

Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Chemical Information Submission System – Section 4

The ‘Chemical Information Submission System’ screen provides a list of submission types from which the user can choose. Based on the selected submission type, the system directs the user to the appropriate application ‘Home’ screen.

The following exhibit shows a screen capture of the ‘Chemical Information Submission System’ screen:

Exhibit 1-1 Chemical Information Submission System Screen – Section 4

The screenshot shows a web application interface. At the top left is the GSPP logo. At the top right, it says "Logged in as: John Doe, Primary Authorized Official" and a "Log Out" button. The main heading is "Chemical Information Submission System". Below this is a prompt "Please Choose a Submission Type" and a dropdown menu currently showing "Section 4 Form". The main content area contains several paragraphs of text explaining the TSCA requirements for Section 4 submissions. At the bottom of the content area is an "OK" button. The footer contains navigation links: "CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk (888) 890-1995".

CDX
CENTRAL DATA
EXCHANGE

Logged in as: John Doe, Primary Authorized Official
Log Out

Chemical Information Submission System

Please Choose a Submission Type

Section 4 Form

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

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

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

The software includes embedded help files and a downloadable user manual to guide you through the Section 4 submission process. Submit information for all reportable chemical substances for each Federal Register Notice citations in one submission.

OK

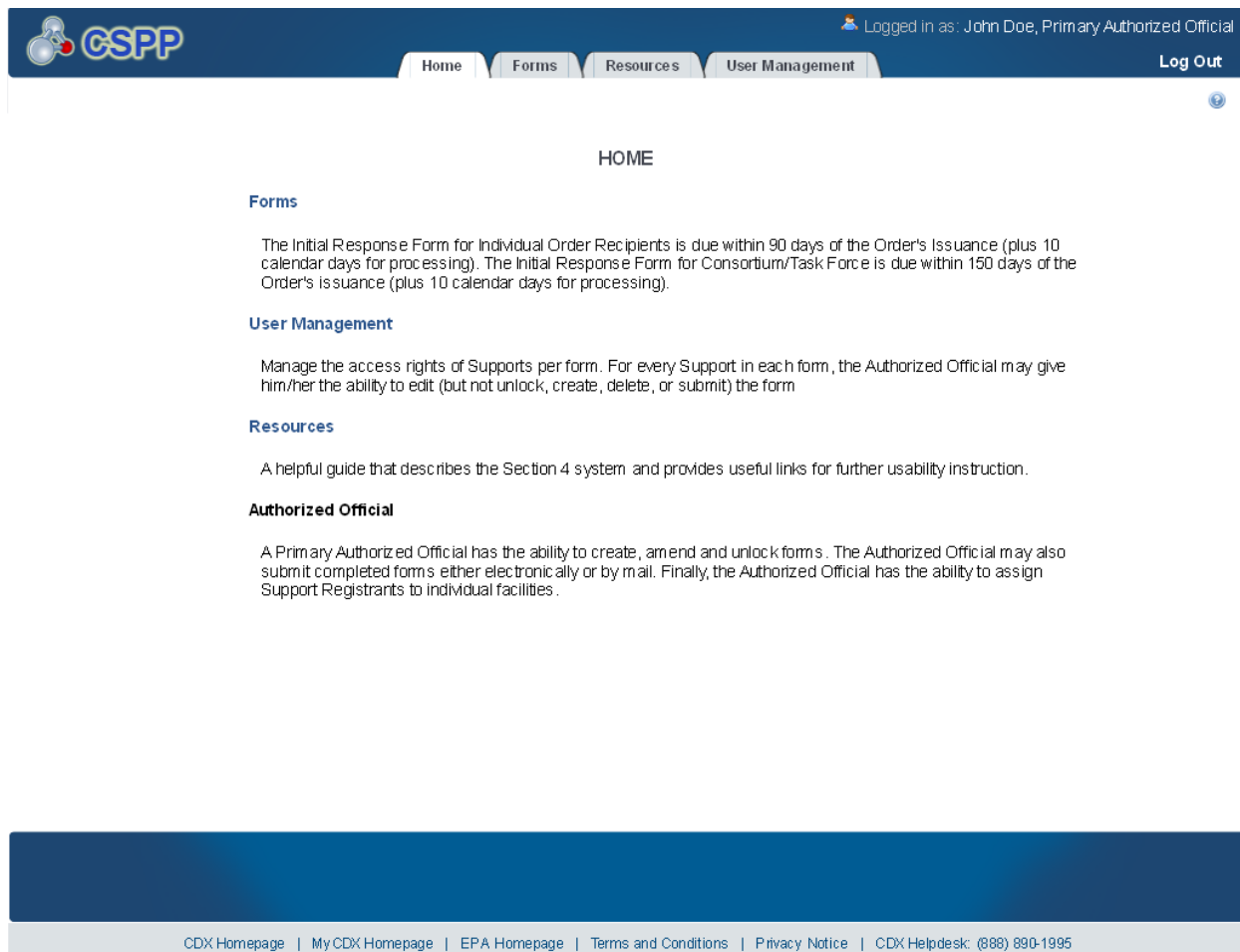
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Home

