

U.S. ENVIRONMENTAL PROTECTION AGENCY

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TSCA §8(a) REPORTING FOR CHEMICAL SUBSTANCES WHEN MANUFACTURED OR PROCESSED AS NANOSCALE MATERIALS: DATA SUBMISSION FORM

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WASHINGTON, D.C. 20460
ATTN: 8(a) Reporting for Chemical Substances Manufactured or Processed as Nanoscale
Materials

[

GENERAL INSTRUCTIONS

- This form is to be used for reporting as prescribed in 40 CFR 704.20. As indicated in that regulation, definitions in TSCA and 40 CFR part 704 apply.
- You must provide information requested in this form to the extent it is known to or reasonably ascertainable by you. "Known to or reasonably ascertainable by" is defined in 40 CFR §704.3. Make reasonable estimates if you do not have actual data.
- You must provide the currently correct Chemical Abstracts (CA) Name of the chemical substance and material characterization data described in Part I, section C4.
- As much of this form is adapted from the Premanufacture Notice (PMN) form (EPA Form No. 7710-25), it may be instructive to read "Instruction Manual for Reporting Under the TSCA §5 New Chemicals Program" (available from the Toxic Substances Control Act (TSCA) Information Service, 202-554-1404, or 202-554-5603(fax) or at <http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm>).
- If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this form, reproduce the sections as needed.
- Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III of this Form, list all attachments, including any continuation sheets, any test data reports or other data and any optional information provided.
- Only one chemical substance may be submitted per form.
- Any information may be claimed as confidential. To assert a claim on the form, mark (X) the confidential box next to the information claimed as confidential. To assert a claim in an attachment, circle or bracket the information claimed as confidential. If information is claimed as confidential, a sanitized version (including attachments) must be provided with your submission and should be labeled as such.
- You are required to submit all existing data concerning the environmental and health effects of the substance known to or reasonably ascertainable by you. Standard literature citations may be submitted for data in the open scientific literature. Submit a complete test data report (written in English, if available), not summary data, unless the test data report appears in the open literature. Clearly identify whether test data is on the chemical substance, on an analog, or from models. Characterize the chemical composition of the tested material.

TEST DATA

Data must be submitted according to the requirements of 40 CFR §704.20. In addition, hazard and exposure test data are most useful if the physical/chemical properties of the nanoscale material relevant to assessing test results are obtained at the initiation of testing. Additional relevant information on preparation of the nanoscale material for administration and storage history of the material between production and administration is not required but can assist in interpretation. **Indicate which of the following data are included in this submission:**

- | | | |
|---|---|--|
| <input type="checkbox"/> Physical / Chemical properties | <input type="checkbox"/> Health effects | <input type="checkbox"/> Environmental effects |
| <input type="checkbox"/> Structure / activity relationships | <input type="checkbox"/> Exposure | <input type="checkbox"/> Environmental fate |

☐ Mark (x) if any information in your submission package is claimed as confidential.


| | | |
|---|------|--------------------------|
| TIME REQUIRED TO COMPLETE THE FORM EPA estimates that it may take, up to 175 hours to complete this form, including time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. More details about the EPA estimate are provided in the Information Collection Request identified as EPA ICR No. 2517.01, approved under OMB Control No. 2070-[tbd], a copy of which is available here [insert url when finalized]. To help us refine that estimate, please provide an estimate of the amount of time in work hours that it took you to complete this form. | | Hours: |
| RESERVED for any additions | | |
| CHECK LIST Please verify that the questions in the following general areas were answered by marking (X) in the boxes. (Answers may include, for example, "N/A," "none," "not known"). <input type="checkbox"/> Physical and chemical characterization <input type="checkbox"/> Risk management information | | |
| STATEMENT | | |
| I certify that to the best of my knowledge and belief: <ol style="list-style-type: none"> The company named in Part I, section A, subsection 1a of this form manufactures, imports, or processes or intends to manufacture, import, or process for a commercial purpose (as those terms are defined in TSCA and 40 CFR Part 704), the chemical substance identified in Part I section B. All information provided in this form is complete and truthful as of the date of submission. I am submitting with this form all existing data concerning the environmental and health effects and all other required data known to or reasonably ascertainable by me as required by 40 CFR §704.20. | | |
| Mark (X) the "Confidential" BOX on the right if you claim the signature and title as confidential. | | Confidential |
| Signature and title of Authorized Official (Original Signature Required) | Date | <input type="checkbox"/> |

