



Section 8(e) Notice User Guide – Primary Support

Environmental Protection Agency

Office of Pollution Prevention and Toxics

Manage Toxic Substances

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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. 2070-0046; EPA ICR No. 0794). Submissions of substantial risk notifications are mandatory (15 U.S.C. 2607(e)), submissions of FYI notifications are voluntary, and respondents may submit their notifications to EPA by mail, express courier, or electronically through EPA's Central Data Exchange. The annual public burden for this collection of information is estimated to be 50.06 hours per initial section 8(e) submission and 4.06 hours per follow-up/supplemental section 8(e) submission. The same estimates apply to FYI initial and follow-up submissions. For CDX registrations, burden per registration is estimated at 0.53 hours. Burden is defined in 5 CFR 1320.3(b). 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. You may send comments regarding the EPA'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 (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Please include the OMB Control No. in any correspondence. Send only comments to this address.

1 Introduction

1.1 Overview

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) ‘Section 8(e) Notice’ application submission process. This document is the user guide for the Primary Support user of the Section 8(e) Notice tool. As a Primary Support, you can edit a submission created by the Primary Authorized Official (AO). You are only able to access submissions to which the Primary AO has granted access.

General information on Section 8(e) Notices is available on the TSCA Section 8(e) website available at <http://www.epa.gov/oppt/tsca8e/>. Information on CDX registration, including user roles that apply to completing a Section 8(e) Notice, is available at <http://cdx.epa.gov/About/UserGuide>

Toxic Substances Control Act (TSCA) regulations require industry to provide the Environmental Protection Agency (EPA) with documentation regarding chemical production, manufacture, distribution, use, disposal, import, and export. As a result, the implementation of TSCA has generated a large volume of documents submitted to the Agency by the regulated community.

TSCA Section 8(e) requires all United States chemical manufacturers, importers, processors, and distributors to notify EPA after obtaining information on any of their chemical substances or mixtures that reasonably supports the conclusion that these substances or mixtures present a substantial risk of injury to health or to the environment.

Anyone subject to the TSCA Section 8(e) reporting requirement should submit a report to EPA within thirty calendar days of obtaining said information. This information may be toxicity or exposure data, full reports, summarized results, limited studies (e.g., range-finding studies), preliminary results, and draft reports that constitute sufficient evidence for Section 8(e) reporting.

General information on TSCA Section 8(e) “notice of substantial risk” is available at <http://www.epa.gov/oppt/tsca8e/>

For questions concerning TSCA Section 8(e) Notice 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 8am – 6pm Eastern Standard Time (EST). For TSCA Section 8(e) Notice reporting requirements, please contact the TSCA Hotline at TSCA-Hotline@epamail.epa.gov or call 202-554-1404.

1.2 Labeling Confidential Information

This user guide presents instructions and screenshots for the ‘Section 8(e) Notice’ electronic application as if you were logged in as the Primary Support. As the Primary Support you are able to edit or modify a Section 8(e) notice. The user may claim certain information as Confidential Business Information (CBI). If the data is claimed as CBI, it will be treated in accordance with Agency confidentiality regulations at 40 CFR part 2, subpart B.

This TSCA Section 8(e) Notice electronic application is optional for the production and submission of these filings. The paper option for filing will continue to be allowed.

Potential users may find that the use of this application saves time, burden and, because it is in an electronic format, provides easy access to reporting forms. Potential users are reminded to carefully read and follow application instructions. Persons who wish to use this application must address all provisions in the application, including those relating to indexing information (i.e., company name, address, chemical name etc.) and those related to CBI submissions, including the requirement for the submission of sanitized or redacted filings.

Please note that certain CBI claims will not be accepted if you choose to use this electronic application for TSCA Section 8(e). For example, chemical name and/or chemical identity, if the chemical is listed on the public portion of the TSCA Inventory, may not be claimed as CBI in a submission using this application. Similarly, the user must enter a non-confidential study title, because it may not be claimed as CBI. EPA does not expect that such information, if evaluated under procedures at 40 CFR part 2, subpart B, would generally be found entitled to confidential treatment.

If the user believes that these or other data elements should be treated as CBI, then the user may use the paper option to file the Section 8(e) Notice and assert CBI claims.

If the user claims the ‘Mixture Percent’ or an uploaded document as CBI, they are required to complete the appropriate substantiation questions prior to submitting their Notice to EPA. If the user claims an uploaded document as CBI, a sanitized document must be provided.

The following fields can be claimed as CBI within the ‘Section 8(e) Notice’ application:

- Technical Contact Information
- Submitting on Behalf of Company information
- Submitting on Behalf of Consortium information
- A single chemical substance that is not on the public TSCA Inventory
- The chemical substances comprising a mixture
- The percent concentrations of individual chemical substances in a mixture
- Any document uploaded within the ‘Document Management’ pop-up window
- All responses to substantiation questions

2 System Requirements:

To use the Section 8(e) Notice application the following are required:

- An e-mail account
- A supported web browser (see Section **Error! Reference source not found.** below) with Java Script enabled.
- Internet access
- Adobe Acrobat Reader 5.0 or higher
- CDX username and password

2.1 Supported Browsers

One of the following supported browsers is required to access the Section 8(e) Notice application:

- Internet Explorer 7 or above
 - Go to the following link to download:
<http://windows.microsoft.com/en-US/internet-explorer/downloads/ie>
- Mozilla Firefox 3.5 or above
 - Go to the following link to download:
<http://www.mozilla.com/en-US/firefox/all-older.html>
- Safari 4 or above
 - Go to the following link to download:
<http://support.apple.com/kb/dl877>
- Google Chrome
 - Go to the following link to download:
<http://www.google.com/chrome>

2.2 Screen Resolution

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

3 Primary Support Functions

This section describes how to:

- Access the application
- Navigate the Section 8(e) Notice ‘Home’ screen
- Complete a Section 8(e) Notice submission
- Complete an amendment

As a Primary Support, you can edit a submission created by the Primary Authorized Official (AO). You are only able to access submissions to which the Primary AO has granted access.

You can save the submission at any point during the data entry process. The save functionality will allow you to return to that same submission at any point in the future. You can print the document at any point; however, the ‘Not For Submission’ watermark will be placed on the portable document format (PDF) document each time the submission is printed.

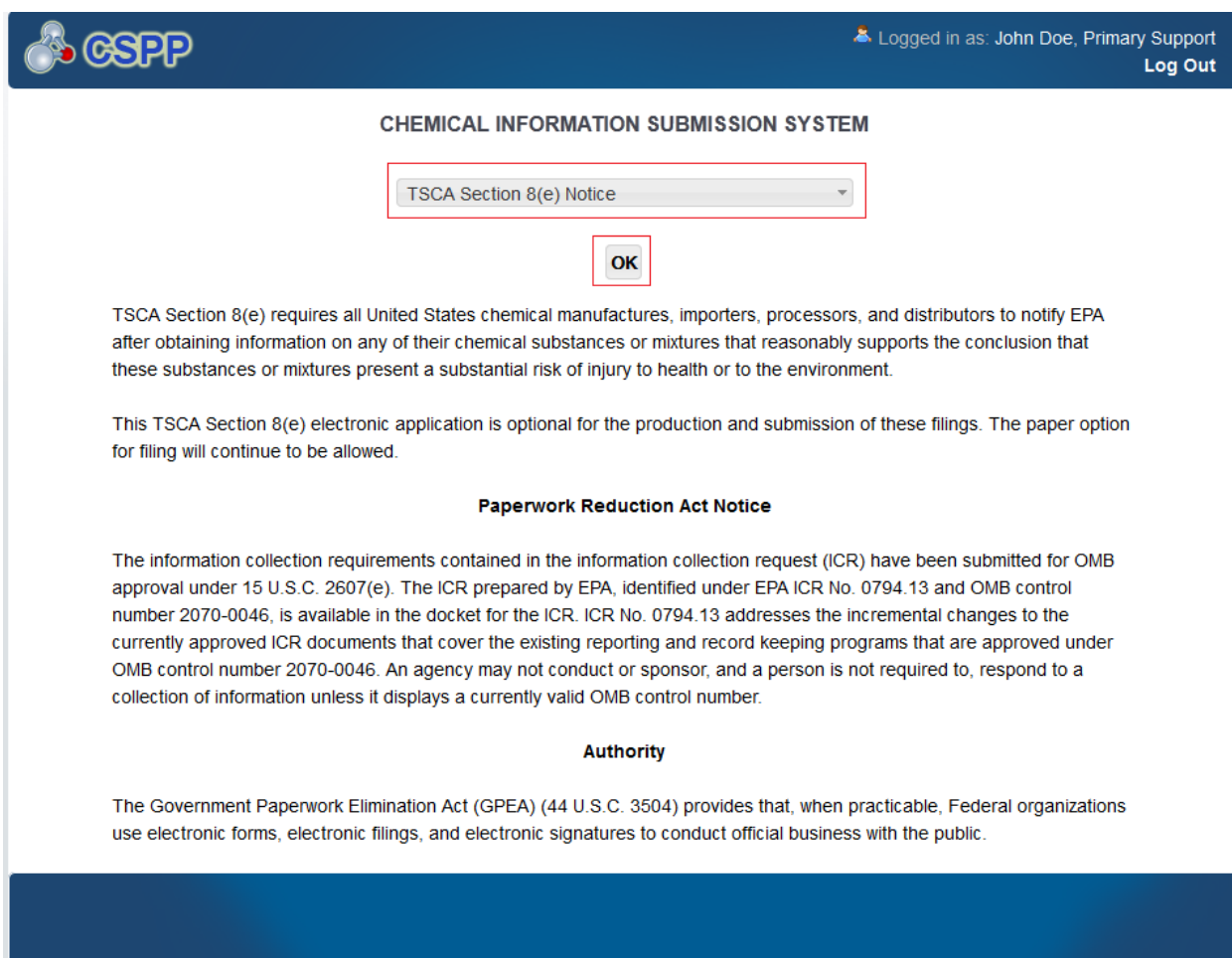
3.1 Log into Section 8(e) Notice Application

After you create an account in CDX and click the ‘Primary Support’ link under the Chemical Safety and Pesticide Programs (CSPP) program service, you will be taken to the ‘Chemical Information Submission System’ screen.

Note: Information on CDX registration, including user roles that apply to completing a Section 8(e) Notice, is available at <http://cdx.epa.gov/About/UserGuide>

Exhibit 3-1 shows a screen capture of the ‘Chemical Information Submission System’ screen:

Exhibit 3-1: Chemical Information Submission System Screen



CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 8(e) Notice

OK

TSCA Section 8(e) requires all United States chemical manufactures, importers, processors, and distributors to notify EPA after obtaining information on any of their chemical substances or mixtures that reasonably supports the conclusion that these substances or mixtures present a substantial risk of injury to health or to the environment.

