Form Approved. O.M.B. No. 2070-0012. Approval Expires 12/31/2022

| U.S. ENVIRONMENTAL PROTECTION AGENCY | | | AGENCY USE ONLY |
|---|---|---|---|
| EPA | PREMANUFACTURE NOTICE<br>FOR NEW CHEMICAL SUBSTANCES | | Date of receipt: 03/04/2022 |
| When completed, send this form to: | If sending by Courier:<br>Office of Pollution Prevention and Toxics<br>Document Control Office (7407M)<br>US EPA, 1201 Constitution Ave NW<br>WASHINGTON, D.C. 20460<br>Contact Numbers: 202-564-8930/8940 | If sending by US Mail:<br>Office of Pollution Prevention and Toxics<br>Document Control Office (7407M)<br>US EPA, 1200 Pennsylvania Ave NW<br>WASHINGTON, D.C. 20460 | Submission Report Number |

| Total Number of Pages | TS Number |
|---|---|
| 24 | 021422 |

**GENERAL INSTRUCTIONS**

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS fee identification number you have generated. Remember, your fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

## Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

## Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

## Part III – LIST OF ATTACHMENTS

For paper submissions, 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, list these attachments, any test data or other data and any optional information included in the notice.

## OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

## CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

## 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 on 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)**

| | | | |
|---|---|---|---|
| [X] | Environmental fate data | [X] | Other Data |
| [X] | Health effects data | [X] | Risk Assessments |
| [X] | Environmental effects data | [ ] | Structure/activity relationships |
| [X] | Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.) | | |
| [ ] | Test data not in the possession or control of the submitter | | |

**TYPE OF NOTICE (Check Only One)**

- [X] **PMN** (Premanufacture Notice)
- [ ] **SNUN** (Significant New Use Notice)
- [ ] **TMEA** (Test Marketing Exemption Application)
- [ ] **LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
- [ ] **LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
- [ ] **LVE** Modification
- [ ] **LOREX** Modification
- [ ] **Mock Submission**
- [ ] Mark (X) if pending Letter of Support

N — IS THIS A CONSOLIDATED PMN (Y/N)?

1 — # of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).

[X] Mark (X) if any information in this notice is claimed as confidential.

# PMN Page 2

The public reporting and recordkeeping burden for this collection of information is estimated to average 93 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form 7710-25 to this address.

**CERTIFICATION --** A printed copy of this signature page, with original signature, must be submitted with CD or paper submission.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

**Additional Certification Statements:**

If you are submitting a PMN, SNUN, LoREX, LVE, or TMEA, check the following Fees Certification statement that applies:

- ☐ The Company named in Part I, Section A is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee as specified in 40 CFR 700.45(c).
- ☒ The Company named in Part I, Section A will remit the fee as specified in 40 CFR 700.45(c).
- ☐ This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).
- ☐ The company named in Part I, Section A is submitting a sustainable futures TME. The company has graduated from EPA's Sustainable Futures program and is therefore exempt from fees for this sustainable futures TME.

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 1 year of the date of the expiration of the 30 day review period.

| | | | | Confidential |
|---|---|---|---|---|
| Signature and title of Authorized Official (Original Signature Required) | *XXX* | Date | XXX | ☒ |

# PMN Page 3

## Part I -- GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

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

| 1a. | Person Submitting Notice (in U.S.) | | | | | Confidential |
|---|---|---|---|---|---|---|
| Name of Authorized Official | (first) XXX | | (last) XXX | | | |
| Position | XXX | | | | | |
| Company | XXX | | | | | X |
| Mailing Address (number & street) | XXX | | | | | |
| City | | State | | Postal Code | XXX | |
| email | XXX | | | | | |

| b. | Agent (if Applicable) | | | | | Confidential |
|---|---|---|---|---|---|---|
| Name of Authorized Official | (first) | | (last) | | | |
| Position | | | | | | |
| Company | | | | | | ☐ |
| Mailing Address (number & street) | | | | | | |
| City | | State | | Postal Code | | |
| e-mail | | Telephone (include area code) | | | | |

| c. | Joint Submitter (if applicable) | | | | | Confidential |
|---|---|---|---|---|---|---|
| If you are submitting this notice as part of a joint submission, mark (X) | | | | | ☐ | |
| Name of Authorized Official | (first) | | (last) | | | |
| Position | | | | | | |
| Company | | | | | | ☐ |
| Mailing Address (number & street) | | | | | | |
| City | | State | | Postal Code | | |
| e-mail | | Telephone (include area code) | | | | |