Part I -- GENERAL INFORMATION

Section A -- SUBMITTER IDENTIFICATION

Confidential

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

| | | | | | |
|--|-------------------------------------|--|-----------|-----------|--------------------------|
| 1a. Person Submitting (in U.S.) | Name of authorized official | | Position | | <input type="checkbox"/> |
| | Company | | | | |
| | Mailing address (number and street) | | | | |
| | City, State, ZIP Code | | | | |
| b. Other Person Submitting (in U.S.) | Name of authorized official | | Position | | <input type="checkbox"/> |
| | Company | | | | |
| | Mailing address (number and street) | | | | |
| | City, State, ZIP Code | | Telephone | Area Code | |
| c. If you are submitting this as part of a joint submission, mark (X) this box.  | | | | | <input type="checkbox"/> |
| Joint Submitter (if applicable) | Name of authorized official | | Position | | <input type="checkbox"/> |
| | Company | | | | |
| | Mailing address (number and street) | | | | |
| | City, State, ZIP Code | | Telephone | Area Code | |
| 2. Technical Contact (in U.S.) | Name of authorized official | | Position | | <input type="checkbox"/> |
| | Company | | | | |
| | Mailing address (number and street) | | | | |
| | City, State, ZIP Code | | Telephone | Area Code | |

Part I – GENERAL INFORMATION – Continued

Section B -- CHEMICAL IDENTITY INFORMATION: **

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

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

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance - Mark (X) ☐ Class 1 or ☐ Class 2

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. **)

c. Identify which method you used to develop or obtain the specified chemical identity information: (check one).

☐

Method 1 (CAS Inventory Expert Service)

☐

Method 2 (Other Source)

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

CAS#

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance - (1) List the immediate 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. (5) Note: the components of a composite can be separate chemical identities. For example in a composite of starch molecules between layers of clay treated with surfactants, the starch, clay, and surfactants might be on the TSCA Inventory, but since the interactions between the components are weak electrical interactions, there is no single chemical substance representing the composite as a whole.

☐

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 residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.

Describe the methods of measurement or the basis for your estimates: GPC ☐ Other ☐: (Specify) _____

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.

- b. Make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. 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 exists) of 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 as a residual in the polymer as manufactured for commercial purposes.
 - (7) - Mark (X) this column if entry in column (6) is confidential.

| Monomer or other reactant and CAS Registry Number (1) | Confidential (2) | Typical composition (3) | Identity (4) | Confidential (5) | Maximum residual (6) | Confidential (7) |
|--|---------------------|----------------------------|-----------------|---------------------|-------------------------|---------------------|
| | | % | | | % | |
| | | % | | | % | |
| | | % | | | % | |
| | | % | | | % | |
| | | % | | | % | |
| | | % | | | % | |
| | | % | | | % | |

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

- c. Identify which method you used to develop or obtain the specified chemical identity information (check one).

☐ Method 1 (CAS Inventory Expert Service)

☐ Method 2 (other source)

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

- e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

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

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 purpose. 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 |
|---|---------------------------|--------------|
| | % | |
| | % | |
| | % | |
| | % | |
| | % | |
| | % | |
| | % | |
| | % | |

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

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

Confidential

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

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

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

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

☐ 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 chemical substance. Provide the CAS Registry Number if available.

| Byproduct (1) | CAS Registry Number (2) | Confidential |
|------------------|----------------------------|--------------|
| | | |
| | | |
| | | |

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

Part I – GENERAL INFORMATION – Continued

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

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

1. Production volume -- Report the production volume during calendar year 20XX. Also estimate the maximum production volume for any consecutive 12-month period during the next three years of production. Make estimates on a 100% chemical substance basis.

