



Section 4(a)(2) of the Toxic Substances Control Act User Guide

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics

EPA #: EPA 745-B-22-001

OMB Control No.: 2070-0030

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Section 4 of the Toxic Substances Control Act (TSCA) allows the United States Environmental Protection Agency (EPA) to require chemical manufacturers (including importers) and processors to develop information on existing chemicals and submit such information to EPA. Under Section 4(a)(1), EPA may issue an order requiring the development of information on a chemical if they find the chemical may present an unreasonable risk of injury to health or the environment and such information is needed to determine whether the chemical presents such an unreasonable risk.

EPA may also issue an order under Section 4(a)(2) requiring the development of information:

- to review a notice submitted under TSCA Section 5 or to perform a risk evaluation under TSCA Section 6(b);
- to implement a requirement imposed in a rule, order, or consent agreement under TSCA Section 5(e) or (f), or in a rule promulgated under Section 6(a);
- at the request of a Federal implementing authority, under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure;
- to determine if a chemical substance or mixture manufactured, processed, or distributed in commerce solely for export presents an unreasonable risk of injury to health or the environment in the U.S., pursuant to TSCA Section 12(a)(2); and
- to prioritize a chemical substance under TSCA Section 6(b) (subject to certain limitations)¹.

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory for certain persons, as specified at 15 U.S.C. 2601 *et. seq.* An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 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 to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), and 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) Section 4 Test Order Submissions. The TSCA section 4 application is the electronic, web-based tool provided by Environmental Protection Agency (EPA) for the submission of data. As a Primary Authorized Official, you can create, modify, and submit. You can also delete data, create amendments, and download the Copy of Record (CoR).

¹ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4-test-orders>.



For questions concerning the Toxic Substances Control Act (TSCA) Section 4 software requirements, please contact the Central Data Exchange (CDX) Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8 am – 6 pm Eastern Standard Time (EST).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. The statements in this document are intended solely as guidance to aid in complying with EPA regulation.



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1. System Requirements

To use the Section 12(b) Export Notification application to submit a Section 12(b) form, the following are required:

- An e-mail account
- JavaScript enabled web browser
- Internet access
- Adobe Acrobat Reader 5.0 or higher
- CDX username and password

1.1 Supported Browsers

One of the following supported browsers is required to access the Section 4 application:

- Vendor supported versions of Internet Explorer (IE) or Edge
 - Go to the following link to download: <https://support.microsoft.com/en-us/help/17621/internet-explorer-downloads>
- Vendor supported versions of Mozilla Firefox
 - Go to the following link to download: <https://www.mozilla.org/en-US/firefox/new/>
- Vendor supported versions of Safari
 - Go to the following link to download: <https://support.apple.com/downloads/>
- Vendor supported versions of Google Chrome
 - Go to the following link to download: <http://www.google.com/chrome>

1.2 Screen Resolution

Screen resolution should be set to 1024 x 768 or greater.

2. User Roles

2.1 Primary Authorized Official (AO) Functions

This section describes how to:

- Access the application
- Navigate the Section 4 'Home' screen
- Assign Supports to complete a form
- Start, complete, and submit an information for a Section 4 Test Order
- Upload an extensible markup language (XML) file
- Download a Copy of Record
- Create an amendment

The Primary AO is responsible for the submission of main forms. As a Primary AO, you can create a new form. You are also responsible for submitting amendments, unlocking submissions, and deleting forms. You can assign Supports (or other authorized individuals) to edit and complete a form on your behalf. The Primary AO can be thought of as a primary company authorized official, specifically in regard to any sponsored individuals.



You can save the form at any point during the data entry process. The save functionality allows you to return to that same form at any point in the future. You can print the form at any point; however, the ‘Not for Submission’ watermark will be placed on the form anytime the form is printed prior to actual submission.

Figure 1, displays a table of the user role capabilities within the Section 4 application:

Table 1: Section 4 User Roles Matrix

Legend	Primary AO	Primary Support
X=Can Perform Function		
	US/Non-US	US/Non-US
Primary Form		
Create Identification Response Form	X	
Creates Test Response Form	X	
Submit Original ACM Forms	X	
Generate Producing Company Unique ID	X	
Edit Primary Form	X	X
Submit an original Forms	X	
Unlock Form Submission (Create an amendment)	X	X
Submit an Amendment of a Form	X	
Assign Supports	X	
Download CoR	X	



3. Accessing the Section 4 Application to submit a Test Order Response

3.1 New Users

- Register in CDX (<https://cdx.epa.gov/>).
- To create a new CDX account, click on the green **[Register with CDX]** button.
- Follow the steps provided by CDX to complete registration for Primary Authorized Official role.

EPA United States Environmental Protection Agency

Home About Recent Announcements Terms and Conditions FAQ Help Virtual Assistant

CDX Central Data Exchange [Contact Us](#)

Log in to CDX

User ID

Password

Show Password

[Forgot your Password?](#)
[Forgot your User ID?](#)
[Warning Notice and Privacy Policy](#)

Welcome

Welcome to the Environmental Protection Agency (EPA) Central Data Exchange (CDX) - the Agency's electronic reporting site. The Central Data Exchange concept has been defined as a central point which supplements EPA reporting systems by performing new and existing functions for receiving legally acceptable data in various formats, including consolidated and integrated data.

Warning Notice and Privacy Policy

Warning Notice

In proceeding and accessing U.S. Government information and information systems, you acknowledge that you fully understand and consent to all of the following:

1. you are accessing U.S. Government information and information systems that are provided for official U.S. Government purposes only;
2. unauthorized access to or unauthorized use of U.S. Government information or information systems is subject to criminal, civil, administrative, or other lawful action;
3. the term U.S. Government information system includes systems operated on behalf of the U.S. Government;
4. you have no reasonable expectation of privacy regarding any communications or information used, transmitted, or stored on U.S. Government information systems;



3.2 Existing Users

- Log into CDX (<https://cdx.epa.gov/>).
- For general questions about CDX, click the **FAQ**, **Help**, or **Contact Us** links at the top of the screen.
- If you are already an existing CDX user, log in with your User ID and Password.

The screenshot shows the EPA Central Data Exchange (CDX) website. At the top, the EPA logo and navigation menu are visible. The navigation menu includes links for Home, About, Recent Announcements, Terms and Conditions, **FAQ**, **Help**, and Virtual Assistant. A **Contact Us** link is also present. Below the navigation menu, the CDX logo and the text "Central Data Exchange" are displayed. The main content area features a "Log in to CDX" section with a login form. The form includes fields for "User ID" and "Password", a "Show Password" checkbox, and "Log In" and "Register with CDX" buttons. Below the login form, there are links for "Forgot your Password?", "Forgot your User ID?", and "Warning Notice and Privacy Policy".

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2. unauthorized access to or unauthorized use of U.S. Government information or information systems is subject to criminal, civil, administrative, or other lawful action;
3. the term U.S. Government information system includes systems operated on behalf of the U.S. Government;
4. you have no reasonable expectation of privacy regarding any communications or information used, transmitted, or stored on U.S.



- Select the **Primary Authorized Official** link, for **CSPP: Submissions for Chemical Safety and Pesticide Programs**.
- If you maintain one organization, choosing the Primary Authorized Official Role will take you directly to the Chemical Information Submission System.
- If you are associated with multiple organizations, choose the relevant Organization Name and Subsequent Program Client ID.
- Select Proceed.

The screenshot shows the EPA CDX Central Data Exchange interface. At the top, there is the EPA logo and navigation links: Home, About, Recent Announcements, Terms and Conditions, FAQ, Help, and Virtual Assistant. Below this is the CDX logo and the text "Central Data Exchange". A user is logged in as BRIGMANWK. The main content area is divided into several sections:

- MyCDX**: Includes links for Inbox, My Profile, Role Sponsorship, Submission History, and Payment History.
- Services**: A table with columns for Status, Program Service Name, and Role. The "Primary Authorized Official" role is highlighted with a red box.
- CDX Service Availability**: A section with a link to "See the status for all program services".
- News and Updates**: A section stating "No news/updates."

At the bottom of the Services section, there are two buttons: "Add Program Service" and "Manage Your Program Services".

Status	Program Service Name	Role
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Accreditation Body (AB) Authorized Official
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Accreditation Body (AB) Support
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Authorized Official
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Support
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Agent/Consultant
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Authorized Official
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Support
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Third-Party Certifier (TPC) Authorized Official
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Third-Party Certifier (TPC) Support



- Select TSCA Section 4 from the drop-down menu and click the [OK] button.

CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 4

OK

The software includes embedded help files and a downloadable user manual to guide you through the Section 4 submission process.

The Toxic Substances Control Act gives EPA authority to issue data development regulations that require manufacturers and processors of existing chemicals to test their chemicals for health and environmental effects. EPA has the broad authority under the law to issue:

Information collection regulations that require the submission of health and safety studies which are known or available to those who manufacture, process, or distribute in commerce specified chemicals; and regulations designed to gather information from manufacturers and processor about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed.

TSCA also requires EPA to develop regulations that establish import/export requirements for chemicals which are subject to certain requirements under TSCA.

Paperwork Reduction Act Notice

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory under TSCA section 4. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be about 137 hours for the average response for a TSCA section 4 action on a per-chemical basis, not including CDX registration, and 0.53 hours per CDX registration. 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, Regulatory Support Division, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr>.



1. Click the [Section 4 Orders] link on the Home page upper banner.

The screenshot shows a navigation menu with the following items: CSPP, Home, Submissions, Section 4 Orders (highlighted with a red box), and User Management. Below the menu, the page content includes sections for Submissions, User Management, and Resources, each with a brief description and a link.

3.3 Navigation Help Action Bar

The action bar is located at the top and bottom of the form on each screen. You can perform the following functions using the top action bar:

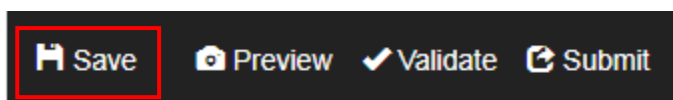
Home: Click the ‘Home’ link to navigate to the Section 4 ‘Home’ screen.

Help: Click the ‘Help’ link to generate a drop-down menu, which displays a link to the user guide.

User ID: Click the user ID link to log out of the application.

