

Upcoming Outreach

- All outreach events can also be found at:
 - <http://epa.gov/oppt/newchems/epmn/epmn-index.htm>
- **Today September 30, 2015 from 1:00 – 4:00 p.m.** The subjects will be discussion of Notice of Commencement (NOC), Biotech, Bona Fide, and SNUR Alternate Control Measures electronic submissions.
 - Conference phone number within the U.S. (877) 608-6616, outside the U.S. (706) 679-4304
 - Conference ID: **9369481**
 - Access the session at:
<https://epa.connectsolutions.com/nocbiotechbonafideacm/>





EPA

United States
Environmental Protection
Agency

Section 5 Notices and Supports Bona Fide Notice, Biotechnology, NOC, and ACM Demo

September 30, 2015

Office of Chemical Safety and Pollution Prevention

Agenda

Speaker: Dr. Kathryn Schechter, CESSD/ICB

- Manage eTSCA Thick Client Files
- Import XML
- Add/Manage Facilities
- Section 5 Notices and Supports Modules
 - Bona Fide Notice
 - Biotechnology
 - Notice of Commencement (NOC)
 - Alternative Control Measures (ACM)
- Resources
- Questions and Answers



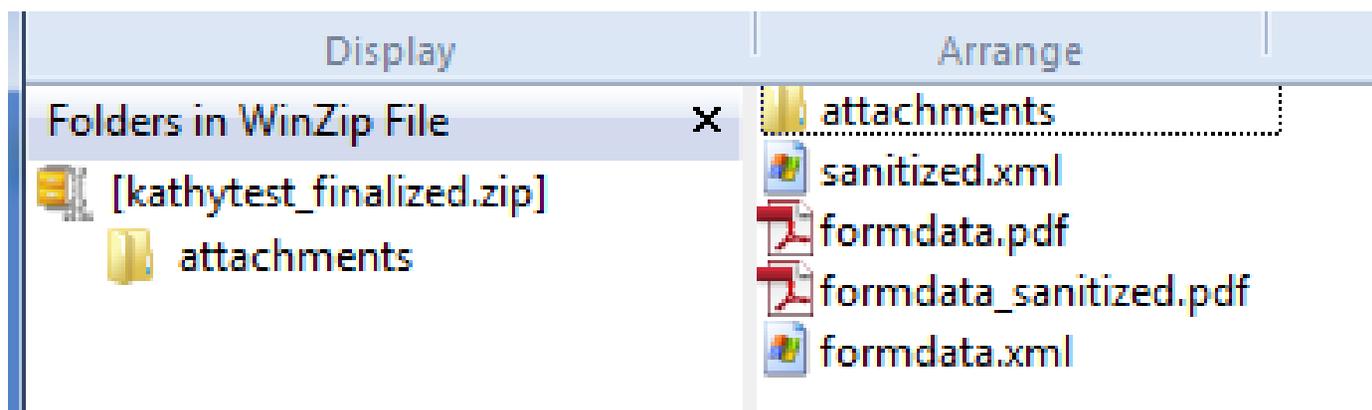
Manage eTSCA Thick Client Files

- There are 3 variations of files:
 - Draft file (editable, does not have form pdf or sanitized data)
 - Finalized file (read-only, contains form pdfs and sanitized data)
 - Copy of Record (read-only, contains form pdfs and sanitized data)



Manage eTSCA Thick Client Files, Continued

- The eTSCA thick client files can be opened with:
 - The eTSCA software (to see the data, print the pdf, open/export attachments)
 - WinZip (either right click and select “Open with” or change the extension to .zip)
 - Draft file will contain only xml and attachments
 - Finalized files and CoRs will contain:



Import XML

Import XML



Premanufacture Notice
Primary Authorized Official

Primary PMN-20150807-
09:47:26 EDT

Releases

 Remove

 Add Operation

Operations Controlled by Others

Operation 1

Industrial Sites
Controlled By
Others

Exposures/Releases

Byproduct
Information

 Remove

 Add Operation

Optional Pollution Prevention

Additional Attachments

Attachment Summary

Optional Cover Letter

Joint Submission

Joint Submission 1

Joint Submitter
Information

Joint Submission
Information

 Remove

 Add Joint Submission

Select the **Type of Notice** for the type of form you wish to file.

Premanufacture Notice (PMN)

PMN Identification

Please enter the TS Number and/or Payment ID (if applicable) that reference the specific form.

TS Number:

Payment ID:

Test Data

Select the **Test Data** that will be included in this notice.

Environmental fate data:	<input type="checkbox"/>	Risk assessments:	<input type="checkbox"/>
Health effects data:	<input type="checkbox"/>	Structure/Activity relationships:	<input type="checkbox"/>
Environmental effects data:	<input type="checkbox"/>	Other data:	<input type="checkbox"/>
Physical/Chemical properties:	<input type="checkbox"/>		
Test data not in the possession or control of the submitter:	<input type="checkbox"/>		

Identify whether any of the below options apply.

Check here if you are filing a joint PMN:

Check here if you have a Letter of Support pending:

Next

Upload XML


Validate


Save


Preview


Submit

Premanufacture Notice
Primary Authorized OfficialPrimary PMN-20150807-
09:47:26 EDT

- General Form Information
- User Fees Certification
- Agent Information
- Technical Contact Information
- Additional Submission Information

Chemicals**Chemical 1**

- Chemical Identification
- Class 1 or 2 Chemical Substances
- Class 2 Substances
- Additional Chemical Information
- Production Volume and Hazard/Safety Information
- Use Information

Physical & Chemical Properties

- Physical and Chemical Properties

UPLOAD XML

Click the Upload XML File button below and select the ZIP archive file you have populated with PMN information. This archive must contain your form XML in a file labeled 'formdata.xml'.

Please refer to the help text for guidance regarding multicomponent consolidated submissions.

[Upload archive file](#)

Warning: When importing an XML file into the current form, if XML validation is passed, all form contents will be overwritten with the information stored within the imported XML file.

[Export XML](#)[Upload XML](#)
Validate
Save
Preview
Submit

Upload XML File Types

- Upload XML applies to a PMN form only
- From data generated using the eTSCA Thick Client (filename.pmn_tsca)
 - Already in the proper format for importing
- From an XML file
 - Generated by the ePMN thin client (could be used to copy from PMN into another)
 - Name the file formdata.xml
 - Create a .zip file; add the formdata.xml file to the .zip file
- Modified XML Schema; generated by an outside source based on the Section 5 XML schema



Data Imported via Upload XML

- An XML file uploaded into an existing form overwrites the contents of the PMN form
- Imported data must still pass validation
- Items that are not imported:
 - Documents (these must be reattached)
 - Add identified sites to a CDX registration profile
 - Check populated data for completeness (including drop-down menus) and validate the form
- Note that imported data is only for the fielded data – attachments will need to be uploaded one at a time





EPA

United States
Environmental Protection
Agency

Adding/Managing Facilities

Office of Chemical Safety and Pollution Prevention

How To Manage Facilities

- For a facility to display as an option in a site drop-down menu, it must be added to the organization in CDX registration
- Facilities can be submitter controlled sites (including toll manufacturing sites) and sites controlled by others (US sites only)
 - Sites for Manufacturing
 - Sites for Processing
 - Sites for Use



How To Manage Facilities, Continued

- In MyCDX, click the 'Manage Your Program Services' button.
- Click the 'CSPP' program service for the organization.
- Click the 'Manage Facilities' link for the active user role.
- Search for a facility or click the 'Create New Facility' link.
- If the facility is not found, click the 'Create New Facility' link to enter the facility information.



CDX Central Data Exchange

[Contact Us](#)
Logged in as JANEDOEV (Log out)

[MyCDX](#) | [Inbox](#) | [My Profile](#) | [Role Sponsorship](#) | [Submission History](#)

Services			Manage
Status	Program Service Name	Role	
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Authorized Official	
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Authorized Official	

CDX Service Availability

[See the status for all program services](#)

News and Updates

No news/updates.

[Add Program Service](#)

[Manage Your Program Services](#)

CDX Help Desk: 888-890-1995 | (970) 494-5500 for International callers



CDX Central Data Exchange

[Contact Us](#)
Logged in as JANEDOEVER ([Log out](#))

You are here: [MyCDX](#)» Manage Program Services

Manage Program Services

[Add Program Service](#)

[Back to MyCDX](#)

[\[Expand All\]](#) [\[Collapse All\]](#)

Test Organization J, 123 Blueberry Lane, Fairfax, VA, US 22033, (703) 227-4019

CSPP: Submissions for Chemical Safety and Pesticide Programs

[+ Request New Role](#)

Role	Program ID	Status	Details
Primary Authorized Official	Facility ID: 86339	Active (Deactivate)	Manage Facilities
Secondary Authorized Official	Facility ID: MULTI-FACILITIES	Active (Deactivate)	Manage Facilities



Registration Information

Organization: CGI TEST COMPANY
Program Service: CSPP
Role: Primary Authorized Official

My Facilities

Add Facilities

Manage Facilities (4 facilities managed)

List View | Map View

The facilities selected for this data flow and role are listed below. You may add facilities by clicking the 'Add Facilities' button or tab. The ability to edit a facility is available from the 'Facility Details' screen which is accessible by clicking the 'Details' link for a facility in the table view or by clicking the 'Details' button on the map view. Please note that facilities with insufficient location information may not appear on the map view.