The 'Home' screen provides the user with links and tabs to access information for the form type, user management, and resources. Additionally, the system provides the user with information relevant to the logged in user's role.

The following exhibit shows a screen capture of the 'Home' screen:

Exhibit 1-2 Home Screen



The screenshot displays the GSPP (Global Support Portal) Home Screen. At the top left is the GSPP logo. The top right corner shows the user is logged in as 'John Doe, Primary Authorized Official' with a 'Log Out' button. A navigation bar contains tabs for 'Home', 'Forms', 'Resources', and 'User Management'. The main content area is titled 'HOME' and is organized into four sections: 'Forms', 'User Management', 'Resources', and 'Authorized Official'. Each section contains a brief description of its function. At the bottom, a dark blue footer bar contains a list of links: 'CDX Homepage', 'My CDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Forms

The Initial Response Form for Individual Order Recipients is due within 90 days of the Order's Issuance (plus 10 calendar days for processing). The Initial Response Form for Consortium/Task Force is due within 150 days of the Order's issuance (plus 10 calendar days for processing).

User Management

Manage the access rights of Supports per form. For every Support in each form, the Authorized Official may give him/her the ability to edit (but not unlock, create, delete, or submit) the form

Resources

A helpful guide that describes the Section 4 system and provides useful links for further usability instruction.

Authorized Official

A Primary Authorized Official has the ability to create, amend and unlock forms. The Authorized Official may also submit completed forms either electronically or by mail. Finally, the Authorized Official has the ability to assign Support Registrants to individual facilities.

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Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

User Management

The 'User Management' screen allows the Authorized Official to manage the access rights of Supports to the appropriate forms within the Section 4 Reporting application. For every Support, the Authorized Official may give him/her the ability to edit (but not unlock, create, delete, or submit) the form.

The following exhibit shows a screen capture of the 'User Management' screen:

Exhibit 1-3 User Management

CDX GSPP Logged in as: John Doe, Primary Authorized Official

Home Forms Resources **User Management** Log Out

USER MANAGEMENT

Select a Federal Register Notice from the dropdown menu to assign and unassign support registrants to the Section 4 Test Rules, ECAs, and MOU form.

Section 4 Test Rules, ECAs, and MOU Federal Register Notice: Federal Register Notice

Section 4 Test Rules, ECAs, and MOU
CASRN

Assign Users

Unassigned **Assigned**

add >>
<< remove

Save

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Section 4 Forms

The 'Section 4' form screen presents the user with a list of forms submitted or started by the AO during the current reporting cycle. Additionally, AOs may begin a new submission from this screen.

The following exhibit shows a screen capture of the 'Section 4' Forms screen:

Exhibit 1-4 Forms Screen

Logged in as: John Doe, Primary Authorized Official

Home Forms Resources User Management Log Out

SECTION 4

Federal Register Notice	CASRN	Status	Modify Date	Submission Date	Copy of Record	Action
75 FR 773 January 6, 2010	3425-22-1	Submitted	09/17/2010	09/17/2010	↓	🔒

Select Federal Register Notice:

Start New Submission

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Submitting Official Information

The ‘Section A – Submitting Official Information’ allows the user to confirm their contact information. The screen is pre-populated with the information entered by the user during CDX registration.