This TSCA Section 8(e) electronic application is optional for the production and submission of these filings. The paper option for filing will continue to be allowed.

Paperwork Reduction Act Notice

The information collection requirements contained in the information collection request (ICR) have been submitted for OMB approval under 15 U.S.C. 2607(e). The ICR prepared by EPA, identified under EPA ICR No. 0794.13 and OMB control number 2070-0046, is available in the docket for the ICR. ICR No. 0794.13 addresses the incremental changes to the currently approved ICR documents that cover the existing reporting and record keeping programs that are approved under OMB control number 2070-0046. 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.

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.

Navigation: Select ‘TSCA Section 8(e) Notice’ from the drop-down menu and click the ‘OK’ button to navigate to the Section 8(e) Notice ‘Home’ screen.

3.2 Home Screen Navigation

You can access the Section 8(e) Notice ‘Home’ screen by selecting ‘Section 8(e) Notice’ from the ‘Chemical Information Submission System’ screen drop-down menu and by clicking the ‘OK’ button.

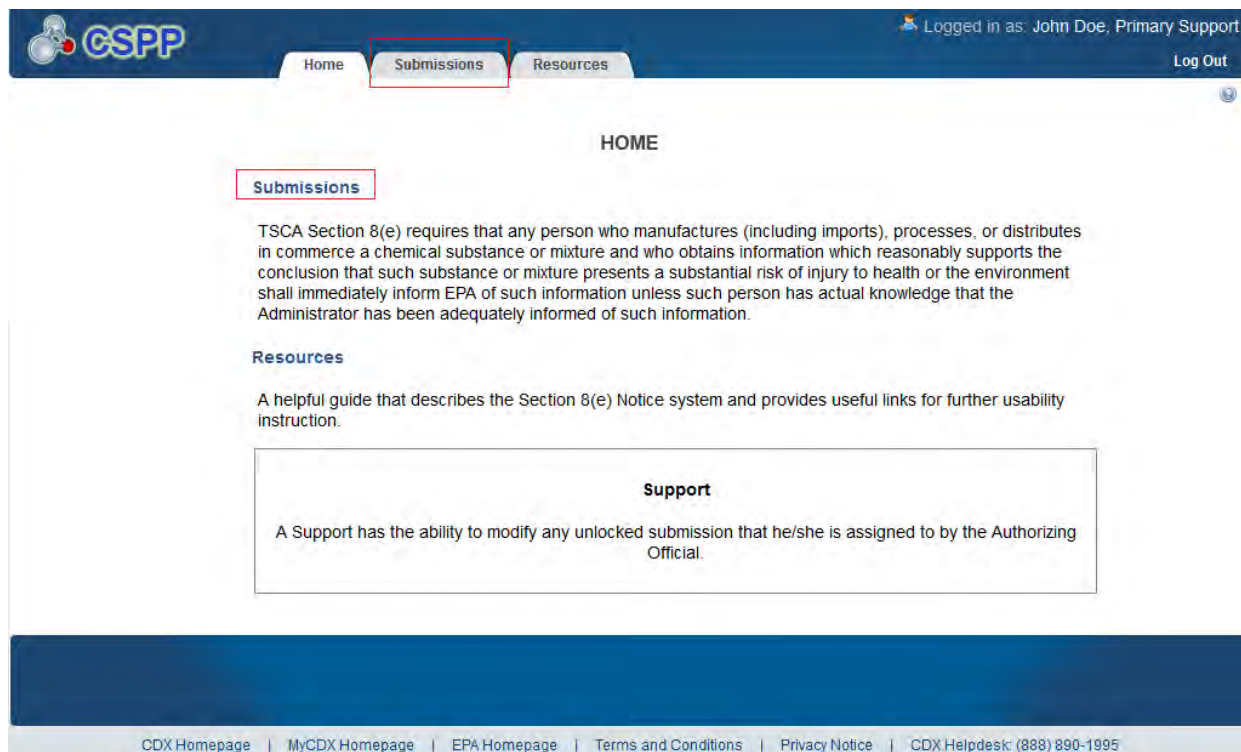
The Section 8(e) Notice ‘Home’ screen is the first screen within the Section 8(e) Notice application. It provides you with links and tabs to access the ‘Section 8(e) Notice’ submissions, and ‘Resources’ screens. To navigate to any of these screens, click the screen link (in blue text), or click the screen tab (located within the application header). The links and tabs provide the same functionality.

- **Submissions:** Click the ‘Submissions’ link or tab to navigate to the ‘Section 8(e) Notice’ submissions screen. You can modify a Section 8(e) Notice submission using the ‘Section 8(e) Notice’ submissions screen. For additional details about the ‘Section 8(e) Notice’ submissions screen, please refer to **Section 3.2.1**.

- **Resources:** Click the ‘Resources’ link or tab to navigate to the ‘Resources’ screen. You can view the Section 8(e) Notice user guide, as well as useful links for further usability instruction on the ‘Resources’ screen. For additional details about the ‘Resources’ screen, please refer to **Section 5**.

Exhibit 3-2 shows a screen capture for the Section 8(e) Notice ‘Home’ screen:

Exhibit 3-2: Section 8(e) Notice Home Screen



Navigation: Click the ‘Submissions’ link or tab to access the ‘Section 8(e) Notice’ submissions screen to edit existing submissions.

3.2.1 Edit Section 8(e) Notice Submission

As a Primary Support, you can edit a Section 8(e) Notice submission. You will be able to access only those submissions for which the Primary AO has assigned you to complete.

3.2.2 Section 8(e) Notice Screen Navigation

You can access the ‘Section 8(e) Notice’ submissions screen by clicking the ‘Submissions’ link from the Section 8(e) Notice ‘Home’ screen, or by clicking the ‘Submissions’ tab located within the application header.

You are only allowed to edit Section 8(e) Notice submissions for which the Primary AO has granted you access. Each column in the ‘Section 8(e) Notice’ submission screen can be sorted by clicking the column headers.

Edit a Submission: To modify an existing Section 8(e) Notice submission, click the ‘Submission Alias’ link for a submission that has a status of ‘In Progress.’ You will be required to enter the passphrase associated with that particular submission in order to access and continue

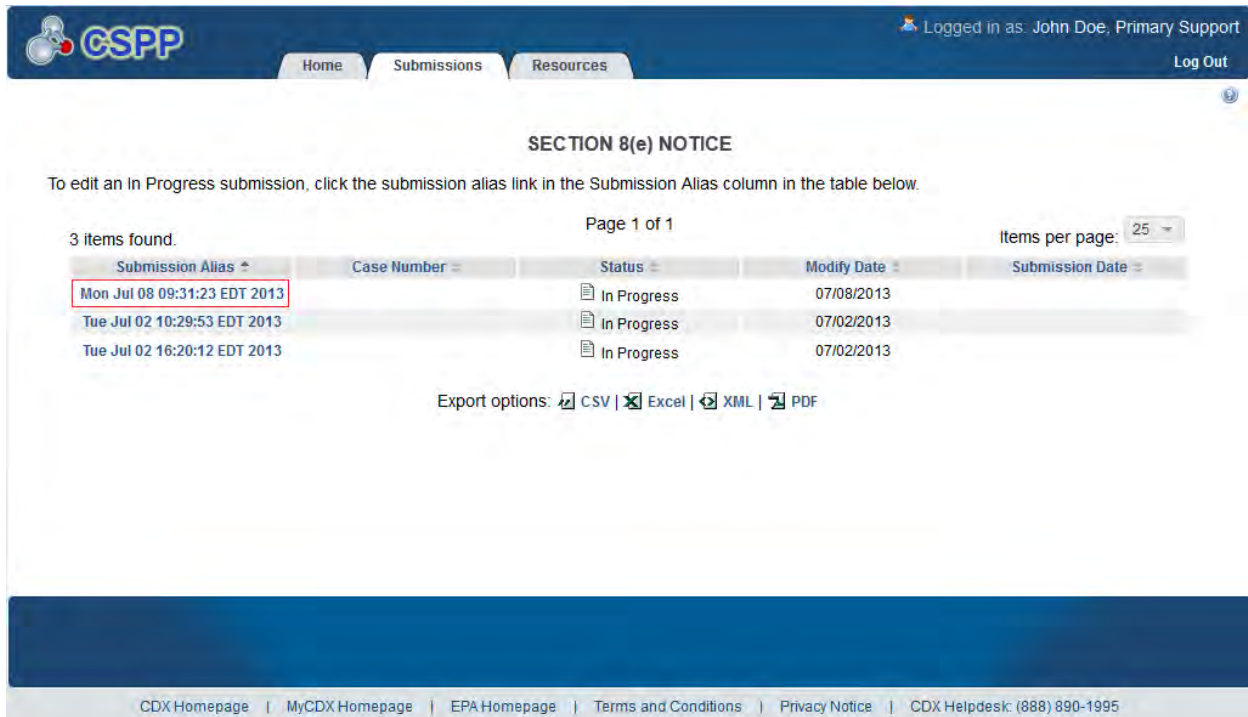
editing the submission. Refer to **Section 3.2.3** for further instructions on viewing and modifying a submission that is ‘In Progress.’

The ‘Section 8(e) Notice’ submissions screen displays the following columns:

- **Submission Alias:** Displays the submission alias provided by the user on the ‘Technical Contact Information’ screen. The ‘Submission Alias’ column will display a time stamp unless you define a unique submission alias on the ‘Technical Contact Information’ screen. The purpose of the submission alias is to help identify each Section 8(e) Notice submission.
- **Case Number:** Displays the case number for the submission. The case number is automatically generated upon submission. The ‘Case Number’ column will display as blank until the Section 8(e) Notice has been submitted successfully.
- **Status:** Displays the status of the Section 8(e) Notice submission. The column will display values as either ‘In Progress’ or ‘Submitted.’
- **Modify Date:** Displays the date the submission was last modified.
- **Submission Date:** Displays the date when you complete the submission to EPA. This date populates only after a Primary AO submits the Section 8(e) Notice submission.
- **Export Options:** Displays ‘CSV,’ ‘Excel,’ ‘XML,’ and ‘PDF’ links for you to export the ‘Section 8(e) Notice’ submissions screen in one of the specified formats as an Excel spreadsheet, Comma-Separated Values (CSV), Extensible Markup Language (XML), or Portable Document Format (PDF).