| 2. | Technical Contact (in U.S.) | | | | | Confidential |
|---|---|---|---|---|---|---|
| Name of Authorized Official | (first) XXX | | (last) XXX | | | |
| Position | XXX | | | | | |
| Company | XXX | | | | | X |
| Mailing Address (number & street) | XXX | | | | | |
| City | XXX | State | XXX | Postal Code | XXX | |
| e-mail | XXX | Telephone (include area code) | | XXX | | |

| | | | | |
|---|---|---|---|---|
| 3. | If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. | XXX | Mark (X) if none ☐ | Confidential X |
| 4. | If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete). | | Mark (X) if none X | Confidential ☐ |
| 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 X | Confidential ☐ |

| 6. | Type of Notice – Mark (X) | | | | | | |
|---|---|---|---|---|---|---|---|
| 1. | Manufacture Only | X | 2. | Import Only | ☐ | 3. | Both ☐ |
| | Binding Option | ☐ | | Binding Option | ☐ | | |

## Part I – GENERAL INFORMATION -- Continued

**Section B – CHEMICAL IDENTITY INFORMATION:** You must provide a currently correct Chemical Abstracts (CA) name of the substance based on current CA index nomenclature rules and conventions.

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. ☐

| 1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual) | Class 1 | Class 2 | CBI |
|---|---|---|---|
| a. Class of substance - Mark (X) | ☐ | ☒ | ☐ |

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on current CA index nomenclature rules and conventions). ☐

Fibroins

CAS Registry Number (if a number already exists for the substance): 9007-76-5

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

**Method 1** (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice) ☒

IES Order Number: 474282

**Method 2** (Other Source) ☐

Enter Attachment filename for Part I, Section B, 1. c.: Original Document: 2 Compiled Attachment 1.pdf ☐

d. Molecular formula: Variable Structure Naturally Derived Protein, Class 2 UVCP ☐

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained. ☐

See Attachment (Original Document: 1 attach.2 compiled.pdf
)

Enter Attachment filename for Part I, Section B, 1. e. ☐

# PMN Page 4a

| 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). | Confidential |
|---|---|

e. (1) List the immediate precursor substance names with their respective CAS Registry Numbers. ☐

| Enter Attachment filename for Part I, Section B, 1. e. (1) | | ☐ |
|---|---|---|

e. (2) Describe the nature of the reaction or process. ☐

Silk filaments are produced by the silkworm Bombyx Mori during its late stages of development. Glandular excretions are spun into raw silk filaments by the worm's mandibles which are wrapped around itself which leads to the formation of the cocoon. The filament is present as two long parallel fibroin strands surrounded by a gummy polypeptide sheath called Sericin. Each strand of silk fibroin is a continuous fiber ranging in length from 700 to 1500 meters.
Historically, sericin has been removed using a process called degumming. The process simply involves boiling the raw silk cocoon in a mild soap to dissolve away the sericin. The silk fibroin is the portion of raw silk commonly identified as silk fiber.
This process simply extracts the silk fibroin from the raw silk cocoon using the historical methods. The resulting silk fibroin fiber is further refined by dissolution into a chaotropic salt solution (calcium chloride, lithium bromide and similar) and then transferred into a dialysis cell. The dialysis removes excess salt from the solution and the final concentration of the aqueous silk solution is about 5-10%. The silk solution is stable at 4 Celsius degree. Or it can be stored at -80 Celsius degree for extended time. Figure #4 in attachment 3 outlines the bench scale process for extracting silk fibroin and the dialysis procedure. The
other attachments outline the glandular biosynthesis of the raw silk fiber by the Bombyx Mori silk worm.

| Enter Attachment filename for Part I, Section B, 1. e. (2) | Original Document: 9 attach.3 compiled.pdf | ☐ |
|---|---|---|

e. (3) Indicate the range of composition and the typical composition (where appropriate). ☒

XXX

| Enter Attachment filename for Part I, Section B, 1. e. (3) | See Attachment Continuation Page | ☐ |
|---|---|---|

