

Section 8(e) Notice Screensho Environmental Protection Agency Section 8(e) Notice Screenshots Office of Pollution Prevention and Toxics Manage Toxic Substances

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2 Section 8(e) Notice Screenshots

2.1 Overview

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/

This document presents screenshots for the 'Section 8(e) Notice' electronic application as if you were logged in as the Primary AO. As the Primary AO you are able to create, modify, delete, and submit an 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
- Submitting Official Information

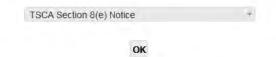


2.2 Section 8(e) Notice Screenshots

Exhibit 2-1: Mock-Up of Chemical Information Submission System Screen



CHEMICAL INFORMATION SUBMISSION SYSTEM



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.



Exhibit 2-2: Mock-Up of Home Screen



Submissions

TSCA Section 8(e) requires that any person who manufactures (including imports), processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

User Management

Manage the access rights of Supports for each Section 8(e) Notice submission. For every Support the Authorized Official may grant him/her the ability to edit (but not unlock, create, delete, or submit) the data.

Resources

A helpful guide that describes the Section 8(e) Notice system and provides useful links for further usability instruction.

Authorized Official

An Authorized Official has the ability to create, amend, and unlock Section 8(e) Notice submissions. The Authorized Official must also submit completed data electronically. Finally, the Authorized Official has the ability to assign Supports to individual submissions.





Exhibit 2-3: Mock-Up of Section 8(e) Notice Submissions Screen

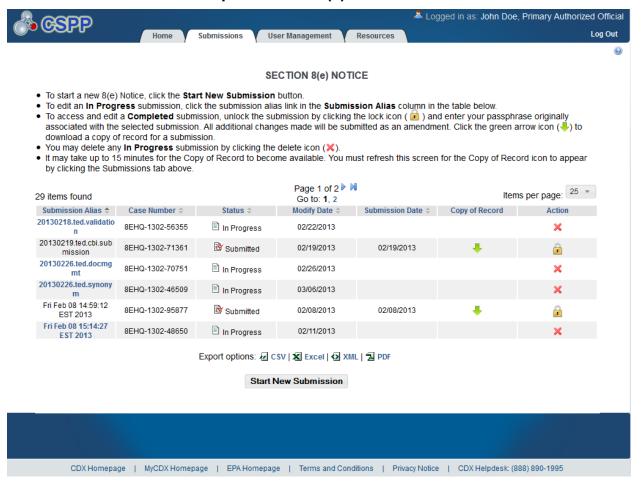




Exhibit 2-4: Mock-Up of Create Passphrase Screen

C-1-2-1-2			Log
	CREATE PAS	SPHRASE	
should contain a combination	hat is at least 8 characters in length and does of letters and numbers. The passphrase you cassociate the same passphrase with multiple	reate may include spaces but should n	
	New Passphrase		
	Confirm New Passphrase		
	rated by an Authorized Official for an individual ata. As an Authorized Official, you are respons		
protect the contents of your da authorized Supports. Note: You will be responsib		ble for remembering your passphrase	and distributing it to only
protect the contents of your da authorized Supports. Note: You will be responsib	ata. As an Authorized Official, you are respons le for remembering the passphrase and dis	ble for remembering your passphrase	and distributing it to only
protect the contents of your da authorized Supports. Note: You will be responsib	ata. As an Authorized Official, you are respons le for remembering the passphrase and dis will not be able to access the Section 8(e) N	ble for remembering your passphrase cributing it to only authorized Suppo otice submission to print, submit, o	and distributing it to only
protect the contents of your da authorized Supports. Note: You will be responsib	ata. As an Authorized Official, you are respons le for remembering the passphrase and dis will not be able to access the Section 8(e) N	ble for remembering your passphrase cributing it to only authorized Suppo otice submission to print, submit, o	and distributing it to only
protect the contents of your da authorized Supports.	ata. As an Authorized Official, you are respons le for remembering the passphrase and dis will not be able to access the Section 8(e) N	ble for remembering your passphrase cributing it to only authorized Suppo otice submission to print, submit, o	and distributing it to only