The following exhibits, show screen captures for the bottom action bar:

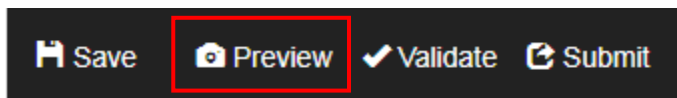
Save: Click the ‘Save’ link at any stage of completing a Section 4 Test Order submission to save the form. To generate and access links to other pages of the form within the navigation tree, you must click the ‘Save’ link within the action bar. After you click the ‘Save’ link, you will receive a message indicating that all data entered in the form has been saved successfully. The save function does not validate any entered data. Click the ‘Previous’ and ‘Next’ buttons on a form to save the data entered within a form. Click the ‘X’ button in the upper right-hand corner of the form in your browser to close the form without saving.



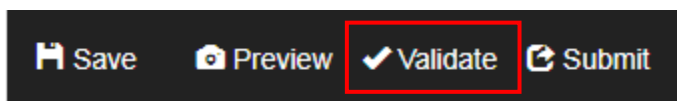
Preview: Click the ‘Preview’ link after uploading a minimum of one chemical to preview the form. After you click the ‘Preview’ link, you will be given the option to view a regular version



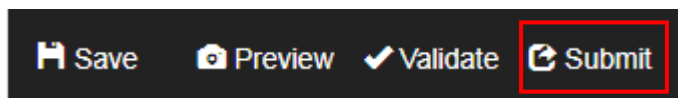
of the PDF(s) or a sanitized version of the PDF(s). Choosing either option will download (a) watermarked PDF version(s) of each chemical identified within the form in a .zip file.



Validate: Click the ‘Validate’ link at any stage of completing a Section 4 Notice of Activity form. A ‘TSCA Section 4 Validation’ window generates when you click the ‘Validate’ link if you disable the pop-up blocker within your internet browser. The ‘Section 4 Validation’ pop-up window displays a report of all warning messages. Refer to **Section Error! Reference source not found.** for more information on validating a form.



Submit: Click the ‘Submit’ link to submit a Section 4 form after completing all sections of a Section 4 form. After you click the ‘Submit’ link a pop-up message displays to confirm the submission process. The form validates during the submission process and displays any applicable warning or error messages. You can continue with the submission process only after clearing all validation errors. Upon successful submission of the form, the application generates and sends an email indicating the successful submission of the form to the submitter’s email address.



CDX Links: Click any of the ‘CDX Links,’ located at the bottom of each screen within the ‘CDX Links’ drop-down menu, at any stage of completing a Section 4 Test Order submission.

- Click the ‘CDX Homepage’ link to navigate to the ‘CDX’ homepage.
- Click the ‘MyCDX Homepage’ link to navigate to the ‘MyCDX’ page.
- Click the ‘EPA Homepage’ link to navigate to the EPA Homepage.
- Click the ‘Terms and Conditions’ link to navigate to the CDX Terms and Conditions screen.
- Click the ‘Privacy Notice’ link to navigate to the CDX Privacy and Security Notice screen.



- [CDX Homepage](#)
- [MyCDX Homepage](#)
- [EPA Homepage](#)
- [Terms and Conditions](#)
- [Privacy Notice](#)

Raise a Bug **CDX Links** ▲ CDX Helpdesk: (888) 890-1995



4. Submit Response to a Test Order

4.1 Test Order Response Deadlines

As Companies receive Test Order requests from EPA, the following deadlines apply:

Table 2: Test Order Response Deadlines

Order Requirement	Recipient's Deadline	EPA Response Deadline*
<ul style="list-style-type: none"> • Identify as a Manufacturer, Processor or Both • Submit Request to Modify Corporate Identity Identified • Choose to Submit Existing Data (Option 2) 	By 30 Days of effective date	45 days of effective date
<ul style="list-style-type: none"> • Claim that You Are Not Subject to this Order (Option 4) 	By 45 Days of effective date	60 days of effective date
<ul style="list-style-type: none"> • Choose to Develop the Information - On Own or as Part of a Consortium (Option 1) • Request an Exemption (Option 3) 	By 65 Days of effective date	80 days of effective date
<ul style="list-style-type: none"> • Submit Draft Study Plan 	By 80 Days of effective date	95 days of effective date
<ul style="list-style-type: none"> • Submit Final Study Plan 	By 110 Days of effective date	125 days of effective date
<ul style="list-style-type: none"> • Submit Final Study Report 	Deadline varies per Test Requirement (See Unit IV and Appendix E)	



4.2 Step 1: Submit an Identification Response

Companies receiving a Test Order request must identify themselves as Manufacturer, Processor or both within 30 days after the effective date of the order.

1. Click the [**Submission Type**] dropdown menu to select the **Identification Response** submission type and click [**Start New Submission**] to prepare the form. All companies receiving a Test Order must complete this step regardless of how they intend to respond to the order (e.g., Joining a Consortium).

The screenshot shows the CSPP web application interface. At the top, there are navigation tabs: Home, Submissions, Section 4 Orders, and User Management. The user is logged in as Brooke Plaisance, Primary Authorized Official (CGI BP). Below the navigation, there are instructions: "To submit an Extension Request, click the calendar icon (📅) in the Current Action Due Date column.", "To download a Copy of Record, click on the plus (+) in the 'Order/Consortium Number' column, then click on the green arrow icon (➡) in the Action column.", "To search for entries, use the Search text box above the table. Note: Search will only work for the current page.", and "After you provide a response to the 'Current Action,' it can take up to 30 minutes for the display to update for the 'Current Action' and 'Next Action' columns. Note that upon submitting a 'Current Action' response that you should have received an email confirmation." There is a search box and a dropdown for "Items Per Page" set to 25. Below this is a table with 6 items found. The table has columns: Order/Consortium Number, Last Action, Current Action, Current Action Due Date, Next Action, Next Action Due Date, and Delete. The table contains 6 rows of data. Below the table are export options: CSV, Excel, XML, and PDF. There is a dropdown menu for "Submission Type" and a "Start New Submission" button.

Order/Consortium Number	Last Action	Current Action	Current Action Due Date	Next Action	Next Action Due Date	Delete
+ TO-1234-9876-791614-01-A	Final Study Plan	Submit Study Report	11/11/2021	N/A	N/A	
+ TO-2021-1008-307895-01-A	N/A	Submit Initial Response	11/06/2021	Submit Study Plan	12/27/2021	✖
+ TO-8878-9876-485648-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/18/2021	✖
+ TO-7777-7777-527723-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/12/2021	✖
+ TO-8798-4897-981494-01-A	N/A	Submit Identification Response	12/12/2021	Submit Draft Study Plan	01/31/2022	✖
+ TO-8648-8648-659742-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/17/2022	✖

Select the submission type and then click **Start New Submission**

Submission Type:

Identification Response

Start New Submission

2. A text box will appear. Enter the Test Order number that was provided to your institution, then click [**Ok**].

3. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed. The ‘Create Passphrase’ screen, allows you to create a passphrase and associate that passphrase with your newly created form.

The application uses the passphrase as an encryption key to protect the contents of the form. You are responsible for remembering the passphrase and distributing it to the appropriate individuals.

If you lose or forget your passphrase, you will not be able to access your submission to print, submit, or make changes. You will need to complete a new submission and create a new passphrase. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

New Passphrase: Enter a passphrase that is between 8 and 20 characters. For maximum security, your passphrase should contain a combination of letters and numbers. Your passphrase should not contain special characters (for example, +, ?, and *).

Confirm Passphrase: Enter the same passphrase that was entered into the ‘New Passphrase’ field. The same passphrase may be associated with multiple forms. The user can choose to have the same passphrase for all forms. Supports do not have the ability to start a new form or create a passphrase for a form.

TSCA Section 4

New Passphrase

Confirm Passphrase

⚠ You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue

Cancel

Determine how is your company going to respond to the Order

The screenshot shows the CSPP interface with the following details:

- Page-Header:** CSPP Home Submissions Section 4 Orders User Management. User: Brooke Plaisance, Primary Authorized Official (CGI BP).
- Left Navigation:** Section 4 Test Orders, Order Number - TO-2021-1208-283259-01-A, Manufacturer/Processor Identification, Contact Information, Technical Contact Information, Submitting Official Information.
- Main Content:**
 - Title:** Manufacturer/Processor Identification Response to Order
 - Order Information - TO-2021-1208-283259-01-A**
 - Effective Date of Order:** 12-08-2021
 - Identification Response Deadline:** 01-07-2022
 - Title of Action:** BrookeP
 - Docket Number:** EPA-HQ-OPPT-2021-1208
 - Instruction:** Indicate if you are a manufacturer, processor, or both. Review the Order for more information ?
 - Order Response Options:**
 - Manufacturer
 - Processor
 - Both
 - Claim that You Are Not Subject to Test Order

Notes:

- Hovering over the blue question mark on this page will give a detailed description to help the user determine the correct response.
- The answer provided will update and drive the Tests required for response in the Identification Response form.

Option 1: Identifying as Manufacturer for the Test Order

1. Select the Manufacturer radio button.
2. Select the Fees Certification that applies to your company.
3. Click **[Next]** to continue.
4. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.



Option 2: Identifying as Processor for the Test Order

1. Select the Processor radio button.
2. Select the Fees Certification that applies to your company.
3. Click **[Next]** to continue.
4. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.

Option 3: Identifying as Both for the Test Order

1. Select the Both radio button.
2. Select the Fees Certification that applies to your company.
3. Click **[Next]** to continue.
4. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.

Option 4: Claim that You Are Not Subject to the Order

You may claim that you are not subject to the Order if you do not manufacture or process the chemical(s) identified in the Order or you believe the Order was otherwise sent to you in error. An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your Identification Response in the CDX portal so that EPA can evaluate the claim.

To claim **Not Subject to Test Order**:

1. Select “Claim that You Are Not Subject to Test Order” as your Order Response Option.



Claim that You Are Not Subject to Test Order

File Name	Document Type	Attachment Date	CBI	Action
-----------	---------------	-----------------	-----	--------

Nothing found to display.

[+ Attach Document](#)

2. Click the blue **[Attach Document]** link.
3. Select **[Not Subject to Order]** as the Document Type.
4. If the attachment has CBI, indicate this, and upload a sanitized document as well.
5. If no documents are uploaded, validation errors will prevent the user from moving forward.
6. Click **[Next]** to continue.



7. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.
8. Once the Identification Response is completed, the Current Action on the Section 4 Orders page should populate as **Submit Initial Response**.

Step 2. Initial Response to the Test Orders

Manufacturers have four options from which to choose to comply with the Order. You will receive an e-mail from EPA that provides the CDX Order number you will use for purposes of responding to the Order. Consult the Order you received for details on each of these options.