EPA Registry ID	Program ID	Facility Name	Facility Address	
110058130785	TSCA82040	AGGREGATE INDUSTRIES, INC.	25232 WILLARD ROAD CHANTILLY, VA 20152	Details Remove
110057220234	TSCA82041	AIR POWER, INC.	43694 JOHN MOSBY HIGHWAY CHANTILLY, VA 20152	Details Remove
110006457645	TSCA82042	AMERICAN AIRLINE, INC.	DULLES INTRNTL ARPT MIDFIELD CHANTILLY, VA 20152	Details Remove
110056520331	TSCA82043	AMG - VA, CHANTILLY	44180 WADE DRIVE CHANTILLY, VA 20152	Details Remove

Add Facilities

You are here: [MyCDX](#)» [Manage Program Services](#)» Manage Facilities

Registration Information

Organization	CGI TEST COMPANY
Program Service	CSPP
Role	Primary Authorized Official

My Facilities

Add Facilities

Find Existing Facility

[< Back to My Facilities](#)

Fill in at least two search criteria to improve search results.

Facility ID

Facility Name

Facility Address

City

State

ZIP Code

Search Facilities

My Facilities

Add Facilities

Facility Search Results (111 facilities found)

List View | [Map View](#)

[< Back to My Facilities](#)

Search Criteria: FAIRFAX, VA 22033

[Change](#)

<input type="checkbox"/>	EPA Registry ID	Facility Name	Facility Address	EPA Programs Reporting	Alternate EPA Registry IDs/Program IDs
<input checked="" type="checkbox"/>	110090093284	22033KTHYT235AK	12605 FAIR LAKES CIR FAIRFAX, VA 22033 i ?	TSCA	TSCA80601
<input checked="" type="checkbox"/>	110090083080	5000 PLEASE SAVE ME	5000 FRS SAVING PROPERLY BOULEVARD FAIRFAX, VA 22033 ?	TSCA	TSCA1481
<input type="checkbox"/>	110090085541	ABC CORPORATION	963 HIGHLAND DRIVE FAIRFAX, VA 22033 i ?	TSCA	TSCA1482
<input type="checkbox"/>	110090081322	ABC INDUSTRIES INC. (DBA ABC ENGRAVERS)	1000 QUEENS PKWYYYYYYYYYYYYYYY FAIRFAX, VA 22033 ?	TSCA	TSCA1483
<input type="checkbox"/>	110037446813	ABERCROMBIE & FITCH	11723 U FAIR OAKS MALL FAIRFAX, VA 22033 ?	TSCA	TSCA763
<input type="checkbox"/>	110037446822	ABERCROMBIE (KIDS)	11731 U FAIR OAKS MALL FAIRFAX, VA 22033 ?	TSCA	TSCA1484

[Proceed with Selections](#)

[Create New Facility](#)

1

2

3

4

5

>

>>|

Registration Information

Organization CGI TEST COMPANY
Program Service CSPP
Role Primary Authorized Official

[My Facilities](#)

[Add Facilities](#)

[Unsaved Facilities](#)

Selected Facilities (1 unsaved facility)

[List View](#) | [Map View](#)

[< Add Additional Facilities](#)

Clicking the 'Save Selected Facilities' button saves the facilities you have selected in the current session so they are available to you the next time you log in. The ability to edit a facility is available from the 'Facility Details' screen which is accessible by clicking the 'Details' link or button for a facility. You may also remove individual facilities by clicking the 'Remove' link or button for a particular facility. Please note that facilities with insufficient location information may not appear on the map view.

EPA Registry ID [?]	Program ID [?]	Facility Name	Facility Address	
110005251324	TSCA88	WORTMAN INC T/A BRIAR OAKS EXXON	12306 LEE JACKSON HWY FAIRFAX, VA 22033	Details Remove

[Save Selected Facilities](#)

[My Facilities](#)[Add Facilities](#)

Manage Facilities (5 facilities managed)

[List View](#) | [Map View](#)

The facilities selected for this data flow and role are listed below. You may add facilities by clicking the 'Add Facilities' button or tab. The ability to edit a facility is available from the 'Facility Details' screen which is accessible by clicking the 'Details' link for a facility in the table view or by clicking the 'Details' button on the map view. Please note that facilities with insufficient location information may not appear on the map view.

EPA Registry ID  	Program ID  	Facility Name 	Facility Address 	
110058130785	TSCA82040	AGGREGATE INDUSTRIES, INC.	25232 WILLARD ROAD CHANTILLY, VA 20152 	Details Remove
110057220234	TSCA82041	AIR POWER, INC.	43694 JOHN MOSBY HIGHWAY CHANTILLY, VA 20152 	Details Remove
110006457645	TSCA82042	AMERICAN AIRLINE, INC.	DULLES INTRNTL ARPT MIDFIELD CHANTILLY, VA 20152 	Details Remove
110056520331	TSCA82043	AMG - VA, CHANTILLY	44180 WADE DRIVE CHANTILLY, VA 20152 	Details Remove
110005251324	TSCA88	WORTMAN INC T/A BRIAR OAKS EXXON	12306 LEE JACKSIN HWY FAIRFAX, VA 22033	Details Remove

[Add Facilities](#)

Facility Search Results (110 facilities found)

[List View](#) | [Map View](#)[< Back to My Facilities](#)**Search Criteria:** FAIRFAX, VA 22033[Change](#)

<input type="checkbox"/>	EPA Registry ID	Facility Name	Facility Address	EPA Programs Reporting	Alternate EPA Registry IDs/Program IDs
<input type="checkbox"/>	110090093284	22033KTHYT235 AK	12605 FAIR LAKES CIR FAIRFAX, VA 22033  	TSCA	TSCA80601
<input type="checkbox"/>	110090083080	5000 PLEASE SAVE ME	5000 FRS SAVING PROPERLY BOULEVARD FAIRFAX, VA 22033 	TSCA	TSCA1481
<input type="checkbox"/>	110090085541	ABC CORPORATION	963 HIGHLAND DRIVE FAIRFAX, VA 22033  	TSCA	TSCA1482
<input type="checkbox"/>	110090081322	ABC INDUSTRIES INC. (DBA ABC ENGRAVERS)	1000 QUEENS PKWYYYYYYYYYYYYYYY FAIRFAX, VA 22033 	TSCA	TSCA1483
<input type="checkbox"/>	110037446813	ABERCROMBIE & FITCH	11723 U FAIR OAKS MALL FAIRFAX, VA 22033 	TSCA	TSCA763
<input type="checkbox"/>	110037446822	ABERCROMBIE (KIDS)	11731 U FAIR OAKS MALL FAIRFAX, VA 22033 	TSCA	TSCA1484

[Create New Facility](#)

1

2

3

4

5

>

>>|

My Facilities

Add Facilities

Create Facility

[< Back to Search Results](#)

Program Acronym CDX: CSPP - FRS: TSCA

Facility Name

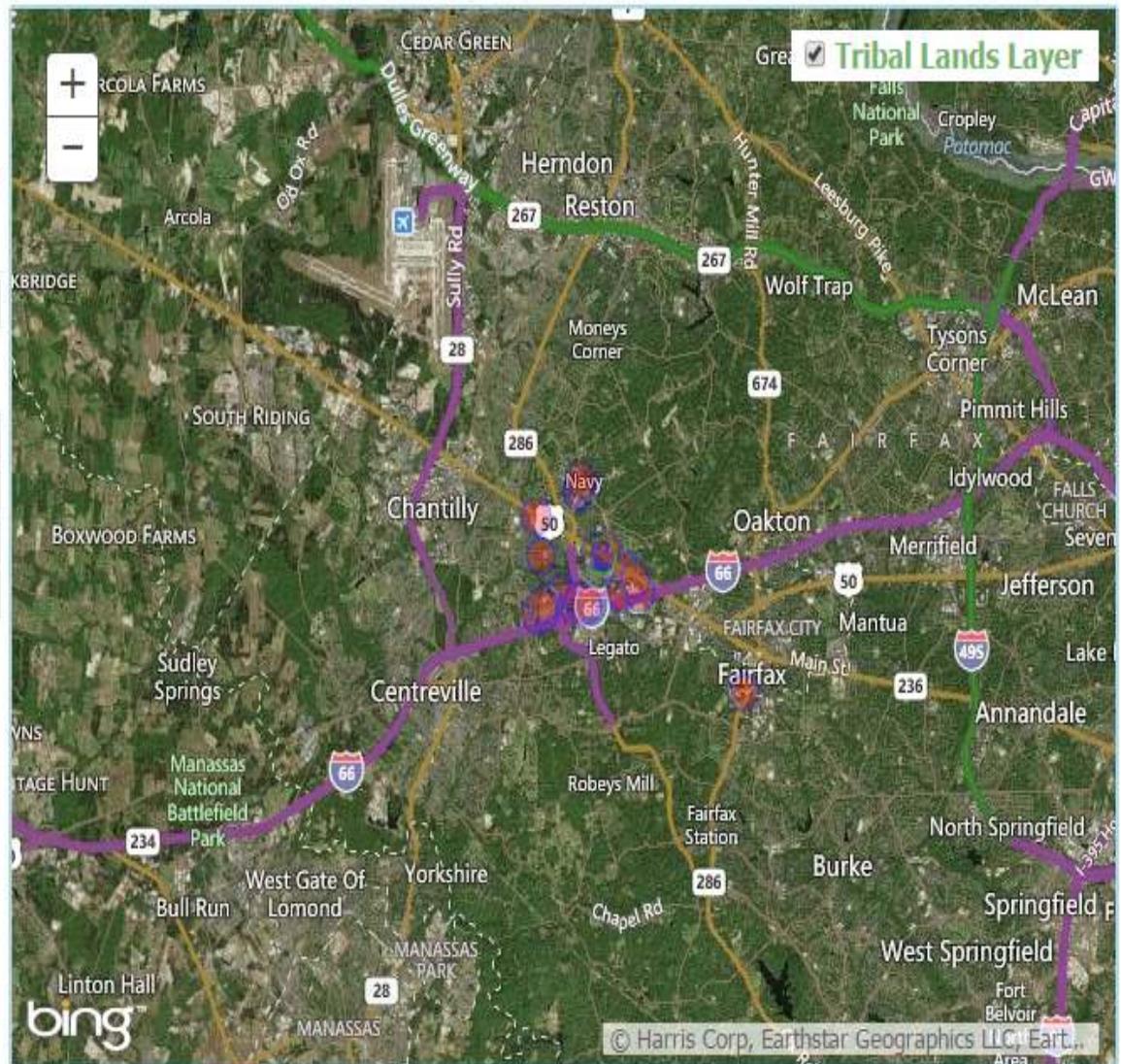
Facility Address

Address 1

Address 2

Fairfax VA 22033

-Select a County-



Map Legend

Map Facility

My Facilities

Add Facilities

Create Facility

[< Back to Search Results](#)

Program Acronym CDX: CSPP - FRS: TSCA

Facility Name

Test Facility Z

Facility Address

2600 LEMONTREE LN

Address 2



Address not found. Standardized address and point on the map shown for the closest nearby address. Please verify standardized address and move the point on the map to the correct location (center of facility).