# Continuation Sheet

| ID | | Field | Range of Composition |
|---|---|---|---|

Original Document: 3 attach.2 compiled_v1a.pdf

Sanitized Document: 10 Attach.4 compiled_san.pdf

# 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 (a) | CAS Registry Number (a) | Maximum Percent % (b) | Confi-dential |
|---|---|---|---|
| Calcium chloride (CaCl2) | 10043-52-4 | 0.1 | |
| Carbonic acid sodium salt (1:2) | 497-19-8 | 0.1 | |
| Lithium bromide (LiBr) | 7550-35-8 | 0.1 | |
| Ethanol | 64-17-5 | 0.1 | |
| Sericin | 60650-88-6 | 0.1 | |
| | | | |

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2.
Silk Fibroin, Fibroins,

Enter Attachment filename for Part I, Section B, 4. ☐

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

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic 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.

Enter Attachment filename for Part I, Section B, 6.

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) | Confi-dential |
|---|---|---|
| Carbonic acid sodium salt (1:1) | 144-55-8 | |
| Calcium chloride (CaCl2) | 10043-52-4 | |
| Sodium hydroxide (Na(OH)) | 1310-73-2 | |
| Lithium bromide (LiBr) | 7550-35-8 | |

Mark (X) this box if the data continues on the next page. ☒

# 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 (a) | CAS Registry Number (a) | Maximum Percent % (b) | Confi-dential |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

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

Enter Attachment filename for Part I, Section B, 4. ☐

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

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic 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.

Enter Attachment filename for Part I, Section B, 6.

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) | Confi-dential |
|---|---|---|
| Ethanol | 64-17-5 | |
| Sericin | 60650-88-6 | |
| | | |
| | | |

Mark (X) this box if the data continues on the next page. ☐

# 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 Below) ☐

Specify Other:

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

Enter Attachment filename for Part I, Section B, 2. a. ☐

b. You must 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) - Choose "yes" from drop down menu 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 specific chemical name (**1**) | CBI (**2**) | Typical composition (**3**) | Include in identity (**4**) | CBI (**5**) | Max residual (**6**) | CBI (**7**) |
|---|---|---|---|---|---|---|
| | | | | | | |
| CAS Registry Number (**1**) | | | | | | |
| | | | | | | |
| CAS Registry Number (**1**) | | | | | | |
| | | | | | | |
| CAS Registry Number (**1**) | | | | | | |
| | | | | | | |
| CAS Registry Number (**1**) | | | | | | |
| | | | | | | |
| CAS Registry Number (**1**) | | | | | | |

Mark (X) this box if the data continues on the next page. ☐

## PMN Page 5a

| c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one). | | | | CBI |
|---|---|---|---|---|
| **Method 1** (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) ☐ | IES Order Number | | **Method 2** (other source) ☐ | |
| Enter Attachment filename for Part I, Section B, 2. c. | | | | ☐ |

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

| CAS Registry Number (if a number already exists for the substance) | | |
|---|---|---|

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

| Enter Attachment filename for Part I, Section B, 2. e. | | ☐ |
|---|---|---|

# Part I -- GENERAL INFORMATION -- Continued

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

**The information on this page refers to consolidated chemical number(s):** [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

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

**1. Production volume --** Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.

| 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) |
|---|---|---|---|
| XXX | XXX | [X] | [ ] |

| Enter Attachment filename for Part I, Section C, 1. | | CBI [ ] |
|---|---|---|

**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 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).

| Category of use (**1**) (by function and application i.e. a dispersive dye for finishing polyester fibers) | CBI (**2**) | Binding Option Mark (X) (**3**) | Production % (**4**) | CBI (**5**) | % in Formulation (**6**) | CBI (**7**) | % of substance expected per use (**8**) | | | | | CBI (**9**) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Site-limited | Consumer* | Industrial | Commercial | Binding Option | |
| Food Coating agent for fruits, vegetables, meats and fish used by food processing/packing companies. | | | XXX | X | XXX | X | XXX | XXX | XXX | XXX | | X |
| Industrial Applications including but not limited to fiber optics, and micro-circuits, R&D development | | | XXX | X | XXX | X | XXX | XXX | XXX | XXX | | X |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |

* 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 new 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 the data continues on the next page. [X]

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 Instruction Manual for examples of generic use descriptions.

| Enter Attachment filename for Part I, Section C, 2. b. | | CBI [ ] |
|---|---|---|

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

| Mark (X) this box if you attach hazard information. | [X] | Binding Option Mark (X) [ ] |
|---|---|---|