Exhibit 3-3 shows a screen capture of the ‘Section 8(e) Notice’ submission screen.

Exhibit 3-3: Section 8(e) Notice Submission Screen



Navigation: Click the ‘Submission Alias’ link that has a status of ‘In Progress’ to navigate to the ‘Enter Passphrase’ screen.

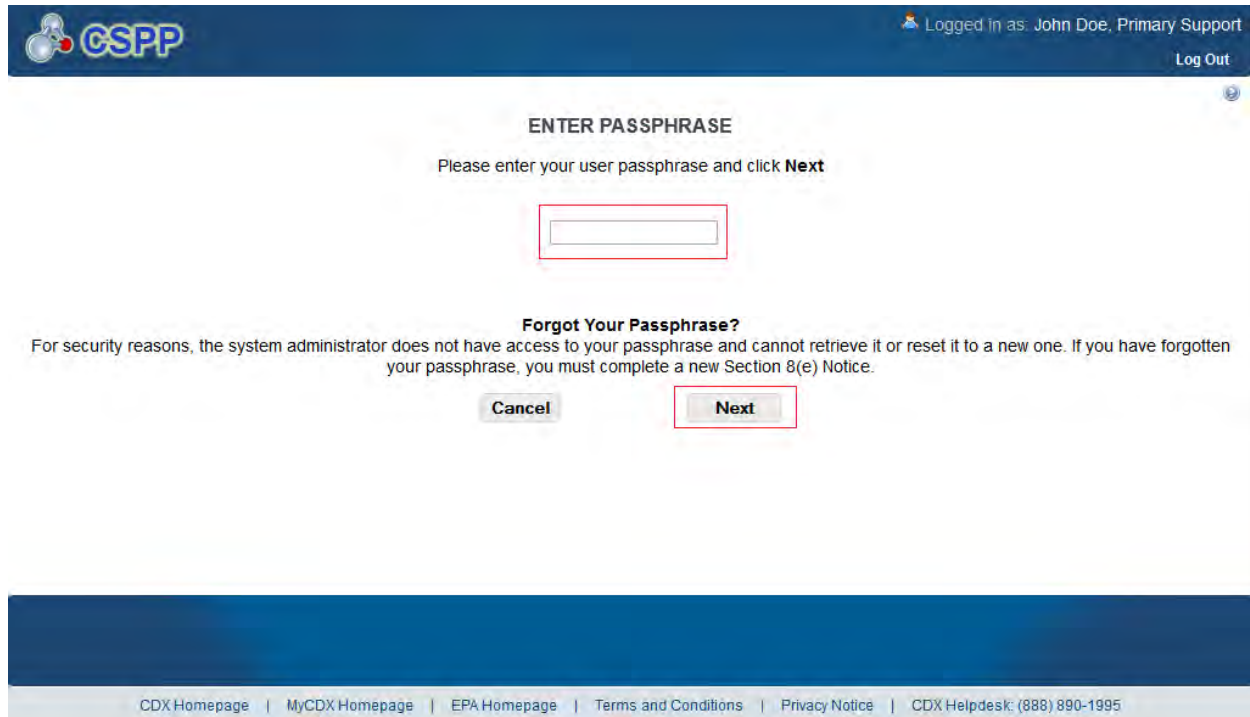
3.2.3 Enter Passphrase Screen

To edit a submission, click the ‘Submission Alias’ link for a submission with a status of ‘In Progress’ on the ‘Section 8(e) Notice’ submissions screen. The ‘Enter Passphrase’ screen allows you to enter the passphrase that is associated with the submission.

Enter Passphrase: Enter the passphrase associated with the submission; the passphrase for the case number you have authority to edit will be given to you by the Primary AO.

Exhibit 3-4 shows a screen capture of the ‘Enter Passphrase’ screen:

Exhibit 3-4: Enter Passphrase Screen



Navigation: Enter the passphrase that was originally created and assigned to you by your AO and click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen.

3.2.4 Navigation Tree

The navigation tree is located on the left hand side of each screen. You can perform the following functions using the navigation tree:

- **Collapse and Expand folders:** Each section of the submission falls under a collapsible folder within the navigation tree, which allows you to save space or easily view items in the navigation tree. When a folder is expanded, you can click the minus sign (-), the folder icon (📁), or the folder title link to collapse that section of the navigation tree. When a folder is collapsed, you can click the plus sign (+), the folder icon (📁), or the folder title link to expand that section of the navigation tree. When you place your cursor over a folder title link, it will highlight in red.
- **Open and Close the Navigation Tree:** To provide more visual form space, a navigation arrow (🔍) that opens and closes the navigation tree is located to the right of the navigation tree. Click the arrow (🔍) to close the navigation tree and increase the space of the form

content. Likewise, click the arrow (▶) on the closed navigation tree to open the navigation tree.

- **Navigate between screens:** You can use the navigation tree to navigate between the various screens within the application. Each screen of the submission is denoted with a form icon (≡). You can click the form icon (≡) or the screen title link to navigate to the selected screen. You must save all information entered on a particular screen before navigating to the next screen or all entered information will be lost. A prompt will appear after you click a link in the navigation tree indicating, 'Are you sure you want to leave the current page? Any unsaved changes will be lost.' If you click the 'OK' button, you will be taken to the requested screen without saving any of the data in the previous screen. If you click the 'Cancel' button, the prompt will close and you will not be taken to the requested screen.
- **Add Chemical:** You can click the 'Add Chemical' button located at the bottom of the navigation tree to add another chemical report within a single submission. Clicking the 'Add Chemical' button will generate another chemical report folder containing a 'Chemical Information' screen and a 'Document Management' screen. The system provides a 'Remove' icon (✖) that allows you to remove any unwanted chemical report folders.

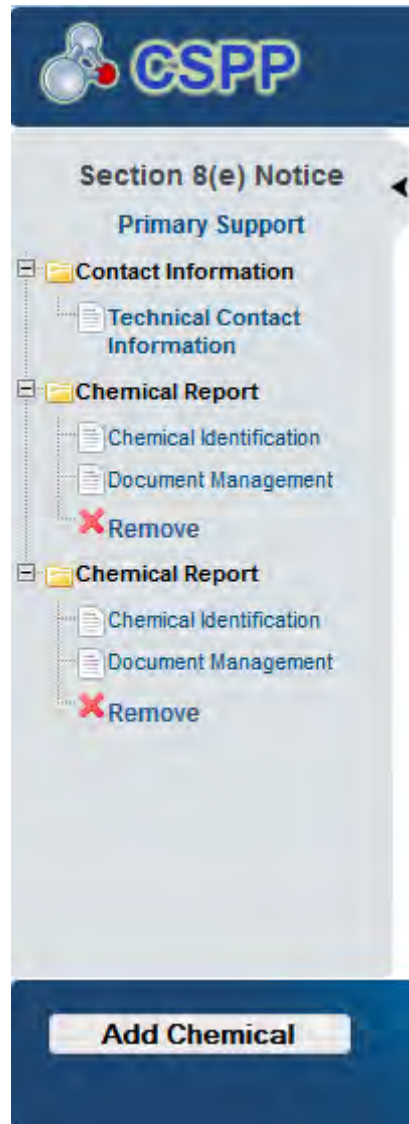
Exhibit 3-5 shows a screen capture of the navigation prompt window:

Exhibit 3-5: Navigation Prompt



Exhibit 3-6 shows the screen capture of the navigation tree:

Exhibit 3-6: Navigation Tree



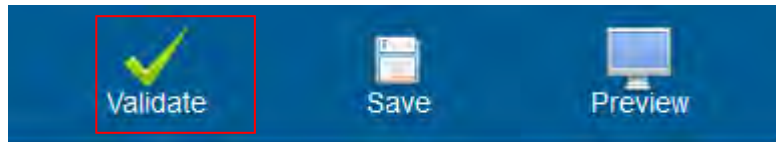
3.2.5 Action Bar

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

- **Validate:** You can click the ‘Validate’ icon (✓) at any stage of completing a Section 8(e) Notice submission to check for certain types of errors in a submission. A ‘Section 8(e) Notice Validation’ pop-up window is generated when you click the ‘Validate’ icon (✓). The ‘Section 8(e) Notice Validation’ pop-up window displays a report of all validation errors relating to a failed validation. Refer to **Section 4** for more information on validating a submission.

The following exhibits, Exhibit 3-7, Exhibit 3-8, and Exhibit 3-9 show the screen captures for the action bar:

Exhibit 3-7: Action Bar – Validate





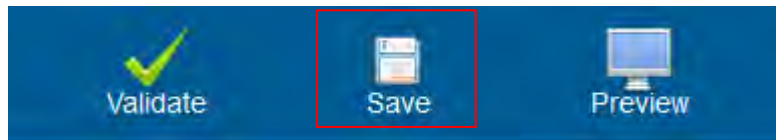
- **Save:** You can click the ‘Save’ icon () at any stage of completing a Section 8(e) Notice submission. After you click the ‘Save’ icon (), the data entered on the screen will save. The ‘Save’ function does not validate any entered data.

Exhibit 3-8: Action Bar – Save





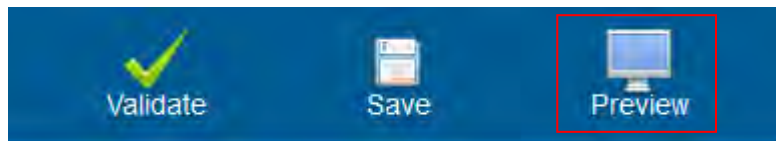
- **Preview:** You can click the ‘Preview’ icon () at any stage of completing a Section 8(e) Notice submission to preview the submission. After you click the ‘Preview’ icon (), a watermarked PDF version of the submission will generate.

Exhibit 3-9: Action Bar – Preview



- **Help Links:** You can click any of the ‘Help’ links, located at the bottom of each screen, at any stage of completing a Section 8(e) Notice submission.
 - If you click the ‘CDX Homepage’ link, you will be taken to the CDX Homepage.
 - If you click the ‘MyCDX Homepage’ link, you will be taken to the CDX Login screen.
 - If you click the ‘EPA Homepage’ link, you will be taken to the EPA Homepage.
 - If you click the ‘Terms and Conditions’ link, you will be taken to the CDX Terms and Conditions screen.
 - If you click the ‘Privacy Notice’ link, you will be taken to the CDX Privacy and Security Notice screen.