OK

Submit

Map Legend

My Facilities

Add Facilities

Create Facility

[< Back to Search Results](#)

Program Acronym CDX: CSPP - FRS: TSCA

Facility Name

CGI

Facility Address

12601 FAIR LAKES CIR

Address 2

FAIRFAX

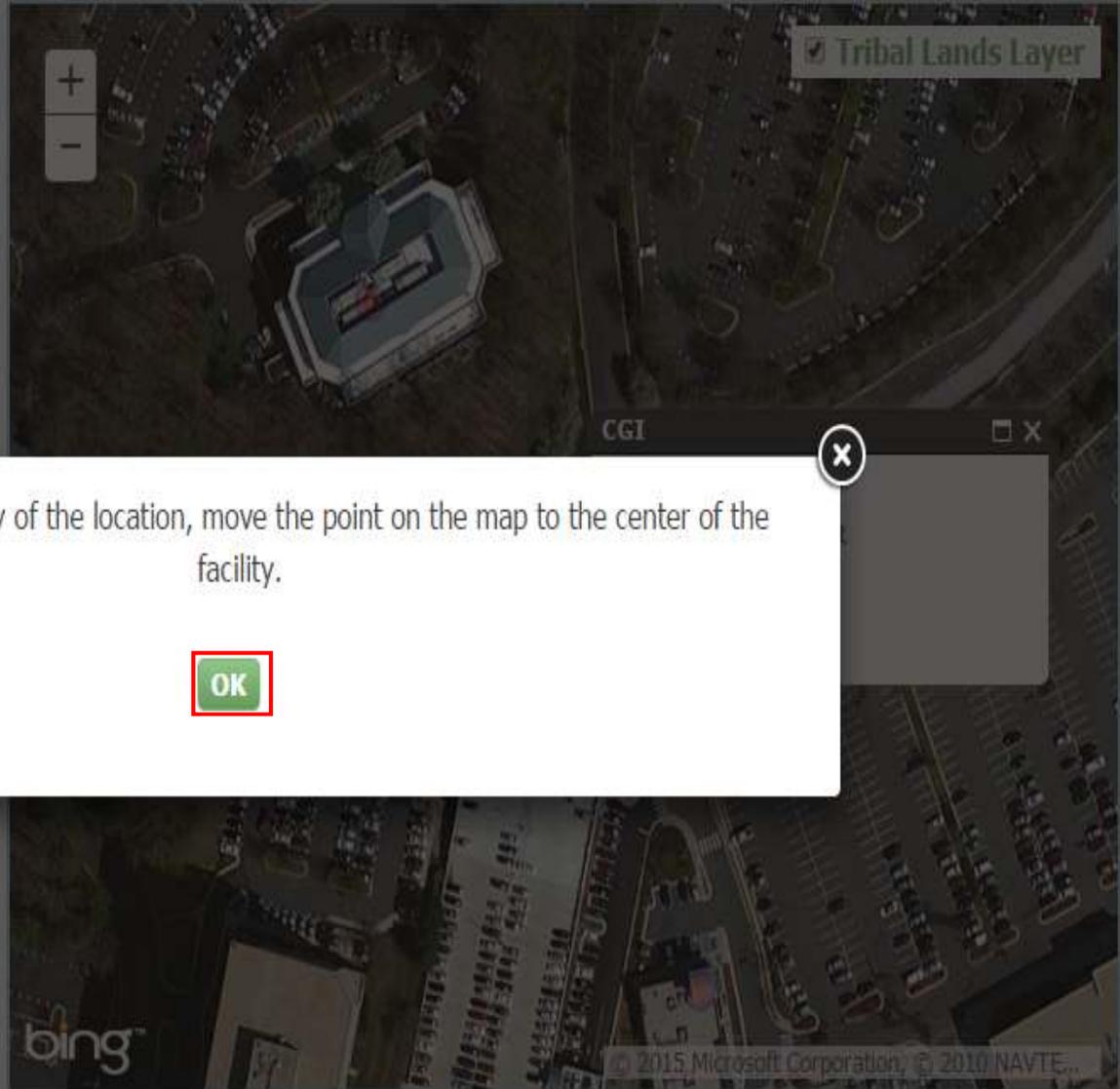
FAIRFAX COUNTY

Standardized - Und

- 12601 Fair Lakes Cir

- Fairfax, VA 22033

- FAIRFAX COUNTY



To improve the accuracy of the location, move the point on the map to the center of the facility.

OK

Map Legend

Submit

My Facilities

Add Facilities

Create Facility

[< Back to Search Results](#)

Program Acronym CDX: CSPP - FRS: TSCA

Facility Name

CGI

Facility Address

12601 FAIR LAKES CIR

Address 2

FAIRFAX VA 22033

FAIRFAX COUNTY

[↻ Standardized - Undo Change](#)

- 12601 Fair Lakes Circle
- Fairfax, VA 22033
- FAIRFAX COUNTY



▶ [Map Legend](#)

Submit

The page at https://dev.epacdx.net says:

Current Reference Code: 025
Current Collection Method: 018
Accuracy: 2
scale: 1754.45794
Latitude: 38.858264
Longitude: -77.381584

OK

My Facilities

Add Facilities

Create Facility

[< Back to Search Results](#)

Program Acronym CDX: CSPP - FRS: TS

Facility Name

CGI

Facility Address

12601 FAIR LAKES CIR

Address 2

FAIRFAX VA 22033

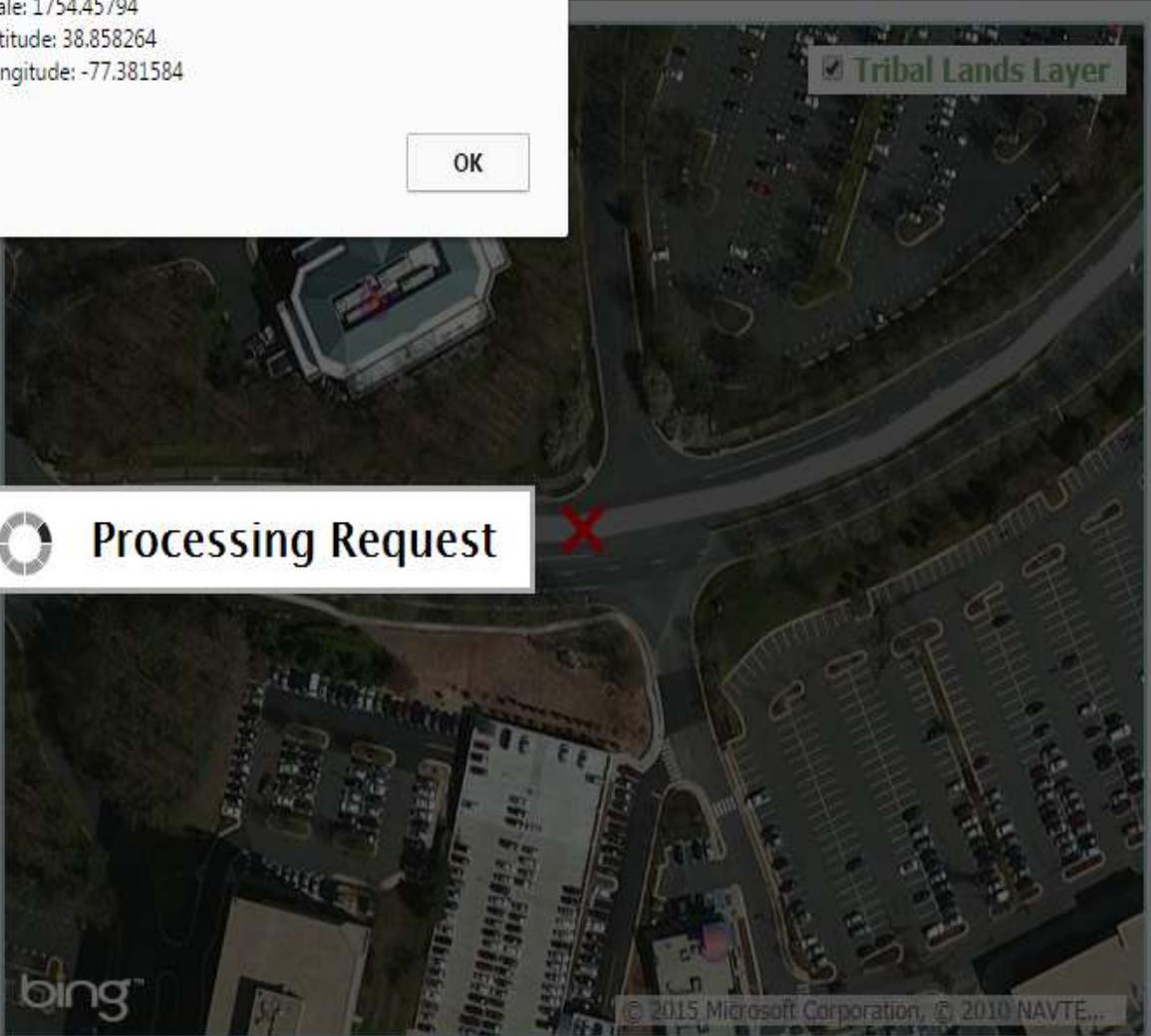
FAIRFAX COUNTY

↻ [Standardized - Undo Change](#)

- 12601 Fair Lakes Circle
- Fairfax, VA 22033
- FAIRFAX COUNTY

Submit

 Processing Request 



Map Legend

Registration Information

Organization	CGI TEST COMPANY
Program Service	CSPP
Role	Primary Authorized Official

[My Facilities](#)

[Add Facilities](#)

[Unsaved Facilities](#)

Selected Facilities (1 unsaved facility)

[List View](#) | [Map View](#)

[< Add Additional Facilities](#)

Clicking the 'Save Selected Facilities' button saves the facilities you have selected in the current session so they are available to you the next time you log in. The ability to edit a facility is available from the 'Facility Details' screen which is accessible by clicking the 'Details' link or button for a facility. You may also remove individual facilities by clicking the 'Remove' link or button for a particular facility. Please note that facilities with insufficient location information may not appear on the map view.