| Production volume for 20XX (kg/yr) (100% chemical substance basis) | Maximum 12-month production volume (kg/yr) (100% chemical substance basis) | Confidential | |
|---|---|--------------|--|
| | | | |

2. Use Information -- 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 substance, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

- a. (1) -- Describe each category of use of the chemical substance by function and application.
 (2) -- Mark (X) this column if entry column (1) is claimed as confidential business information (CBI).
 (3) -- Estimate the percent of total production volume devoted to each category of use.
 (4) -- Mark (X) this column if entry in column (4) is claimed as CBI.
 (5) -- Estimate the percent of the 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.
 (6) -- Mark (X) this column if entry in column (6) is claimed as CBI.
 (7) -- Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate.
 (8) -- Mark (X) this column if entry(ies) in column (8) is (are) claimed as CBI.

| Category of use (1) (by function and application i.e. a coating for automobile body parts) | CBI | | Production % | CBI | % in Formulation | CBI | % of substance expected per use (7) | | | | CBI | |
|---|-----|--|--------------|-----|------------------|-----|--|----------|------------|------------|-----|-----|
| | (2) | | (3) | (4) | (5) | (6) | Site-limited | Consumer | Industrial | Commercial | | (8) |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |
| | | | % | | % | | | | | | | |

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ 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.

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

3. Hazard Information -- Include a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which is provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the substance. List in part III hazard information you include.

☐ Mark (X) this box if you attach hazard information.

Part I – GENERAL INFORMATION – Continued

Section C --Continued

Mark (X) the “CBI” box next to any item you claim as confidential.

CBI

4. Material characterization – Describe characteristics of the nanoscale material used to distinguish it from other discrete forms of the nanoscale material, as described in 40 CFR 704.xxx(a), including but not limited to the particle size, morphology, encapsulation, and formulation.

☐

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

5. Briefly describe any unique or enhanced properties that arise from the nanoscale features of the material, particularly in contrast to any non-nanoscale varieties that exist.

☐

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

6. Briefly explain why this material is designed and/or produced to be a nanoscale material.

☐


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

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the CBI box next to any item you claim as confidential.

Complete section A for each type of manufacture, processing, or use operation involving the chemical substance at industrial sites you control.
See instructions manual

| | | | |
|--|--|-------------|--------------------------|
| 1. Operation description | | | CBI |
| a. Identity -- Enter the identity of the site at which the operation occurs. | | | |
| Name | | | <input type="checkbox"/> |
| Site address (number and street) | | | |
| City, County, State, ZIP code | | | |
| If the same operation occurs at more than one site, enter the number of sites. Identify the 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.  | | | <input type="checkbox"/> |
| <input type="checkbox"/> Mark (X) this box if you attach a continuation sheet. | | | |
| b. Type -- Mark (X) <input type="checkbox"/> Manufacturing <input type="checkbox"/> Processing <input type="checkbox"/> Use | | | |
| c. Amount and Duration -- Complete 1 or 2 as appropriate | | | |
| 1. Batch | Maximum kg/batch (100% chemical substance) | Hours/batch | Batches/year |
| 2. Continuous | Maximum kg/day (100% chemical substance) | Hours/day | Days/year |
| d. Process description | | | |
| (1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.). | | | |
| (2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, 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 chemical substance. If releasing to two media at the same step, assign a second release number for the second medium. | | | |
| <input type="checkbox"/> Mark (X) this box if you attach a continuation sheet. | | | |

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER – Continued

2. Occupational Exposure -- Make separate confidentiality claims for the description of worker activity, physical form of the chemical substance, number of workers exposed, and duration of activity. Mark (X) in the "CBI" column next to any item you claim as confidential.

