

Cover Letter

XXX



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

U.S. ENVIRONMENTAL PROTECTION AGENCY

AGENCY USE ONLY



EPA

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

Date of receipt: 12/20/2021

When completed, send this form to:

If sending by Courier: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940

If sending by US Mail: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460

Submission Report Number

Total Number of Pages

TS Number

25

WF93DB

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.

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).

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.

Test Data (Check Below any included in this notice)

- Environmental fate data
Health effects data
Environmental effects data
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
Other Data
Risk Assessments
Structure/activity relationships

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.

TYPE OF NOTICE (Check Only One)

- 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

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.

- IS THIS A CONSOLIDATED PMN (Y/N)?
of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).
Mark (X) if any information in this notice is claimed as confidential.



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	<input checked="" type="checkbox"/>
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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			<input checked="" type="checkbox"/>		
Position	XXX							
Company	XXX							
Mailing Address (number & street)	XXX							
City		State		Postal Code	XXX			
email	XXX							
b.	Agent (if Applicable)						Confidential	
Name of Authorized Official	(first) XXX		(last) XXX			<input checked="" type="checkbox"/>		
Position	XXX							
Company	XXX							
Mailing Address (number & street)	XXX							
City	XXX	State	XXX	Postal Code	XXX			
e-mail	XXX	Telephone (include area code)		XXX				
c.	Joint Submitter (if applicable)						Confidential	
If you are submitting this notice as part of a joint submission, mark (X)						<input type="checkbox"/>		
Name of Authorized Official	(first)		(last)			<input type="checkbox"/>		
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			<input checked="" type="checkbox"/>		
Position	XXX							
Company	XXX							
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.				Mark (X) if none	Confidential		
					<input checked="" type="checkbox"/>	<input type="checkbox"/>		
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	Confidential		
					<input checked="" type="checkbox"/>	<input type="checkbox"/>		
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	Confidential		
					<input checked="" type="checkbox"/>	<input type="checkbox"/>		
6.	Type of Notice – Mark (X)							
1.	Manufacture Only	<input type="checkbox"/>	2.	Import Only	<input type="checkbox"/>	3.	Both	<input checked="" type="checkbox"/>
	Binding Option	<input type="checkbox"/>		Binding Option	<input type="checkbox"/>			



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Continuation Sheet

ID P3SB1bC2	Field Part I, Section A, 2
<p>First Name: XXX Last Name: XXX Position: XXX Company Name: XXX Address: XXX City: XXX State: XXX Postal Code: XXX Country: XXX Email: XXX Telephone: XXX CBI: Y</p>	



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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.			<input type="checkbox"/>
1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)		Class 1	Class 2
a. Class of substance - Mark (X)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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).		<input type="checkbox"/>	
.beta.-N-Acetylhexosaminidase			
CAS Registry Number (if a number already exists for the substance)		9012-33-3	
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	Method 2 (Other Source)
<input type="checkbox"/>			<input checked="" type="checkbox"/>
Enter Attachment filename for Part I, Section B, 1. c.		Original Document: 1 ID Method 2_SciFinder Rep... <input type="checkbox"/>	
d. Molecular formula	XXX		<input checked="" type="checkbox"/>
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.			<input checked="" type="checkbox"/>
See Attachment (Sanitized Document: 2 Chemical Structure Inform...)			
Enter Attachment filename for Part I, Section B, 1. e.			<input type="checkbox"/>



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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. XXX		<input checked="" type="checkbox"/>
Enter Attachment filename for Part I, Section B, 1. e. (1)	Sanitized Document: 20 Fermentation Raw Material...	<input checked="" type="checkbox"/>
e. (2) Describe the nature of the reaction or process. XXX		<input checked="" type="checkbox"/>
Enter Attachment filename for Part I, Section B, 1. e. (2)	See Attachment Continuation Page	<input type="checkbox"/>
e. (3) Indicate the range of composition and the typical composition (where appropriate). XXX		<input checked="" type="checkbox"/>
Enter Attachment filename for Part I, Section B, 1. e. (3)		<input type="checkbox"/>



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SANITIZED SUBMISSION

Continuation Sheet

ID		Field	Nature of Reaction
			Sanitized Document: 18 Process Description_Tier ...
			Sanitized Document: 19 Tier1 exemption_Dec 20 20...



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SANITIZED SUBMISSION

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)	Confidential

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.

XXX

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)	Confidential

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



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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:

Table with 3 columns: (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.