The following exhibit shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 1-5 Submitting Official Information Screen

Section 4 Test Rules, ECAs, and MOU

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Contact Information > Submitting Official Information

Primary Authorized Official

75 FR 773 January 6, 2010

Contact Information

Submitting Official Information

Submitting on Behalf of Consortium

Technical Contact

Sponsoring Firms

Letter of Intent

Chemical Identification and Test Rules

Additional Information/Submitter Requests

Remove

Study Plan

Document Management

Additional Information/Submitter Requests

Remove

Results

Document Management

Remove

Test Rule Substantiation

SECTION A - SUBMITTING OFFICIAL INFORMATION

This is the appropriate individual to contact for further information:

This is a submission on behalf of a consortium:

This is a submission on behalf of another company:

Prefix: Mr.

First Name: John

Middle Initial: D

Last Name: Doe

Suffix:

Company Name: CGI Federal

Telephone: (888) 890-1995

Email Address: cgifederal@cgifederal.com

Mailing Address 1: 12601 Fair Lakes Circle

Mailing Address 2:

City: Fairfax

State: Virginia

Zip: 22033

Previous Next

Add Federal Register Notice

Validate Save Preview Submit

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Submitting on Behalf of Consortium

The ‘Section A.1.1 – Submitting on Behalf of Consortium’ screen allows users to submit Section 4 forms on behalf of a consortium covered under the reporting requirement. The screen presents a list of text fields that allows the user to input contact information for each consortia member.

The following exhibit shows a screen capture of the ‘Submitting on Behalf of Consortium’ screen:

Exhibit 1-6 Submitting on Behalf of Consortium Screen

Logged in as: John Doe, Primary Authorized Official

Home Forms Resources User Management Log Out

Section 4 Test Rules, ECAs, and MOU

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Contact Information > Submitting on Behalf of (A.1)

Primary Authorized Official

75 FR 773 January 6, 2010

Contact Information

- Submitting Official Information
- Submitting on Behalf of Consortium
- Technical Contact
- Sponsoring Firms

Letter of Intent

- Chemical Identification and Test Rules
- Additional Information/Submitter Requests
- Remove

Study Plan

- Document Management
- Additional Information/Submitter Requests
- Remove

Results

- Document Management
- Remove

Test Rule Substantiation

SECTION A.1.1 - SUBMITTING ON BEHALF OF CONSORTIUM

Fill out the fields below for each industry consortia member. Click the Save & Add Sponsor button to add each member.

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Sponsor Name:

Telephone:

Email Address:

Mailing Address 1:

Mailing Address 2:

City:

State:

Zip:

Save & Add Sponsor

Consortium Name:

Sponsor Name	Contact	Action
Company 1		X
Company 2		X
Company 3		X
Company 4		X

Previous Next

Add Federal Register Notice

Validate Save Preview Submit

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Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Submitting on Behalf of

The ‘Section A.1 – Submitting on Behalf of’ screen allows users to submit Section 4 forms on behalf of another company covered under the reporting requirement. The screen presents a list of text fields that allows the user to input contact information of the manufacturing or processing establishment on whose behalf the submission is made.

The following exhibit shows a screen capture of the ‘Submitting on Behalf of’ screen:

Exhibit 1-7 Submitting on Behalf of Screen

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Contact Information > Submitting on Behalf of (A.1)

SECTION A.1 - SUBMITTING ON BEHALF OF

Fill out the fields below for the manufacturing or processing establishment on whose behalf this submission is being made.

This is the appropriate individual to contact for further information:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Telephone:

Email Address:

Mailing Address 1:

Mailing Address 2:

City:

State:

Zip:

Previous Next

Add Federal Register Notice

Validate Save Preview Submit

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Technical Contact

The ‘Technical Contact’ screen allows the user to add multiple technical contacts, if needed. The system will provide a virtual rolodex address book dropdown menu listing all added technical contacts.