EPA Registry ID ?	Program ID ?	Facility Name	Facility Address	
<i>Pending</i>	<i>Pending</i>	CGI	12601 FAIR LAKES CIR FAIRFAX, VA 22033 FAIRFAX COUNTY	Details Remove

[Save Selected Facilities](#)

[My Facilities](#)[Add Facilities](#)

Manage Facilities (6 facilities managed)

[List View](#) | [Map View](#)

The facilities selected for this data flow and role are listed below. You may add facilities by clicking the 'Add Facilities' button or tab. The ability to edit a facility is available from the 'Facility Details' screen which is accessible by clicking the 'Details' link for a facility in the table view or by clicking the 'Details' button on the map view. Please note that facilities with insufficient location information may not appear on the map view.

EPA Registry ID  	Program ID  	Facility Name 	Facility Address 	
110058130785	TSCA82040	AGGREGATE INDUSTRIES, INC.	25232 WILLARD ROAD CHANTILLY, VA 20152 	Details Remove
110057220234	TSCA82041	AIR POWER, INC.	43694 JOHN MOSBY HIGHWAY CHANTILLY, VA 20152 	Details Remove
110006457645	TSCA82042	AMERICAN AIRLINE, INC.	DULLES INTRNTL ARPT MIDFIELD CHANTILLY, VA 20152 	Details Remove
110056520331	TSCA82043	AMG - VA, CHANTILLY	44180 WADE DRIVE CHANTILLY, VA 20152 	Details Remove
110090085907	TSCA85900	CGI	12601 FAIR LAKES CIR FAIRFAX, VA 22033 FAIRFAX COUNTY	Details Remove
110005251324	TSCA88	WORTMAN INC T/A BRIAR OAKS EXXON	12306 LEE JACKSIN HWY FAIRFAX, VA 22033	Details Remove

[Add Facilities](#)

Section 5 Notices and Supports Demo

- Section 5 Notices and Supports Tool Demo for the Bona Fide Notice, Biotechnology, NOC, and ACM modules



Demo of Section 5 Notices and Supports Web Tool

- CDX Login
- Chemical Information Submission System
- Home
- Section 5 Notices and Supports Forms
 - Bona Fide Notice
 - Biotechnology
 - Notice of Commencement (NOC)
 - Alternative Control Measures (ACM)
- Resources



Demo of Section 5 Notices and Supports Tool



Demo of Section 5 Notices and Supports Web Tool

CSPP Primary Authorized Official



Office of Chemical Safety and Pollution Prevention
Call-In: 1-877-608-6616 Access Code: 9369481 |



Log in to CDX

User ID

Password

[Log In](#)

[Register with CDX](#)

[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;

CDX Central Data Exchange

[Contact Us](#)
Logged in as JANEDOEOPPT ([Log out](#))

[MyCDX](#) | [Inbox](#) | [My Profile](#) | [Submission History](#)

Services Manage		
Status	Program Service Name	Role
	CROMERRTEST: CROMERR Test Sandbox	Development Sandbox
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Authorized Official
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Authorized Official
	TRIMEweb: Toxic Release Inventory Made Easy Web	TRI-MEweb
	TSCA: TSCA	PMN Client Download and View Support Registrants

CDX Service Availability

[See the status for all program services](#)

News and Updates

No news/updates.

[Add Program Service](#) | [Manage Your Program Services](#)



CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN

OK

Section 5 of TSCA, EPA's New Chemicals Program, helps manage the potential risk to human health and the environment from chemicals prior to entry to the marketplace. Anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by Section 5 of TSCA to provide EPA with notice before initiating the activity. A Premanufacture Notice, or PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical. Additional notice types which use the PMN form are listed to reflect different circumstances under which a chemical may be manufactured or imported such as Significant New Use Notices (SNUN), Low Volume Exemptions (LVE), Test Market Exemption Applications (TMEA), and Low Volume and Low Release Exemptions (LoREX). Biotechnology notice forms will be used to submit Microbial Commercial Activity Notices (MCAN), TSCA Experimental Release Applications (TERA), Tier 1 Exemptions, Tier 2 Exemptions, and Biotechnology Test Market Exemption Applications (Biotechnology TMEA). For a PMN or MCAN, the manufacturing or importing company must also notify EPA via a Notice of Commencement within 30 days after the start of the first manufacture or import of the chemical for non-exempt commercial purposes. To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ("Bona Fide Notice").

Please note: The public reporting and recordkeeping burden for this collection of information is estimated to average 93 hours per response for PMN, SNUN, LVE, and LOREX applications (TMEA is estimated to average 88 hours per response), including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The public reporting and recordkeeping burden for this collection of information is estimated to average 290 hours per response for MCAN applications and the NOC is estimated to average 0.8 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form (7710-25) (PMN) or Form 6300-14 (Biotechnology) or Form 7710-56 (NOC) to this address.

The software includes submission forms, embedded help files and a downloadable user manual to guide you through the Section 5 Notices and Supports submission process. Click OK to complete a Section 5 Notices and Supports reporting form, using the Section 5 Notices and Supports software. If you are not reporting on Section 5 Notices and Supports, please select a different application in the drop-down menu.

HOME



Forms

The TSCA Section 5 Notices and Supports Reporting rule requires anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity.

Use the following forms to report new chemicals to EPA: Premanufacture Notice form (EPA Form 7710-25) should be used to submit PMNs, LVEs, SNUNs, LOREXs, TMEAs, Modifications for LVEs and LoREX submissions; Biotechnology Notice form (EPA Form 6300-14) should be used to submit MCANs, TERAs, Tier I Exemptions, Tier 2 Exemptions, and Biotechnology TMEAs; Notice of Commencement form (NOC, EPA Form 7710-56) should be used to submit Notices of Commencement for PMNs and MCANs; ACM 40 CFR 721.30 form (TBD) should be used to report proposed Alternative Control Measures for published SNURs; or Bona Fide Notice (TBD) for any requests to determine if a chemical is on the TSCA inventory. The Support form is used to submit supplemental information for Premanufacture and Biotechnology notices, such as Test Data, Correspondences, and Amendments to older submissions.

To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ('Bona Fide Notice').

User Management

Manage the access rights of Support persons (including Agents/Consultants) for each Section 5 Notices and Support form.

Resources

Displays links to helpful guidance documents and websites for TSCA and Section 5.

Authorized Official

An Authorized Official has the ability to create, delete, amend, unlock, and submit all Section 5 Notices and Support forms electronically to EPA. The Authorized Official also has the ability to assign Supports (including Agents/Consultants) to individual forms.

Demo of Section 5 Notices and Supports Web Tool

Bona Fide Notice



Office of Chemical Safety and Pollution Prevention
Call-In: 1-877-608-6616 Access Code: 9369481 |

SECTION 5 NOTICES AND SUPPORTS FORMS



- If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click **Start New Form**.
- To edit an In Progress form, click the form alias link in the Alias column in the table below.
- To access and edit a form previously submitted through CDX, unlock the form by clicking the lock () icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.
- To download a copy of record for a submitted form, click the green arrow () icon and enter the passphrase when prompted.
- You may delete any form that has not yet been submitted by clicking the delete () icon.
- All columns may be sorted by clicking the column header.

10 items found.

Page 1 of 1

Items Per Page:

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Copy of Record	Action
ACM-20141202-08:58:13 EST	ACM		ACM-14-0062	In Progress	01/07/2015	12/31/2014		
Biotechnology-20141202-08:53:54 EST	Biotechnology	TERA		In Progress	01/07/2015			
Bona Fide-20141202-08:57:56 EST	Bona Fide		BF-15-0019	In Progress	01/07/2015	01/06/2015		
NOC-20141202-08:50:01 EST	NOC			In Progress	01/07/2015			
Primary PMN-20141202-08:50:01 EST	Primary PMN	PMN		In Progress	01/14/2015			

Bona Fide-20141202-08:57:56 EST	Bona Fide		BR-15-0019	In Progress	01/07/2015	01/06/2015		
NOC-20141202-08:50:01 EST	NOC			In Progress	01/07/2015			✗
Primary PMN-20141201-11:36:29 EST	Primary PMN	PMN		In Progress	01/14/2015			✗
Primary PMN-20141231-11:57:16 EST	Primary PMN	LOREX		In Progress	01/06/2015			✗
Primary PMN-20150729-16:50:24 EDT	Primary PMN	LVE_MODIFICA TION	LM-15-0006, LM- 15-0007	Submitted	07/30/2015	07/30/2015	↓	🔒
Support-20141202-08:48:56 EST	Support	Other Correspondence	P-15-0001	Submitted	12/23/2014	12/23/2014	↓	🔒
Support-20141231-09:02:07 EST	Support	Suspension Request	P-15-0001	In Progress	12/31/2014			✗
Support-20150730-10:43:07 EDT	Support			In Progress	07/30/2015			✗

Export options:  CSV |  Excel |  XML |  PDF

Select the form type and then click **Start New Form**
 Form Type:

Start New Form

CREATE PASSPHRASE

Please create a passphrase that is at least 8 characters in length. To better protect your form, your passphrase should contain a combination of letters and numbers. Your passphrase may include spaces, but should not contain special characters (for example, +, ?, and *).