Table with 7 columns: Monomer or other reactant specific chemical name (1), CBI (2), Typical composition (3), Include in identity (4), CBI (5), Max residual (6), CBI (7). Includes rows for CAS Registry Number (1).

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



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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) <input type="checkbox"/>	IES Order Number		Method 2 (other source) <input type="checkbox"/>	
Enter Attachment filename for Part I, Section B, 2. c.				<input type="checkbox"/>
d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.				<input type="checkbox"/>
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.				<input type="checkbox"/>
Enter Attachment filename for Part I, Section B, 2. e.				<input type="checkbox"/>



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SANITIZED SUBMISSION

Part I -- GENERAL INFORMATION -- Continued

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

The information on this page refers to consolidated chemical number(s): 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	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Enter Attachment filename for Part I, Section C, 1.			CBI <input type="checkbox"/>

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)	Prod uction % (4)	CBI (5)	% in Form- ulation (6)	CBI (7)	% of substance expected per use (8)					CBI (9)
							Site- limited	Con- sumer*	Industrial	Com- mercial	Binding Option	
XXX	X		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.



- 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.

Biocatalyst used in a variety of products

Enter Attachment filename for Part I, Section C, 2. b.	Sanitized Document: 7 Doc 3 - End Use Informati...	CBI	<input checked="" type="checkbox"/>
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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 handling, 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.





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SANITIZED SUBMISSION

Continuation Sheet

ID		Field	Part I, Section C, 2.a. Additional Consumer Use Text
<p>Category of Use: XXX : Biocatalyst used in a variety of products</p> <p>Attachments:</p> <p>XXX</p>			



PMN2021P8

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. Confidential

Name: XXX
Site address (number and street): XXX
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

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

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

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

Table with 4 columns: Batch/Continuous, Maximum kg/batch/day, Hours/batch/day, Batches/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.
(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...
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

XXX [X]



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SANITIZED SUBMISSION

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





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SANITIZED SUBMISSION

Continuation Sheet

ID		Field	Process Description
Sanitized Document: 4 Doc 1a - Manufacturing Op...			
Sanitized Document: 5 Doc 1b - Submitter Waste ...			



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SANITIZED SUBMISSION

Continuation Sheet

ID		Field	Process Description
			Sanitized Document: 4 Doc 1a - Manufacturing Op...
			Sanitized Document: 5 Doc 1b - Submitter Waste ...



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): 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)	
Sampling		XXX		XXX		X	1		0.25	1	
Sampling		XXX		XXX		X	1		0.25	1	
Sampling		XXX		XXX		X	1		0.25	1	
Loading into Transport Containers		XXX		XXX		X	2		1.5	1	

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.



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 (1)	Amount of New Substance Released		CBI (3)	Medium of release e.g. Stack air (4)	Control technology and efficiency (you may wish to optionally attach efficiency data)			CBI (6)
	(2a)	(2b)			(5a)	Binding Mark (X)	(5b)	
Sample Disposal 1		100%		Other: Landfill-Land Application (see waste disposal attachment)	Landfill-Land Application (see waste disposal attachment)		0%	
Sample Disposal 2		100%		Other: Landfill-Land Application (see waste disposal attachment)	Landfill-Land Application (see waste disposal attachment)		0%	
Filter Disposal 1		100%		Other: Landfill	Landfill		0%	
Sample Disposal 3		100%		Other: Landfill-Land Application (see waste disposal attachment)	Landfill-Land Application (see waste disposal attachment)		0%	
Equipment Cleanin		100%		Other: Landfill-Land Application (see waste disposal attachment)	Landfill-Land Application (see waste disposal attachment)		<10%	

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

(7) Mark (X) the destination(s) of releases to water.		NPDES#	CBI
<input type="checkbox"/>	POTW--provide name(s)		<input type="checkbox"/>
<input type="checkbox"/>	Navigable waterway- provide name(s)		<input type="checkbox"/>
<input type="checkbox"/>	Other--Specify		<input type="checkbox"/>

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): 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	XXX	Confidential	<input checked="" type="checkbox"/>
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See Attachment (Sanitized Document: 6 Doc 2 - Processing Operat...)

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

Confidential

XXX

Enter Attachment filename for Part II, Section B on the bottom of page 10a.

Sanitized Document: 6 Doc 2 - Processing Operat...