Exhibit 3-10 shows the screen capture of the action bar ‘Help’ links:

Exhibit 3-10: Action Bar – Help Links

[CDX Homepage](#) |
 [MyCDX Homepage](#) |
 [EPA Homepage](#) |
 [Terms and Conditions](#) |
 [Privacy Notice](#) |
 [CDX Helpdesk: \(888\) 890-1995](#)

3.2.6 Technical Contact Information Screen

You can access the ‘Technical Contact Information’ screen by clicking the submission alias link of a form that has a status of ‘In Progress’ and entering the associated passphrase.

The ‘Technical Contact Information’ screen allows you to submit on behalf of another company or submit on behalf of a consortium. To identify that you are submitting on behalf of another entity, the system provides the radio button for ‘This is a submission on behalf of a consortium.’ To identify that you are submitting on behalf of another company, the system provides the radio button for ‘This is a submission on behalf of another company.’ The system will only allow you to select one radio button per submission.

If you are submitting on behalf of another company, select the ‘This is a submission on behalf of another company’ radio button. This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, you can enter the contact information for the manufacturing or processing establishment on whose behalf the submission is being made into the ‘Submitting on Behalf Of Company’ screen upon clicking the ‘Next’ button. If the radio button for ‘This is a submission on behalf of a consortium’ is selected, you are taken to the ‘Submitting on Behalf of Consortium’ screen upon clicking the ‘Next’ button. If you select the ‘N/A’ radio button, you are signifying that you are neither making a submission on behalf of a consortium nor making a submission on behalf of another company and are taken to the ‘Chemical Identification’ screen upon clicking the ‘Next’ button.

The following fields are displayed on the ‘Technical Contact Information’ screen:

- **CBI:** Checking this checkbox will claim the technical contact information as CBI.
- **Submission Alias:** This field is auto-populated with a time stamp and displays on the ‘Section 8(e) Notice’ submissions screen within the ‘Submission Alias’ column. This field is editable should you choose to provide your own submission alias.
- **N/A:** Selecting the ‘N/A’ radio button allows you to signify that you are neither making a submission on behalf of a consortium nor making a submission on behalf of another company.
- **This is a submission on behalf of a consortium:** Selecting the ‘This is a submission on behalf of a consortium’ radio button allows you to identify yourself as an individual submitting on behalf of a consortium.
- **This is a submission on behalf of another company:** Selecting the ‘This is a submission on behalf of another company’ radio button allows you to identify yourself as an individual submitting on behalf of another company.
- **Copy CDX Registration:** Clicking the ‘Copy CDX Registration’ button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** Displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact’s first name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This is a required field.
- **Middle Initial:** Enter the technical contact’s middle initial. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.

- **Last Name:** Enter the technical contact's last name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Suffix:** Displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **Company Name:** Enter the technical contact's company name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the technical contact's daytime phone number; US or international. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Email Address:** Enter the technical contact's email address. The email address must follow the standard email address format: john.doe@abc.com. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Mailing Address 1:** Enter the first line of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **State:** Enter the state of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field if the 'Country' field is 'United States.'
- **Postal Code:** Enter the postal code of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Country:** Displays all available countries. Select the country of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 3-11: Technical Contact Information Screen shows the screen capture of the 'Technical Contact Information' screen:

Exhibit 3-11: Technical Contact Information Screen

Navigation: If you selected the ‘This is a submission on behalf of another company’ radio button, click the ‘Next’ button to navigate to the ‘Submitting on Behalf of Company’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree. If you selected the ‘This is a submission on behalf of a consortium’ radio button, click the ‘Next’ button to navigate to the ‘Submitting on Behalf of Consortium’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Consortium’ link within the navigation tree. If you have selected the ‘N/A’ radio button, click the ‘Next’ button to navigate to the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Chemical Identification’ link within the navigation tree.

3.2.7 Submitting on Behalf Of Company Screen

You can access the ‘Submitting on Behalf Of Company’ screen by selecting the ‘This is a submission on behalf of another company’ radio button and clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

The ‘Submitting on Behalf Of Company’ screen presents you with a list of fields that allow you to input the contact information for the manufacturing or processing establishment on whose behalf the submission is being made.

The following fields are displayed on the ‘Submitting on Behalf of Company’ screen:

- **CBI:** Checking this checkbox will claim the ‘Submitting on Behalf of Company’ information as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This is a required field.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- **Last Name:** Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This is a required field.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This is a required field.
- **Phone Number:** Enter the daytime telephone number of the manufacturing or processing establishment contact for whom the submission is being made; US or international. This field does not accept dashes. This is a required field.
- **Email Address:** Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This is a required field.
- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the ‘Country’ field is defined as ‘United States.’

- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This is a required field.
- **Country:** Enter the country of the mailing address of the manufacturing or processing establishment contact. This is a required field.

Exhibit 3-12 shows the screen capture of the ‘Submitting on Behalf of Company’ screen:

Exhibit 3-12: Submitting on Behalf of Company Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Chemical Identification’ link within the navigation tree.

3.2.8 Submitting on Behalf of Consortium Screen

You can access the ‘Submitting on Behalf of Consortium’ screen by selecting the ‘This is a submission on behalf of a consortium’ radio button and by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Consortium’ link within the navigation tree.

The 'Submitting on Behalf of Consortium' screen allows you to enter contact information for each consortium member. The system provides you with the ability to identify the consortium name. The contact information of the logged in user will pre-populate the first consortium field set. This information is editable. To add a consortium member, click the 'Add' button to display fields that can be populated and saved. You can click the 'Save' button for each consortium member added to capture all information entered on the screen. A minimum of two consortium members must be added to pass validation.

The following fields are displayed on the 'Submitting on Behalf of Consortium' screen:

- **CBI:** Checking this checkbox will claim the 'Submitting on Behalf of Consortium' information as CBI.
- **Consortium Name:** Enter the name of the consortium.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes and captures the consortium member contact's prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the consortium member contact's first name. This field is required.
- **Middle Initial:** Enter the consortium member contact's middle initial.
- **Last Name:** Enter the consortium member contact's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the consortium member contact's suffix.
- **Company Name:** Enter the consortium member contact's company name. This field is required.
- **Phone Number:** Enter the consortium member contact's day time telephone number; US or international. This field does not accept dashes. This field is required.
- **Email Address:** Enter the consortium member contact's email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the consortium member contact's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the consortium member contact's mailing address.
- **City:** Enter the city of the consortium member contact's mailing address. This is a required field.
- **State:** Enter the state of the consortium member contact's mailing address. This field is required only if the country field is set to 'United States.'
- **Postal Code:** Enter the postal code of the consortium member contact's mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the consortium contact. This is a required field.

Exhibit 3-13 shows the screen capture for the 'Submitting on Behalf of Consortium' screen:

Exhibit 3-13: Submitting on Behalf of Consortium Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Chemical Identification’ link within the navigation tree.

3.2.9 Chemical Identification Screen

You can access the ‘Chemical Identification’ screen by clicking the ‘Next’ button from the ‘Submitting on Behalf Of Company’ screen (if you selected the ‘This is a submission on behalf of another company’ radio button), by clicking the ‘Next’ button from the ‘Submitting on Behalf of Consortium’ screen (if you selected the ‘This is a submission on behalf of a consortium’ radio button), or by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen (if you selected the ‘N/A’ radio button). You can also access this screen by clicking the ‘Chemical Identification’ link within the navigation tree.

The 'Chemical Identification' screen provides a 'Chemical Alias' field to help distinguish between chemical reports when there is more than one chemical report. If you provide a chemical alias, the chemical alias will display within the navigation tree. If you do not provide a chemical alias, 'Chemical Report' will remain as the title of each chemical report folder.

To access Substance Registry Services (SRS) you will identify if you are reporting for a mixture by selecting the 'Yes' or 'No' radio button for 'Is this a submission for a mixture?.' If you identify you are submitting for a mixture, the system provides a 'Please provide the mixture, compound, or product name' optional text box. The mixture name text box does not appear if you select 'No' for 'Is this a submission for a mixture?'.

The following fields are displayed on the 'Chemical Identification' screen:

- **Chemical Alias:** The chemical alias is used to help distinguish between chemical reports within the navigation tree when there is more than one. A chemical alias can be created for each chemical report folder. If a chemical alias is not identified, 'Chemical Report' will remain as the chemical report folder title within the navigation tree.
- **This is a submission for a mixture:** Selecting the 'Yes' radio button captures if you are reporting for a mixture.
- **Please check this checkbox if the mixture is CBI:** Clicking this checkbox will claim the entire chemical mixture as CBI. Checking the CBI checkbox will disable all individual chemical CBI checkboxes.
- **Please provide the mixture, compound, or product name:** Enter the mixture, compound, or product's name.
- **Add:** Clicking the 'Add' button will generate a chemical substance field set.
- **Search SRS:** Clicking the 'Search SRS' button will generate a pop-up window to perform an SRS search. Refer to **Section 3.2.9.1** for further details.
- **Chemical Identifying Number:** Displays the chemical identifying number for the specified chemical substance.
- **Chemical Name:** Displays the chemical name of the specified substance.
- **Synonym:** Displays the chemical synonym(s) identified by the user. Clicking the 'Add' icon (+) will allow you to enter up to three synonyms for the identified chemical substance. Click the 'Delete' icon (X) to delete a synonym.
- **Mixture (%):** Enter the percent composition of each chemical within a mixture. This displays only when you have identified the submission is for a mixture.
- **Mixture % CBI:** Checking this checkbox will claim all mixture percent information as CBI.

Exhibit 3-14 shows the screen capture of the 'Chemical Identification' screen for a user reporting for a mixture:

Exhibit 3-14: Chemical Identification Screen: Submission Is for a Mixture

The screenshot displays the CDX Chemical Identification screen. At the top, it shows the user is logged in as John Doe, Primary Support. The navigation menu includes Home, Submissions, and Resources. The main content area is titled 'CHEMICAL IDENTIFICATION' and contains the following fields and options:

- Chemical Alias:** A text input field.
- Is this a submission for a mixture?** Radio buttons for 'Yes' (selected) and 'No'.
- Please check this checkbox if the mixture is CBI:** A checked checkbox.
- Please provide the mixture, compound, or product name:** A text input field.

A pop-up window titled 'Expand All | Collapse All' is open, containing the following elements:

- SRS Search:** A button to search EPA's Substance Registry Services (SRS).
- Chemical Identifier:** A text input field.
- Chemical Name:** A text input field.
- Synonym:** A text input field with a green plus icon.
- Mixture %:** A text input field.
- Mixture % CBI:** A checkbox.
- Save:** A button highlighted with a red box.

Below the pop-up window, there is an 'Add' button and a 'Next' button (highlighted with a red box). The bottom navigation bar includes 'Add Chemical', 'Validate', 'Save', and 'Preview' buttons. The footer contains links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk (888) 890-1995.