New Passphrase:

Confirm New Passphrase:

As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized Supports.

Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

[Cancel](#)

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Bona Fide (Bona Fide-20150730-15:15:17 EDT) > General Document Information

GENERAL DOCUMENT INFORMATION

The form alias is a required field that allows the user to give the Bona Fide a name to be displayed in the 'Alias' field on the Section 5 Notices and Supports Forms screen. Its purpose is to make it easier for you to distinguish between multiple forms. If an alias is not selected, the field will default to the date and time the Bona Fide was created. The form alias may be changed at any time.

Form Alias:

Please check all applicable checkboxes below:

This Bona Fide Notice can be claimed entirely as Confidential Business Information (CBI). Please check the 'I claim the entirety of the submission as CBI' checkbox to claim your entire submission as CBI.

I claim the entirety of the submission as CBI:

The technical contact is a subject matter expert (SME) who is capable of answering questions related to the chemical within the Bona Fide. The technical contact does not have to physically work at the site reported but must possess extensive knowledge on the chemical reported in order to answer EPA's questions pertaining to the submission. Please check the 'Technical Contact' checkbox below to identify a technical contact for your submission.

Technical Contact:

The 'Letter of Support' screen is used to enter contact information regarding the Letter of Support submitter who will submit information separately for the Bona Fide. The email address will be used to send the secondary submitter the unique identification number to tie the Letter of Support, completed by



Validate



Save



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Please check all applicable checkboxes below:

This Bona Fide Notice can be claimed entirely as Confidential Business Information (CBI). Please check the 'I claim the entirety of the submission as CBI' checkbox to claim your entire submission as CBI.

I claim the entirety of the submission as CBI:

The technical contact is a subject matter expert (SME) who is capable of answering questions related to the chemical within the Bona Fide. The technical contact does not have to physically work at the site reported but must possess extensive knowledge on the chemical reported in order to answer EPA's questions pertaining to the submission. Please check the 'Technical Contact' checkbox below to identify a technical contact for your submission.

Technical Contact:

The 'Letter of Support' screen is used to enter contact information regarding the Letter of Support submitter who will submit information separately for the Bona Fide. The email address will be used to send the secondary submitter the unique identification number to tie the Letter of Support, completed by the secondary submitter, to the primary Bona Fide completed by the primary submitter. Please check the 'Letter of Support' checkbox below to identify a Letter of Support submitter.

Letter of Support:

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← [Bona Fide \(Bona Fide-20150730-15:15:17 EDT\)](#) > [Primary Contact Information](#)

PRIMARY CONTACT INFORMATION

The primary contact fields have been pre-populated based on the information you provided during CDX registration but may be edited if necessary. The 'Job Title' field is required.

Prefix:	<input type="text" value="Miss"/>
First Name:	<input type="text" value="Jane"/>
Middle Initial:	<input type="text" value="E"/>
Last Name:	<input type="text" value="Doe"/>
Suffix:	<input type="text"/>
Title:	<input type="text"/>
Company Name:	<input type="text" value="TEST COMPANY"/>
Phone Number:	<input type="text" value="8888901995"/> <small>(Do not enter any dashes (-) in Phone Number field above.)</small>
Phone Extension:	<input type="text" value="12345"/>
Email Address:	<input type="text" value="Jane.Doe@test.com"/>
Mailing Address 1:	<input type="text" value="12601 FAIR LAKES CIRCLE"/> <small>Street address, P.O. box, company name, etc.</small>
Mailing Address 2:	<input type="text"/> <small>Apartment, suite, etc.</small>
City:	<input type="text" value="FURRY"/>



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First Name:

Middle Initial:

Last Name:

Suffix:

Title:

Company Name:

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

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

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← Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Technical Contact Information

TECHNICAL CONTACT INFORMATION

Please enter the information for the technical contact who will be responsible for providing additional information if required.

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Title:

Company Name:

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

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:



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Middle Initial:

Last Name:

Suffix: ▼

Title:

Company Name:

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

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State: ▼

Postal Code:

Country:

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Bona Fide
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← [Bona Fide \(Bona Fide-20150730-15:15:17 EDT\)](#) > [Statement of Intent](#)



STATEMENT OF INTENT

Please select whether you intend to manufacture and/or import the chemical.

Manufacture:

Import:

Date of expected Section 5 notification if the result is that the chemical is not on the inventory.

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Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Letter of Support Submitter Information

LETTER OF SUPPORT SUBMITTER INFORMATION

Please enter the contact information for the Letter of Support submitter who will be completing the Letter of Support.

Prefix:	<input type="text"/>
First Name:	<input type="text"/>
Middle Initial:	<input type="text"/>
Last Name:	<input type="text"/>
Suffix:	<input type="text"/>
Title:	<input type="text"/>
Company Name:	<input type="text"/>
Phone Number:	<input type="text"/>
	(Do not enter any dashes (-) in Phone Number field above.)
Phone Extension:	<input type="text"/>
Email Address:	<input type="text"/>
Mailing Address 1:	<input type="text"/>
	Street address, P.O. box, company name, etc.
Mailing Address 2:	<input type="text"/>
	Apartment, suite, etc.
City:	<input type="text"/>
State:	<input type="text"/>
Postal Code:	<input type="text"/>
Country:	<input type="text"/>

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← Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Letter of Support Submission Information

LETTER OF SUPPORT SUBMISSION INFORMATION

Please include instructions you wish the Letter of Support submitter to see. Clicking the link below will relay the information in this text box to your Letter of Support submitter via **unencrypted e-mail**.

Unique Identifier for Letter of Support Submission: f1c344b9-3bc5-4dba-aa20-9e8b148e4f22

This is the unique identification number for your joint submitter. [Notify the Secondary Submitter of the letter of support submission](#).

The Secondary Submitter will need this identification number to complete the form. It is your responsibility to ensure that your secondary submitter understands how to complete the Bona Fide form and sends the information to EPA by the end of the submission period. The information collected in the primary and secondary form(s) will be linked by the unique identifier. The form will not undergo a review process until all forms have been received.

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- Primary Comment
- Technical Document
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- Letter of Support Submission
- Letter of Support Submission
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- Chemical Information
- Site Information
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- Document
- Optional Comment

From: Jane.Doe@test.com

CC:

To:
Enter email addresses separated by semicolons (;) or commas (,). Click in this box to start entering email addresses.

Subject: 2016 Bona Fide

Message: As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a letter of support submission for this 2016 Bona Fide form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Bona Fide form for the letter of support submission. Unique Identifier f1c344b9-3bc5-4dba-aa20-9e8b148e4f22

Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.

Additional Comments:

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← [Bona Fide \(Bona Fide-20150730-15:15:17 EDT\)](#) > [Chemical Identification Information](#)

CHEMICAL IDENTIFICATION INFORMATION

Chemical Type

Complete either item 1 (Class 1 or 2/Biotechnology Chemical Substance) or 2 (Polymer) as appropriate. Indicate which selection you intend to complete below.

Class 1 or 2/Biotechnology Chemical Substance Polymer

Chemical Alias:

The chemical alias is an optional field that changes the folder name in the navigation tree on the left-hand side of the screen.

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[Bona Fide \(Bona Fide-20150730-15:15:17 EDT\) > Class 1 or 2/Biotechnology Chemical Substances](#)**CLASS 1 OR 2/BIOTECHNOLOGY CHEMICAL SUBSTANCES****Class 1 or 2/Biotechnology Chemical Substances
Chemical Identification Information**[Expand All](#) | [Collapse All](#)

[Cancel](#)

Class of Substance: Class 1 Class 2/Biotechnology

Click the button below to search EPA's Substance Registry Services (SRS) for the desired chemical.

Add Chemical ID

CASRN:
Chemical Name:

ID Method
 Method 1 (CAS Inventory Expert Service) Method 2 (Other Method)

Attach IES Report

File Name	Description	Actions
-----------	-------------	---------

Molecular Formula: (optional)

Chemical Structure Diagram: (optional)
Include an attachment for the chemical structure diagram below.

Attach Chemical Structure

File Name	Description	Actions
-----------	-------------	---------

Save

Click the Add New Chemical button to add chemical name and structural information for a new chemical.

Add New Chemical[Previous](#)[Next](#)

Validate



Save



Preview



Submit



ADD CHEMICAL ID

Enter the specific or partial, currently correct Chemical Abstracts (CA) Index name and/or the corresponding Chemical Abstract Services Registry Number (CASRN). Click Search and select the appropriate CA Index name/CASRN combination.

Please note a result does not imply the chemical is on the TSCA inventory.

Please search by CASRN or CA Index Name

1. CASRN:	Matches exactly	<input type="text"/>
2. CA Index Name or Other Synonym:	Begins with <input type="text"/>	<input type="text"/>
		<input type="button" value="Search"/>

Please enter the chemical name and CASRN if not found.