Exhibit 2-5: Mock-Up of Technical Contact Information Screen

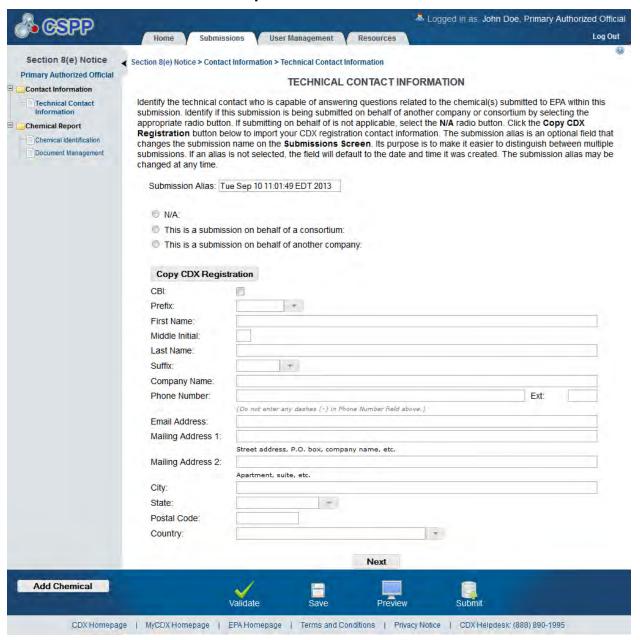




Exhibit 2-6: Mock-Up of Submitting on Behalf of Consortium Screen

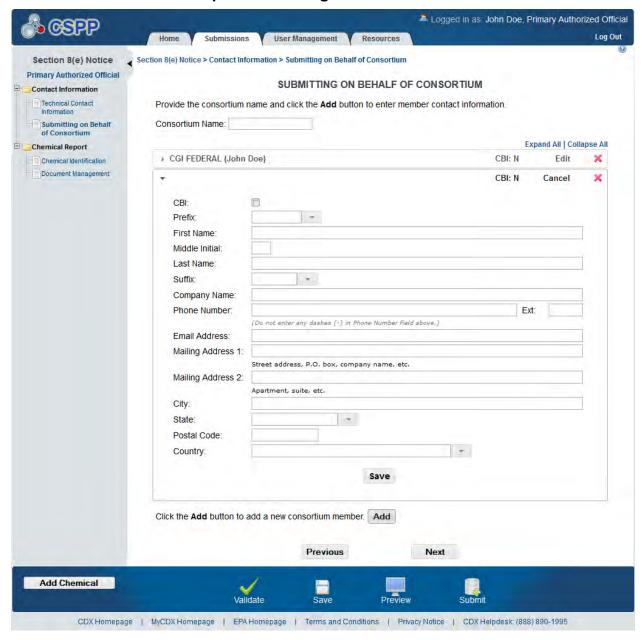




Exhibit 2-7: Mock-Up of Submitting on Behalf of Company Screen

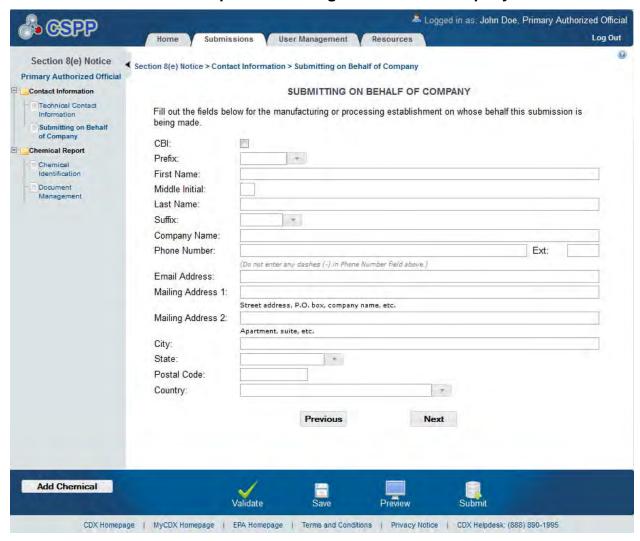




Exhibit 2-8: Mock-Up of Chemical Identification Screen – No Mixture (Able to claim chemical as CBI)