- (1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
- (2) -- Mark (X) this column if entry in column (1) is claimed CBI.
- (3) -- Describe any protective equipment and engineering controls used to protect workers.
- (4) -- Indicate the physical form(s) of the chemical substance (e.g., solid: crystal, granule, powder, or dust) and % chemical substance (if part of a mixture) at the time of exposure.
- (5) -- Mark (X) this column if entry in column (4) is claimed CBI.
- (6) -- Estimate the maximum number of workers involved in each activity for all sites combined.
- (7) -- Mark (X) this column if entry in column (6) is claimed CBI.
- (8) and (9) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
- (10) -- Mark (X) this column if entries in columns (8) and (9) are claimed CBI.

| Worker activity (i.e., bag dumping, filling drums) | CBI | Protective Equipment/ Engineering Controls | | Physical forms(s) and % substance (4) | | CBI | # of Workers Exposed (6) | CBI | Maximum Hrs/day | Duration Days/yr | CBI |
|---|-----|---|--|---|--|-----|-----------------------------------|-----|--------------------|---------------------|------|
| (1) | (2) | (3) | | | | (5) | | (7) | (8) | (9) | (10) |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
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| | | | | | | | | | | | |

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

3. Environmental Release and Disposal -- Make separate confidentiality claims for the release number and the amount of the chemical substance released and other release and disposal information. Mark (X) in the CBI column next to each item you claim as confidential.

- (1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
- (2) -- Estimate the amount of the substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
- (3) -- Mark (X) in this column if entries in columns (1) and (2) are claimed as CBI.
- (4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the substance is released from that release point.
- (5) -- a. Describe control technology, if any, and control efficiency that is used to limit the release of the substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that is used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
- (6) -- Mark (X) in this column if entries in columns (4) and (5) are claimed as CBI.
- (7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is claimed as CBI.

| Release Number (1) | Amount of substance released | | CBI | Media of release e.g. stack air (4) | Control technology and efficiency (you may wish to optionally attach efficiency data) | | CBI |
|--------------------------|------------------------------|------|-----|--|---|------|-----|
| | (2a) | (2b) | (3) | | (5a) | (5b) | (6) |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

(7) Mark (X) the ☐ POTW provide name(s) below: ☐ Navigable waterway ☐ Other - Specify ☐ provide NPDES # ☐ CBI

destination(s) of releases to water. _____

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

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 chemical substance at sites you do not control. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the 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, 55 gallon 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 a 100% chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and 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 chemical substance. (4) Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

of sites _____

☐

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 % chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
 (7) -- Estimate the percent of the 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 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 that is used to limit the release of the substance to the environment.
 (14) -- Identify byproducts which result from the operation.
 (3), (5), (8), (11), (13) and (15) -- Mark (X) in these columns if any of the proceeding entries are claimed as CBI.

| Letter of Act-ivity (1) | # of Workers Exposed (2) | CBI (3) | Duration of Exposure | | CBI (5) | Protective Equip. / Engineering Controls/ Physical Form and % Substance (6) | % in Form-ulation (7) | CBI (8) | Release Number (9) | Amount of Substance Released | | CBI (11) | Media of Release & Control Technology (12) | CBI (13) |
|----------------------------|-----------------------------|------------|----------------------|------|------------|--|--------------------------|------------|-----------------------|------------------------------|-------|-------------|---|-------------|
| | | | (4a) | (4b) | | | | | | (10a) | (10b) | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |

(14) -- Byproducts:

(15)

☐

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

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section A / B, Subsection 2. Occupational Exposure – Continued. b. Details of protective equipment / engineering controls.

(Use this form both for sites controlled by submitter and by others. Make copies as necessary.)

Provide the following information:

- (1) – The worker activities listed in Section A.2 or B.1 for which protective equipment/engineering controls are in use.
- (2) – A brief description of the rationale for selecting the protective equipment/engineering controls, including internal exposure control limits, data and the methods used to generate the data that informed the decision.
- (3) – A brief description of the cleaning, reuse, and/or disposal of the protective equipment
- (4) – A brief description of any data (personal and/or area), units (e.g., mass conc., surface area, or particle number conc.) and Any exposure monitoring methods used.

Mark (X) in the “CBI” column next to any item you claim as confidential.