PMN2021P10-1

Continuation Sheet

ID	P10SB1(a)(4)1	Field	Part II, Section B, 1(a)(4). Operation Site Locations
<p>No sites identified. Operation Alias: Processing Operation</p>			



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
			(4a)	(4b)					
Sampling	1		0.25	100		XXX		XXX	X
Unloading from	1		0.75	100		XXX		XXX	X
Disposal of	1		0.75	100		XXX		XXX	X

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
	(10a)	(10b)			
Sample Disposal		100%		Off-site Incineration Off-site Incineration	
Disposal of		100%		POTW See biodeg study on surrogate - expect >90% removal in POTW	
Equipment		100%		POTW See biodeg study on surrogate - expect >90% removal in POTW	

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

(14) Byproducts:	<input type="text"/>	(15) CBI <input type="checkbox"/>
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Enter Attachment filename for Part II, Section B.	<input type="text"/>
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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.

Enter Attachment filename for Pollution Prevention Page 11.



**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	Safety Data Sheet (SDS)	US SDS v2_Redacted public version (7).pdf	7	Hazard Information Section (PMN Submission)	
2	End Use Information Document	Doc 3 - End Use Information_Oct 28 2021_Redacted public	2	Use Information (PMN Submission)	
3	Chemical Structure Information	Chemical Structure Information_Redacted public	1	Class 1 or 2 Substances Chemical Structure Diagram (PMN Submission)	
4	ID Method 2_SciFinder	ID Method 2_SciFinder Report_non CBI (3).pdf	3	Class 1 or 2 Substances ID Method (PMN Submission)	
5	Precursor material information	Fermentation Raw Materials_Precursor materials_	1	B.1.e.1. Precursor Substances (PMN Submission)	
6	Production organism description	Process Description_Tier 1 organism_Dec 20	1	B.1.e.2. Nature of Reaction (PMN Submission)	
7	Tier 1 Exemption Certification	Tier1 exemption_Dec 20 2021_Redacted Public Version	3	B.1.e.2. Nature of Reaction (PMN Submission)	
8	Manufacturing Operation Document	Doc 1a - Manufacturing Operation_Oct 29	5	Submitter Controlled Operations (Manufacturing Operation)	
9	Waste Disposal Processes	Doc 1b - Submitter Waste Disposal Processes_Oct 28	2	Submitter Controlled Operations (Manufacturing Operation)	
10	Processing Operation Document	Doc 2 - Processing Operation_Oct 25	3	Industrial Sites Controlled By Others (Processing Operation)	
11	Skin Irritation Study	Skin Irritation_Redacted public version (22).pdf	22	Additional Attachments	
12	Mutation Study	Mutation Test_Redacted public	38	Additional Attachments	
13	Hazard Characterization Discussion	Hazard Characterization Information_Oct 15 2021_non	1	Additional Attachments	
14	Eye Irritation	Eye Irritation_Redacted public version (24).pdf	24	Additional Attachments	
15	Supporting Hazard Information	Enzymes-Detergents-and-	5	Additional Attachments	
16	Daphnia Acute Toxicity Study	Daphnia Acute Toxicity_Redacted public version	24	Additional Attachments	
17	Supporting Biodegradation Information	Biodegradation_Analog Read Across_non CBI.pdf	2	Additional Attachments	
18	Supporting Hazard Information	Basketer final_DMEL_DNEL_2010_non	7	Additional Attachments	
19	Supporting Hazard Information	Allergy in Adulthood_NZ results	14	Additional Attachments	
20	Algal Toxicity Study	Algal Growth Inhibition_Redacted public version (37).pdf	37	Additional Attachments	

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): 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		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Vapor Pressure @ Temperature	°C	<input type="checkbox"/>				Torr		
Density/relative density		<input type="checkbox"/>				g/cm ³		
Solubility								
@ Temperature	°C	<input type="checkbox"/>				g/L		
Solvent								
Solubility in Water @ Temperature	°C	<input type="checkbox"/>				g/L		
Melting Temperature		<input type="checkbox"/>				°C		
Boiling / Sublimation temperature @	Torr	<input type="checkbox"/>				°C		
Spectra		<input type="checkbox"/>						
Dissociation constant		<input type="checkbox"/>						
Octanol / water partition coefficient		<input type="checkbox"/>						
Henry's Law constant		<input type="checkbox"/>						
Volatilization from water		<input type="checkbox"/>						
Volatilization from soil		<input type="checkbox"/>						
pH@ concentration		<input type="checkbox"/>						
Flammability		<input type="checkbox"/>						
Explosibility		<input type="checkbox"/>						
Adsorption / Coefficient		<input type="checkbox"/>						
Particle Size Distribution		<input type="checkbox"/>						
Other – Specify		<input type="checkbox"/>						