliance, innovation, and cooperation with government agencies. The annotated PMN form should be viewed as a complement to EPA's other PMN information guides, specifically, the Chemistry Assistance Manual for Premanufacture Notification Submitters and the (draft) revised Instructions for Completing the Premanufacture Notice Form. Any comments or questions on this annotated PMN form can be directed to Greg McCarney, 3M Regulatory Affairs Specialist, at 612-736-0360.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca S. Cool".

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch



U. S. ENVIRONMENTAL PROTECTION

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

To all users: This guide to preparing your PMN has been reviewed by EPA experts. Their comments and suggestions have been incorporated in the guidance provided. This guide is not intended as legal guidance for your specific compliance requirements under TSCA new chemical regulations.

When completed send this form to

DOCUMENT CONTROL OFFICER
OFFICE OF POLLUTION PREVENTION
AND TOXIC SUBSTANCES, 7407
U.S. E.P.A. 401 M STREET, SW
WASHINGTON, D.C. 20460

EPA will assign a case number after declaring the PMN complete

After completing the notice, enter a total page count

Enter the total number of pages

Document control number

EPA case number

TSCA PMNs are not required for substances used only for FDA and FIFRA regulated purposes, but pesticide intermediate(s) are subject to PMN requirements, unless the intermediate(s) are also used as pesticides. PMNs are also not required for chemical substances made solely for export, but refer to rules at 40CFR 720.30(e).

R&D can be conducted prior to PMN filing and review, but risk evaluation, hazard communication and recordkeeping requirements are in effect. Refer to 40 CFR 720.36.

If you submit studies or other substance test data, you need to provide a characterization of the tested material so that EPA reviewers understand exactly what was tested.

Any health and safety studies (including environmental studies) on the PMN substance in your company's possession must be submitted as attachments to the PMN. Study reports obtained during the review period must be promptly forwarded to the Document Control Officer. Note that relevant studies are not limited to the neat PMN substance. Data on related substances can be voluntarily submittable if they relate to risks of the PMN substance.

Data previously submitted to OPPT/EPA with no claims of confidentiality need not be resubmitted if the EPA recipient or submission identity is clearly described.

Exemption notices have limitations, and exemption substances are not added to the TSCA inventory. The LVE exemption has restrictions on production volume, indicated use, production sites, and indicated personal protection measures. The MSDS (your hazard communication) becomes an integral part of the LVE notice.

CONFIDENTIALITY CLAIMS

Review confidentiality claims to ensure they are justified; avoid unsupportable CBI claims. CBI claims for health and safety studies are limited; see 40 CFR 720.90.

Three copies of the PMN are required. If CBI is claimed, one copy of a sanitized PMN must also be sent to EPA with the CBI copies.

INSTRUCTIONS

Known to or reasonably ascertainable by you. Make reasonable estimates if you do not.

The PMN submitter provides a TS- code number. If you hold your company confidential, avoid a company-sequential or identifiable code number.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

- Environmental fate data Yes
- Health effects data Yes
- Environmental effects data Yes
- Physical/Chemical Properties Yes
- Other data Yes
- Risk assessments
- Structure/activity relationships
- Test data not in the possession or control of the submitter

*A physical and chemical properties section is required on this form.

TYPE OF NOTICE

- PMN (Premanufacture Notification)
- INTERMEDIATE PMN (Intermediate PMN)
- SNUN (Significant New Use Notification)
- TMEA (Test Marketing Exemption)
- LVE (Low Volume Exemption)
- LOREX (Low Release Exemption)
- LVE Modification

A 'Consolidated PMN' allows you to submit two or more (maximum of six) structurally similar substances, with equivalent risk characteristics, under a single PMN notice. Consolidated PMNs require prior review and approval by EPA.

A prenotice communication with an EPA New Chemicals Prenotice Branch coordinator is required. A PC number must be obtained and reported on page 3 of the form.

IS THIS A CONSOLIDATED PMN? Yes

of chemicals _____
Prenotice Communication # required, enter # on page 3)

Public reporting burden for this collection of information is estimated to average 110 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M. St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Act (2070-0012), Washington, D.C. 20503.

CERTIFICATION

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

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.
2. All information provided in this notice is complete and truthful as of the date of submission.
3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, statement that applies:

PMN notices are to be based on actual commercial intent, not speculation. The person who certifies with their signature below attests that the information provided is correct, to the best of his/her knowledge, and that test data are submitted in compliance with 40 CFR 720.50.