The following exhibit shows a screen capture of the ‘Technical Contact’ screen:

Exhibit 1-8 Technical Contact Screen

The screenshot displays the GSPP (Global Site Profile) interface. At the top, the user is logged in as 'John Doe, Primary Authorized Official'. The navigation menu includes 'Home', 'Forms', 'Resources', 'User Management', and 'Log Out'. The breadcrumb trail indicates the current location: 'Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Contact Information > Technical Contact (A.2)'. The main heading is 'SECTION A.2 - TECHNICAL CONTACT'. Below this, a text block explains that users can select a contact from a dropdown or create a new one. A red box highlights the checkbox 'This is the appropriate individual to contact for further information: '. The form fields are as follows:

Select:	David Duvall	OR	Create New Contact
Prefix:	Mr.	Default Contact:	<input checked="" type="checkbox"/>
First Name:	David		
Middle Initial:	W		
Last Name:	Duvall		
Suffix:			
Company Name:	ABC Company		
Telephone:	555-555-5555		
Email Address:	David.Duval@gmail.com		
Mailing Address 1:	324 Powers Road		
Mailing Address 2:			
City:	Springfield		
State:	Rhode Island		
Zip:	98565		

At the bottom of the form, there are 'Previous' and 'Next' buttons. Below the form is a dark blue bar with icons for 'Validate', 'Save', 'Preview', and 'Submit'. A button labeled 'Add Federal Register Notice' is also visible on the left side of this bar. The footer contains links to 'CDX Homepage', 'My CDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

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Sponsoring Firms

The ‘Sponsoring Firms’ screen allows the user to input the contact information for the firm(s) which will be sponsoring the tests. The user is required to report the sponsoring firms when submitting a Letter of Intent.

The following exhibit shows a screen capture of the ‘Sponsoring Firms’ screen:

Exhibit 1-9 Sponsoring Firms Screen

Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Contact Information > Sponsoring Firms

SPONSORING FIRMS

Please fill out the information for Sponsoring Firm(s) below:

Firm:

Telephone:

Mailing Address 1:

Mailing Address 2:

City:

State:

Zip:

Save & Add Firm

Previous Next

Firm Name	Action
firm-0	X
firm-1	X
firm-2	X
firm-3	X

Add Federal Register Notice

Validate Save Preview Submit

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Chemical Identification and Test Rules

The 'Chemical Identification and Test Rules' screen gives the user the opportunity to assign chemicals to the sponsors which intend to use them for testing. The user should click the 'Assign Chemicals' button to complete this task.

The following exhibit shows a screen capture of the 'Chemical Identification and Test Rules' screen:

Exhibit 1-10 Chemical Identification and Test Rules Screen

Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

- Contact Information
 - Submitting Official Information
 - Submitting on Behalf of Information
 - Submitting on Behalf of Consortium
 - Technical Contact
 - Sponsoring Firms
- Letter of Intent
 - Chemical Identification and Test Rules**
 - Additional Information/Submitter Requests
 - Remove
- Study Plan
 - Document Management
 - Additional Information/Submitter Requests
 - Remove
- Results

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Letter Of Intent > Chemical Identification and Test Rules

CHEMICAL IDENTIFICATION AND TEST RULES

Click the Assign Chemicals button to identify the chemical substance(s) the sponsor(s) intends to use in each of the tests.