CBI

(1) Worker activity / Protective equipment / Engineering Control

☐

(2) Rationale for selecting equipment / controls, associated internal exposure control limit / data / methods

☐

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

(3) Cleaning, reuse, and/or disposal of protective equipment

☐

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

(4) Exposure monitoring data (personal and/ or area), units (e.g., mass conc., surface area, or particle number conc.), and methods used

☐

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

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

Section A.3 / Section B, subsection 2. Environmental Release and Disposal – Continued. Details of control technology.

(Use this form both for sites controlled by submitter and by others. Make copies as necessary)

To assist EPA in gaining a better understanding of the need for and the types of control technology used at the release points in the manufacture and handling of engineered nanoscale materials, provide the following information for each release point for which control technology is used:

- (1) – The Release Number, as identified in the process description, part II, section A, subsection 1d(3) (page 8).
- (2) – A brief description of the rationale for selecting the control technology.
- (3) – Data and measurement methods of waste treatment efficiency studies.

**Release
Number (1)**

Mark (X) in the “CBI” column next to any item you claim as confidential.

CBI

(2) Rationale for selecting control technology

☐

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

(3) Data and measurement methods of waste treatment or purification studies

☐

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

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

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued**Section C – Lifecycle**

Mark (X) the “CBI” box next to any item you claim as confidential.

CBI

1. In addition to the information already given, provide a brief overview of the lifecycle of the material, including all workplaces that manufacture, process, or use the material, methods of packaging and transporting the material, all expected general population, environmental, and consumer uses, and the manufacturing and processing methods of the material or any consumer products containing the material. If not included in Sections A or B above, include a description of the end of life disposal or disposition of products containing the nanoscale material.

☐☐

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

Section D – Misc. Health, Exposure, Hazard Information

Mark (X) the “CBI” box next to any item you claim as confidential.

CBI

1. Describe any training, hazard communication (e.g. MSDS), etc. specific to the nanoscale material that is provided to workers.

☐☐

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

2. Estimate the total number of individuals—other than previously described workers—(e.g. general public, consumers) who may be exposed to the material and the duration of the exposure.

☐☐

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

3. Describe any other procedure, equipment, etc. being used to mitigate exposure to the material.

☐☐

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

4. Describe product labeling and any customer training specific to the nanoscale material.

☐☐

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

5. Describe other risk management practices specific to the nanoscale material.

☐☐

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

Part III - 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 section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the substance. Please include information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control.

Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the substance to potential alternatives may be provided.

See Pollution Prevention Guidance in Instructions Manual for guidance and examples.

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in 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 chemical substance in comparison to existing chemical substances used in similar application; or (6) the extent to which the chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

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

Part IV -- LIST OF ATTACHMENTS

List and then attach continuation sheets for sections of the form; test data and other data (including physical/chemical properties and structure/activity information), and optional information you are providing. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) in the "Confidential" column next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. Include with the sanitized copy of the form a sanitized version of any attachment in which you claim information as confidential.

| Attachment name | Attachment page number(s) | Confidential |
|-----------------|---------------------------|--------------|
|-----------------|---------------------------|--------------|

[illegible]

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

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

1. To assist EPA's review of physical and chemical properties data, summarize data you have already provided or used to complete the reporting form. Identify the property measured, the page of the form on which the property appears, the value of the property, the units in which the property is measured (as necessary), the physical state of the neat substance, and whether or not the property is claimed as confidential. If properties are not measured for the neat (100% pure) chemical substance then the measured mixtures or formulations can be noted (% substance in ____). It is noted that, for nanoscale materials, protocols and methods may not exist or be standardized for measurement of the physical and chemical properties listed in this worksheet.