1. The list of tests required will display based on your Identification Response. If your Identification Response was “Manufacturer” you will see test(s) required for Manufacturers only; if you selected “Processor” you will only see tests that are required when acting or responding as Processor. If the test is required for both or your response was Both, Manufacturer and Processor, you will see all the tests that are required for both.
2. For each test, select how you intend to respond to the required test(s). You can:
 - a. **Develop Information**
 - b. **Submit Existing Information**
 - c. **Request an Exemption**
 - d. **Join a Consortium**
3. Verify the Chemical Information that the test order applies to. Determine which selection applies best to each Test Response; select the appropriate value from the drop-down menu under the **Test Response** column. This step must be completed for each test.

The screenshot shows the CSPP interface for 'Section 4 Test Orders'. The left sidebar contains navigation links for 'Initial Response To Order', 'Contact Information', and 'Submitting Official Information'. The main content area is divided into 'Chemical Information' and 'Test Response Information'. The 'Chemical Information' section shows details for Ethanol (Chemical Substance Identifier: 64-17-5). The 'Test Response Information' section contains a table with columns for Test, Test Response, Study Plan Deadline, Study Report Deadline, and Status. A dropdown menu is open for the 'Test Response' column, highlighting the options: Develop Information, Submit Existing Information, Request an Exemption, and Join Consortium.

Test	Test Response	Study Plan Deadline	Study Report Deadline	Status
Octanol Solubility - OECD 105 with EPA modifications (Select Response Type)	Select...	04-20-2021	04-20-2021	Not Started
Water Solubility - OECD 105 with EPA modifications (Select Response Type)	Select...	04-20-2021	04-20-2021	Not Started
Particulates Not Otherwise Regulated, Respirable - NIOSH 0600 (Select Response Type)	Select...	04-20-2021	04-20-2021	Not Started



4. Click **[Next]** to continue.

Option 1: Develop the Information

If you choose to develop information in response to the Order, you must select this option in the CDX form. The Order provides information on the required tests, required protocols/methodologies, and deadlines for the Order.

1. To submit a response as **Develop Information:**

Octanol Solubility - OECD 105 with EPA modifications Response

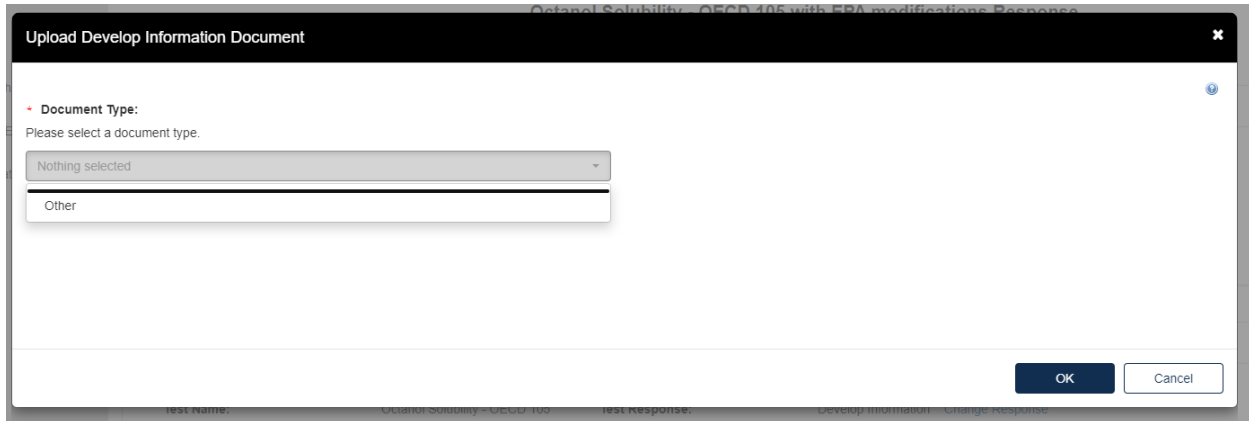
Order Information			
Order Number:	TO-2021-0423-052519-01-A	Initial Response Deadline:	07-19-2021
Docket Number:	EPA-HQ-OPPT-2021-0423	Effective Date of Order:	04-20-2021
Title of Action:	users		

Test Information			
Test Name:	Octanol Solubility - OECD 105 with EPA modifications	Test Response:	Develop Information Change Response

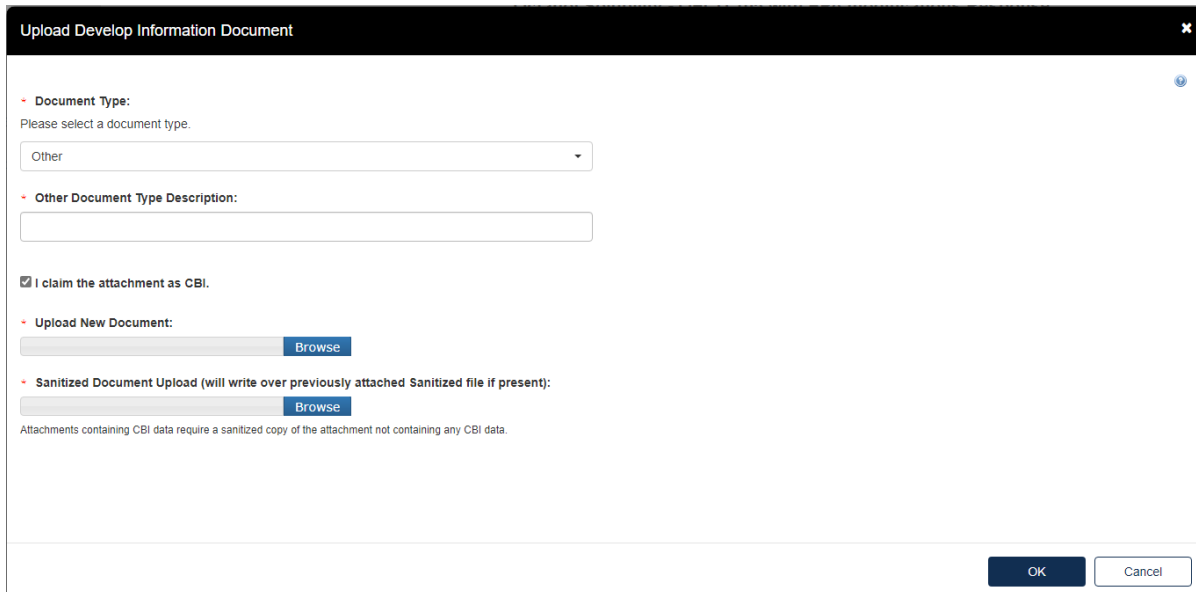
Octanol Solubility - OECD 105 with EPA modifications Response Documents				
File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				
+ Attach Document				

[Previous](#) [Next](#)

2. Click **[Attach Document]**



- a. The **Upload Develop Information Document** pops up. Click the drop-down menu under Document Type and select **Other**.
- b. Provide the **Document Type Description**. Fill out the information highlighted by the red asterisk.
- c. If the attachment contains **Confidential Business Information (CBI)**, indicate this by selecting the “**I claim the attachment as CBI**” checkbox, and upload a sanitized (marked up version that covers the information that is confidential) of the document as well.



- d. Click the **[OK]** button to continue.



Test Information

Test Name: Octanol Solubility - OECD 105 with EPA modifications **Test Response:** [Develop Information](#) [Change Response](#)

Octanol Solubility - OECD 105 with EPA modifications Response Documents

File Name	Document Type	Attachment Date	CBI	Action
correct_epmn.pdf	Other - test	04-26-2021	N	✖

[+ Attach Document](#)

[Previous](#) [Next](#)

3. Click **[Next]** to continue.
4. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.

Option 2: Submit Existing Information

If you choose to respond to the Order by submitting an existing study and/or other relevant information that you believe EPA has not considered, your Identification Response in EPA’s CDX portal must include the study and/or other relevant information, along with supporting rationale that explains how the study and/or other relevant information meets part or all of the information described as necessary in the Order.

1. To **Submit Existing Information:**

Water Solubility - OECD 105 with EPA modifications Response

Order Information

Order Number: TO-2021-0423-052519-01-A **Initial Response Deadline:** 07-19-2021
Docket Number: EPA-HQ-OPPT-2021-0423 **Effective Date of Order:** 04-20-2021
Title of Action: users

Test Information

Test Name: Water Solubility - OECD 105 with EPA modifications **Test Response:** [Submit Existing Information](#) [Change Response](#)

Water Solubility - OECD 105 with EPA modifications Response Documents

File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				

[+ Attach Document](#)

[Previous](#) [Next](#)



2. Click the blue **[Attach Document]** link

Upload Existing Information Document

Document Type:
Please select a document type.

Nothing selected

Study Report
Rationale Document
Other

OK Cancel

3. To attach a **Study Report**:

Upload Existing Information Document

Document Type:
Please select a document type.

Study Report

I claim the attachment as CBI.

Upload New Document:
Browse

Date Study Completed:

Study Report Title:

Test Guideline Number(s):
Please select...

Is Study Published?
 Yes No

Chemical Tested	CASRN/Accession	Action
<input type="text"/>		

Author(s) of Study: Add

Search SRS

OK Cancel

- a. Fill out the information highlighted by the red asterisk.
- b. If the attachment has CBI, indicate this, and upload a sanitized document as well.

4. To attach a **Rationale Document**:

Upload Existing Information Document ✕

*** Document Type:**
Please select a document type.

Rationale Document

I claim the attachment as CBI.

*** Upload New Document:**

- a. Fill out the information highlighted by the red asterisk.
- b. A rationale document must contain the following:
 1. The Order number, the chemical identity, and the CAS No. of the test substance subject to this Order on which the application is based.
 2. The specific testing requirement(s) which the submitted study obviates.
 3. The existing information rationale should explain how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in the Order.
 4. The name, mailing address, telephone number, and e-mail address of applicant.
 5. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.
- c. If the attachment has CBI, indicate this, and upload a sanitized document as well. Note that although only one row with the CBI document will display on the table, both the CBI and Sanitized documents are stored in that upload.
- d. The type of test response that is indicated will affect what Response Documents are needed. If something is needed and not uploaded you will see the following alerts. You will not be able to proceed until the appropriate documents are uploaded for each section.

Water Solubility - OECD 105 with EPA modifications Response Documents

File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				
+ Attach Document				
<div style="display: flex; justify-content: space-between;"> <div style="color: red; font-size: small;"> <p>! At least one Rationale document must be uploaded.</p> <p>! At least one Study Report document must be uploaded.</p> </div> </div>				

5. When the correct documents have been uploaded, click **[Next]** to continue.
6. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.



Option 3: Request an Exemption

Any person required by the Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

1. To Request an Exemption:

Test Information

Test Name: Particulates Not Otherwise Regulated, Respirable - NIOSH 0600

Test Response: Request an Exemption [Change Response](#)

Exemption Reason

Information has been submitted on an equivalent chemical and submission of information by the exemption applicant would be duplicative of information which has been submitted to the Administrator.