Assign Chemicals

Previous Next

Add Federal Register Notice

Validate Save Preview Submit

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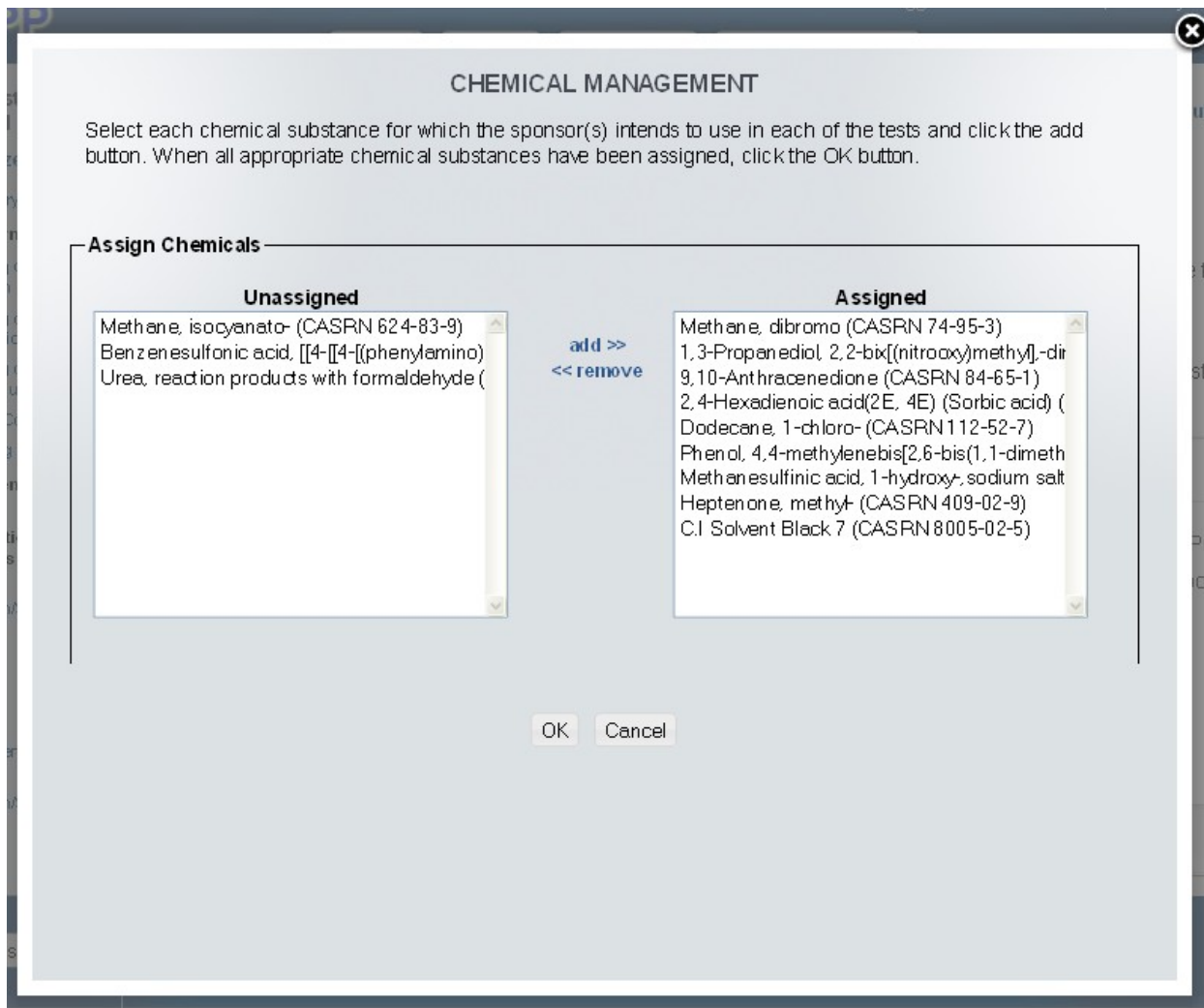
Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Chemical Management

The 'Chemical Management' pop-up displays all chemicals associated with the submission and allows them to be assigned to a specific sponsor for testing. Once assigned, the chemicals will display on the 'Chemical Identification and Test Rules' screen.

The following exhibit shows a screen capture of the 'Chemical Management' pop-up screen:

Exhibit 1-11 Chemical Management Pop-Up



Chemical Identification and Test Rules

The ‘Chemical Identification and Test Rules’ screen gives the user the opportunity to assign chemicals to the sponsors which intend to use them for testing. The user should click the ‘Assign Chemicals’ button to complete this task.

The following exhibits show screen captures of the ‘Chemical Identification and Test Rules’ screen after it is populated:

Exhibit 1-12 Chemical Identification and Test Rules Screen (populated) Scroll 1

Logged in as: John Doe, Primary Authorized Official

Home Forms Resources User Management Log Out

Section 4 Test Rules, ECAs, and MOU < Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Letter Of Intent > Chemical Identification and Test Rules

Primary Authorized Official

75 FR 773 January 6, 2010

Contact Information

- Submitting Official Information
- Submitting on Behalf of Information
- Submitting on Behalf of Consortium
- Technical Contact
- Sponsoring Firms

Letter of Intent

- Chemical Identification and Test Rules**
- Additional Information/Submitter Requests
- Remove

Study Plan

- Document Management
- Additional Information/Submitter Requests
- Remove

Results

CHEMICAL IDENTIFICATION AND TEST RULES

Click the Assign Chemicals button to identify the chemical substance(s) the sponsor(s) intends to use in each of the tests.