- **CBI:** Checking the CBI checkbox will claim the chemical as CBI. The CBI checkbox only appears if the chemical is not found on the TSCA inventory list.
- **This is a submission for a mixture:** Selecting the 'No' radio button captures that the user is not reporting for a mixture.
- **Search SRS:** Clicking the 'Search SRS' button will generate a pop-up window to perform an SRS search. Refer to **Section 3.2.9.1** for further details.
- **Chemical Identifier:** Displays the chemical identifying number for the specified chemical substance.
- **Chemical Name:** Displays the chemical name of the specified substance.

- **Synonym:** Displays the chemical synonym(s) identified by the user. Clicking the ‘Add’ icon (+) will allow you to enter up to three synonyms for the identified chemical substance. Click the ‘Delete’ icon (X) to delete a synonym.

Exhibit 3-15 shows the screen capture for the ‘Chemical Identification’ screen for reporting for a single chemical substance:

Exhibit 3-15: Chemical Identification Screen: Submission Is Not For a Mixture

Navigation: Click the ‘Next’ button to navigate to the ‘Document Management’ screen. You can also access this screen by clicking the ‘Document Management’ link within the navigation tree.

3.2.9.1 Search Substance Registry Services

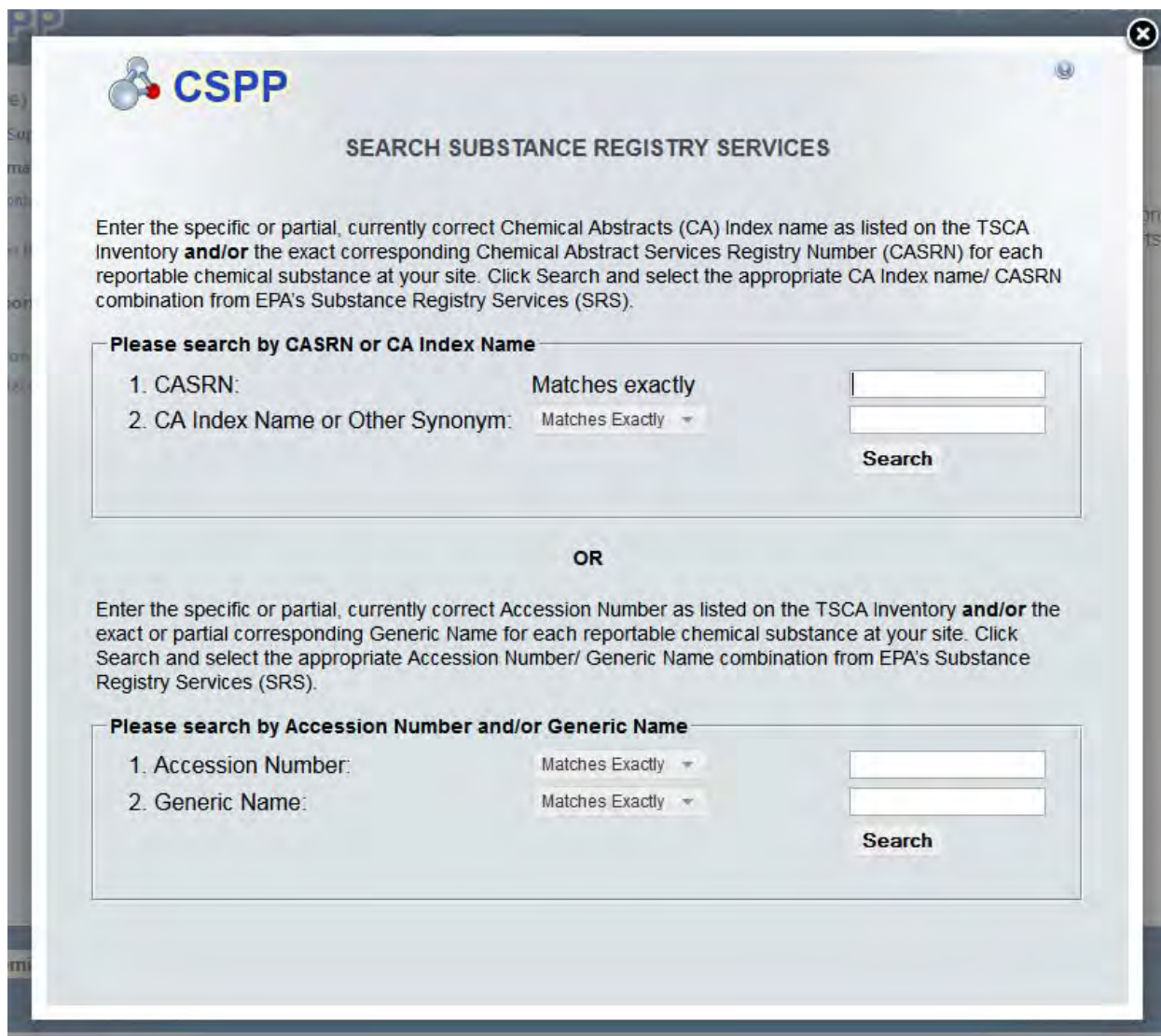
Click the ‘Search SRS’ button to generate the ‘Substance Registry Services’ pop-up window. You can search for the chemical(s) being reported by the ‘Chemical Abstract Service Registry Number (CASRN),’ ‘CA Index Name or Other Synonym,’ ‘Accession Number,’ or ‘Generic Name.’ After you have searched for and selected a chemical and clicked the ‘OK’ button, the selected chemical information will populate the ‘Chemical Identification’ screen. See Section 3.2.9.2 below if you don’t know the CAS or Accession Number.

- **CASRN:** Enter the CASRN of the chemical.
- **CA Index Name or Other Synonym:** Enter the CA Index Name or Other Synonym of the chemical. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’
- **Accession Number:** Enter the accession number of the chemical. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’

- **Generic Name:** Enter the generic name of the chemical. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’

Exhibit 3-16 shows the screen capture for the ‘Search Substance Registry Services’ pop-up window:

Exhibit 3-16: Search Substance Registry Services Pop-up Window



Navigation: Click the ‘X’ button in the upper-right hand corner of the ‘Search SRS’ window to close the ‘Substance Registry Services Search’ pop-up window and return to the ‘Chemical Identification’ screen.

3.2.9.2 Chemical Not Found in Substance Registry Services

You can access the ‘Chemical Not Found in Substance Registry Services’ screen by entering known information into the SRS window and performing a search. If there are no results, a message will be returned stating ‘There were no results returned.’ If you are sure the chemical does not exist in SRS, please click the ‘Create New Chemical’ button to enter the chemical information. Clicking the ‘Create New Chemical’ button on the ‘Search Substance Registry

Services' screen takes you to the 'Chemical Not Found in Substance Registry Services' screen. Click the 'Cancel' button to go back to the 'Search Substance Registry Services' screen. When entering information into the 'Chemical Not Found in Substance Registry Services' screen at least one of the following four fields is required; 'Accession Number,' 'CASRN,' 'Premanufacture Notice (PMN) Number,' or 'International Union of Pure and Applied Chemistry (IUPAC) Name'

If you do not know the accession number, CASRN, PMN number, or IUPAC number, check the 'Unknown' checkbox. Once you check the 'Unknown' checkbox, the above mentioned fields are disabled and you are only required to enter a chemical name (or descriptor).

- **Unknown:** Checking the 'Unknown' checkbox disables the 'Accession Number,' 'CASRN,' 'PMN Number,' and 'IUPAC Name' fields and requires you to enter the chemical name in the 'Chemical Name (descriptor)' field.
- **Accession Number:** If known, enter the accession number of the chemical.
- **CASRN:** If known, enter the CASRN of the chemical.
- **PMN Number:** If known, enter the PMN number of the chemical.
- **IUPAC Name:** If known, enter the IUPAC name of the chemical.
- **Chemical Name (descriptor):** Enter the chemical name/descriptor of the chemical being reported. This is a required field when the 'Unknown' checkbox is checked.

Exhibit 3-17 shows the screen capture for the 'Chemical Not Found in Substance Registry Services' pop-up window:

Exhibit 3-17: Chemical Not Found in Substance Registry Services Pop-up Window

CSPP

CHEMICAL NOT FOUND IN SUBSTANCE REGISTRY SERVICES

Complete all known chemical substance information in the below fields. Click the 'OK' button when all known chemical substance information has been fulfilled.

If you need to go back to the SRS search screen, please click 'Cancel'.

Chemical ID

Unknown:

Accession Number:

CASRN:

PMN Number:

IUPAC Name:

Chemical Name (descriptor):

Cancel OK

Navigation: Click the 'OK' button to populate the entered information and navigate to the 'Chemical Identification' screen. Click the 'Cancel' button to navigate to the 'Search Substance Registry Services' screen.

The following fields are displayed on the 'Chemical Identification' screen if a chemical is not found in SRS Search:

- **CBI:** Checking this checkbox will claim the chemical identity as CBI.
- **Chemical Identifier:** Displays which identifier you used to label the chemical. The chemical identifier will vary depending on the data entered in the 'Chemical Not Found In Substance Registry Services' screen.
- **Chemical Name (descriptor):** Displays the chemical name (or descriptor) of the chemical being reported entered in the 'Chemical Not Found In Substance Registry Services' screen.
- **Synonym:** Enter the chemical synonym(s).. Clicking the 'Add' icon (+) will allow you to enter up to three synonyms for the identified chemical substance. Click the 'Delete' icon (✖) to delete a synonym.

Exhibit 3-18 shows the screen capture for the ‘Chemical Identification’ screen populated with a chemical not found in the SRS search:

Exhibit 3-18 Chemical Identification Screen (Populated with chemical not found in SRS Search)

Navigation: Click the ‘Next’ button to navigate to the ‘Document Management’ screen.

3.2.10 Document Management Screen

You can access the ‘Document Management’ screen by clicking the ‘Next’ button from the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Document Management’ link within the navigation tree.

The ‘Document Management’ screen allows you to upload documents related to Section 8(e) Notice reporting requirements. To add Section 8(e) Notice documents, click the ‘Add Document’ button. Clicking the ‘Add Document’ button generates the ‘Document Management’ pop-up window.