Information is being developed on an equivalent chemical in accordance with a rule, order, or consent agreement under TSCA section 4(a), and submission of information by the exemption applicant would be duplicative of information which is being developed in accordance with such rule, order, or consent agreement.

Particulates Not Otherwise Regulated, Respirable - NIOSH 0600 Response Documents

File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				

[Attach Document](#)

[Previous](#) [Next](#)

- Click the appropriate radio button that coincides with the correct **Exemption Reason**.
- Click the blue **[Attach Document]** link.

Document Type:

Please select a document type.

Nothing selected

- Rationale Document
- Statement of Financial Responsibility
- Other

OK Cancel

- If the attachment has CBI, indicate this, and upload a sanitized document as well.
- To attach a **Rationale Document**:
 - Fill out the information highlighted by the red asterisk.
 - A rationale document must contain the following:
 - The Order number, the chemical identity, and the CAS No. of the test substance subject to this Order on which the application is based.
 - The specific testing requirement(s) from which an exemption is sought.
 - The basis for the exemption request when another company(ies) has/have submitted the information or is developing information for an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.



4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.
 5. The equivalence data specified in Enclosure A.
 6. The name, mailing address, telephone number, and e-mail address of applicant.
 7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.
5. To attach a **Statement of Financial Responsibility**:
- a. A statement of financial responsibility must contain the following:
 1. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.
 2. A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:
“I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based.”
 - b. If no documents are uploaded, validation errors will prevent the user from moving forward.

Exemption Reason

Information has been submitted on an equivalent chemical and submission of information by the exemption applicant would be duplicative of information which has been submitted to the Administrator.

Information is being developed on an equivalent chemical in accordance with a rule, order, or consent agreement under TSCA section 4(a), and submission of information by the exemption applicant would be duplicative of information which is being developed in accordance with such rule, order, or consent agreement.

Particulates Not Otherwise Regulated, Respirable - NIOSH 0600 Response Documents

File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				

[Attach Document](#)

At least one Rationale document must be uploaded.

At least one Statement of Financial Responsibility document must be uploaded.

[Previous](#) [Next](#)

2. Click **[Next]** to continue.
3. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.

Option 4: Join a Consortium Response to Order

If you intend to join a consortium to share in the cost of developing the required information, you must first individually in CDX, state your intention to participate in a testing consortium for each specific chemical and specific test. The consortium lead will not be able to add you to the consortium until you select “Join Consortium” as a response for each test you will respond via a consortium.

The designated lead for the consortium must submit the Initial Response and required information on behalf of the consortium and its member companies by the deadlines listed on the Order. After the results of the last required test of the Order is submitted and EPA accepts the information as



complying with the Order, or EPA accepts existing information submitted by the Consortium, EPA will then provide notification of compliance with the Order to the Order Recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with the Order and is individually liable in the event of any failure to comply with the Order. If the consortium fails to submit the information or meet any of the requirements of the Order on your behalf, you will be in violation of the Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received the Order at the top of the Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing.

1. To submit a response as **Join Consortium:**
2. Select “Join Consortium” as your Order Response Option.

Order Information			
Order Number:	TO-2021-0423-052519-01-A	Initial Response Deadline:	07-19-2021
Docket Number:	EPA-HQ-OPPT-2021-0423	Effective Date of Order:	04-20-2021
Title of Action:	users	Consortium Initial Response Deadline:	8-18-2021
		Consortium Study Plan Deadline:	10-17-2021
		Consortium Study Report Deadline:	2-18-2023

Test Information			
Test Name:	Octanol Solubility - OECD 105 with EPA modifications	Test Response:	Join Consortium Change Response
<input type="checkbox"/> I claim my organization's membership in this consortium CBI			

Octanol Solubility - OECD 105 with EPA modifications Response Documents				
File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				
Attach Document				

[Previous](#) [Next](#)

1. In **Test Information**, click the checkbox to claim membership in the Consortium as CBI.



Test Information

Test Name: Octanol Solubility - OECD 105 with EPA modifications **Test Response:** [Join Consortium](#) [Change Response](#)

I claim my organization's membership in this consortium CBI I wish to receive emails related to my consortium's submissions

- a. If you wish to receive emails related to the consortium, click the related checkbox.
2. Click the blue **[Attach Document]** link.

Document Type:
Please select a document type.
Other

Other Document Type Description:
test

I claim the attachment as CBI.

Upload New Document:
Browse

OK Cancel

- a. Select the **Document Type** drop down. Fill out the information highlighted by the red asterisk.
- b. If the attachment has CBI, indicate this, and upload a sanitized document as well.
- c. Click **[OK]**.
3. Click **[Next]** to continue.

If at some point during a submission you wish to change the Test Response, all originally uploaded documents will be erased.

Attention

Warning: changing response will clear all previously submitted information. Press OK to continue

Ok Cancel



4. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.



a. Creating a Consortium Initial Response to Order (Consortium Lead)

The designated lead for the consortium must submit the Consortium Initial Response and required information on behalf of the consortium and its member companies by the deadlines listed on the Order. After the results of the last required test of the Order are submitted and EPA accepts the information as complying with the Order, or EPA accepts existing information submitted by the Consortium, EPA will then provide notification of compliance with the Order to the Order Recipients and the designated lead of the consortium.

After submitting your **Initial Response** for your company, if you are the Consortium Lead, select [**Consortium Initial Response to Order**] and follow the steps below to complete the submission.

For **Consortium Initial Response to Order** Submission Type:

1. Select Consortium Initial Response to Order, then click [**Start New Submission**]

Select the submission type and then click **Start New Submission**

Submission Type:

Start New Submission

2. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

TSCA Section 4

New Passphrase

Confirm Passphrase

You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue



3. Fill out all relevant information on Consortium Initial Response to Order screen
 - a. Add Consortium Name and all Order Numbers associated with the Consortium in question.
 - i. Once the Order Number is added to the field, click **[Add Member]** to load the Member into the form.
 - b. Add Test Responses via the drop-down list in the Test Response Information section.
 - c. For each test, select how you intend to respond to the required test(s). You can:
 - i. **Develop Information**
 - ii. **Submit Existing Information**
 - iii. **Defer to Recipient**
4. Click **[Next]**.

Consortium Initial Response to Order

Consortium Information

Consortium Name:

Order Number: **Add Member**

Order Number	Consortium Member Name	Action
TO-2021-0526-816084-01-A	CGI FEDERAL	✖

Order Information

Chemical Substance Name(Regulatory Name): Benzene, 1-chloro-4-nitro-

Chemical Substance Identifier: 100-00-5 Consortium Initial Response Deadline: 09-22-2021

Test Response Information

Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Test Response	Status	Study Plan Deadline	Study Report Deadline
OECD 307 Aerobic and Anaerobic Transformation in Soil	Develop Information	In Progress	11-21-2021	03-25-2023
OECD 302B Inherent Biodegradability, Zahn-Wellens/EVPA Test	Develop Information	In Progress	11-21-2021	03-25-2023
OECD 314 Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater	Submit Existing Information	In Progress	11-21-2021	03-25-2023

Next

Option 1: If Submitting Existing Information:

1. Choose **Submit Existing Information**, navigating to the Test Response will offer the choice to **Change Response** or **Attach Document** for responding to the Test.
 - a. Choosing **[Change Response]** will return the user to the Consortium Information page where they will be able to change their drop-down choice.
 - b. Clicking **[Attach Document]** will open a pop-up window for attaching a Test Response document.
 - i. Once in the pop-up window, choose **Document Type**, which depending on choice will open different options.
2. If user selects **Study Report** as the Document Type, they will be required to upload an attachment and complete other fields related to the study being reported.
 - a. Fill out all required fields denoted by the red asterisk.



• Document Type:
Please select a document type.

Study Report

I claim the attachment as CBI.

• Upload New Document:
 Browse

• Date Study Completed:

• Study Report Title:

Is Study Published?
 Yes No

Test Guideline Number(s):
Please select...

Author(s) of Study: **Add**

Chemical Tested	CASRN/Accession	Action
Search SRS		

OK

3. If the user selects **Rationale Document**, they will be required to upload the Rationale Document as an attachment to the Test Response.
 - a. Click **[Browse]** to upload attachment for response and click checkbox if claiming the attachment as CBI.
 - b. If attachment is claimed CBI, a sanitized version is required to be attached as well.
 - c. Click **[OK]** to exit pop-up window.

Upload Existing Information Document

• Document Type:
Please select a document type.

Rationale Document

I claim the attachment as CBI.

• Upload New Document:
 Browse

OK

4. If the user selects **Other**, they will be required to upload an attachment to the Test Response.
 - a. Add **Document Type Description** for attachment.
 - b. Click **[Browse]** to upload attachment for response and click checkbox if claiming the attachment as CBI.
 - c. If attachment is claimed CBI, a sanitized version is required to be attached as well.
 - d. Click **[OK]** to exit pop-up window.

5. Once all Test Responses are completed, click **[Next]**.
6. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.
7. Once the form has processed and migrated, the **Current Action** will become **Submit Draft Study Plan**.

Option 2: If Developing Information:

1. Choose **Develop Information**, navigating to the Test Response will offer the choice to **Change Response** or **Attach Document** for responding to the Test.
 - a. Choosing **[Change Response]** will return the user to the Consortium Information page where they will be able to change their drop-down choice.
 - b. Clicking **[Attach Document]** will open a pop-up window for attaching a Test Response document.
 - i. Once in the pop-up window, choose **Document Type** and add **Document Type Description**.
 - ii. Click **[Browse]** to upload attachment for response and click checkbox if claiming the attachment as CBI.
 - iii. If attachment is claimed CBI, a sanitized version is required to be attached as well.
 - iv. If the same attachment(s) will be used for other Test Responses in the Consortium, the user can check the box to **Associate Documents to Other Tests**.