- The Company named in Part I, Section A has remitted the fee of \$2500 specified in 40 CFR 720.43 (b), or
- The Company named in Part I, Section A has remitted the fee of \$1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or
- The Company named in Part I, Section A is a small a fee of \$100 in accordance with 40 CFR 700.45 (b).

Notice(s) for chemical intermediates submitted together in sequence with a final PMN are eligible for a reduced review fee of \$1,000 for each intermediate notice.

If you are submitting a **low volume exemption (LVE)** application in accordance with 40 CFR 723.50 (c) (1) or a **Low release and low exposure exemption (LoREX)** application in accordance with 40 CFR 723.50 (c) (2), check the following certification statements:

- The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
- The manufacturer is familiar with the terms of this section and will comply with those terms; and
- The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
- If this application is for an LVE in accordance with 40 CFR 723.50 (c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 90 days of the date of the 30 day review period.

Amended LVE rules took effect May 30, 1995, and are listed at 40 CFR 723.50. EPA must be able to conclude that manufacture, processing and use of the LVE substance will not result in an unreasonable risk to health or the environment. Review applicable exemption rules for LVE or LoREX applications.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

Confidential

Signature and title of Authorized Official (Original Signature Required)

Date

Signature of agent - (if applicable)

If your company's identity is CBI, the sanitized copy cannot be signed. Otherwise, both the CBI and sanitized original copies require an original certification signature.

Part I -- GENERAL INFORMATION

Section A -- SUBMITTER IDENTIFICATION

Confidential

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1a. Person Submitting Notice (in U.S.)

Name of authorized official _____ Position _____

Company _____

If the company identity is CBI, this section is also CBI and will be so marked.

Mailing address (number and street) _____

City, State, ZIP Code _____

b. Agent (if applicable)

Name of authorized official _____ Position _____

Company _____

Complete the 'Agent' section only if an agent outside your company assists with preparing the notice.

Mailing address (number and street) _____

The agent must also sign the general certification on page two of the form.

City, State, ZIP Code _____

Telephone _____

Number _____

c. If you are submitting this notice as part of a joint submission, mark (X) this box.

Joint Submitter (if applicable)

A Joint Submitter files a PMN form containing information known to them and not available to the original submitter. They must certify their information and sign their PMN notice. The PMN review period will not commence until EPA has received all required notice information from you and the joint submitter. Note: It is also possible for joint submitters to be equal partners, with all information shared between them.

A joint submitter is not the same as a third party that files a 'letter of support' which provides confidential information to EPA in support of your premanufacturing notice. (e.g., chemical identity of their proprietary reactant used in production of your polymer PMN; or, documentation of their polymer exemption substance you use to manufacture a polymer, or chemical identity of a PMN substance, whose identity is held confidential from you, that wish to import.)

2. Technical Contact (in U.S.)

Name _____ Position _____

Company _____

Mailing address (number and street) _____

City, State, ZIP Code _____

The technical contact should be a person available by telephone during normal business hours who can provide EPA with additional information on the new chemical substance during the notice review period. EPA also encourages listing a back-up contact person.

If the company is held as CBI, the contact is usually, but not necessarily, claimed as CBI.

3. If you and EPA have had any prenotice communication numbers, exemption notice number, or Bona fide notice identifier assigned by EPA. If there are none that apply, mark the negative certification boxes to the right.

List any prenotice communication numbers, exemption notice number, or Bona fide notice identifier assigned by EPA. If there are none that apply, mark the negative certification boxes to the right.

Mark (X) if none

4. If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.

Mark (X) if none

5. If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.

Mark (X) if none

6. Check the boxes to indicate your intent to manufacture in the US, to import the PMN chemical, or both.

1. Manufacture Only
 Binding Option Mark (x)

2. Import Only
 Binding Option Mark (x)

3. Both

Part I -- GENERAL INFORMATION

Section B -- CHEMICAL IDENTITY INFORMATION

If a third party will file a letter of support or act as a joint submitter and provide proprietary chemical substance information, check this box.

substance information

Mark (X) the "Confidential" box next to

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right.

Identify the name, company, and address of that person in a continuation sheet

Confidential

Class 1: a single molecular entity that can be represented by a single, definite structural diagram

For Class 1 and class 2 substances, see the instructions of class 1 and class 2 substances, see the instructions. 1 Class 1 or 2 Class 2

Class 2: a substance whose composition cannot be represented by a single, definite chemical structural diagram. Class 2 substances include substances of unknown, variable, or uncertain composition, complex mixtures or reaction products, or well-defined substances without specific structures.