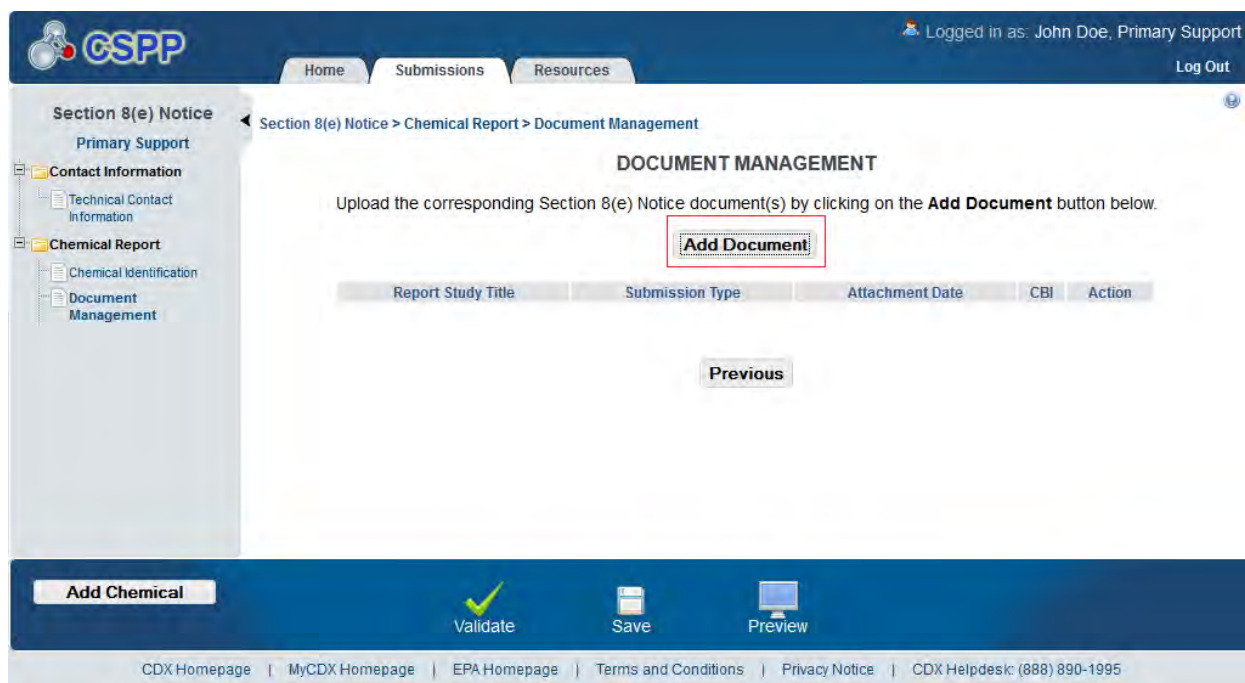
The ‘Document Management’ pop-up window allows you to attach the submission types: ‘Initial Submission,’ ‘Follow-up Submission, and ‘Final Report Submission.’

The ‘Document Management’ table displays the ‘Report Study Title’ of the document, the document type, the date the document was attached, and the CBI status of the document. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon (✘) located under the ‘Action’ column. Clicking the report study title link generates the ‘Document Management’ pop-up window. This allows you to view and edit the attached documents.

- **Add Document:** Clicking the ‘Add Document’ button generates the ‘Document Management’ pop-up window.
- **Report Study Title:** Displays the file name and file extension of the attached file. Clicking the file name link displays the ‘Document Management’ pop-up window and allows you to view and edit the attached document.
- **Submission Type:** Displays the submission type chosen in the ‘Document Management’ pop-up window.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays ‘N’ or ‘Y’ depending on if the CBI checkbox was checked.
- **Action:** Clicking the ‘Delete’ icon (✖) will delete the specified row and all contents within. A warning message displays to confirm the deletion of the document.

Exhibit 3-19 shows the screen capture of the ‘Document Management’ screen:

Exhibit 3-19: Document Management Screen



The ‘Document Management’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must enter a report study title and attach one document. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Select the document you wish to attach and click the ‘Open’ button. If a document is marked as ‘CBI’ then a sanitized copy of the document must be attached. To save the attached document to the ‘Document Management’ screen, click the ‘OK’ button within the ‘Document Management’ pop-up window.


- **Report Study Title:** Enter the report study title that is unique to this chemical report. This field is required. This study title must be non-confidential.
- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded document as CBI.

- **Submission Type:** Allows you to select the submission type for the attachments. Displays the following options: ‘Initial Submission,’ ‘Follow-up Submission,’ and ‘Final Submission.’
- **Original Document:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded summary/abstract document as CBI.
- **Summary/Abstract:** Displays ‘Yes’ and ‘No’ radio buttons. If you select the ‘Yes’ radio button a document upload will generate. Click the ‘Browse’ button to generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Effects:** Allows you to select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’
- **Endpoints:** Allows you to select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the ‘Effects’ drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Error! Reference source not found. for a complete list of values that are found within each of the drop-down menus on the ‘Document Management’ pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 3-20 shows the screen capture of the ‘Document Management’ pop-up window:

Exhibit 3-20: Document Management Pop-Up Window



CSPP

DOCUMENT MANAGEMENT

Select the submission type and browse for the document.

Note: For security purposes, documents are only saved when there are no validation errors. If there are any validation errors, all documents must be reattached.

Report Study Title:

Submission Type:

CBI:

Document Upload: Browse

Sanitized Document Upload: Browse

Summary/Abstract: Yes: No:

CBI:

Document Upload: Browse

Sanitized Document Upload: Browse

Effects:

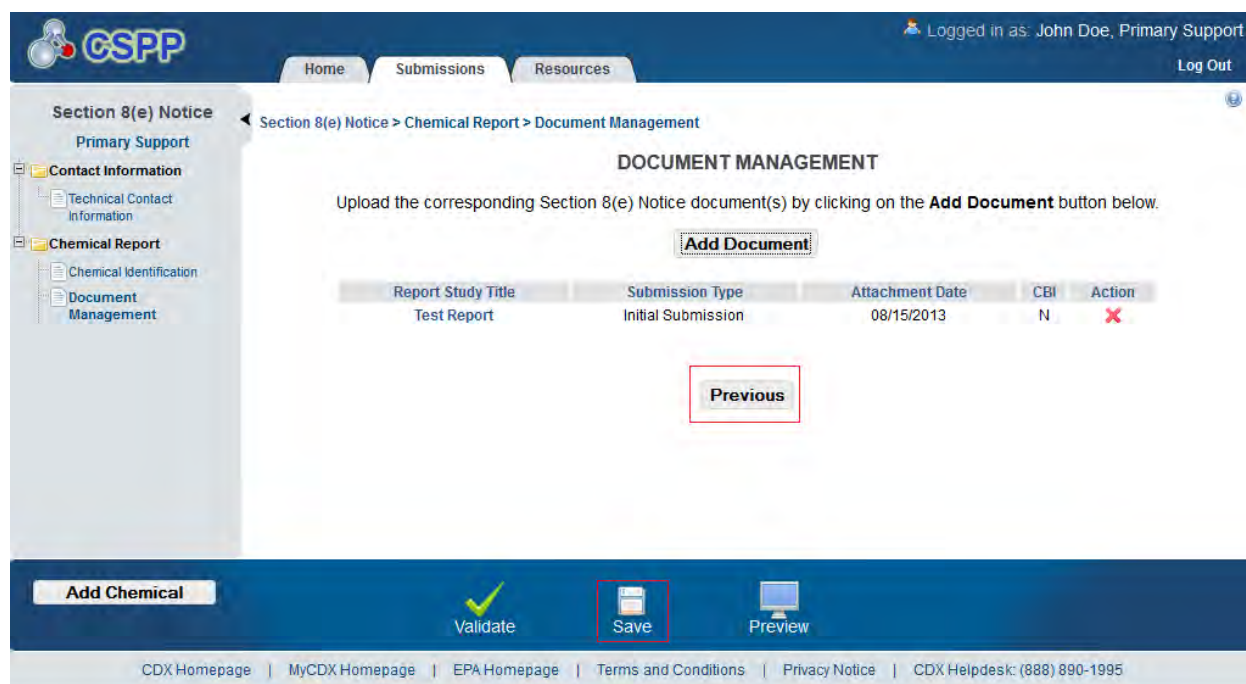
EndPoints:

OK Cancel

Navigation: Upload all required documentation and click the ‘OK’ button to save all data to the ‘Document Management’ table.

Exhibit 3-21 shows the screen capture of the ‘Document Management’ screen populated with data:

Exhibit 3-21: Document Management Screen (Populated)



Navigation: Click the ‘Next’ button to navigate to the ‘Substantiation’ screen if a chemical or document was claimed as CBI. If no chemical or document was claimed as CBI click the ‘Save’ button located in the bottom action bar.

3.2.11 TSCA Health and Safety Filing Substantiation Questions

Users completing submissions within the Section 8(e) Notice application may claim confidentiality for information within the TSCA Section 8(e) submission. If you are claiming CBI within the TSCA Section 8(e) Notice submission, you must complete substantiation questions and submit detailed written explanations to substantiate all CBI claims. Sanitized copies of all documents claimed as CBI must be submitted to be placed in the TSCA public docket.

The system allows you to complete Section 8(e) Notice substantiation for chemicals claimed as CBI as well as documents claimed as CBI. If you only claim the submitting official information, or the technical contact information as CBI, the system does not require the submitter to complete substantiation.

The system takes you to the substantiation sections of the application. Each time you claim an item as CBI that allows substantiation; the system generates an alert that informs you substantiation must be completed for items claimed as CBI.

The system will auto-populate substantiation questions for which the information has already been provided within the Section 8(e) Notice application. The substantiation questions are logically separated into sections within the application to streamline the substantiation process. Each question has functionality built into the system dependent upon your responses.

3.2.12 Substantiation Screen

The ‘Substantiation’ screen presents you with substantiation questions that pertain to the chemical substance(s) and document(s) claimed as CBI. The ‘Substantiation’ screen presents you with substantiation questions that allow answers to be entered as free text in text fields or by selecting ‘Yes’ or ‘No’ radio buttons.

You can access the ‘Substantiation’ screen by clicking the ‘Next’ button from the ‘Document Management’ screen if the chemical substance(s) has been claimed as CBI or a document has been claimed as CBI. You can also access the screen by clicking the ‘Substantiation’ link within the navigation tree. All of the fields on the ‘Substantiation’ screens are required.

Substantiation Question 1:

Is the subject chemical on the TSCA Inventory or otherwise available in commerce in the United States? If it is a mixture, is the mixture in commerce?

- **Yes/No:** Allows you to identify if the substance is commercially available.
- **CBI:** Checking this checkbox will claim the answer as CBI.

Substantiation Question 2:

Is the subject chemical or mixture expected to be subject to TSCA or is it expected to be used for a non-TSCA purpose?