Assign Chemicals

For the chemical substance(s) listed below, identify the testing requirement(s) to be performed on the specified substance.

Methane, dibromo (CASRN 74-95-3) ✓

- Determination of Vapor Pressure
- Determination of General Physico-Chemical Properties
- Algal Growth Inhibition Test
- Chromosome Aberration Test in Human Lymphocytes In Vitro
- Acute Toxicity to Rainbow Trout
- Acute Toxicity to Daphnia Magna
- Oral (Gavage) Reproduction/Developmental Toxicity Screening Test in the Rat

1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (CASRN 78-11-5) ⚠

Add Federal Register Notice

Validate Save Preview Submit

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Exhibit 1-13 Chemical Identification and Test Rules Screen (populated) Scroll 2

Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

Contact Information

- Submitting Official Information
- Submitting on Behalf of Information
- Submitting on Behalf of Consortium
- Technical Contact
- Sponsoring Firms

Letter of Intent

- Chemical Identification and Test Rules
- Additional Information/Submitter Requests
- Remove

Study Plan

- Document Management
- Additional Information/Submitter Requests
- Remove

Results

Home Forms Resources User Management Log Out

Logged in as: John Doe, Primary Authorized Official

Methane, dibromo (CASRN 74-95-3) ✓

1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (CASRN 78-11-5) ✓

9,10-Anthracenedione (CASRN 84-65-1) ✓

2,4-Hexadienoic acid(2E, 4E) (Sorbic acid) (CASRN 110-44-1) ✓

Dodecane, 1-chloro- (CASRN 112-52-7) ✓

Phenol, 4,4-methylenebis[2,6-bis(1,1-dimethylethyl)]-(CASRN 118.82-1) ⚠

- Existing data for Determination of Water Solubility and n-Octanol/Water Partition Coefficient
- Existing data for Bacterial Reverse Mutation Test (Ames Test)
- Re submittal for Bacterial Reverse Mutation Test (Ames Test)
- Existing data for Acute Oral Mammalian Toxicity Test


Methanesulfinic acid, 1-hydroxy-, sodium salt (1:1) (CASRN 149-44-0) ⚠

Add Federal Register Notice

Validate Save Preview Submit

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Exhibit 1-14 Chemical Identification and Test Rules Screen (populated) Scroll 3


Logged in as: John Doe, Primary Authorized Official

[Home](#) | [Forms](#) | [Resources](#) | [User Management](#)

[Log Out](#)

Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

- Contact Information**
 - Submitting Official Information
 - Submitting on Behalf of Information
 - Submitting on Behalf of Consortium
 - Technical Contact
 - Sponsoring Firms
- Letter of Intent**
 - Chemical Identification and Test Rules**
 - Additional Information/Submitter Requests
 - ✖ Remove
- Study Plan**
 - Document Management
 - Additional Information/Submitter Requests
 - ✖ Remove
- Results**

▶ Dodecane, 1-chloro- (CASRN 112-52-7) ✔

▼ Phenol, 4,4-methylenebis[2,6-bis(1,1-dimethylethyl)-](CASRN 118.82-1) ⚠

Existing data for Determination of Water Solubility and n-Octanol/Water Partition Coefficient

Existing data for Bacterial Reverse Mutation Test (Ames Test)

Re-submittal for Bacterial Reverse Mutation Test (Ames Test)

Existing data for Acute Oral Mammalian Toxicity Test

▶ Methanesulfinic acid, 1-hydroxy-, sodium salt (1:1) (CASRN 149-44-0) ⚠


▶ Heptenone, methyl- (CASRN 409-02-9) ⚠


▶ C.I Solvent Black 7 (CASRN 8005-02-5) ⚠


Previous Next

Add Federal Register Notice

✔
Validate


Save


Preview


Submit

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Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Additional Information / User Requests

The ‘Additional Information/User Requests’ screen allows user to input additional information and documents to address issues such as exemptions, exemption appeals, time extensions, etc.