OECD 307 Aerobic and Anaerobic Transformation in Soil Response

Consortium Information

Consortium Name:	TESTING CONSORTIUM	Consortium Initial Response Deadline:	09-22-2021
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Test Information

Test Name:	OECD 307 Aerobic and Anaerobic Transformation in Soil	Test Response:	Develop Information Change Response
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OECD 307 Aerobic and Anaerobic Transformation in Soil Response Documents

File Name	Document Type	Attachment Date	CBI	Action
Nothing found to display.				
Attach Document				

[Previous](#) [Next](#)

1. To complete the submission, navigate to the **Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report** section.

Option 3: If Defer to Recipient

1. If the test required is not a test your consortium will provide documentation for, please defer the applicable test to the Individual Company so they can provide the test information.
2. Choose **Defer to Recipient**, navigating to the Test Response will offer the choice to **Change Response** or **Attach Document** for deferring the Test.
 - a. Choosing [**Change Response**] will return the user to the Consortium Information page where they will be able to change their drop-down choice.
 - b. Clicking [**Attach Document**] will open a pop-up window for attaching a Test Response document.
 - i. Once in the pop-up window, choose **Document Type** and add **Document Type Description**.
 - ii. Click [**Browse**] to upload attachment for response and click checkbox if claiming the attachment as CBI.
 - iii. If attachment is claimed CBI, a sanitized version is required to be attached as well.
 - iv. If the same attachment(s) will be used for other Test Responses in the Consortium, the user can check the box to **Associate Documents to Other Tests**.



5. Submit Draft and Final Study Plan and Final Study Report

Step 1: Submitting a Draft Study Plan

If you choose to develop the required information to comply with the Order, you must obtain and review the required protocols/methodologies. You may not modify the required protocols/methodologies unless you first consult with the Agency and obtain Agency approval of any planned modification prior to submitting your initial study plan. The draft study plan is due to the Agency 80 days after the effective date of the Order.

The Draft Study Plan must contain the following information:

1. The Order number, excluding the unique 6-digit company number so as to protect each company's private access to the reporting module via Central Data Exchange (https://www.epa.gov/sites/production/files/2021-01/documents/cdx_user_guide_faq_page_includes_breaks.pdf). This should look similar to the following example with Xs used in place of the unique company number: TO-2020-0000-XXXXXX-00-0. The remainder of the Order number should be identical to the number received with the Order.
2. Name of test to be covered by the test protocol/methodology.
3. The name/number of the protocol/methodology identified by Table 1.1 in the Order which you intend to follow, or a copy of the identified protocol/methodology with your modifications that the EPA has approved, or a copy of the protocol/methodology you requested to use which EPA has approved. If approval for the identified protocol/methodology with your modifications or the use of a protocol/methodology you requested to use is not granted by EPA in time to be included in the study plan, they must be referenced as "submitted and pending approval" and the final protocol/methodology submitted later, once approved, in final form in an amended study plan.
4. The rationale for any modification, or pending modification, of the identified protocol/methodology. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant protocols/methodologies.
5. The identity and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. Per the respective protocol, the purity and Certificate of Analysis of the test substance should be included.
6. The sampling and analytical method that will be used, including whether the sampling method was validated by an approved organization (*e.g.*, NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO)) or an industrial hygiene/analytical laboratory.



7. For dermal exposure monitoring, the procedures used to optimize collection efficiency and extraction of the test chemical to ensure that 60% to 125% of the test chemical will be analyzed using the analytical method identified.
8. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.
9. The sampling strategy that will be used for sample collection, including sample location, flow rates, sampling time, field blanks and sample replication; the sample handling, storage and transport procedures and whether they will be followed; the sample pumps and other instruments and whether they will be properly calibrated with primary standard equipment.
10. For exposure-related testing, the number of samples to be taken for each similar exposure group, and how the workers or others will be selected for sampling (*e.g.*, random sampling, select workers with highest likelihood of exposure or some other statistically valid sampling strategy, and other relevant information suggested by the American Industrial Hygiene Association (AIHA)²). Also include the number of samples and length of sampling periods that will be taken to ensure the results are statistically significant for worker and ONU exposure groups, and indicate the statistical method used to demonstrate that the number of samples and length are statistically significant. A list must be included to contain all job descriptions/titles and work activities where workers and ONUs may be exposed and the total number of workers and ONUs per shift and number of shifts per day, length of shifts, length of shifts if not full, number of operating days/year for job description/title or work activities, and information on industrial hygiene (IH) programs (*e.g.*, respirator testing program).
11. The specific number of quality assurance field samples (including sample volume for limits of detection and quantification) and analytical QA/QC protocols to be followed (*e.g.*, specific number of field blanks, replicates of field samples, and replicate samples). NIOSH 95-117 (Kennedy et al., 1995) provides guideline for sampling and analytical method development and evaluation.
12. The rationale for any combination of protocols/methodologies; the rationale for species/strain selection, dose selection (and supporting data), and route or method of exposure; description of diet to be used and its source (including nutrients and contaminants and their concentration); for in-vitro and/or ex-vivo test systems, a

² The strategy for assessing occupational exposures recommended by the AIHA for successful evaluation include the following: a) collecting information and data to characterize the project site (or facility), process, operations, work force, and environment; b) defining similar exposure groups by process, task, environment, and engineering controls; c) developing exposure profile (*e.g.*, by assigning qualitative ratings on exposure, health effects, and uncertainty to each similar exposure groups); d) determine the acceptability of exposure and need for additional exposure monitoring; and e) re-assess the exposure profiles and data collection, as needed (AIHA, 2015).



description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

13. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.
14. The names, mailing addresses, phone numbers, and e-mail addresses of the appropriate individual(s) for EPA to contact concerning the planned test.
15. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.
16. Description of data and results that contain data supporting information that facilitate quality review of the results, *e.g.*, facility process descriptions, operation and process parameters, sampling and monitoring parameters, sample populations, job description/title and the number of workers for each job description or activity and the total daily duration of exposure, engineering controls (*e.g.* local exhaust ventilation), room volume, air exchange rates, air changes per hour of work area, ventilation rates, air speeds, work practices, and personal protective equipment used.

Prior to initiating any test, the Company/Consortium must first address EPA's input on the initial study plan and receive EPA's acceptance of the final study plan. EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results.

All testing must follow the EPA accepted final study plan. If problems occur during testing, the Company/Consortium must request EPA's approval before modifying the accepted final study plan.

You must also secure EPA's approval prior to submitting the initial study plan, if you wish to use a protocol/methodology not listed in the Order. Within your initial study plan, you must submit a detailed description of the protocol/methodology you are requesting to use or your requested modifications of the required protocol/methodology and your reason(s) for using a different or modified protocol/methodology. Indicate whether and how the requested protocol/methodology is appropriate and whether its deviations from the protocol/methodology required by the Order are such that they could alter the validity of the study. If EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before EPA will approve your request. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under the Order. Development of information required by its Order, which does not fully comply with the terms of the Order, may result in a violation of TSCA section 15.



EPA has identified the protocols/methodologies that must be followed to perform each required test. They are listed in Table 1.1 and may include protocols/methodologies (also known as test guidelines) from OECD or OCSPP/OPPTS. These protocols/methodologies are available via the Internet. It is highly recommended that your final test report be submitted along with the data in the associated OECD harmonized template format which can be located at <https://www.oecd.org/ehs/templates/harmonised-templates.htm>³. If questions and /or issues arise during Study Plan development, EPA encourages consultation with the Agency prior to submitting the Study Plan.

If, after the study plan has been submitted or after testing is underway, you need to make a modification to an identified protocol/methodology or need to use a different protocol/methodology, you must submit a request to EPA.

For purposes of satisfying the requirements of the Order, you are required to follow the Good Laboratory Practice (GLP) standards described in 40 CFR part 792, as specified in the CFR on the day the Order is signed. You are also required to provide a statement of compliance with these GLP standards when submitting information to EPA pursuant to the Order.

After the Initial Response to Order is completed, the next step is to **Submit Draft Study Plan** for the tests that are required based on the identification the user submitted to EPA on Step 1.

1. On the Home page, click the blue link **Submit Draft Study Plan** in the Next Action column.
2. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

³ <https://www.oecd.org/ehs/templates/harmonised-templates.htm>.

TSCA Section 4

New Passphrase

Confirm Passphrase

You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue

Cancel

3. Click the blue **Attach Study Plan Document** link.

Test Order Study Plan

Order Information - TO-8088-1565-307458-01-A

Title of Action: learning **Docket Number:** EPA-HQ-OPPT-8088-1565

Chemical Information

Chemical Substance Identifier: 67875-37-0
Chemical Substance Name (Regulatory Name): 1,6-Hexanediamine, N1-(6-aminohexyl)-, homopolymer
Chemical Group: Work Plan Chemicals
 TRI Chemicals List **Chemical Category:** Cinnamyl Derivatives Category
 Higher Olefins Category
 Peroxides
 Substituted Diphenylamines Category

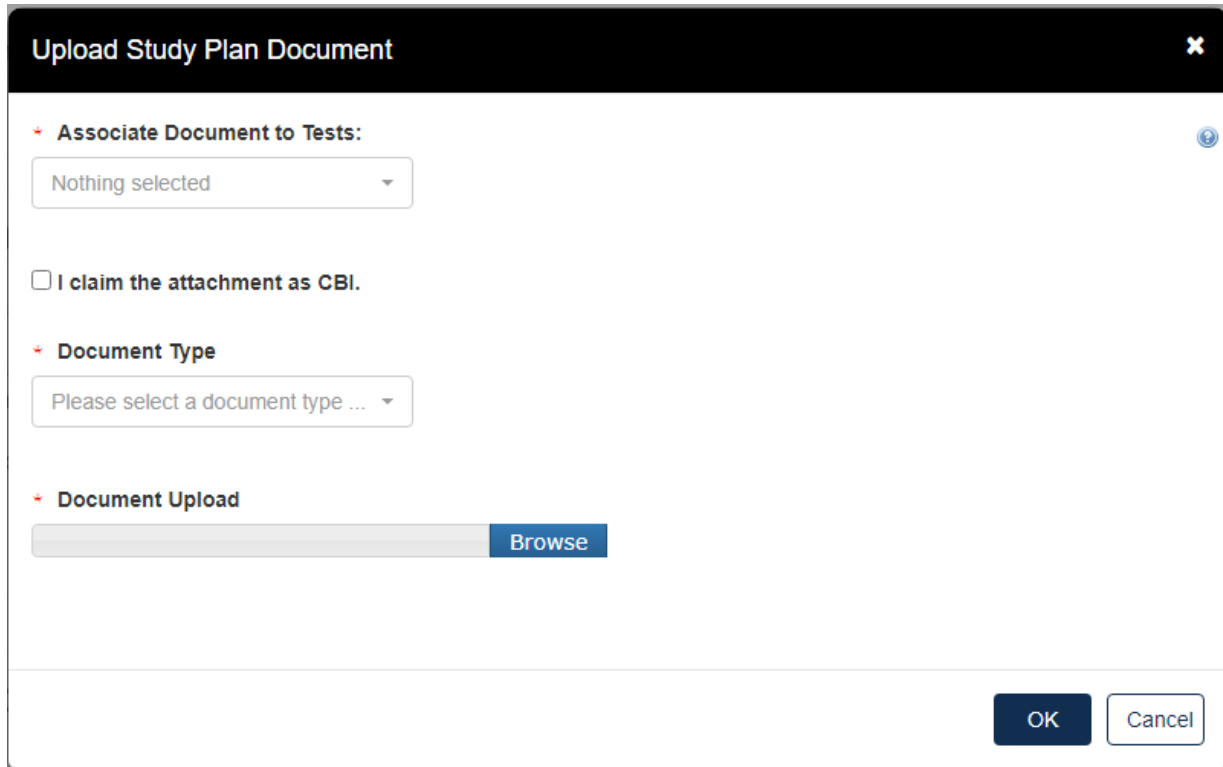
Study Plan Documents

[Attach Study Plan Document](#)

Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis	03/01/2021	03/31/2021	Not Started

4. Click the [Associate Documents to Tests] drop down.



Upload Study Plan Document [Close]

✦ **Associate Document to Tests:** [Nothing selected]

I claim the attachment as CBI.