| | Mark (X) if provided | Page number | Value | Measured or Estimate (M or E) | Confidential Mark (X) |
|---|----------------------------|----------------|----------------------------|-------------------------------------|--------------------------|
| Physical state of neat substance | | | ____ (s) ____ (l) ____ (g) | | |
| Vapor pressure @ Temperature _____ °C | | | Torr | | |
| Density/relative density | | | g/cm ³ | | |
| Solubility @ Temperature _____ °C Solvent _____ | | | g/L | | |
| Solubility in water @ Temperature _____ °C | | | g/L | | |
| Melting temperature | | | °C | | |
| Boiling / sublimation temperature @ _____ torr pressure | | | °C | | |
| Spectra | | | | | |
| Dissociation constant | | | | | |
| | | | | | |
| Octanol / water partition coefficient | | | | | |
| Henry's Law constant | | | | | |
| Volatilization from water | | | | | |
| Volatilization from soil | | | | | |
| pH @ concentration _____ | | | | | |
| Flammability | | | | | |
| Explosibility | | | | | |
| Adsorption / coefficient | | | | | |
| | | | | | |
| | | | | | |

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET Cont – Nanoscale Materials Specific Data

2. To assist EPA's review of physical and chemical properties data, summarize data you have already provided or used to complete the reporting form. Identify the property measured, the page of the form on which the property appears, the value of the property, the units in which the property is measured (as necessary), the physical state of the neat substance, and whether or not the property is claimed as confidential. If properties are not measured for the neat (100% pure) chemical substance then the measured mixtures or formulations can be noted (% substance in ____). It is noted that, for nanoscale materials, protocols and methods may not exist or be standardized for measurement of the physical and chemical properties listed in this worksheet.

| Property | Mark (X) if provided | Page number | Value | Measured / Estimated (M or E) | CBI Mark (X) |
|---|----------------------------|----------------|---|-------------------------------------|--------------------|
| General Characteristics | | | | | |
| Crystal structure | | | | | |
| Agglomeration state | | | | | |
| Particle Characteristics | | | | | |
| Particle size distribution | | | Provide graph with percentage of particles in each diameter class. For elongated particles, provide length distribution graph showing the percentage of particles in each length class. | | |
| Mean particle size (diameter and/or length) | | | nm | | |
| Standard deviation from mean | | | | | |
| Largest particle size (diameter and/or length) | | | nm | | |
| Smallest particle size (diameter and/or length) | | | nm | | |
| Aspect ratio | | | | | |
| Average aerodynamic diameter | | | nm | | |
| Average particle mass | | | g | | |
| Particle shape | | | | | |
| Surface Characteristics | | | | | |
| Surface area | | | m ² /g | | |
| Average particle surface area | | | m ² | | |
| Surface charge (Zeta potential) | | | mV | | |
| Porosity | | | | | |
| Surface chemical composition | | | | | |
| Surface / volume ratio | | | | | |
| Other | | | | | |
| Other | | | | | |
| | | | | | |
| | | | | | |

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

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET Cont– Nanoscale Materials Specific Data

assist EPA’s review of physical and chemical properties data, summarize data you have already provided or used to complete the reporting form. Identify the property measured, the page of the form on which the property appears, the value of the property, the units in which the property is measured (as necessary), the physical state of the neat substance, and whether or not the property is claimed as confidential. If properties are not measured for the neat (100% pure) chemical substance then the measured mixtures or formulations can be noted (% substance in ____). It is noted that, for nanoscale materials, protocols and methods may not exist or be standardized for measurement of the physical and chemical properties listed in this worksheet.

| | Mark (X) if provided | Page number | Value | Measured / Estimated (M or E) | CBI Mark (X) |
|--|----------------------------|----------------|-------|-------------------------------------|--------------------|
|--|----------------------------|----------------|-------|-------------------------------------|--------------------|

Fate and Transport

| | | | | | |
|---|--|--|--|--|--|
| Diffusion rate | | | | | |
| Gravitational settling rate | | | | | |
| Sorption rate | | | | | |
| Deposition rate | | | | | |
| Wet and dry transport | | | | | |
| Biodegradation rate | | | | | |
| Bioaccumulation | | | | | |
| Biotransformation | | | | | |
| Influence of redox/photochemical reaction | | | | | |

Other

| | | | | | |
|-------|--|--|--|--|--|
| Other | | | | | |
|-------|--|--|--|--|--|

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