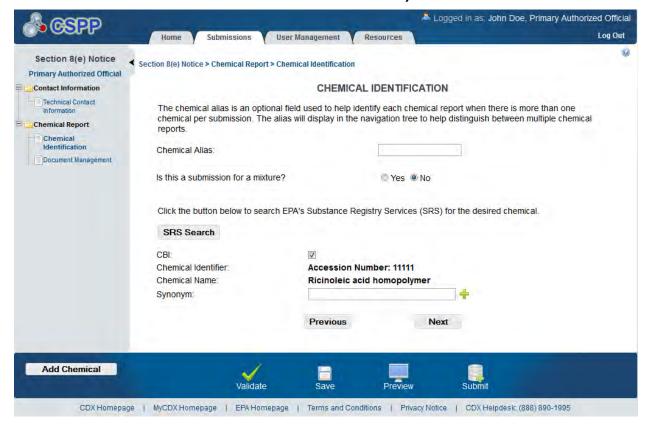




Exhibit 2-9: Mock-Up of Chemical Identification – No Mixture (Not able to claim chemical as CBI)

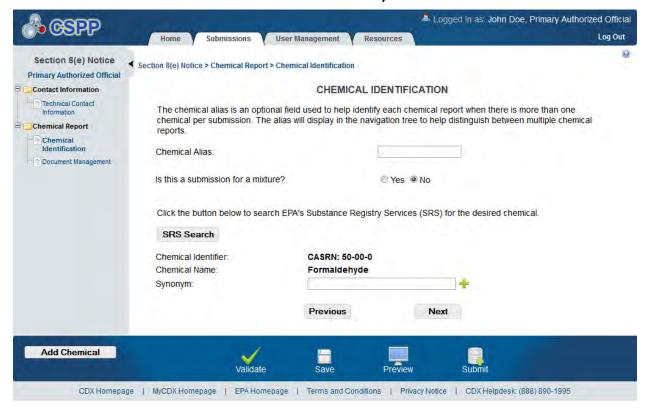




Exhibit 2-10: Mock-Up of Chemical Identification Screen - Mixture

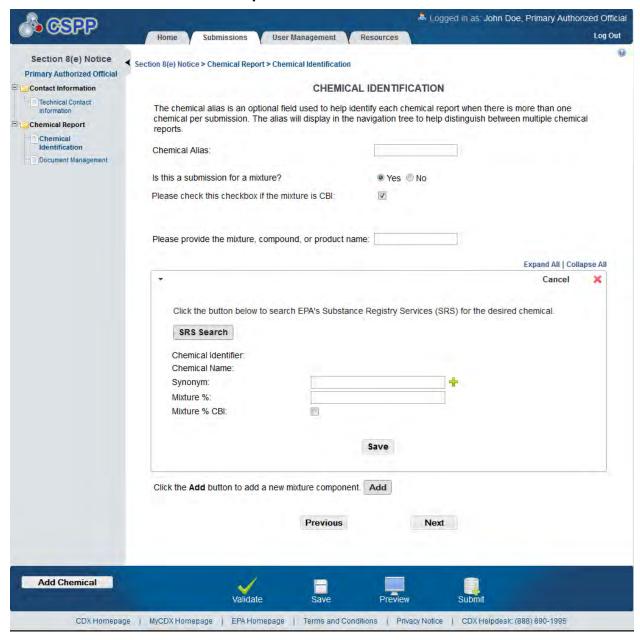




Exhibit 2-11: Mock-Up of the Search Substance Registry (SRS) Search Pop-Up Window