✦ **Document Type**
Please select a document type ...

✦ **Document Upload**
[File Input] **Browse**

OK **Cancel**

- a. The dropdown menu will list options applicable to the test(s) associated with the documents.
- b. Click the [**Document Type**] drop down to select the type of document that will be uploaded; Study Plan, Modification, Correspondence, or Study Plan – OHT Template File.
- c. If the attachment has CBI, indicate this, and upload a sanitized document as well.
- d. Click [**OK**].

Upload Study Plan Document ✕

+ **Associate Document to Tests:**
?

OECD 316 Phototransformation of ▾

I claim the attachment as CBI.

+ **Document Type**

Please select a document type ... ▾

Please select a document type ...

- Study Plan
- Modification
- Correspondence
- Study Plan - OHT Template File

Browse

OK

Cancel

e. If no documents are uploaded, this alert will show

Study Plan Documents

+ [Attach Study Plan Document](#)
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis ▾	03/01/2021	03/31/2021	Not Started

❗ All Tests must have at least one Study Plan document uploaded.

f. When documents are uploaded, the user is able to click the blue arrow button to see what has been uploaded, the type, the attachment date, and CBI information.

Study Plan Documents

+ [Attach Study Plan Document](#)
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis ▾	03/01/2021	03/31/2021	Passes Validation

File Name	Document Type	Attachment Date	CBI	Action
Sec4.docx	Study Plan	04-26-2021	N	✕

5. Click **[Next]** to continue.
6. To complete the submission, navigate to the [Submitting a Response](#) section.



Step 2: Submitting a Final Study Plan

The final study plan is due to the Agency 110 days after the effective date of the Order.

The Final Study Plan must contain the following information:

1. The Order number, excluding the unique 6-digit company number so as to protect each company's private access to the reporting module via Central Data Exchange (https://www.epa.gov/sites/production/files/2021-01/documents/cdx_user_guide_faq_page_includes_breaks.pdf). This should look similar to the following example with Xs used in place of the unique company number: TO-2020-0000-XXXXXX-00-0. The remainder of the Order number should be identical to the number received with the Order.
2. Name of test to be covered by the test protocol/methodology.
3. The name/number of the protocol/methodology identified by Table 1.1 in the Order which you intend to follow, or a copy of the identified protocol/methodology with your modifications that the EPA has approved, or a copy of the protocol/methodology you requested to use which EPA has approved. If approval for the identified protocol/methodology with your modifications or the use of a protocol/methodology you requested to use is not granted by EPA in time to be included in the study plan, they must be referenced as "submitted and pending approval" and the final protocol/methodology submitted later, once approved, in final form in an amended study plan.
4. The rationale for any modification, or pending modification, of the identified protocol/methodology. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant protocols/methodologies.
5. The identity and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. Per the respective protocol, the purity and Certificate of Analysis of the test substance should be included.
6. The sampling and analytical method that will be used, including whether the sampling method was validated by an approved organization (e.g., NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO)) or an industrial hygiene/analytical laboratory.
7. For dermal exposure monitoring, the procedures used to optimize collection efficiency and extraction of the test chemical to ensure that 60% to 125% of the test chemical will be analyzed using the analytical method identified.
8. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of



equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

9. The sampling strategy that will be used for sample collection, including sample location, flow rates, sampling time, field blanks and sample replication; the sample handling, storage and transport procedures and whether they will be followed; the sample pumps and other instruments and whether they will be properly calibrated with primary standard equipment.
10. For exposure-related testing, the number of samples to be taken for each similar exposure group, and how the workers or others will be selected for sampling (*e.g.*, random sampling, select workers with highest likelihood of exposure or some other statistically valid sampling strategy, and other relevant information suggested by the American Industrial Hygiene Association (AIHA)⁴). Also include the number of samples and length of sampling periods that will be taken to ensure the results are statistically significant for worker and ONU exposure groups, and indicate the statistical method used to demonstrate that the number of samples and length are statistically significant. A list must be included to contain all job descriptions/titles and work activities where workers and ONUs may be exposed and the total number of workers and ONUs per shift and number of shifts per day, length of shifts, length of shifts if not full, number of operating days/year for job description/title or work activities, and information on industrial hygiene (IH) programs (*e.g.*, respirator testing program).
11. The specific number of quality assurance field samples (including sample volume for limits of detection and quantification) and analytical QA/QC protocols to be followed (*e.g.*, specific number of field blanks, replicates of field samples, and replicate samples). NIOSH 95-117 (Kennedy et al., 1995) provides guideline for sampling and analytical method development and evaluation.
12. The rationale for any combination of protocols/methodologies; the rationale for species/strain selection, dose selection (and supporting data), and route or method of exposure; description of diet to be used and its source (including nutrients and contaminants and their concentration); for in-vitro and/or ex-vivo test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.
13. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.
14. The names, mailing addresses, phone numbers, and e-mail addresses of the appropriate individual(s) for EPA to contact concerning the planned test.

⁴ The strategy for assessing occupational exposures recommended by the AIHA for successful evaluation include the following: a) collecting information and data to characterize the project site (or facility), process, operations, work force, and environment; b) defining similar exposure groups by process, task, environment, and engineering controls; c) developing exposure profile (*e.g.*, by assigning qualitative ratings on exposure, health effects, and uncertainty to each similar exposure groups); d) determine the acceptability of exposure and need for additional exposure monitoring; and e) re-assess the exposure profiles and data collection, as needed (AIHA, 2015).



15. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.
16. Description of data and results that contain data supporting information that facilitate quality review of the results, *e.g.*, facility process descriptions, operation and process parameters, sampling and monitoring parameters, sample populations, job description/title and the number of workers for each job description or activity and the total daily duration of exposure, engineering controls (*e.g.* local exhaust ventilation), room volume, air exchange rates, air changes per hour of work area, ventilation rates, air speeds, work practices, and personal protective equipment used.

Prior to initiating any test, the Company/Consortium must first address EPA's input on the initial study plan and receive EPA's acceptance of the final study plan. EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results.

All testing must follow the EPA accepted final study plan. If problems occur during testing, the Company/Consortium must request EPA's approval before modifying the accepted final study plan.

You must also secure EPA's approval prior to submitting the initial study plan if you wish to use a protocol/methodology not listed in the Order. Within your initial study plan, you must submit a detailed description of the protocol/methodology you are requesting to use or your requested modifications of the required protocol/methodology and your reason(s) for using a different or modified protocol/methodology. Indicate whether and how the requested protocol/methodology is appropriate and whether its deviations from the protocol/methodology required by the Order are such that they could alter the validity of the study. If EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before EPA will approve your request. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under the Order. Development of information required by its Order, which does not fully comply with the terms of the Order, may result in a violation of TSCA section 15.

EPA has identified the protocols/methodologies that must be followed to perform each required test. They are listed in Table 1.1 and may include protocols/methodologies (also known as test guidelines) from OECD or OCSPP/OPPTS. These protocols/methodologies are available via the Internet. It is highly recommended that your final test report be submitted along with the data in the associated OECD harmonized template format which can be located at



<https://www.oecd.org/ehs/templates/harmonised-templates.htm>⁵. If questions and /or issues arise during Study Plan development, EPA encourages consultation with the Agency prior to submitting the Study Plan.

If, after the study plan has been submitted or after testing is underway, you need to make a modification to an identified protocol/methodology or need to use a different protocol/methodology, you must submit a request to EPA.

For purposes of satisfying the requirements of the Order, you are required to follow the Good Laboratory Practice (GLP) standards described in 40 CFR part 792, as specified in the CFR on the day the Order is signed. You are also required to provide a statement of compliance with these GLP standards when submitting information to EPA pursuant to the Order.

After the Draft Study Plan has been submitted (Step 4a), the next action is to submit a Final Study Plan.

1. On the Home page, click the blue link **Submit Final Study Plan** in the Next Action column.
2. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

CSPP Home Submissions Section 4 Orders User Management

TSCA Section 4

New Passphrase

Confirm Passphrase

⚠ You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue Cancel

⁵ <https://www.oecd.org/ehs/templates/harmonised-templates.htm>.



3. Click the blue **Attach Study Plan Document** link.

Test Order Study Plan

Order Information - TO-8088-1565-307458-01-A

Title of Action: learning **Docket Number:** EPA-HQ-OPPT-8088-1565

Chemical Information

Chemical Substance Identifier: 67875-37-0

Chemical Substance Name (Regulatory Name): 1,6-Hexanediamine, N1-(6-aminohehexyl)-, homopolymer

Chemical Group: Work Plan Chemicals
TRI Chemicals List

Chemical Category: Cinnamyl Derivatives Category
Higher Olefins Category
Peroxides
Substituted Diphenylamines Category

Study Plan Documents

[Attach Study Plan Document](#)
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis	03/01/2021	03/31/2021	Not Started

4. Click the **[Associate Documents to Tests]** drop down.

Upload Study Plan Document ✕

▾ **Associate Document to Tests:** ⓘ

Nothing selected ▾

I claim the attachment as CBI.

▾ **Document Type**

Please select a document type ... ▾

▾ **Document Upload**

a. The dropdown menu will list options applicable to the test(s) associated with the documents.

- b. Click the **[Document Type]** drop down to select the type of document that will be uploaded; Study Plan, Modification, Correspondence, or Study Plan – OHT Template File.
- c. If the attachment has CBI, indicate this, and upload a sanitized document as well.
- d. Click **[OK]**.

- e. If no documents are uploaded, this alert will show

Study Plan Documents

Attach Study Plan Document
 Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis	03/01/2021	03/31/2021	Not Started

All Tests must have at least one Study Plan document uploaded.

- f. When documents are uploaded, the user is able to click the blue arrow button to see what has been uploaded, the type, the attachment date, and CBI information.