# Continuation Sheet

| ID | | Field | Part I, Section C, 2.a. Additional Consumer Use Text |
|---|---|---|---|

Category of Use: Food Coating agent for fruits, vegetables, meats and fish used by food processing/packing companies.
Consumer Use: null
Attachments:
Category of Use: Industrial Applications including but not limited to fiber optics, and micro-circuits, R&D development
Consumer Use: null
Attachments:

# 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

**The information on pages 8 and 8a refer to consolidated chemical number(s):** [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

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.

| | | | | Confi-dential |
|---|---|---|---|---|
| Name | XXX | | | |
| Site address (number and street) | XXX | | | [X] |
| City | XXX | County | XXX | |
| State | XXX | ZIP code | XXX | |

| | | |
|---|---|---|
| If the same operation will occur 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. → | XXX | [X] |
| Mark (X) this box if the data continues on the next page. | [ ] | |

b. Type -- Mark (X) Manufacturing [ ] Processing [ ] Use [ ] — [X]

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

| | | | | Confi-dential |
|---|---|---|---|---|
| 1. Batch | Maximum kg/batch (100% new chemical substance) | Hours/batch | Batches/year | [X] |
| | XXX | XXX | XXX | |
| 2. Continuous | Maximum kg/day (100% new chemical substance) | Hours/day | Days/year | [ ] |
| | | | | |

d. Process description — Mark (X) to indicate your willingness to have your process description binding. → [ ]

(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% new 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 new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

[X]

XXX

## PMN Page 8a

| Diagram of the major unit operation steps. | Confidential ☐ |
|---|---|

See Attachment Continuation Page

| Enter Attachment filename for Part II, Section A, 1. d. | See Attachment Continuation Page ☐ |
|---|---|

# Continuation Sheet

| ID | | Field | Process Description |
|---|---|---|---|

Sanitized Document: 5 attach.6 compiled_san.xlsx
Sanitized Document: 6 attach.7A_san.xlsx
Sanitized Document: 7 attach.7B_san.xlsx

# Continuation Sheet

| ID | | Field | Process Description |
|---|---|---|---|

Sanitized Document: 5 attach.6 compiled_san.xlsx

Sanitized Document: 6 attach.7A_san.xlsx

Sanitized Document: 7 attach.7B_san.xlsx

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

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

**The information on pages 9 and 9a refer to consolidated chemical number(s):** [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

**2. Occupational Exposure --** You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box 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 confidential business information (CBI).
(3) -- Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
(5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
(7) -- Mark (X) this column if entries in columns (3) and (5) are confidential business information (CBI).
(8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
(9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

| Worker activity (i.e., bag dumping, filling drums) (1) | CBI (2) | Protective Equipment/ Engineering Controls (3) | Binding Option Mark (X) (4) | Physical form(s) & % new substance (5) | Binding Option Mark (X) (6) | CBI (7) | # of Workers Exposed (8) | CBI (9) | Maximum Duration | | CBI (12) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Hrs/Day (10) | Days/Yr (11) | |
| XXX | X | Gloves, protective clothing and respiratory protection | | solid raw silk cocoons, 70 | | | XXX | X | XXX | XXX | X |
| XXX | X | Gloves, protective clothing | | Wet solid silk fibroin fiber, 100 | | | XXX | X | XXX | XXX | X |
| XXX | X | Gloves, protective clothing | | Solid fibroin fiber, 100 | | | XXX | X | XXX | XXX | X |
| XXX | X | Gloves, protective clothing | | Solid, 5 | | | XXX | X | XXX | XXX | X |
| XXX | X | Gloves, protective clothing | | Liquid, 10 | | | XXX | X | XXX | XXX | X |
| XXX | X | Gloves, protective equipment | | Liquid, 0.5 | | | 4 | | 2 | 360 | |
| | | | | | | | | | | | |
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Mark (X) this box if the data continues on the next page. [ ]

Enter Attachment filename for Part II, Section A on the bottom of page 9a. [ ]

# PMN Page 9a

**3. Environmental Release and Disposal** -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box 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 new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (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 new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new 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 will be 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) this column if entries in columns (4) and (5) are confidential business information (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 confidential business information (CBI).