The following exhibit shows a screen capture of the ‘Additional Information / User Requests’ screen:

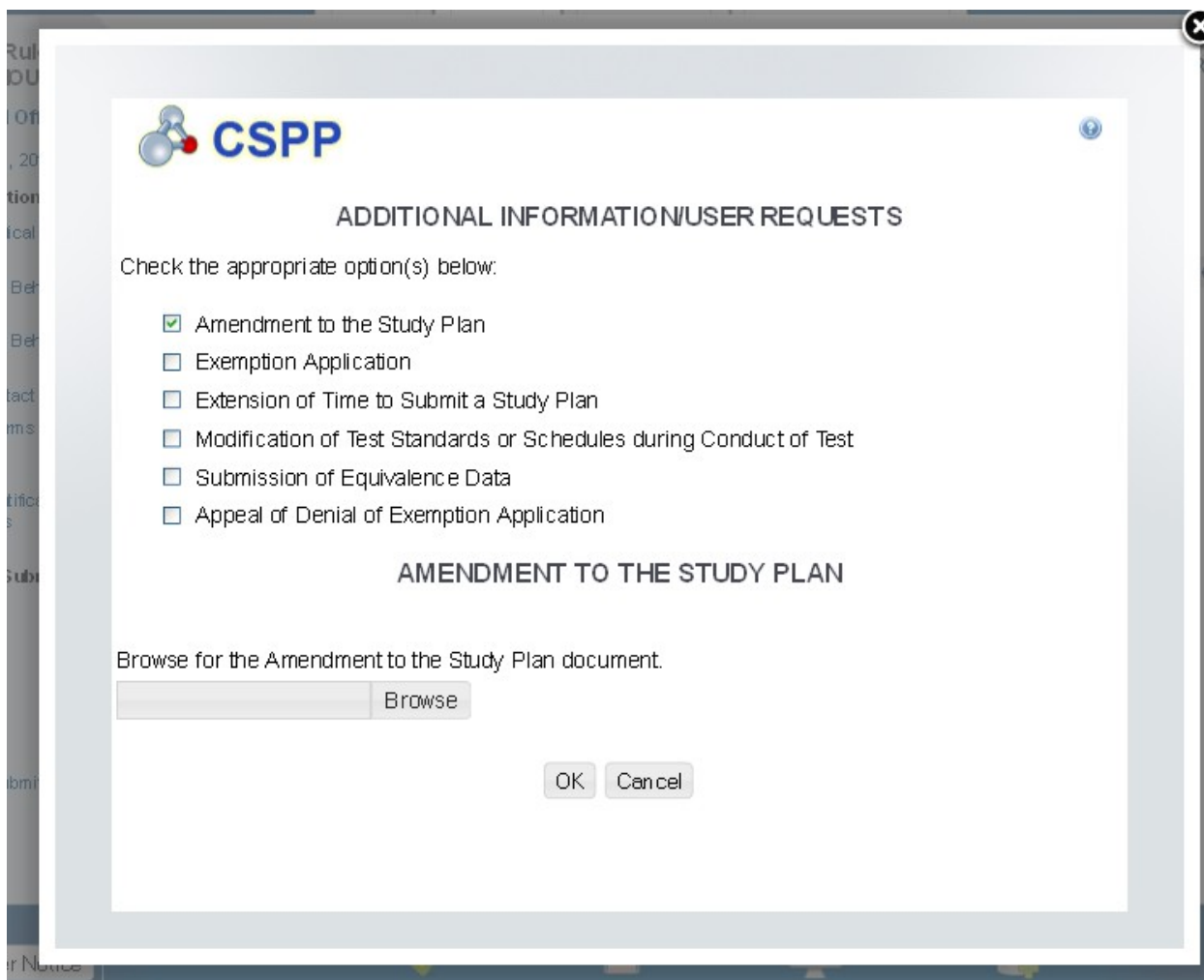
Exhibit 1-15 Additional Information/User Requests Screen

Amendment to the Study Plan

The 'Amendment to the Study Plan' pop-up allows the user to provide additional information about a study plan. The user can upload and document and identify the type of document through this pop-up.