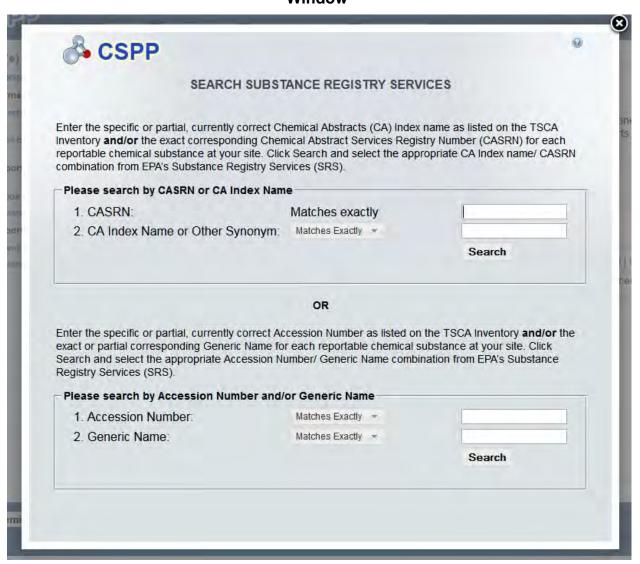




Exhibit 2-12: Mock-Up of the Chemical Not Found in Substance Registry Services Pop-Up Window





Exhibit 2-13: Mock-Up of Document Management Screen

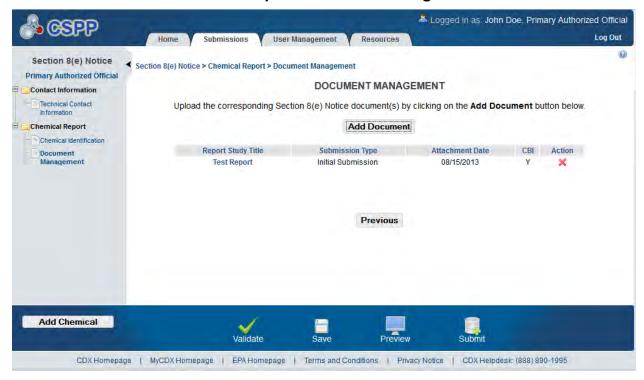




Exhibit 2-14: Mock-Up of Document Management Pop-Up Window (Display Submission Type)





Exhibit 2-15: Mock-Up of Document Management Pop-up Window (Display Effects)

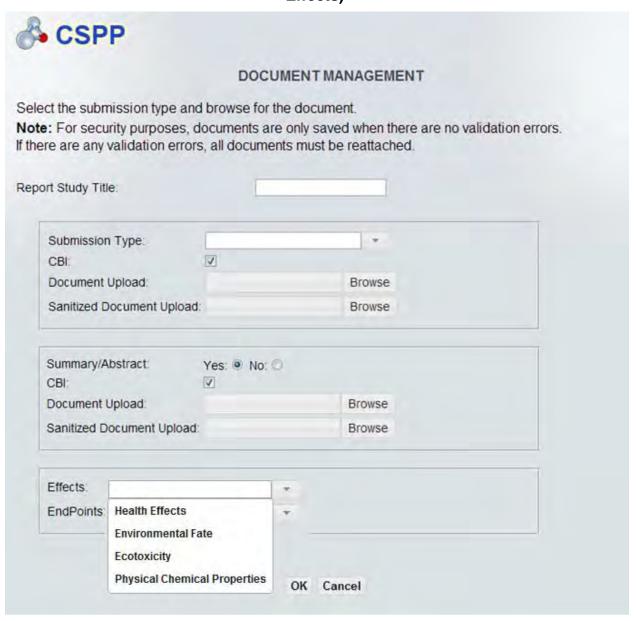
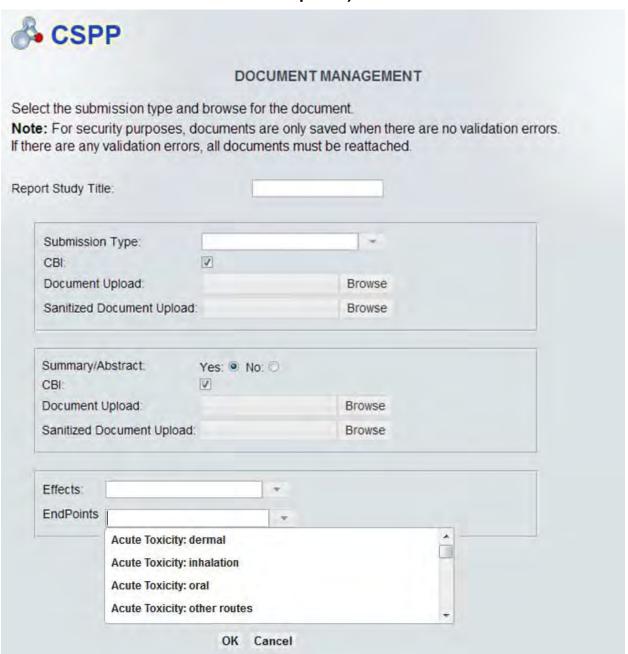