CAS is a contractor to EPA. The CAS Inventory Expert Service can provide a TSCA-compliant Ninth Collective Index (9CI) Chemical Abstracts (CA) name for your PMN substance; only a name developed by this procedure meets 'Method 1' criteria. An error by CAS will not hold up review of your PMN if your chemical name was developed by Method 1. Include the nomenclature assignment documentation as an attachment to the PMN.

An alternative method of providing a name, such as a STN database report, qualifies as 'Method 2'. If you provide a chemical name using Method 2, and EPA determines the name to be in error, review of your PMN will be halted until the name is corrected and the entire notice may need to be resubmitted along with the correct name.

d. Molecular formula and CAS Registry Number (if a number already exists for the substance)

The molecular formula must give the correct identity and number of atoms of each element contained in the PMN molecule. This is required for a Class 1 substance and for Class 2 substances that have a definite molecular formula.

CAS #

Provide a CAS Registry number if one has already been assigned by CAS. Seeking the assignment of a new CAS registry number may jeopardize confidentiality, and is not required for your notice.

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a complete and correct chemical structure diagram. (1) Provide the name of the substance and the name of the precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

A Class 1 structural diagram should clearly and completely indicate the identity of the atoms and the nature and location of the bonds joining the atoms. Ionic charges and known stereochemical details should be provided. Carbon atoms in ring systems do not need to be explicitly shown.

Class 2 substances: follow the requirements in (e.) above. Provide partial, or complete, or representative structural diagrams to the extent possible. The diagram should indicate the characteristic or variable compositional structural components of the substance.

If you are unsure of the exact structure, provide the best information you have and indicate that it is your best estimate of the chemical structure.

Polymer information is reported on Page 5.

Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.)

Confidential

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture.

Indicate maximum weight percent of low molecular weight species (not including 500 and below 1,000 absolute molecular weight of that composition.

Describe the methods of measurement or the basis for your estimates: GPC _____

- i) lowest number average molecular weight: _____
- ii) maximum weight % below 500 molecular weight: _____
- iii) maximum weight % below 1000 molecular weight: _____

Mark (X) this box if you attach a continuation sheet.

GPC is a well-established method for establishing Mn and weight fractions below 500 and 1,000 Daltons. It may not be useful for all polymer evaluations, however. Solubility problems and misleading calibration standards can lead to questionable GPC data.

b. You must make separate confidentiality claims for monomer or other reactant identity. Mark (X) the "Confidential" box next to any item you claim as confidential.

- (1) -- Provide the specific chemical name and CAS Registry Number (if a number is available) for each monomer or other reactant used in the manufacture of the polymer.
- (2) -- Mark (X) this column if entry in column (1) is confidential.
- (3) -- Indicate the typical weight percent of each monomer or other reactant in the polymer.
- (4) -- Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
- (5) -- Mark (X) this column if entries in columns (3) and (4) are confidential.
- (6) -- Indicate the maximum weight percent of each monomer or other reactant that may be present in the polymer when manufactured for commercial purposes.
- (7) -- Mark (X) this column if entry in column (6) is confidential.

Correction estimates can be documented and presented in cases where only a soluble fraction of the polymer can be analyzed.

Indicate the maximum weight percent of each unreacted monomer or other reactant.

Monomer or other reactant and CAS Registry Number
(1)

Confidential (2)	Typical composition (3)	Identity Mark (X) (4)	Confidential (5)	Maximum residual (6)	Confidential (7)
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List all reactants that are used in the manufacture of the polymer including those used at 2 percent by weight or less. This includes monomers, free radical initiators, chain transfer agents, chain terminating agents, and cross-linking agents.

Each prepolymer to be charged should be identified by a correct chemical name and applicable CAS Registry number (for the prepolymer as a whole)

Review which components & data require confidential check-off.

Composition: list the typical percentage you intend to make. You will be able to modify the % level as long as all components used to name the polymer are still present. (This is true for reactants used at >2% or those at 2% or less with column 4 checked. If listed reactants are at 2% or less, without column 4 checked, they can be eliminated, but they cannot exceed 2%. See note on Identity Mark.

Reactants at > 2% by weight are automatically included in the TSCA Inventory description of the polymer.

Identity Mark, column 4: check this only if you need to include a minor (2% or less) reactant in the polymer name. This will allow a minor component to be increased above 2% by weight without the need for a new PMN.

However, an Identity Marked reactant must always be intentionally present.

Mark (X) this box if you attach a continuation sheet.

c. Please identify which method you used to develop or obtain the specified chemical name.

Method 1

Indicate the method of nomenclature determination, and provide the assigned chemical name in (d.) Include the nomenclature documentation as an attachment to the PMN.

d. The currently used chemical name is

Method 1 is reserved for nomenclature determinations made by CAS Inventory Expert Service. (Contact CAS at 1-800-631-1884 and ask for the Inventory Expert Service.)