| Release Number | Amount of New Substance Released | | CBI | Medium of release e.g. Stack air | Control technology and efficiency (you may wish to optionally attach efficiency data) | | | CBI |
|---|---|---|---|---|---|---|---|---|
| (1) | (2a) | (2b) | (3) | (4) | (5a) | Binding Mark (X) | (5b) | (6) |
| Air Emissons | 0.0001 | | | Fugitive Air | Not Applicable | | Not applicable | |
| Process Water | 0.0001 | | | POTW | Process water filtered and discharged to WWTP | | Not Applicable | |
| Process Water | 0.0001 | | | POTW | Wet silk fibroin spun dry to remove excess rinse water/WWTP | | Not Applicable | |
| Process Water | 0.0001 | | | POTW | Water soap wash mesh bags used to hold cocoons/WWTP | | Not Applicable | |
| Process Water | 0.0001 | | | POTW | salt solution remaining after dialysis WWTP | | Not Applicable | |
| Cleaning | 0.0001 | | | POTW | Sodium hydroxide solution used to clean dialysis cell WWTP | | Not Applicable | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

Mark (X) this box if the data continues on the next page. ☐

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

Enter Attachment filename for Part II, Section A. ☐

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

### Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

**The information on pages 10 and 10a refer to consolidated chemical number(s):** [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

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(a). Operation Description** -- To claim information in this section as confidential, bracket (e.g. {}) 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) -- Either in the diagram or in the text field 1(b) below, 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 all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).

(3) -- Either in the diagram or in the text field 1(b) below, 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):

| | Number of Sites | 0 | Confidential [ ] |
|---|---|---|---|

See Attachment (Original Document: 14 attach.10 compiled(2).pdf
)

**1(b).** (Optional) This space is for a text description to clarify the diagram above. Confidential [ ]

End uses vary and applications for the use of silk fibroin are currently under development. The current major use for silk fibroin is as a food coating applied by spraying or dipping to apply a thin coating. Silk fibroin is a replacement for petroleum wax coatings currently used.
Biomedical and Industrial applications are in development and actual processes have not been determined at this time.
End use applications highlighted in Attach.10, suggest the silk fibroin will be used in highly controlled environments. Proposed applications involve using the silk fibroin to extrude fibers of specific dimensions for use in weaving or printing devices ranging from organ scaffolds to microcircuits, implantable biosensors, bone repair agents, as a replacement for glass/carbon fiber in laminated panels, and fiber optic based devices. Typically the applications in highly controlled environments such as clean rooms, and generally involve highly automated minimized worker contact or exposure.

| Enter Attachment filename for Part II, Section B on the bottom of page 10a. | Original Document: 14 attach.10 compiled(2).pdf [ ] |
|---|---|

# Continuation Sheet

| ID | P10SB1(a)(4)1 | Field | Part II, Section B, 1(a)(4). Operation Site Locations |
|---|---|---|---|

No sites identified. Operation Alias: Silk Fibroin End User

# PMN Page 10a

**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, if any, 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 | # of Workers Exposed | CBI | Duration of Exposure | | CBI | Protective Equip./Engineering Controls/Physical Form | % new substance | % in Formulation | CBI |
|---|---|---|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4a) | (4b) | (5) | (6) | (6) | (7) | (8) |
| | | | | | | | | | |
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| Release Number | Amount of New Substance Released | | CBI | Media of Release & Control Technology | CBI |
|---|---|---|---|---|---|
| (9) | (10a) | (10b) | (11) | (12) | (13) |
| | | | | | |
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Mark (X) this box if the data continues on the next page. ☐

**(14)** Byproducts: | **(15) CBI** ☐

Enter Attachment filename for Part II, Section B. ☐

# OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in the following section as confidential, bracket (e.g. {}) 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 PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. 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. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. The 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 media (e.g., air to water) or nonenvironmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as

(1) an overall reduction in risk to human health or the environment;
(2) a reduction in the generation of waste materials through recycling, source reduction or other means;
(3) a reduction in the use of hazardous starting materials, reagents, or feedstocks;
(4) a reduction in potential toxicity, human exposure and/or environmental release; or
(5) 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.