Chemical Name:

CASRN:



ATTACH IES REPORT

Attach the IES Report below

Type

Other

Attachment

Select the file to attach

File:

Browse

Description

Provide a description of the attachment

Cancel

OK



ATTACH CHEMICAL STRUCTURE

Attach the chemical structure document below

Type

Attachment

Select the file to attach

File:

Description

Provide a description of the attachment

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← Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Class 2/Biotechnology Substances

CLASS 2/BIOTECHNOLOGY SUBSTANCES

Class 2/Biotechnology Substance Details

Fill in below for a class 2/biotechnology substance. (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition (where appropriate).

Precursor Substances

Search SRS Click the Search SRS button on the left to search or enter a precursor substance.

Chemical Name	CASRN	Action
---------------	-------	--------

Nature of Reaction

Range of Composition (Optional)

Optional Attachments

Attach Document

File Name	Description	Action
-----------	-------------	--------

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SEARCH SUBSTANCE REGISTRY SERVICES

Enter the specific or partial, currently correct Chemical Abstracts (CA) Index name as listed on the TSCA Inventory and/or the exact corresponding Chemical Abstract Services Registry Number (CASRN). Click Search and select the appropriate CA Index name/CASRN combination from EPA's Substance Registry Services (SRS).

Please search by CASRN or CA Index Name

1. CASRN:	Matches exactly	<input type="text"/>
2. CA Index Name or Other Synonym:	Begins with <input type="text"/>	<input type="text"/>
		<input type="button" value="Search SRS"/>

Please enter the chemical name and CASRN if not found if not found in SRS.

Chemical Name:

CASRN:

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Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Polymer Identification Information

POLYMER IDENTIFICATION INFORMATION

[Expand All](#) | [Collapse All](#)

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 - Chemical 23626**
 - Polymer Identification Information**
 - Monomers and Other Reactants
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[Cancel](#) 

Click the button below to add a substance to this document.

Add Chemical ID

CASRN:
Chemical Name:

ID Method

Method 1 (CAS Inventory Expert Service) Method 2 (Other Method)

Chemical Structure Diagram (optional):
Include an attachment for the chemical structure diagram below.

Attach Chemical Structure

File Name	Description	Actions
Save		

Click the Add New Chemical button to add chemical name and structural information for a new chemical.

Add New Chemical

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← Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Monomers and Other Reactants

MONOMERS AND OTHER REACTANTS

Select the Add Monomer button to add monomers that make up the polymer composition.

[Expand All](#) | [Collapse All](#)

Cancel

Click the button below to search EPA's Substance Registry Services (SRS) for the desired chemical.

Search SRS

CAS Registry Number:
Monomer or other reactant:

Include in Identity:

Typical Composition: %

Save

Click to add a monomer **Add Monomer**

Composition Total:0%

Optional Attachments

Attach Document

File Name	Description	Actions
-----------	-------------	---------

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← [Bona Fide \(Bona Fide-20150730-15:15:17 EDT\)](#) > [Use Information](#)

USE INFORMATION

How will the substance be used?

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← Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Submitter Site Identification

SUBMITTER SITE IDENTIFICATION

Site of Manufacture or Port of Entry:
Please identify a site for reporting or port of entry.

[Add Site](#)

List of Submitter Sites

EPA Registry ID	Site of Manufacture or Port of Entry	Site Name	Address	Actions

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ADD SITE

Select a site from the drop-down menu below:

EPA Registry ID:

Facility Name:

Facility Address:

City:

State:

Postal Code:

Site Type:

Add Site

Cancel

Actions

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Bona Fide (Bona Fide-20150730-15:15:17 EDT) > Document Management

DOCUMENT MANAGEMENT

Please attach at least one of each of the following documents:

- **Spectrum of Substance:** Infrared spectrum or alternative spectra or other data which identify the substance.
- **Statement of Commercialization:** 1) A brief statement indicating how long the substance has been in commercial use outside of the United States. 2) The name of a country in which it has been commercially used. 3) Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.
- **Statement of Research and Development:** A brief description of the research and development activities conducted to date related to the substance.

You can also attach other documents.

[Attach Document](#)

Document Name	Document Type	Action
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← [Bona Fide \(Bona Fide-20150730-15:15:17 EDT\)](#) > [Optional Cover Letter](#)

OPTIONAL COVER LETTER

If you would like to include a cover letter, please use the space below.

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Demo of Section 5 Notices and Supports Web Tool

Biotechnology



Office of Chemical Safety and Pollution Prevention
Call-In: 1-877-608-6616 Access Code: 9369481 |



CREATE PASSPHRASE

Please create a passphrase that is at least 8 characters in length. To better protect your form, your passphrase should contain a combination of letters and numbers. Your passphrase may include spaces, but should not contain special characters (for example, +, ?, and *).

New Passphrase:

Confirm New Passphrase:

As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized Supports.

Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

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Biotechnology
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- [General Form Information](#)
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Biotechnology (Biotechnology-20150730-16:35:04 EDT) > General Form Information

GENERAL FORM INFORMATION

You may enter an alias for easier form identification or the system will provide a time stamp.

Form Alias:

III. Type of Submission:

TS Number:

IV. Text/Comments CBI:

Please describe the submission and/or attachment.

Please provide your Biotech submission information in one or more attachments.

Attach Document

File Name	Description	Pages	CBI	Actions
	Check here if you are filing a consolidated Biotechnology form:	<input type="checkbox"/>	Number of Microorganisms: <input type="text"/> (2-20)	
	Check here if you are filing a joint Biotechnology form:	<input type="checkbox"/>		
	Check here if you have a Letter of Support pending:	<input type="checkbox"/>		

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Biotechnology
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← [Biotechnology \(Biotechnology-20150730-16:35:04 EDT\)](#) > [Joint Submitter Information](#)

JOINT SUBMITTER INFORMATION

Please enter the information for the joint submitter who will be responsible for supporting the information on the form. Check to claim information as CBI.

Check here to claim this information as CBI:

First Name:

Last Name:

Position:

Company Name:

Phone Number:

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

Phone Extension:

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country: United States

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 - Joint Submitter Information
 - Joint Submission Information
 - Add Joint Submission
- Letter Of Support
 - Letter of Support 1
 - Letter of Support Submitter Information
 - Letter of Support Submission Information
 - Remove
 - Add Letter Of Support
- Technical Contact Information
- Optional Cover Letter

Biotechnology (Biotechnology-20150730-16:35:04 EDT) > Joint Submission Information

JOINT SUBMISSION INFORMATION

Please include instructions you wish the joint submitter to see. Clicking the link below will relay the information in this text box to your joint submitter via **unencrypted e-mail**.

Unique Identifier for Joint Submission: f920bc0d-245f-4bc5-918c-1796dfdac98f

This is the unique identification number for your joint submitter. [Notify the Secondary Submitter of the Joint Submission](#).

The Secondary Submitter will need this identification number to complete the form. It is your responsibility to ensure that your secondary submitter understands how to complete the Biotechnology form and sends the information to EPA by the end of the submission period. The information collected in the primary and secondary form(s) will be linked by the unique identifier. The form will not undergo a review process until all forms have been received.

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From: Jane.Doe@test.com

CC:

To:
Enter email addresses separated by semicolons (;) or commas (,). Click in this box to start entering email addresses.

Subject: 2016 Biotechnology

Message: As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a joint submission for this 2016 Biotechnology form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Biotechnology form for the joint submission.

Unique Identifier f920bc0d-245f-4bc5-918c-1796dfdac98f

Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.

Additional Comments:

Biotechnology
Primary Authorized OfficialBiotechnology-20150730-
16:35:04 EDT General Form Information **Joint Submission** **Joint Submission 1** Joint Submitter
Information Joint Submission
Information Remove Add Joint Submission **Letter Of Support** **Letter of Support 1** Letter of Support
Submitter
Information Letter of Support
Submission
Information Add Letter Of Support Technical Contact Information Optional Cover Letter[Biotechnology \(Biotechnology-20150730-16:35:04 EDT\)](#) > Letter of Support Submitter Information**LETTER OF SUPPORT SUBMITTER INFORMATION**

Please enter the information for the letter of support submitter who will be responsible for supporting the information on the form. Check to claim information as CBI.

Check here to claim this information as CBI: First Name: Last Name: Position: Company Name: Phone Number:

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

Phone Extension: Email Address: Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City: State: Postal Code: Country: [Previous](#)[Next](#)

Validate



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Preview



Submit

Biotechnology
Primary Authorized Official
Biotechnology-20150730-16:35:04 EDT

- General Form Information
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 - Joint Submitter Information
 - Joint Submission Information
 - Remove
 - Add Joint Submission
- Letter Of Support
 - Letter of Support 1
 - Letter of Support Submitter Information
 - Letter of Support Submission Information
 - Add Letter Of Support
- Technical Contact Information
- Optional Cover Letter

Biotechnology (Biotechnology-20150730-16:35:04 EDT) > Letter of Support Submission Information

LETTER OF SUPPORT SUBMISSION INFORMATION

Please include instructions you wish the Letter of Support submitter to see. Clicking the link below will relay the information in this text box to your Letter of Support submitter via **unencrypted e-mail**.

Unique Identifier for Letter of Support Submission: 6a1700d1-1c3a-4ba5-b463-e23622c3f36e

This is the unique identification number for your Letter of Support submitter. The Secondary Submitter will need this identification number to complete the form. [Notify the Secondary Submitter of the Letter of Support submission](#).

It is your responsibility to ensure that your secondary submitter understands how to complete the Biotechnology form and sends the information to EPA by the end of the submission period. The information collected in the primary and secondary form(s) will be linked by the unique identifier. The form will not undergo a review process until all forms have been received.

Previous

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From: Jane.Doe@test.com

CC:

To:
Enter email addresses separated by semicolons (;) or commas (,). Click in this box to start entering email addresses.

Subject: 2016 Biotechnology

Message: As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a letter of support submission for this 2016 Biotechnology form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Biotechnology form for the letter of support submission.

Unique Identifier 6a1700d1-1c3a-4ba5-b463-e23622c3f36e

Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.