Inventory listings for similar polymers.

e. Provide a corrected chemical name, if one can be reasonably ascertained.

Represent the polymer with a structural diagram, to the extent it can be shown.

Random polymers cannot be definitively represented, as different hypothetical monomer combinations can occur, but a representative structural model must still be provided, as complete as can be reasonably ascertained by a chemist. Merely indicating "Random polymer" is not acceptable to EPA.

Provide a basic representation of the monomer structural units and 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 precursors.

Mark (X)

Polymers that are siloxanes, silicones, certain polyglycols, and vinylacetals are named on the TSCA inventory by the repeat groups rather than their starting materials.

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities

(a) -- Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
 (b) -- Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity and CAS Registry Number
(a)

Maximum
percent
(b)

Confidential

An impurity is a chemical substance that you do not intend to be present with your PMN substance. Your intent is thus the primary determinant as to impurity status.

List all known impurities that are unintentionally present, regardless of their weight percent. List the expected maximum percentage of each impurity and indicate its confidentiality status. Unreacted feedstocks to the reaction should be listed.

An impurity may be suggestive of chemical precursors or chemical processes. Review whether the identity of certain impurities justifies CBI protection.

%
%
%
%
%
%

Mark (X) this box if you attach a continuation sheet.

4. Synonyms -- Enter any chemical synonyms for the new chemical substance identified in subsection 1 or 2.

Synonyms include common chemical names used in scientific or technical literature, and code numbers or code names referenced in the PMN and its attachments. Review which synonyms may be proprietary and require CBI protection. Chemical name synonyms must be consistent with the chemical structure and thus not misleading.

Mark (X) this box if you

Confidential

5. Trade Identification -- List trade names for the new chemical substance identified in subsection 1 or 2.

List any trade name that is used or will be used for the neat chemical substance, whether or not they are registered brands / trade marks. Review CBI status.

Mark (X) this box if you attach a continuation sheet.

6. Generic chemical name -- If you claim chemical identity as confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

If the chemical identity is confidential, a generic chemical identity that is as specific as possible is required. The generic name should reveal the chemical identity to the maximum extent possible, must be consistent with the chemical structure, and must not be misleading.

Mark (X) this box if you attach a continuation sheet.

7. Byproducts -- Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct
(1)

CAS Registry Number
(2)

Confidential

List any byproducts that you reasonably anticipate will result from the manufacture, processing, use and disposal of the new chemical substance at sites under your control. Provide the specific chemical name, CAS numbers if they can be determined, and the confidential status of the byproducts formed. If no byproducts are formed, enter "None".

Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

Your production volumes should be estimated as accurately as possible, but you are not bound to your estimates unless you check the binding option box. Include amounts you intend to produce for export. Provide an estimate of the first 12 months of production and the maximum production volume for any consecutive 12 month period during the first 3 years of commercial manufacture.

LVE notices are limited to a maximum of 10,000 kg for any 12 month period.

Are there some potential concerns for your PMN/LVE substance? Setting a binding production limit may be a useful risk management option.

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (x)

2. Use Information -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

- a. (1) -- Describe each intended category of use of the new chemical substance by function and application.
- (2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
- (3) -- Indicate your willingness to have the information provided in column (1) binding.
- (4) -- Estimate the percent of total production for the first three years devoted to each category of use.
- (5) -- Mark (X) this column if entry in column (4) is confidential business information (CBI).
- (6) -- Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
- (7) -- Mark (X) this column if entry in column (6) is confidential business information (CBI).
- (8) -- Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
- (9) -- Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Production volume estimates relate to market intent and are normally claimed confidential by submitters.

Category of use (1) <small>(by function and application i.e. a dispersive dye for film)</small>	CBI	Binding Option Mark (x)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	% of substance expected per use (8)					CBI (9)
							Site-limited	Consumer	Industrial	Commercial	Binding Option	
At least one TSCA regulated use must be provided.												
Provide the requested information for each separate use of the PMN substance. The category of use information should be specific enough to allow EPA reviewers to anticipate potential exposure patterns for the new substance. (e.g., merely indicating "Dye" is not sufficient - is it a photographic dye, a reactive dye for nylon fibers, or a dye to be incorporated in a polymer marking film?)			%		%		Break down the use(s) by percentage for the indicated end user categories.					
LVE notices limit you to your stated category of use(s), so make sure your description fully encompasses all intended uses for any LVE.							Site-limited means the substance will only be used on the contiguous property unit where manufactured and will not intentionally be removed from the site except for waste disposal.					