Exhibit 2-16: Mock-Up of Document Management Pop-Up Window (Display Endpoints)



^{**}Note: Please find all the possible drop-down options in Appendix A.



Exhibit 2-17: Mock-Up of Substantiation Screen





Exhibit 2-18: Mock-Up of Substantiation (continued)

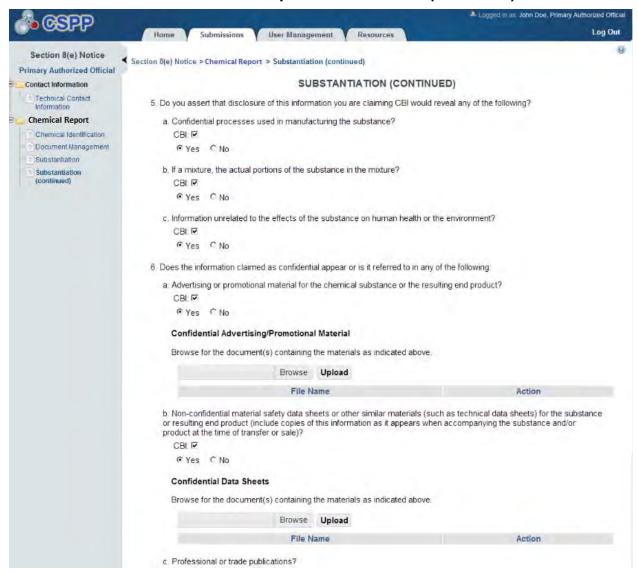
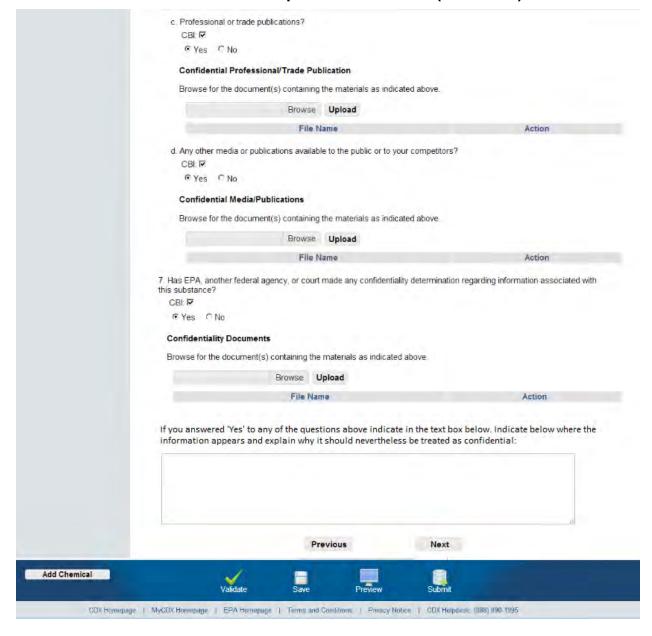




Exhibit 2-19: Mock-Up of Substantiation (continued)





3 Appendix A

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

First Dropdown:

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

Second Dropdown

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

Third Dropdown

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

Fourth Dropdown

- Title: Endpoints
- Contains the following values
 - o 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
 - Eve 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
- o 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
- o 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
- o 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