Additional Comments:

Biotechnology
Primary Authorized Official
Biotechnology-20150730-16:35:04 EDT

Biotechnology (Biotechnology-20150730-16:35:04 EDT) > Technical Contact Information

TECHNICAL CONTACT INFORMATION

To add a new Technical Contact click the **Add Technical Contact** button. [Add Technical Contact](#)

Last Name	First Name	Address	CBI	Actions
-----------	------------	---------	-----	---------

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 - Letter of Support Submission Information
 - Remove
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ADD TECHNICAL CONTACT

Please enter information for the technical contacts that will be contacted to answer questions regarding information in the form. Check to claim information as CBI or click the 'Copy CDX Registration' button to populate from CDX (if applicable).

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

Check here to claim this information as CBI:

First Name:

Last Name:

Position:

Company Name:

Phone Number:

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

Phone Extension:

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Biotechnology
Primary Authorized Official
Biotechnology-20150730-16:35:04 EDT

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Biotechnology (Biotechnology-20150730-16:35:04 EDT) > Optional Cover Letter

OPTIONAL COVER LETTER

If you would like to include a cover letter, write it here.

Check here to claim this information as CBI:

[Previous](#)


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Demo of Section 5 Notices and Supports Web Tool

Notice of Commencement



Office of Chemical Safety and Pollution Prevention

Call-In: 1-877-608-6616

Access Code: 9369481



CREATE PASSPHRASE

Please create a passphrase that is at least 8 characters in length. To better protect your form, your passphrase should contain a combination of letters and numbers. Your passphrase may include spaces, but should not contain special characters (for example, +, ?, and *).

New Passphrase:

Confirm New Passphrase:

As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized Supports.

Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

[Cancel](#)

[Next](#)

Notice of Commencement
Primary Authorized Official

NOC-20150730-16:51:20 EDT

- General Form Information
- Technical Contact Information
- Chemical Information
- Site Information
- Optional Cover Letter

← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [General Form Information](#)

GENERAL FORM INFORMATION

You may enter an alias for easier form identification or the system will provide a time stamp.

Form Alias:

Part II - Premanufacture Notice (PMN) 'P' or Microbial Commercial Activity Notice (MCAN) 'J' Case Number

Case Number:

Please enter the case number in the following format: P-XX-XXXX, where 'XX' indicates the year in which the case number is generated.

Manufacture/Import Information

Please provide the following information. Date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) For importees, the date of commencement is the date that the new chemical substance clears U.S. Customs.

- First Commercial Manufacture
- First Commercial Importation

Next



Notice of Commencement
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- General Form Information
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← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [Technical Contact Information](#)

TECHNICAL CONTACT INFORMATION

To add a new Technical Contact click the **Add Technical Contact** button. [Add Technical Contact](#)

Last Name	First Name	Address	CBI	Actions
-----------	------------	---------	-----	---------

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← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [Chemical Information](#)

CHEMICAL INFORMATION

Part V - Specific Chemical Identity

[Expand All](#) | [Collapse All](#)

▼ **CASRN:** Cancel 

Click the button below to search EPA's Substance Registry Services (SRS) for the desired chemical.

Search SRS

CASRN:
Chemical Name:
CBI:

Generic Chemical Name

PLEASE NOTE: EPA will be closely assessing the generic name at this time; please make sure that your generic name is a good generic name that only hides the proprietary parts of the ID.

Save

Click the **Add New Chemical** button to add chemical name and structural information for a new chemical component.

Add New Chemical

Part VII - Substance Identity Confidentiality Status

- I wish to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in waiver of your claim.
- I previously claimed the substance identity as confidential and hereby relinquish that claim.
- I did not claim the substance identity as confidential in my original PMN submission.

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 - CBI Substantiation Part 3
- Optional Cover Letter

← Notice of Commencement (NOC-20150730-16:51:20 EDT) > Site Information

SITE INFORMATION

Part IV - Manufacturing Plant Site(s) or Importing Site(s)

Importers, provide street address of destination.

Click to add a new site: [Add Site](#)

Registry ID	Site Name	Address	CBI	Actions
-------------	-----------	---------	-----	---------

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- Optional Cover Letter



ADD SITE

Select a site from the drop-down menu below:

CBI:

Alias:

EPA Registry ID:

Facility Name:

Facility Address:

City:

State:

Postal Code:

Add Site Cancel

Actions

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← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [CBI Substantiation Part 1](#)

CBI SUBSTANTIATION PART 1

Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.

(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?

(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the



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Notice of Commencement Primary Authorized Official

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- Optional Cover Letter

a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?

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 - CBI Substantiation Part 3
- Optional Cover Letter

← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [CBI Substantiation Part 2](#)

CBI SUBSTANTIATION PART 2

Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.

(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g. in technical journals or other publications; in libraries; or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?



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Primary Authorized Official

NOC-20150730-16:51:20 EDT

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 - CBI Substantiation Part 1
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 - CBI Substantiation Part 3
- Optional Cover Letter

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product; in effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

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← [Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [CBI Substantiation Part 3](#)

CBI SUBSTANTIATION PART 3

Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any persistent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.



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 - CBI Substantiation Part 1
 - CBI Substantiation Part 2
 - CBI Substantiation Part 3
- Optional Cover Letter

(K) Has EPA, another Federal agency, or any Federal court made any persistent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

[Attach Document](#)

File Name	Description	Pages	CBI	Actions
-----------	-------------	-------	-----	---------

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in 40 CFR 720.90(b)(2). **(Persons must answer this question if a health and safety study was provided at any time in the new chemical process.)**

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 - CBI Substantiation Part 3
- Optional Cover Letter**

[Notice of Commencement \(NOC-20150730-16:51:20 EDT\)](#) > [Optional Cover Letter](#)

OPTIONAL COVER LETTER

If you would like to include a cover letter, write it here.

Check here to claim this information as CBI:

[Previous](#)



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Demo of Section 5 Notices and Supports Web Tool

Alternative Control Measures (ACM)



Office of Chemical Safety and Pollution Prevention

Call-In: 1-877-608-6616

Access Code: 9369481

NOC-20141202-08:50:01 EST	NOC			In Progress	01/07/2015				✗
NOC-20150730-16:51:20 EDT	NOC			In Progress	07/30/2015				✗
Primary PMN-20141201-11:36:29 EST	Primary PMN	PMN		In Progress	01/14/2015				✗
Primary PMN-20141231-11:57:16 EST	Primary PMN	LOREX		In Progress	01/06/2015				✗
Primary PMN-20150729-16:50:24 EDT	Primary PMN	LVE_MODIFICATION	LM-15-0006, LM-15-0007	Submitted	07/30/2015	07/30/2015	↓	🔒	
Support-20141202-08:48:56 EST	Support	Other Correspondence	P-15-0001	Submitted	12/23/2014	12/23/2014	↓	🔒	
Support-20141231-09:02:07 EST	Support	Suspension Request	P-15-0001	In Progress	12/31/2014				✗
Support-20150730-10:43:07 EDT	Support			In Progress	07/30/2015				✗

Export options: [CSV](#) | [Excel](#) | [XML](#) | [PDF](#)

Select the form type and then click **Start New Form**

Form Type: Alternative Control Measures (ACM)

Start New Form



CREATE PASSPHRASE

Please create a passphrase that is at least 8 characters in length. To better protect your form, your passphrase should contain a combination of letters and numbers. Your passphrase may include spaces, but should not contain special characters (for example, +, ?, and *).

New Passphrase:

Confirm New Passphrase:

As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized Supports.

Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

[Cancel](#)

[Next](#)

CONTACT INFORMATION

You may enter an alias for easier form identification or the system will provide a time stamp.

Form Alias:

To add a new Contact click the **Add Contact** button.

[Add Contact](#)

Last Name	First Name	Address	CBI	Actions
-----------	------------	---------	-----	---------

[Next](#)



ADD CONTACT

Please enter the information for the contacts who will be responsible for supporting the information on the form. For multiple contacts, click the **Add Contact** button to populate a table with multiple contacts. Check to claim information as CBI or to populate from CDX (if applicable).

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

Check here to claim this information as CBI:

First Name:

Last Name:

Company Name:

Phone Number:

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

Phone Extension:

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

[Cancel](#)

[OK](#)

ACM
Primary Authorized Official
ACM-20150730-17:29:25 EDT

- Contact Information
- Attachments**

ACM (ACM-20150730-17:29:25 EDT) > Attachments

ATTACHMENTS

Please remember to upload documentation that fulfills the following requirements under 721.33:

- 1) The specific chemical identity of the substance.
- 2) A detailed description of the activities involved.
- 3) The specifications of the alternative worker exposure control measures or environmental release control measures.
- 4) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified which pertain to the substance for which the request is being submitted.
- 5) The data and information described in 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Pollution Prevention and Toxics, EPA.

Attach Document

File Name	Description	Pages	Date	CBI	Action
-----------	-------------	-------	------	-----	--------

Please provide the specific section in subpart E to which the proposed Alternative Control Measure refers.