*If you have identified consumer uses, provide expanded detail of how the PMN substance will be used, what its concentration will be, and how it may be further reacted when used as a consumer product. A continuation sheet will be needed to provide this level of detail.

Mark (X) this box if you attach a continuation sheet.

b. Generic use description

If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

If necessary to protect confidential use information, the category of use data provided above can be claimed CBI, and a generic (non-CBI) use will be provided here.

e.g., "Surfactant for mineral ore aqueous extraction" (CBI) vs. "surfactant" (generic)

Mark (X) this box if you attach a continuation sheet.

3. Hazard Information: provide the MSDS for the PMN substance or intermediate or product mixture (that contains it) as an attachment to the PMN. Also include hazard warning statements or labels, if relevant. The personal protection requirements of the MSDS become integral requirements of a Low Volume Exemption notice.

Binding Option Mark (x)

Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual.

1. Operation description

a. Identity -- Enter the identity of the site at which the operation will occur.

Confidential

Name

Site address

City, County

Where will the PMN substance be manufactured (or processed or used)? List the plant locations. If the submitting company is confidential, this data will also be claimed as CBI.

This page is duplicated to provide separate information pages for manufacturing, processing, and use activities. Each stage of PMN substance handling results in potential human exposure and environmental release.

of sites

If the same operation will be performed at additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments.

Mark (X) this box if you attach a continuation sheet.

b. Type --
Mark (X)

Manufacturing

Processing

Use

c. Amount and Duration -- Complete 1 or 2 as appropriate

1. Batch

Maximum kg/batch (100% new chemical substance)

Hours/batch

Batches/year

2. Continuous

Maximum kg/day (100% new chemical substance)

Provide batch or continuous process information as required above, based on your maximum production (generally for the third year of estimated production). These data are normally kept confidential by submitters.

d. Process description Mark (X) to indicate your willingness to disclose

- (1) Diagram the major unit operation steps and chemical conversions. In (e.g., gallon drum, rail car, tank truck, etc.).
- (2) Provide the identity, the approximate weight (by kg/day or kg/batch) of materials and feedstocks (including reactants, solvents, and catalyst chemicals (note frequency if not used daily or per batch)).
- (3) Identify by number the points of release, including small or intermittent releases.

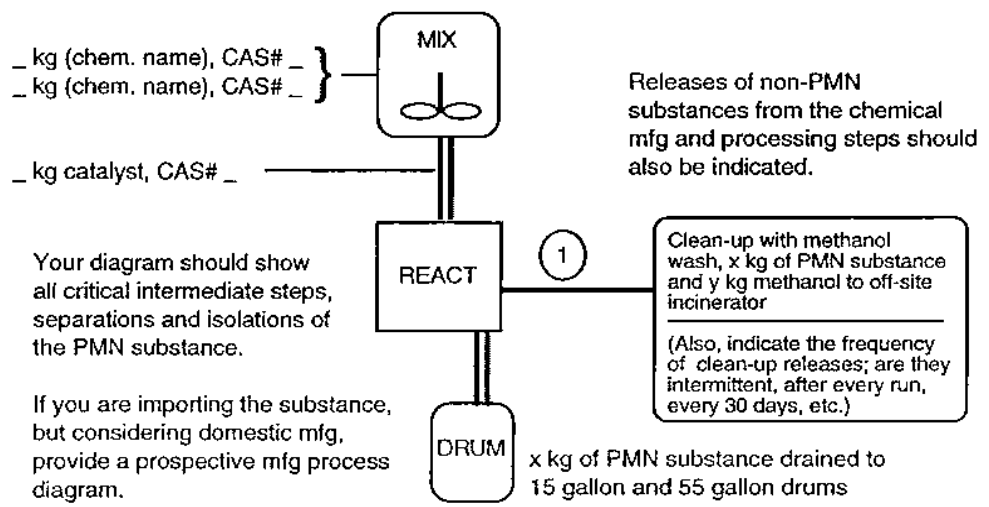
The maximum daily or batch production multiplied by the days per year or batches should agree with the maximum production estimate provided on page 7.

The required manufacturing (and processing) flow diagram is frequently provided as a full page attachment on a following page, to allow sufficient room for detail.

The diagram should show all reactants and other starting materials as inputs to typical process unit operations. Input and output amounts should be listed, and should allow the EPA reviewer to follow all process steps, the disposition of the PMN substance, and all waste streams.

Number all waste streams for reference on page 9, 3.(1) of the PMN form.

Simplified Example Only:



Your diagram should show all critical intermediate steps, separations and isolations of the PMN substance.