Study Plan Documents

[Attach Study Plan Document](#)

Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Study Report Deadline	Status	
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis	03/01/2021	03/31/2021	Passes Validation	
File Name	Document Type	Attachment Date	CBI	Action
Sec4.docx	Study Plan	04-26-2021	N	

5. Click **[Next]** to continue.
6. To complete the submission, navigate to the [Submitting a Response](#) section.



Step 3: Submitting a Final Study Report

- Once the **Final Study Plan** has been completed a blue **Submit Final Study Report** will appear. Click the blue **Submit Final Study Report** to begin.

TO-1565-1654-233703-01-A	Study Plan	Submit Study Report	02/28/2021	N/A	N/A
Submission Type	Submission Status	Submission Date	Action		
Study Plan	Completed	04-20-2021			

- Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

CSPP
Home
Submissions
Section 4 Orders
User Management

TSCA Section 4

New Passphrase

Confirm Passphrase

You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue
Cancel

- Under **Study Report Documents**, click the blue **Attach Study Report Documents** link.

Test Order Study Report

Order Information - TO-1565-1654-233703-01-A

Title of Action:	Jewels Test	Docket Number:	EPA-HQ-CPPT-1565-1654
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Chemical Information

Chemical Substance Identifier:	00-00-0		
Chemical Substance Name (Regulatory Name):	Formaldehyde		
Chemical Group:	Clean Water Act (CWA) Priority Pollutant List Clean Air Act Hazardous Air Pollutants HAP Chemicals List Perfluorinated Substances List Selected Chemical Ingredients List Top Chemical Substances for Initial Risk Evaluation under TSCA TRI Chemicals List TSCA §12(b) Export Notification Chemicals List Work Plan Chemicals	Chemical Category:	Acrylates/Methacrylates Aldehydes Aliphatic Amines Aliphatic Monocyclics Category Alkylamines Alkyl Acrylates CS - C13 Category Alkyl Acrylates CS-C13 Category Alkyl Diphenyl Oxide Disulfonates (ADPODS) Category Alkyl Nitrites Category Chloroalkenes Category

Study Report Documents

Attach Study Report Document
Click the category name to attach documents to each test name to view a listing of the attached test documents.

Test	Study Report Deadline	Status
Octanol Solubility - OECD 105 with EPA modifications	02/28/2021	Not Started
Water Solubility - OECD 105 with EPA modifications	02/28/2021	Not Started
Particulates Not Otherwise Regulated, Respirable - NIOSH 0600	02/28/2021	Not Started
NIOSH 1003* Hydrocarbons, halogenated 1003	02/28/2021	Not Started

Next

Technical Contact Information



- a. Click the **Associate Documents to Tests**: drop down to select the appropriate test.
- b. Click the **Document Type** drop down to select the document type associated with the test.

Upload Study Report Document

Associate Document to Tests:
Octanol Solubility - OECD 105 with EPA modifications

I claim the attachment as CBI.

Document Type
Please select a document type ...
Study Report
Study Plan - OHT Template File
Other

Browse

OK Cancel

- c. If nothing is uploaded a red alert message will appear.

Study Report Documents

Attach Study Report Document
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Report Deadline	Status
Octanol Solubility - OECD 105 with EPA modifications	02/28/2021	Not Started
Water Solubility - OECD 105 with EPA modifications	02/28/2021	Not Started
Particulates Not Otherwise Regulated, Respirable - NIOSH 0600	02/28/2021	Not Started
NIOSH 1003* Hydrocarbons, halogenated 1003	02/28/2021	Not Started

All Tests must have at least one Study Report document uploaded.

- d. For **Document Type: Study Report**, fill out the information highlighted by the red asterisk.

Octanol Solubility - OECD 105 with EPA modifications

I claim the attachment as CBI.

Document Type
Study Report

Document Upload
Browse

Date Study Completed:

Study Report Title:

Is Study Published?
 Yes No

Test Guideline Number(s):
Please select...

Study Citation:

Author(s) of Study:

Search SRS

Chemical Tested CASRN/Accession Action

OK Cancel

- a. If the attachment has CBI, indicate this. Click **[OK]** to continue.



- When the documents have been successfully uploaded, the Status will change to Passes Validation. Click **[Next]** to continue.

Study Report Documents

[Attach Study Report Document](#)
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Report Deadline	Status
Octanol Solubility - OECD 105 with EPA modifications	02/28/2021	Passes Validation
Water Solubility - OECD 105 with EPA modifications	02/28/2021	Passes Validation
Particulates Not Otherwise Regulated, Respirable - NIOSH 0600	02/28/2021	Passes Validation
NIOSH 1003* Hydrocarbons, halogenated 1003	02/28/2021	Passes Validation

Next

- To complete the submission, navigate to the [Submitting a Response](#) section.
- When all submissions are completed, you will be able to download or unlock to edit the document from the main queue.

TO-8088-1565-393116-01-A	Submit Study Report	N/A	N/A	N/A	N/A
Submission Type	Submission Status	Submission Date	Action		
Individual Initial Response To Order	Completed	02-24-2021			
Study Plan	Completed	03-03-2021			
Study Report	Completed	03-03-2021			

6. Submitting an Extension Request

Should EPA fail to respond within 15 days, an automatic extension will be provided **only** to those deadlines for submissions that were received by the original specified deadline.

6.1 Extension Request for the Identification Response

1. Click the [Submission Type] dropdown menu to select the **Identification Response** submission type and click [Start New Submission] to prepare the form. All companies receiving a Test Order must complete this step regardless of how they intend to respond to the order (e.g., Joining a Consortium).

The screenshot shows the CSDP web application interface. At the top, there are navigation tabs: Home, Submissions, Section 4 Orders, and User Management. The user is identified as Brooke Plaisance, Primary Authorized Official (CGI BP). Below the navigation, there are instructions on how to download a copy of a record and how to search for entries. A search box is present. Below the search box, it indicates that 6 items were found. A table displays the following data:

Order/Consortium Number	Last Action	Current Action	Current Action Due Date	Next Action	Next Action Due Date	Delete
+ TO-1234-9876-791614-01-A	Final Study Plan	Submit Study Report	11/11/2021	N/A	N/A	
+ TO-2021-1008-307895-01-A	N/A	Submit Initial Response	11/06/2021	Submit Study Plan	12/27/2021	X
+ TO-8878-9876-485648-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/18/2021	X
+ TO-7777-7777-527723-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/12/2021	X
+ TO-8798-4897-981494-01-A	N/A	Submit Identification Response	12/12/2021	Submit Draft Study Plan	01/31/2022	X
+ TO-8648-8648-659742-01-A	Identification Response	Submit Draft Study Plan	01/30/2022	Submit Final Study Plan	11/17/2022	X

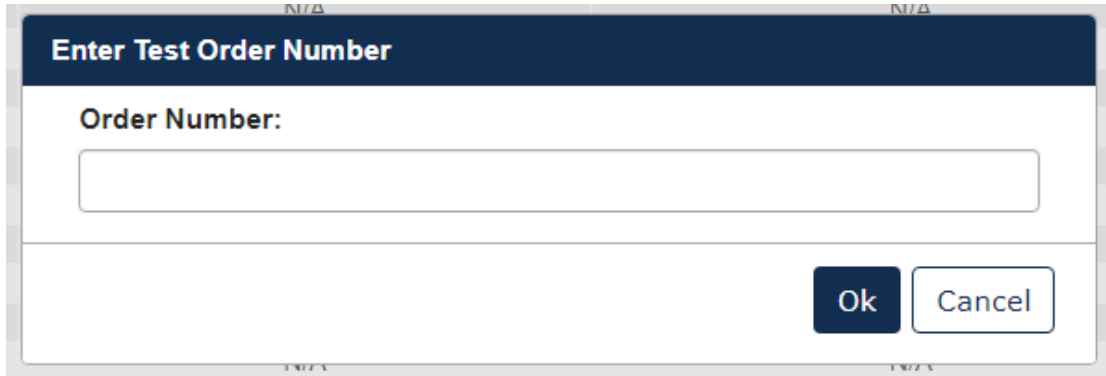
Below the table, there are export options for CSV, Excel, XML, and PDF. A dropdown menu for 'Submission Type' is set to 'Identification Response', and a 'Start New Submission' button is visible.

Select the submission type and then click **Start New Submission**

Submission Type: Identification Response

Start New Submission

2. A text box will appear. Enter the Test Order number that was provided to your institution, then click [Ok].



3. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed. The ‘Create Passphrase’ screen, allows you to create a passphrase and associate that passphrase with your newly created form.

The application uses the passphrase as an encryption key to protect the contents of the form. You are responsible for remembering the passphrase and distributing it to the appropriate individuals.

If you lose or forget your passphrase, you will not be able to access your submission to print, submit, or make changes. You will need to complete a new submission and create a new passphrase. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

New Passphrase: Enter a passphrase that is between 8 and 20 characters. For maximum security, your passphrase should contain a combination of letters and numbers. Your passphrase should not contain special characters (for example, +, ?, and *).

Confirm Passphrase: Enter the same passphrase that was entered into the ‘New Passphrase’ field. The same passphrase may be associated with multiple forms. The user can choose to have the same passphrase for all forms. Supports do not have the ability to start a new form or create a passphrase for a form.



TSCA Section 4

New Passphrase

Confirm Passphrase

⚠ You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

4. After creating the passphrase, click on the **[Save]** button on the Manufacturer/Processor Identification Response page and click on the **[Home]** tab to return to the home page.
5. Click the calendar icon next to the due date icon next to the due date in the **[Current Action Due Date]** column for the Identification Response you are trying to extend.

Order/Consortium Number	Last Action	Current Action	Current Action Due Date	Next Action	Next Action Due Date	Delete
+ TO-2021-0401-081025-01-A	N/A	Submit Initial Response	07/24/2021	Submit Study Plan	10/22/2021	X
+ TO-1-1-672592-01-A	Initial Response	Submit Study Plan	08/05/2020	Submit Study Report	08/20/2020	X
+ TO-8523-8523-945519-01-A	N/A	Submit Identification Response	05/31/2020	Submit Initial Response	N/A	X

6. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

TSCA Section 4

New Passphrase

Confirm Passphrase

⚠ You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

7. Attach the Rational Document to justify the request for Extension.



Associate Document to Tests:

OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis

I claim the attachment as CBI.

Document Type

Rationale Document

Rationale

[Empty text area for Rationale]

Document Upload

Browse

OK Cancel

8. Type in the dates that you are proposing to have as the new deadline. Click [Next] to continue.
9. To complete the submission, navigate to **Step 7: Submitting a Response**.