ACM Citation at 40 CFR 721:

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Demo of Section 5 Notices and Supports Web Tool

Submission Process



Office of Chemical Safety and Pollution Prevention
Call-In: 1-877-608-6616 Access Code: 9369481

SUBMITTING OFFICIAL INFORMATION



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

This confirmation is required to proceed with the submission process

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

First Name: Jane
Middle Initial: E
Last Name: Doe
Job Title: Not Applicable
Company Name: TEST COMPANY
Phone Number: 8888901995
Email Address: Jane.Doe@test.com
Mailing Address 1: 12601 FAIR LAKES CIRCLE
Mailing Address 2:
City: FAIRFAX
State: VA
Postal Code: 22033
Country: US

[Cancel](#)

[Next](#)

BONA FIDE INTENT TO MANUFACTURE OR IMPORT



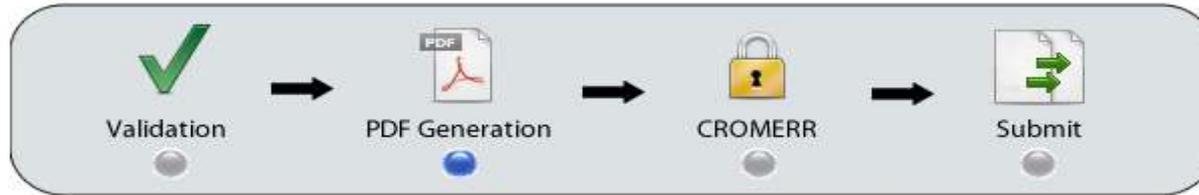
I certify, under penalty of law, that the following is true:

- The submitter of this notice intends to manufacture or import the identified substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 720.25.

[Cancel](#)

[I Certify](#)

SUBMISSION PROCESS: PDF GENERATION



Generating a finalized PDF file of your submission



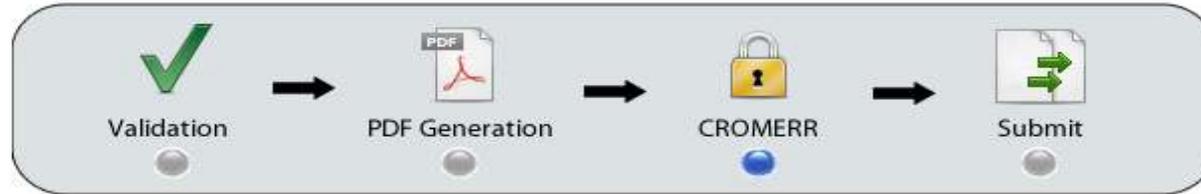
Processing. Please wait...

SUBMISSION PROCESS: PDF GENERATION

Your PDF preview transaction was successful!

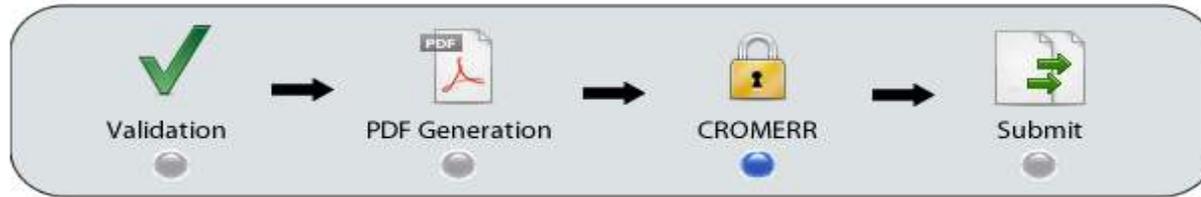


CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) CERTIFICATION



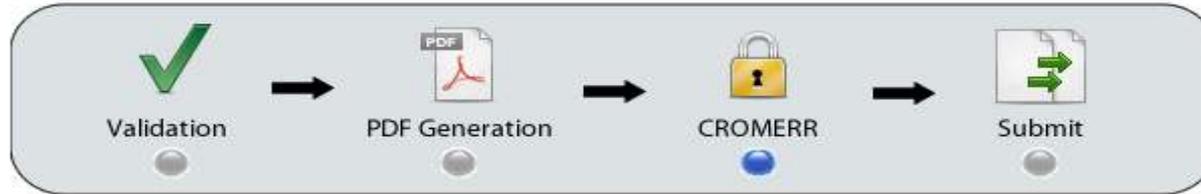
I certify, under penalty of law, that this document and all attachments were prepared under my direction of supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted 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.

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN



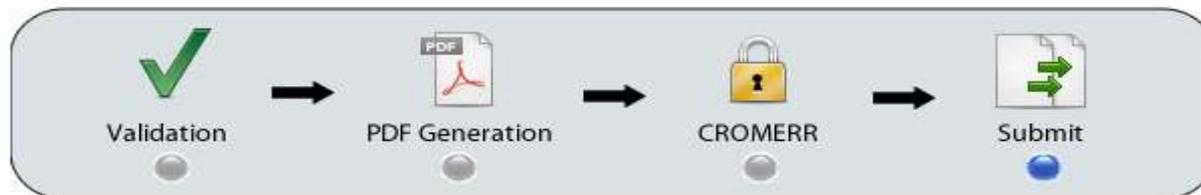
Please login with your CDX password:

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SECURITY QUESTION

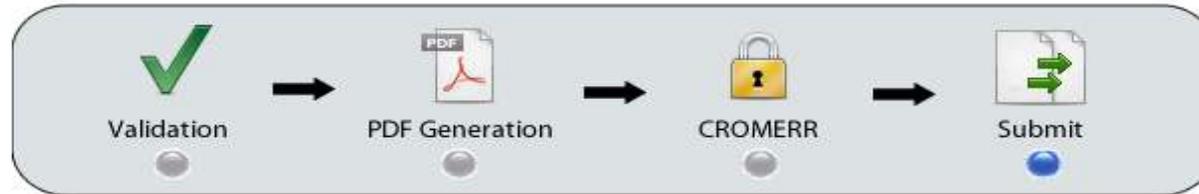


What is your favorite song?

SUBMIT TO CDX



I hereby certify to the best of my knowledge and belief that (1) all information entered on this form is complete and accurate; and (2) any confidentiality claims are true and correct as to that information for which they have been asserted. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SUBMISSION 

The submission was sent to the EPA. The Copy of Record link to allow for download of the Copy of Record and signature for this submission will appear in the Forms list when the EPA receives and processes your submission.

Finish

Copy of Record

- Reasons to Download the CoR
 - Downloaded files are unencrypted
 - Downloaded files can be organized and easier to locate
 - Provides a method to keep each version of a submission as the Section 5 thin client only stores the latest version of the submission



HOME



Forms

The TSCA Section 5 Notices and Supports Reporting rule requires anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity.

Use the following forms to report new chemicals to EPA: Premanufacture Notice form (EPA Form 7710-25) should be used to submit PMNs, LVEs, SNUNs, LOREXs, TMEAs, Modifications for LVEs and LoREX submissions; Biotechnology Notice form (EPA Form 6300-14) should be used to submit MCANs, TERAs, Tier I Exemptions, Tier 2 Exemptions, and Biotechnology TMEAs; Notice of Commencement form (NOC, EPA Form 7710-56) should be used to submit Notices of Commencement for PMNs and MCANs; ACM 40 CFR 721.30 form (TBD) should be used to report proposed Alternative Control Measures for published SNURs; or Bona Fide Notice (TBD) for any requests to determine if a chemical is on the TSCA inventory. The Support form is used to submit supplemental information for Premanufacture and Biotechnology notices, such as Test Data, Correspondences, and Amendments to older submissions.

To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ('Bona Fide Notice').

User Management

Manage the access rights of Support persons (including Agents/Consultants) for each Section 5 Notices and Support form.

Resources

Displays links to helpful guidance documents and websites for TSCA and Section 5.

Authorized Official

An Authorized Official has the ability to create, delete, amend, unlock, and submit all Section 5 Notices and Support forms electronically to EPA. The Authorized Official also has the ability to assign Supports (including Agents/Consultants) to individual forms.



RESOURCES

Section 5 Notices and Supports User Guide

This guide describes each screen of the Section 5 Notices and Supports software and provides information on how to use the system to complete a Section 5 Notices and Supports form. The guide also contains instructions for registering with CDX, submitting the Section 5 Notices and Supports form and amending a previous submission. You can download and print the guide for quick reference.

[User Guide](#)

Helpful Web Links

Click the link provided below to access additional information related to the Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs.

[Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs](#)

Click the link provided below to access additional information related to TSCA Biotechnology Regulations.

[Microbial Products of Biotechnology: Final Rule \(62 FR 17910\)](#)

Click the link provided below to access additional information related to Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms.

[Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms](#)

Click the link provided below to access additional information related to the Central Data Exchange (CDX).

[CDX Homepage](#)

Click the link provided below to access additional information related to the Toxic Substances Control Act (TSCA) Chemical Substances Inventory.

[TSCA Chemical Substances Inventory](#)

Click the link provided below to access additional information related to Substance Registry Services.

[Substance Registry Services \(SRS\)](#)

Click the link provided below to access additional information related to the Facility Registry System.

[Facility Registry System \(FRS\)](#)

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Click the link provided below to access additional information related to Inventory Expert Services.

[CAS Inventory Expert Services](#)

Click the link provided below to access additional information related to the National Pollutant Discharge Elimination System.

[National Pollutant Discharge Elimination System \(NPDES\)](#)

Click the link provided below to access additional information related to the New Chemicals Program.

[New Chemicals Program Homepage](#)

Click the link provided below to access information related to the status of Section 5 Notices.

[Status of Section 5 Notices](#)

For technical assistance, please call CDX helpdesk at (888) 890-1995. For assistance on how to fill out the forms (content) or for policy questions, please call (202) 554-1404 Monday to Friday 8:30 a.m. - 5:00 p.m. EST or e-mail the TSCA Hotline at TSCA-Hotline@epamail.epa.gov.

Resources

- Resources
 - Resources screen within Section 5 Notices and Supports web application provides useful links and user guides
- Contacts
 - TSCA Hotline: 202-564-3011, or TSCA-Hotline@epamail.epa.gov
 - CDX Helpdesk: 888-890-1995, or helpdesk@epacdx.net
- The slides and audio file from this session will be made available at: <http://epa.gov/oppt/newchems/epmn/epmn-index.htm> for your download
- Email questions or comments to eTSCAreporting@epa.gov



Questions & Answers



Office of Chemical Safety and Pollution Prevention
Call-In: 1-877-608-6616 Access Code: 9369481 |