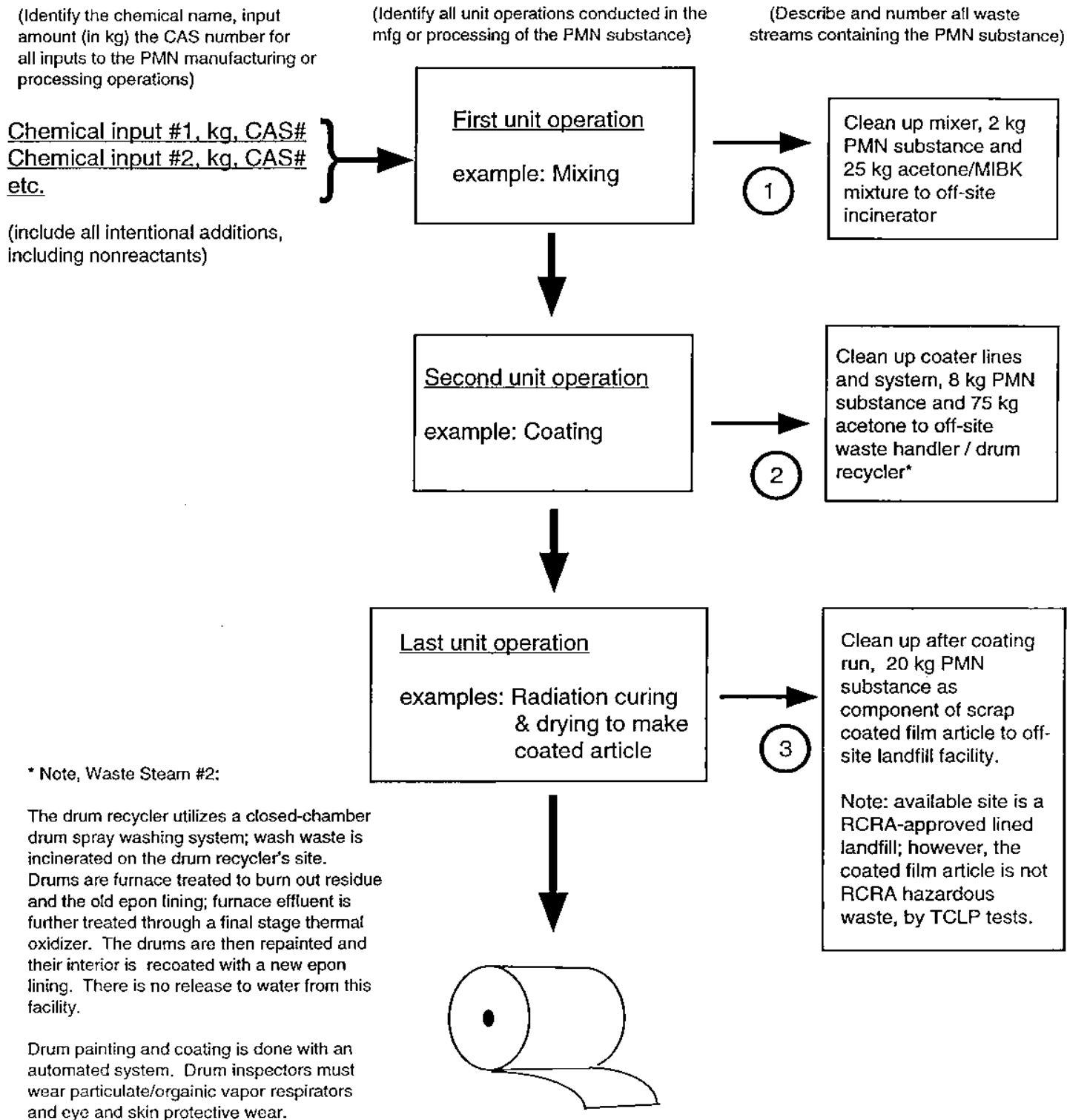
If you are importing the substance, but considering domestic mfg, provide a prospective mfg process diagram.

Mark (X) this box if you attach a continuation sheet.

Manufacturing / Processing Operations Diagram

Processing Reference Example

(Mark This Page if it Contains TSCA CBI)



* Note, Waste Stream #2:

The drum recycler utilizes a closed-chamber drum spray washing system; wash waste is incinerated on the drum recycler's site. Drums are furnace treated to burn out residue and the old epon lining; furnace effluent is further treated through a final stage thermal oxidizer. The drums are then repainted and their interior is recoated with a new epon lining. There is no release to water from this facility.