- **Yes/No:** Allows you to identify if the substance is expected to be used for a non-TSCA purpose.
- **CBI:** Checking this checkbox will claim the answer as CBI.

Substantiation Question 3:

Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor’s access to your customers. Address each piece of information claimed CBI separately.

- **CBI:** Checking this checkbox will claim the answer as CBI
- A text field is available for you to answer the question.

Substantiation Question 4:

For what period do you assert your claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period.

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Event:** Allows you to enter the appropriate information to complete the question.
- **Date:** Provides a calendar widget for you to specify the date to which the claim of confidentiality extends.

If you answered ‘Yes’ to any of the questions above indicate why in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential:

- A text box is displayed and allows you to enter any text.

Exhibit 3-22 shows the screen captures for the ‘Chemical Substantiation’ screen:

Exhibit 3-22: Substantiation Screen

Section 8(e) Notice | Logged in as: John Doe, Primary Support | Home | Submissions | User Management | Resources | Log Out

Section 8(e) Notice > Chemical Report Substantiation

Primary Support

Substantiation

1. Is the subject chemical on the TSCA inventory or otherwise available in commerce? If it is a mixture, is the mixture in commerce?
 CBI:
 Yes No

2. Is the subject chemical or mixture expected to be subject to TSCA or is it expected to be used for a non-TSCA purpose?
 CBI:
 Yes No

3. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.
 CBI:

4. For what period do you assert your claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period.
 CBI:
 Event
 Date: 12/31/2013

If you answered 'Yes' to any of the questions above indicate in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential:

Previous **Next**

Add Chemical **Validate** **Save** **Preview**

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Navigation: Answer all substantiation questions and click the ‘Next’ button to navigate to the ‘Substantiation (continued)’ screen.

3.2.13 Substantiation (continued) Screen

The 'Substantiation (continued)' screen presents you with substantiation questions that require answers to be entered as free text in text fields or by selecting 'Yes' or 'No' radio buttons.

You can access the 'Substantiation (continued)' screen by clicking the 'Next' button from the 'Substantiation'. All of the fields on the 'Substantiation (continued)' screen are required.

Substantiation Question 5A:

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

Confidential processes used in manufacturing the substance?

Clicking the 'Yes' radio button will bring up another question:

- **CBI:** Checking this checkbox will claim the answer as CBI.

Substantiation Question 5B:

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

If a mixture, the actual portions of the substance in the mixture?

Clicking the 'Yes' radio button will bring up another question:

- **CBI:** Checking this checkbox will claim the answer as CBI.

Substantiation Question 5C:

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

Information unrelated to the effects of the substance on human health or the environment?

Clicking the 'Yes' radio button will bring up another question:

- **CBI:** Checking this checkbox will claim the answer as CBI.

Substantiation Question 6A:

Does the information claimed as confidential appear or is it referred to in any of the following:

Advertising or promotional material for the chemical substance or the resulting end product?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Browse for the document(s) containing the materials as indicated above:** Browse for the specified document and click the 'Upload' button.

Substantiation Question 6B:

Does the information claimed as confidential appear or is it referred to in any of the following:

Non-confidential material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale)?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Browse for the document(s) containing the materials as indicated above:** Browse for the specified document and click the 'Upload' button.

Substantiation Question 6C:

Does the information claimed as confidential appear or is it referred to in any of the following:

Professional or trade publications?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Browse for the document(s) containing the materials as indicated above:** Browse for the specified document and click the 'Upload' button.

Substantiation Question 6D:

Does the information claimed as confidential appear or is it referred to in any of the following:

Any other media or publications available to the public or to your competitors?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Browse for the document(s) containing the materials as indicated above:** Browse for the specified document and click the 'Upload' button.

Substantiation Question 7:

Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?

Clicking the 'Yes' radio button brings up another question:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Browse for the document(s) containing the materials as indicated above:** Browse for the specified document and click the 'Upload' button.
- **If you answered 'Yes' to any of the questions above indicate in the text box below. Indicate below where the information appears and explain why it**

should nevertheless be treated as confidential: Displays a text field for you to enter the appropriate information to complete the question.

Exhibit 3-23 and Exhibit 3-24 **Error! Reference source not found.** show the screen capture for the ‘Substantiation (continued)’ screen.

Exhibit 3-23: Substantiation (continued) Screen (Scroll 1)

GSPP Logged in as: John Doe Primary Support

Home Submissions User Management Resources Log Out

Section 8(e) Notice < Section 8(e) Notice > Chemical Report > Substantiation (continued)

Substantiation (CONTINUED)

5. Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

a. Confidential processes used in manufacturing the substance?
 CBI:
 Yes No

b. If a mixture, the actual portions of the substance in the mixture?
 CBI:
 Yes No

c. Information unrelated to the effects of the substance on human health or the environment?
 CBI:
 Yes No

6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting end product?
 CBI:
 Yes No

Confidential Advertising/Promotional Material
 Browse for the document(s) containing the materials as indicated above.

Browse

File Name	Action

b. Non-confidential material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale)?
 CBI:
 Yes No

Confidential Data Sheets
 Browse for the document(s) containing the materials as indicated above.

Browse

File Name	Action

c. Professional or trade publications?

Exhibit 3-24: Substantiation (continued) Screen (Scroll 2)

c. Professional or trade publications?
CBI:
 Yes No

Confidential Professional/Trade Publication
Browse for the document(s) containing the materials as indicated above.

Browse

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

d. Any other media or publications available to the public or to your competitors?
CBI:
 Yes No

Confidential Media/Publications
Browse for the document(s) containing the materials as indicated above.

Browse

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

7 Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?
CBI:
 Yes No

Confidentiality Documents
Browse for the document(s) containing the materials as indicated above.

Browse

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

If you answered 'Yes' to any of the questions above indicate in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential:

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpline: \(888\) 890-1995](#)

Navigation: Answer all of the substantiation questions and click the 'Save' button located in the action bar.

4 Validate

You can click the ‘Validate’ icon (✓) at any stage of completing a Section 8(e) Notice. The ‘Section 8(e) Notice Validation’ pop-up window is displayed when you click the ‘Validate’ icon (✓) in the action bar. The ‘Section 8(e) Notice Validation’ pop-up window displays a report of all validation errors. During the validation process, the application validates each screen of the Section 8(e) Notice to find missing and invalid data. For example, if a document is claimed as CBI a sanitized version of the document must be uploaded. If a sanitized version is not uploaded, you will be unable to complete the submission.

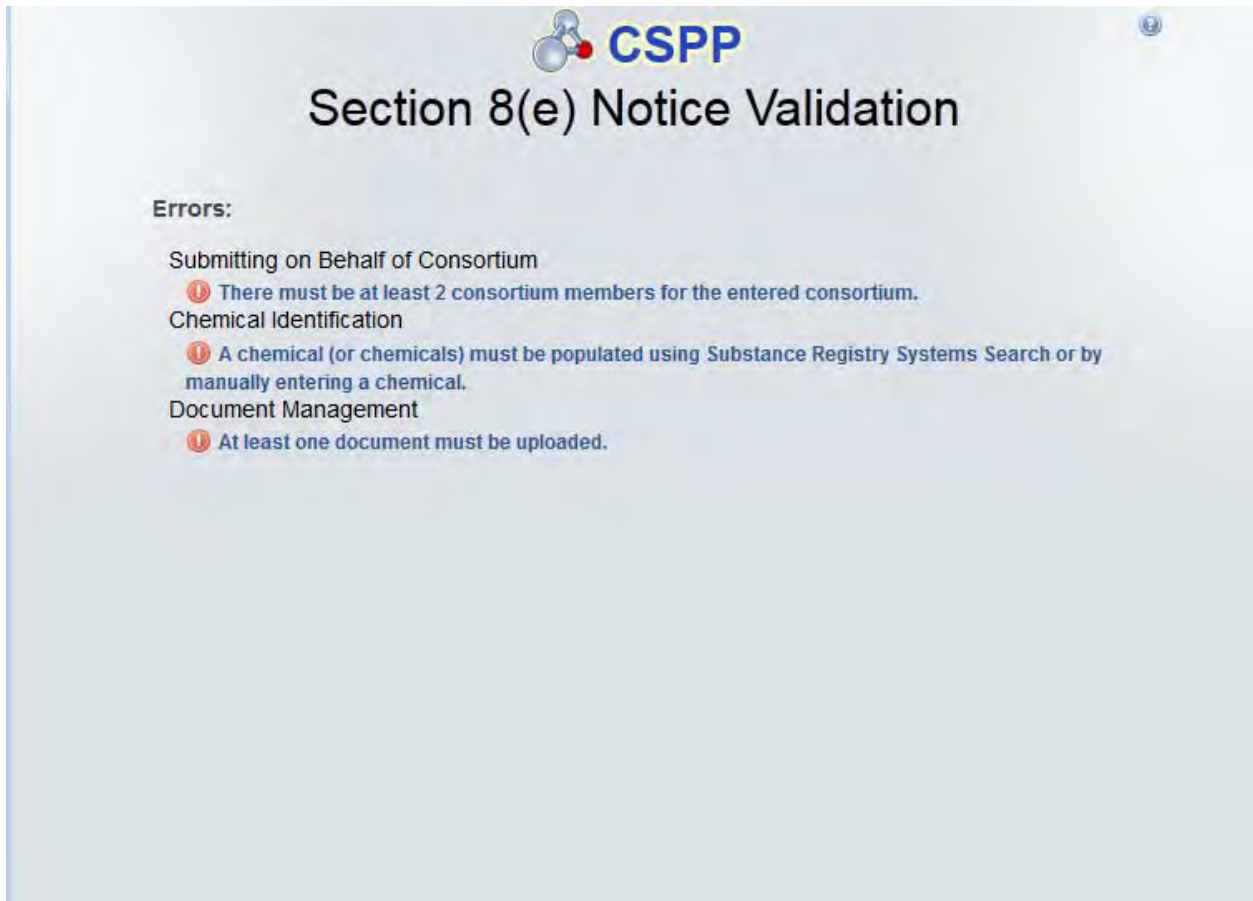
Validation Errors: Errors are denoted by an ‘Error’ icon (❗) and can be fixed by clicking the error link. The links will display the *Screen Title Name* (e.g., Chemical Identification) and the associated error. For example, if you claimed an uploaded document as CBI and have not attached a sanitized copy prior to validation, the system would display a validation error similar to ‘*Document Management: ❗ You have uploaded a CBI document. A sanitized copy is required.*’ After you click a link, the main application screen will display the screen where the error occurred so you can easily fix the error. Once you have fixed the error(s), click the ‘Validate’ icon (✓) again to refresh the ‘Section 8(e) Notice Validation’ pop-up window. If the information you fixed passes validation, the error will be removed from the ‘Section 8(e) Notice Validation’ pop-up window. You must fix all validation errors to successfully submit to EPA via CDX.