**Information provided in this section will be taken into consideration during the review of this substance. See PMN Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.**

XXX

| Enter Attachment filename for Pollution Prevention Page 11. | Sanitized Document: 8 attac.9 compiled_san.pdf | X |
|---|---|---|

## Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of any paper attachments. In the Number of Pages column below, enter the inclusive page numbers of each attachment for paper submissions or enter the total number of pages for each attachment for electronic submissions. Electronic attachments can be identified by filename.
Mark (X) the "Confidential" box next to any attachment name or filename you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

| # | Attachment Name | Attachment Filename | Number of Pages | Associated PMN Section Number | CBI |
|---|---|---|---|---|---|
| 1 | Hazard Information | Attach.5 compiled.pdf | 49 | Hazard Information Section (Chemical 1869330) | |
| 2 | Silk Fibroin Analytical Data [CBI for page 4 and 5 of attachment 12] | attach.12 compiled_san.pdf | 7 | Physical and Chemical Properties Worksheet Continued (Chemical | |
| 3 | Chemical Structure Diagram | attach.2 compiled.pdf | 30 | Class 1 or 2 Substances Chemical Structure Diagram (Chemical | |
| 4 | IES Report | Compiled Attachment 1.pdf | 9 | Class 1 or 2 Substances ID Method (Chemical 1869330) | |
| 5 | Published papers regarding the silk worm production of silk and extraction process. | attach.3 compiled.pdf | 31 | B.1.e.2. Nature of Reaction (Chemical 1869330) | |
| 6 | Chemical Structure Diagram | attach.2 compiled_v1a.pdf | 30 | B.1.e.3. Range of Composition (Chemical 1869330) | |
| 7 | Structure and chemical make up of silk fibroin. [CBI only for pages 49 and 50 of attachment 4] | Attach.4 compiled_san.pdf | 50 | B.1.e.3. Range of Composition (Chemical 1869330) | |
| 8 | Process Diagram | attach.6 compiled_san.xlsx | 1 | Submitter Controlled Operations (Operation 1) | |
| 9 | Dry process flow diagram | attach.7A_san.xlsx | 1 | Submitter Controlled Operations (Operation 1) | |
| 10 | Wet process flow diagram | attach.7B_san.xlsx | 1 | Submitter Controlled Operations (Operation 1) | |
| 11 | Description of product uses in manufacturing in the envisioned markets | attach.10 compiled(2).pdf | 138 | Industrial Sites Controlled By Others (Silk Fibroin End User) | |
| 12 | OECD 301B Ready/Ultimate Biodegradability | attach.11 compiled_san.pdf | 20 | Additional Attachments | |
| 13 | Employee hour clarification, internal worker hazard assessment, and 3rd party employee health and | attach.8 compiled_san.pdf | 23 | Additional Attachments | |
| 14 | Waste Water Discharge Approvals and Analysis. Filter Waste characterization. Filter disposal | attac.9 compiled_san.pdf | 8 | Optional Pollution Prevention | |
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Mark (X) this box if the data continues on the next page. ☐

# PMN Page 13

## PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

**The information on this page refers to chemical number(s):** [X] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

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 value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. Give the attachment number (found on page 12) in column (b). 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 the 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) | | Unit | Mark X if Provided | Attachment Number (b) | Value (c) | | | Measured or Estimate (M or E) | CBI Mark (X) (d) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | (solid) | (liquid) | (gas) | | |
| Physical state of neat substance | | | [ ] | | [ ] | [ ] | [ ] | | |
| Vapor Pressure @ Temperature | | °C | [ ] | | | | Torr | | |
| Density/relative density | | | [ ] | | | | g/cm3 | | |
| Solubility | | | [ ] | | | | g/L | | |
| @ Temperature | | °C | | | | | | | |
| Solvent | | | | | | | | | |
| Solubility in Water @ Temperature | | °C | [ ] | | | | g/L | | |
| Melting Temperature | | | [ ] | | | | °C | | |
| Boiling / Sublimation temperature @ | | Torr | [ ] | | | | °C | | |
| Spectra | | | [ ] | | | | | | |
| Dissociation constant | | | [ ] | | | | | | |
| Octanol / water partition coefficient | | | [ ] | | | | | | |
| Henry's Law constant | | | [ ] | | | | | | |
| Volatilization from water | | | [ ] | | | | | | |
| Volatilization from soil | | | [ ] | | | | | | |
| pH@ concentration | | | [ ] | | | | | | |
| Flammability | | | [ ] | | | | | | |
| Explodability | | | [ ] | | | | | | |
| Adsorption / Coefficient | | | [ ] | | | | | | |
| Particle Size Distribution | | | [ ] | | | | | | |
| Other – Specify | | | [ ] | | | | | | |