Drum painting and coating is done with an automated system. Drum inspectors must wear particulate/organic vapor respirators and eye and skin protective wear.



Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

2. Occurrence of exposure to the PMN substance. (1) EPA is attempting to estimate exposure levels, the number of workers potentially exposed, and possible routes and duration of exposure to the PMN substance. (2) Work with your plant engineers to develop accurate data. Review the CBI status of data you provide. (3) Enter the maximum days/year any one worker will engage in each activity. (4) Enter maximum hours/day any one worker will engage in specific activity. (5) Be as specific as possible on physical form - see item (5) above on the PMN form. (e.g., is the PMN substance isolated as a crystalline or amorphous powder, wet cake, flake solid, granular solid, or a fused solid?) (6) If data on particle size of solids are available, it should be included as an attachment. For wet cakes, a % moisture estimate may prevent EPA from making an estimate that is too conservative. (7) - Mark (X) this column if entry in column (5) is confidential. (8) - Estimate the maximum number of workers involved in each activity. (9) - Mark (X) this column if entry in column (8) is confidential. (10) and (11) - Estimate the maximum duration of the activity in hours per day and days per year. (12) - Mark (X) this column if entries in columns (10) and (11) are confidential.

Worker activity (e.g. bag dumping, filling drums)	CBI	Protective Engineering Controls	Option Mark (x)	(e.g. solid, powder, liquid, gas, etc.) and % new substance	Binding Option Mark (x)	CBI	# of Workers Exposed	CBI	Maximum Hrs/day	duration Days/yr	CBI
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
List all worker activities with potential exposure to the PMN substance; e.g., QC Sampling, Draining, Packaging, Clean-up. List one activity per line.											

Mark (X) this box if you attach a continuation sheet.

3. Environmental releases of the PMN substance. (1) The information on exposure and environmental releases is related to the flow diagram from the previous page. This page is duplicated and filled out for each flow diagram supplied in the PMN (manufacturing, each processing description, and any use diagrams). The information provided should focus on the PMN substance. (2) EPA reviewers pay particular attention to human exposure and environmental release data under their TSCA mandate to protect against unreasonable risks from new chemical substances. In the absence of this information, EPA will make its own estimates of worker exposure and and environmental release, which are usually conservative. Present data that is accurate and as complete as possible. (3) Release estimates should be consistent with the release levels shown on the preceding flow diagram. (4) Include intermittent release estimates from cleaning of equipment and transportation containers, even if cleaned off-site. (5) Environmental release and control technology data: Refer to the instructions listed in 3. (4) & (5) on page 9 of the PMN form. (6) Release estimates should be consistent with the release levels shown on the preceding flow diagram. (7) Environmental release and control technology data: Refer to the instructions listed in 3. (4) & (5) on page 9 of the PMN form.

Release Number	(2a)	(2b)	(3)	e.g. stack air (4)	(5a)	Distilling Mark (x)	(5b)	CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	(6)	(5b)	(6)

(7) Mark (X) the destination(s) of releases to water. POTW provide name(s) below: Navigable waterway Other - Specify provide NPDES # CBI

Mark (X) this box if you attach a continuation sheet.

If there are releases to water, provide information in this bottom section regarding POTW(s), releases to navigable waterways, and NPDES numbers. Review confidentiality, since these data may identify your company by location, and may require CBI protection.

Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. Complete a separate section B for each type of processing, or use operation involving the new chemical substance. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1. **Operation Description** - To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential.
- (1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify- e.g. 5 gallon pails, 55gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity. (2) -- Provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) -- Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. (4) Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

of sites

Provide to the maximum extent possible process information and diagrams for your 'downstream' industrial processors and users.

This will enable EPA to better understand an important part of the life cycle of your PMN substance. In the absence of this information, EPA will make its own estimates and assumptions about worker exposure and environmental releases, which are usually conservative.

This information can be claimed confidential. Confidential information provided in this section should be bracketed or circled and marked to indicate its CBI status.

Mark (X) this box if you attach a continuation sheet.

2. **Worker Exposure/Environmental Release**
- (1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
- (2) -- Estimate the number of workers exposed for all sites combined.
- (4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
- (6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls used to protect workers.
- (7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
- (9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
- (10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
- (12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
- (14) -- Identify byproducts which may result from the operation.
- (3), (5), (8), (11), (13) and (15) - Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure		CBI (5)	Protective Equip. / Engineering Controls/ Physical Form and % new substance (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released		CBI (11)	Control Technology (12)	CBI (13)
			(4a)	(4b)						(10a)	(10b)			

Provide as much information as you can gather from industrial processors or users of your PMN substance. Providing this information will eliminate the need for EPA to make default assumptions about exposure and releases at sites beyond your control, which will likely be conservative assumptions that could alter their risk assessments of your premanufacturing notification.