6.2 Extension Request for the Draft and Final Study Plan or Final Study Report

1. To submit an Extension Request, click the calendar icon next to the due date in the [Current Action Due Date] column.

Order/Consortium Number	Last Action	Current Action	Current Action Due Date	Next Action	Next Action Due Date
TO-8088-1565-307458-01-A	Initial Response	Submit Study Plan	03/01/2021	Submit Study Report	03/31/2021

2. Choose a secure passphrase that can be remembered for the purposes of accessing the form while it is In Progress or the Copy of Record and Communications after submission is completed.

TSCA Section 4

New Passphrase

Confirm Passphrase

⚠ You are responsible for remembering your passphrase!

If you lose or forget your passphrase, you will not be able to access your Section 4 form to print, submit, or make changes. You will need to complete a new Section 4 form and create a new passphrase for the submission. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Continue

Cancel

3. Click the **[Selected Tests]** drop down, to choose which test(s) that is requesting an extension.

Extension Request to Order

Order Information

Order Number: TO-8088-1565-307458-01-A Chemical Substance Name (Regulatory Name): 1,6-Hexanediamine, N1-(6-aminohexyl)-, homopolymer
 Chemical Substance Identifier: 67875-37-0 (CASRN)

Selected Tests:
 Please select the test(s) for which you would like to request an extension.

Nothing selected

OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis

Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Proposed Study Plan Deadline	Study Report Deadline	Proposed Study Report Deadline	Status
Nothing found to display.					

Next
 Technical Contact Information

4. Click the blue **[Attach Extension Document]** link to upload appropriate documentation.

Order Information

Order Number: TO-8088-1565-307458-01-A Chemical Substance Name (Regulatory Name): 1,6-Hexanediamine, N1-(6-aminohexyl)-, homopolymer
 Chemical Substance Identifier: 67875-37-0 (CASRN)

Selected Tests:
 Please select the test(s) for which you would like to request an extension.

[Attach Extension Document](#)
 Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Proposed Study Plan Deadline	Study Report Deadline	Proposed Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis 📄	03-01-2021	<input type="text"/>	03/31/2021	<input type="text"/>	Not Started

- a. Select the Test to which the documents relate and select the **[Document Type]** drop down to indicate what documents are being uploaded.

- b. For a Rationale Document:



c. For a Correspondence:

Upload Extension Request Document

Associate Document to Tests:

OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis

I claim the attachment as CBI.

Document Type

Correspondence

Document Upload

Browse

OK Cancel

- d. If the information is CBI, indicate by marking the checkbox and uploading a sanitized version as well.
5. Type in the dates that you are proposing to have as the new deadline. Click **[Next]** to continue.

Order Information

Order Number: TO-8088-1565-307458-01-A **Chemical Substance Name (Regulatory Name):** 1,6-Hexanediamine, N1-(6-aminohexyl)-, homopolymer

Chemical Substance Identifier: 67875-37-0 (CASRN)

Selected Tests:
Please select the test(s) for which you would like to request an extension.

OECD 316 Phototransformati

Attach Extension Document
Click the drop down menu arrow next to each test name to view a listing of the attached test documents.

Test	Study Plan Deadline	Proposed Study Plan Deadline	Study Report Deadline	Proposed Study Report Deadline	Status
OECD 316 Phototransformation of Chemicals in Water - Direct Photolysis	03-01-2021	05/05/2021	03/31/2021	05/31/2021	In Progress

Next
Technical Contact Information

6. To complete the submission, navigate to **Step 7: Submitting a Response**.
7. When the **Extension Request** has been completed, it will show in the main queue.

Submission Type	Submission Status	Submission Date	Action
Study Plan	Completed	04-20-2021	↓ 🔒
Extension Request	Completed	04-20-2021	↓ 🔒

- a. If at any point a document has been completed, but has been opened to be edited, the Submission Type will turn blue and the lock icon will be unlocked.



TO-1565-1654-714919-01-A	N/A	Submit Initial Response	05/16/2021	Submit Study Plan	02/22/2021
Submission Type		Submission Status		Submission Date	Action
Individual Initial Response To Order		Completed		03-31-2021	

- b. When a communication from the EPA is received, an envelope will show alongside the submission type under the Test Order number.

TO-1565-1654-614567-01-A	Submit Study Report	N/A	N/A	N/A	N/A
Submission Type		Submission Status		Submission Date	Action
Individual Initial Response To Order		Completed - Payment Received		02-26-2021	
Study Plan		Completed - Payment Received		02-26-2021	
Study Report		Completed - Payment Received		03-01-2021	

- c. If you have submitted a Test Order to Join Consortium, once it is completed in your queue you will see:

TO-1500-8367-311558-01-A	Initial Response	N/A	N/A	N/A	N/A
Submission Type		Submission Status		Submission Date	Action
Individual Initial Response To Order		Completed		04-01-2021	

8. To complete the submission, navigate to **Step 7: Submitting a Response**.



7. Submitting a Response, Draft Study Plan, Final Study Plan or Final Study Report

The submission steps are common and required across all the different forms and stages of the response process. Please follow these steps to complete the submission process to EPA.

1. Technical Contact Information

- c. Fill out all required **Technical Contact Information** denoted by red asterisk or click [**Copy CDX Registration**] to fill in with the information from CDX.
- d. If Technical Contact Information is **CBI**, please check the **CBI** checkbox.

Technical Contact Information

Identify the technical contact who is capable of answering questions related to the chemical(s) submitted to EPA within this submission. Click the 'Copy CDX Registration' button to copy your information from CDX Registration.

Click here to copy your information from CDX Registration: Copy CDX Registration

CBI

Prefix

* First Name

Middle Initial

* Last Name

Suffix

* Company Name

* Phone Number Ext.

Do not enter any dashes (-) in Phone Number field above

* Email Address

* Mailing Address 1

Street address, company name, etc.

Mailing Address 2

Apartment, suite, etc.

* City

* State

* Postal Code

* Country

Previous Next

- e. Click [**Next**] to continue.

2. Submitting Official Information:

- a. If this is CBI, indicate this by clicking the CBI checkbox.
- b. Fill out **Job Title** of this page.
- c. Click the checkbox to Confirm and Proceed.



d. If you are submitting on behalf of another company, indicate that by clicking the checkbox.

3. Click **[Submit]** to continue.

Submitting Official Information

The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.

Submitter is CBI

Prefix: Mrs

First Name: Jilliane

Middle Initial: (

Last Name: Conley

- Job Title:

Company Name: Jewelstesting

Phone Number: 3374841699

Email Address: jilliane.conley@cgi.com

Mailing Address 1: 684 Wylie Dr

Mailing Address 2:

City: Baton Rouge

State: LA

Postal Code: 70808

This confirmation is required to proceed with the submission process

- Please confirm that you are the legally responsible party from the submitting company.

Please select if you are submitting on behalf of another company.



4. **Instructions for Substantiating Confidential Business Information (CBI) Claims**, if necessary.
 - a. If any CBI claims have been made, the **[Continue]** button on the Submitting Official Information page will display the CBI Substantiation page.
 - b. To add the corresponding substantiation documents, select the **[Attach Document for CBI Substantiation]** link.
 - c. To opt-out from providing the CBI Substantiation documents, check the Substantiation Opt.

Instructions for Substantiating Confidential Business Information (CBI) Claims

The Frank R. Lautenberg Chemical Safety for the 21st Century Act created a number of new requirements for those making confidential business information (CBI) claims in TSCA submissions. Among these requirements is an obligation to substantiate most CBI claims at the time of submission.

Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

- A. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
- B. Marketing and sales information;
- C. Information identifying a supplier or customer;
- D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
- E. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
- F. Specific production or import volumes of the manufacturer or processor; and
- G. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at <https://www.epa.gov/tscabi/what-information-include-cbi-substantiations>.

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8850, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c)(2) or has been previously substantiated, select the following "Substantiation Opt Out" checkbox and provide a detailed explanation why you believe substantiation is not required.

Substantiation Opt-Out

Select a file to attach (will write over previously attached file if present):

Check if the Substantiation Document is CBI:

5. Once this has been completed, the buttons **[Previous]** and **[Submit]** will appear.

TSCA Certification

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.

- a. Click the **[Confirm]** button to begin the submission process.
- b. The form validation will identify any errors in the form. Otherwise, No Validation Errors Found will display
- c. Click the **[PDF Generation]** button to generate the PDF for the submission. The **[Regular PDF]** button will display any information marked as CBI while the **[Sanitized PDF]** button will provide such information, masked. The PDF(s) can be downloaded for external storage.



Validation

No validation errors were found. Click the "PDF Generation" button to continue the submission process.

6. Click the **[Sign, Encrypt and Submit]** button to access the eSignature Widget

PDF Generation

Click the "Regular PDF" or "Sanitized PDF" button to view a PDF of the Section 4 form. If you make no CBI claims, the two versions will be the same. Please do NOT send a copy of the PDF to the EPA. Click the "Sign, Encrypt, and Submit" button to complete the submission process.

7. Click **[Accept]**

I certify, under penalty of law that the information provided in this document is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

- a. Complete the eSignature Widget.
- b. Enter the Authentication Password and enter the Answer to the Verification Question.
- c. Click the **[Sign]** button to complete the submission.
- d. Click the **[X]** in the upper right corner of the eSignature Widget window to cancel the submission.

eSignature Widget

<p>1. Authentication</p> <p>Log into CDX</p> <p>User: JILLIANE.CONLEY</p> <p>Password: ●●●●●●●●</p> <p>Show Password <input type="checkbox"/></p> <p>Welcome Jilliane Conley</p>	<p>2. Verification</p> <p>Question: What was your high school's mascot?</p> <p>Answer: ●●●●</p> <p>Show Answer <input type="checkbox"/></p> <p>Correct Answer</p>	<p>3. Sign File</p> <p><input type="button" value="Sign"/></p>
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Submission Finished

The submission was sent to the EPA. The Copy of Record link allows you to download of the Copy of Record and signature for this submission. The Copy of Record link will appear in the Submissions list when the EPA receives and processes your submission. Click the "Home" button to go back to the Home screen.

[Home](#)

8. Click the **[Home]** button to return to the Section 4 Home Page.
 - a. Select Submissions at the top to view the Status of a submitted form.

8. Glossary

Consortia - Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions - Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without EPA participation. EPA has promulgated regulations that explain how EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 Orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an Order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR § 791.

Manufacturer - The term "manufacture" means to import into the customs territory of the United States, produce, or manufacture. 15 U.S.C. § 2602(9). Import also includes importing the chemical as an impurity in an article.

Processor - The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture. 15 U.S.C. § 2602(13).