Warning Messages: Warnings are denoted by a ‘Warning’ icon (⚠) and can be fixed by clicking the warning link. The links will display the *Screen Title* and the associated warning. After you click a link, the main application screen will display the section where the warning occurred so you can easily fix the warning. Once you have fixed the warning(s), click the ‘Validate’ icon (✓) again to refresh the ‘Section 8(e) Notice Validation’ pop-up window. If the information you fixed passes validation, the warning will be removed from the ‘Section 8(e) Notice Validation’ pop-up window. You can pass validation and continue to submit a form to CDX with active warning messages.

You can close the ‘Section 8(e) Notice Validation’ pop-up window by clicking the ‘X’ button located at the top right of the ‘Section 8(e) Notice Validation’ pop-up window.

Exhibit 4-1 shows the screen captures for the 'Section 8(e) Notice Validation' pop-up window:

Exhibit 4-1: Section 8(e) Notice Validation Pop-Up Window



5 Resources

You can access the ‘Resources’ screen by clicking the ‘Resources’ link on the Section 8(e) Notice ‘Home’ screen or by clicking the ‘Resources’ tab located in the application header. The ‘Resources’ screen provides you with a link to the Section 8(e) Notice user guide as well as additional helpful links. Click the ‘User Guide’ link to access the Section 8(e) Notice user guide document.

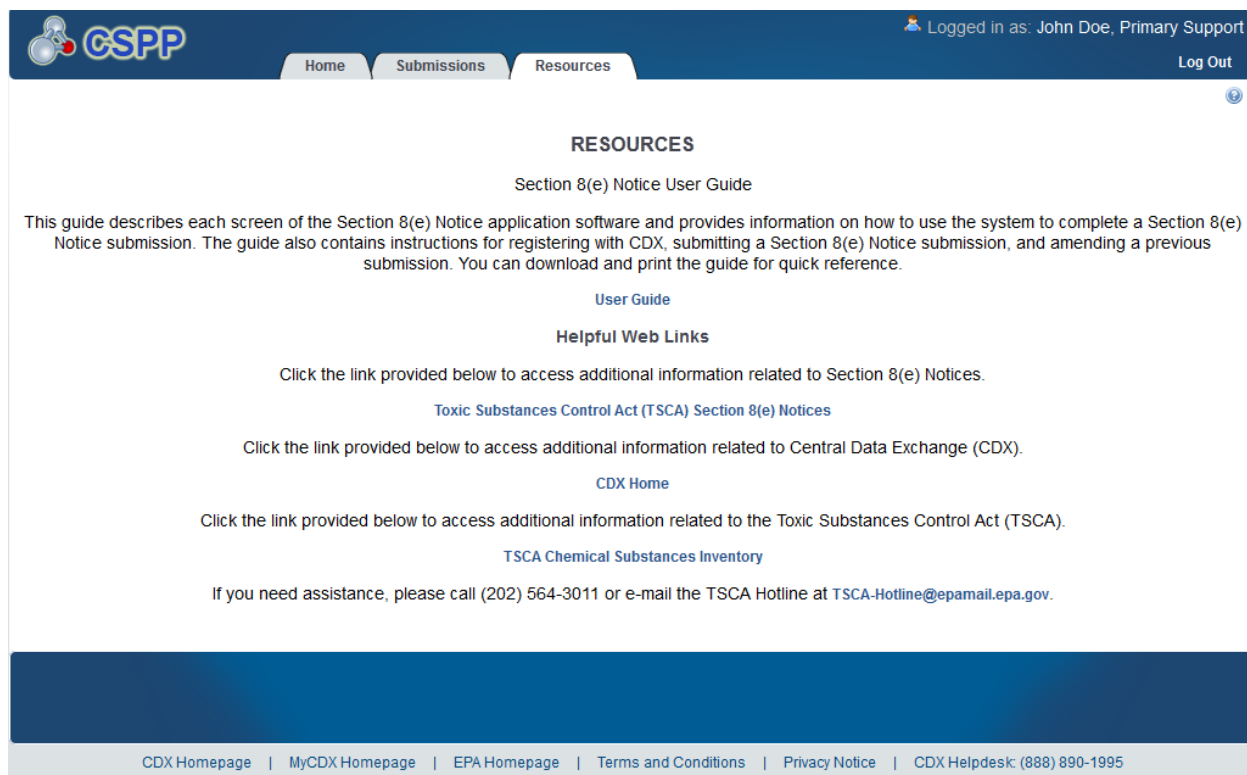
Toxic Substances Control Act (TSCA) Section 8(e) Notices and Section 8(e) Notice Submissions: If you click this link, a new internet browser window will generate displaying EPA’s TSCA Section 8(e) Notices screen.

CDX Home: If you click this link, a new internet browser window will generate displaying the CDX Homepage.

TSCA Chemical Substances Inventory: If you click this link, a new internet browser window will generate displaying the TSCA Chemical Substances Inventory screen.

Exhibit 5-1 shows the screen capture of the ‘Resources’ screen:

Exhibit 5-1: Resources Screen



RESOURCES

Section 8(e) Notice User Guide

This guide describes each screen of the Section 8(e) Notice application software and provides information on how to use the system to complete a Section 8(e) Notice submission. The guide also contains instructions for registering with CDX, submitting a Section 8(e) Notice submission, 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 Section 8(e) Notices.

[Toxic Substances Control Act \(TSCA\) Section 8\(e\) Notices](#)

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

[CDX Home](#)

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

[TSCA Chemical Substances Inventory](#)

If you need assistance, please call (202) 564-3011 or e-mail the TSCA Hotline at TSCA-Hotline@epamail.epa.gov.

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Appendix A. Definitions, Acronyms, and Abbreviations

The following table displays all the definitions, acronyms, and abbreviations used in this document and their full name.

Definitions, Acronyms, and Abbreviations

Acronym	Full Name
AO	Authorized Official
CA	Chemical Abstract
CASRN	Chemical Abstract Service Registry Number
CBI	Confidential Business Information
CDX	Central Data Exchange
CSPP	Submissions for Chemical Safety and Pesticide Programs
CSV	Comma-Separated Values
EPA	Environmental Protection Agency
EST	Eastern Standard Time
IUPAC	International Union of Pure and Applied Chemistry
OPPT	Office of Pollution Prevention and Toxics
PDF	Portable Document Format
PMN	Premanufacture Notice
SRS	Substance Registry Services
TSCA	Toxic Substances Control Act
UVCB	Unknown or Variable Composition or Complex Reaction product or Biological Material
XML	Extensible Markup Language

Appendix B. Submission Types, Effects, and Endpoints

The following appendix displays all possible options within each drop-down menu on the 'Document Management' pop-up window.

First Dropdown:

- Title: Submission Type
- Contains the following values
 - Initial Submission
 - Follow-Up Submission
 - Final Submission

Second Dropdown

- Title: Summary/Abstract Submission
- Contains the following values
 - Yes
 - No

Third Dropdown

- Title: Effects
- Contains the following values
 - Health Effect
 - Ecotoxicity
 - Environmental Fate
 - Physical-Chemical Properties

Fourth Dropdown

- Title: Endpoints
- Contains the following values
 - For Health Effect (shows when Health Effect is selected from third dropdown)
 - Basic Toxic kinetics
 - Dermal Absorption
 - Acute Toxicity: oral
 - Acute Toxicity: inhalation
 - Acute Toxicity: dermal
 - Acute Toxicity: other routes
 - Skin irritation/corrosion
 - Eye irritation
 - Skin sensitization
 - Respiratory sensitization
 - Repeated Dose toxicity: oral
 - Repeated Dose toxicity: inhalation

- Repeated Dose Toxicity: dermal
- Repeated Dose Toxicity: other routes
- Genetic Toxicity in vitro
- Genetic Toxicity in vivo
- Carcinogenicity
- Toxicity to Reproduction
- Developmental Toxicity/teratogenicity
- Toxicity to reproduction: other studies
- Neurotoxicity
- Immunotoxicity
- Specific investigations: other studies
- Health surveillance data
- Epidemiological data
- Direct observations: clinical cases, poisoning incidents and other
- Sensitization data (humans)
- Exposure related observations in humans: other data
- Toxic effects on livestock and pets
- Additional toxicological information
- Other
- For Ecotoxicity (shows when Ecotoxicity is selected from third dropdown)
 - Short-term toxicity to fish
 - Long-term toxicity to fish
 - Short-term toxicity to aquatic invertebrates
 - Long-term toxicity to aquatic invertebrates
 - Toxicity to aquatic algae and cyanobacteria
 - Toxicity to aquatic plants other than algae
 - Toxicity to microorganisms
 - Toxicity to other aquatic organisms
 - Sediment toxicity
 - Toxicity to soil macroorganisms except arthropods
 - Toxicity to terrestrial arthropods
 - Toxicity to terrestrial plants
 - Toxicity to soil microorganisms
 - Toxicity to birds
 - Toxicity to other above-ground organisms
 - Biological effects monitoring
 - Biotransformation and kinetics
 - Additional ecotoxicological information
 - Other

- For Environmental Fate (shows when Environmental Fate is selected from third dropdown)
 - Photo transformation in air
 - Hydrolysis
 - Photo transformation in water
 - Photo transformation in soil
 - Biodegradation in water: screening test
 - Biodegradation in water and sediment: simulation tests
 - Biodegradation in soil
 - Mode of degradation in actual use
 - Bioaccumulation: aquatic/sediment
 - Bioaccumulation: terrestrial
 - Adsorption/desorption
 - Henry's Law constant
 - Distribution Modeling
 - Other Distribution Data
 - Monitoring Data
 - Field Studies
 - Additional Information on Environmental Fate and Behavior
 - Other
- For Physical-Chemical Properties (shows when Physical-Chemical Properties is selected from third dropdown)
 - Appearance/Physical
 - Melting Point
 - Boiling Point
 - Density
 - Particle size distribution
 - Vapor Pressure
 - Partition Coefficient
 - Water Solubility
 - Solubility in Organic Solvent
 - Surface Tension
 - Flash Point
 - Auto Flammability
 - Flammability
 - Explosiveness
 - Oxidizing Properties
 - Oxidation Reduction Potential
 - Stability in organic solvents and identity of relevant degradation products
 - Storage stability and reactivity towards container material

- Stability: thermal, sunlight, metals
- pH
- Dissociation constant
- Viscosity
- Additional physic-chemical information
- Other