Providing sound information enables EPA to develop a more accurate risk assessment of your PMN substance, and improves your own risk assessment of your PMN substance prior to submitting the notice to the Agency.

(14) -- Byproducts: (15)

Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential.

In this effort manu inform and s includ modi subst comp discha recyc regula this in expos (e.g., perfo All in of thi manu

Review the guidance of the PMN form for this page and the comments provided here. EPA strongly encourages submitters to provide pollution prevention data in their notices, as this information assists the Agency in balancing the benefits of a PMN substance against its unique risks.

While Agency staffers frequently receive information on the benefits of the PMN substance with respect to its use(s), data on pollution prevention effects are rarely included. This section should be utilized to indicate to EPA benefits in terms of the raw materials incorporated, the manufacturing process, emission reductions, less toxic waste byproducts, or lower risks upon end use and disposal. Consider the entire life cycle of the PMN substance in your evaluation.

Also consider opportunities for product stewardship or other risk management controls that could significantly reduce risk characteristics of the new substance. (e.g., disposal techniques that can be easily implemented and substantially reduce waste toxicity.)

Initiatives in the New Chemicals Program such as the Environmental Technology Initiative (ETI) for Chemicals, and the Pollution Prevention Recognition Project, are geared towards incorporating this type of information into the Agency's risk management decision making and recognizing innovative chemical design or technological innovation that shows potential for environmental and human health benefits.

Confidential information provided in this section should be bracketed or circled and marked to indicate its CBI status.

Describe the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

Pollution Prevention Information

Are there Pollution Prevention benefits associated with the new PMN chemical? Does it allow reduction or elimination of (more) toxic solvents? Does it reduce disposal to land, or in safer forms, compared to the chemistry it replaces? Can it be recycled more easily than existing materials? Does your manufacturing process eliminate or reduce the use / release of hazardous substances?

Describe any pollution prevention benefits here, and indicate if this information is confidential business information. Attempt to quantify the expected benefits to the extent possible and avoid exaggeration and highly speculative statements.

Mark (X) this box if you attach a continuation sheet.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Measured or Estimate (M or E)	Confidential Mark (X) (d)
Physical state of neat substance			____ (s) ____ (l) ____ (g)		
Vapor pressure @ Temperature _____ °C			_____ Torr		
Density / relative density					
Solubility @ Temperature _____ Solvent _____					
Solubility in water @ Temperature _____					
Melting temperature					
Boiling/sublimation temperature @ _____					
Spectra					
Dissociation constant					
Particle size distribution					
Octanol/water partition coefficient					
Henry's Law constant					
Volatilization from water					
Volatilization from soil					
pH @ concentration _____					
Flammability					
Explosibility					
Adsorption/coefficient					
Other - Specify					

Provide any data listed on this page which you have in your possession for the PMN substance, either measured or estimated. Mark all relevant columns for each data row you provide. There are entry rows for unlisted properties data at the bottom of this worksheet.

The data entered on this page should reflect the neat PMN substance, whereas the MSDS data frequently indicates formulated (mixture) properties.

EPA's risk assessment process does utilize physiochemical properties, as some of the attributes listed here can relate directly to chemical risks. Among the most useful parameters of a new substance to EPA are the boiling point, the melting point, vapor pressure, the octanol/water partition coefficient, water solubility, Henry's Law Constant, hydrolysis, spectral data (MS, proton and C13 NMR, IR, and UV absorption) and the soil/sediment adsorption coefficient. In the absence of this data, EPA will estimate to the extent possible physiochemical data to aid in their risk evaluations.

Indicate whether the value you provide is based on an actual test measurement (M) or was estimated (E). Note that EPA staffers indicate that data qualifiers such as 'negligible' or 'soluble' are not useful descriptions.

You are not required to generate the listed test data if you do not have it.

Physical / chemical properties data may be so unique that they could in the future link the PMN substance to a commercial product or may tend to identify unique classes of chemical substances, and therefore some data elements may represent confidential business information. Review the CBI status of each entry carefully, and avoid making unsupportable claims.

For more detailed information on completing the PMN form, refer to the EPA guides titled "Instructions for Completing the Premanufacture Notice Form" and "Chemistry Assistance Manual for Premanufacture Notification Submitters". The latter guide was authored by Stephen DeVito and Carol Farris of EPA (EPA 744-R-97-003, March 1997), and is also commercially published in hardcover book form.