The following exhibit shows a screen capture of the 'Amendment to the Study Plan' pop-up screen:

Exhibit 1-16 Amendment to the Study Plan Pop-Up



The screenshot shows a pop-up window titled 'CSPP' with the subtitle 'ADDITIONAL INFORMATION/USER REQUESTS'. The window contains a list of options for user requests, with 'Amendment to the Study Plan' selected. Below the list is a section titled 'AMENDMENT TO THE STUDY PLAN' with a 'Browse' button for uploading a document. At the bottom are 'OK' and 'Cancel' buttons.

CSPP

ADDITIONAL INFORMATION/USER REQUESTS

Check the appropriate option(s) below:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

AMENDMENT TO THE STUDY PLAN

Browse for the Amendment to the Study Plan document.

Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Exemption Application

The 'Exemption Application' pop-up allows users to request exemptions from certain study requirements. The user should select the appropriate exemption checkboxes and provide reasoning for why the exemption is warranted.

The following exhibit shows a screen capture of the 'Exemption Application' pop-up screen:

Exhibit 1-17 Exemption Application Pop-Up

Extension of Time to Submit a Study Plan

Modification of Test Standards or Schedules during Conduct of Test

Submission of Equivalence Data

Appeal of Denial of Exemption Application

EXEMPTION APPLICATION

Check all testing requirement(s) from which an exemption is sought:

Determination of Vapor Pressure

Determination of General Physico-Chemical Properties

Algal Growth Inhibition Test

Chromosome Aberration Test in Human Lymphocytes In Vitro

Acute Toxicity to Rainbow Trout

Provide the basis for the exemption request below:

OK Cancel

Extension of Time to Submit Study Plan

The 'Extension of Time to Submit Study Plan' pop-up allows the user to request a time extension to submit their study information. The user should select the appropriate extension checkboxes and provide reasoning for why the extension is warranted.

The following exhibit shows a screen capture of the 'Extension of Time to Submit Study Plan' pop-up screen:

Exhibit 1-18 Extension of Time to Submit Study Plan Pop-Up

ADDITIONAL INFORMATION/USER REQUESTS

Check the appropriate option(s) below:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

EXTENSION OF TIME TO SUBMIT STUDY PLAN

Please state why the EPA should grant the extension in the text box below:

OK Cancel

Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Modification of Test Standards or Schedule during Conduct of Test

The ‘Modification of Test Standards or Schedule during Conduct of Test’ pop-up allows the user to request a modification of testing standards. The user should select the appropriate modification checkboxes and provide reasoning for why the extension is warranted.

The following exhibit shows a screen capture of the ‘Modification of Test Standards or Schedule during Conduct of Test’ pop-up screen:

Exhibit 1-19 Modification of Test Standards or Schedule during Conduct of Test Pop-Up

ADDITIONAL INFORMATION/USER REQUESTS

Check the appropriate option(s) below:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

MODIFICATION OF TEST STANDARDS OR SCHEDULES DURING CONDUCT OF TEST

Please enter below appropriate explanation and rationale for the modification:

OK Cancel

Submission of Equivalence Data

The 'Submission of Equivalence Data' pop-up allows users filing for exemption to submit for equivalency when a test rule promulgated under section 4 requires the testing of two or more test substances which are forms of the same chemical.

The following exhibit shows a screen capture of the 'Submission of Equivalence Data' pop-up screen:

Exhibit 1-20 Submission of Equivalence Data Pop-Up

CSPP

ADDITIONAL INFORMATION/USER REQUESTS

Check the appropriate option(s) below:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

SUBMISSION OF EQUIVALENCE DATA

Browse for the appropriate Equivalence Data document.

CBI: Browse

OK Cancel

Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Appeal of Denial of Exemption Application

The 'Appeal of Denial of Exemption Application' pop-up allows the user to request an appeal of a previous EPA exemption decision. The user should select the appropriate appeal checkboxes and provide reasoning for why the exemption should be reconsidered.

The following exhibit shows a screen capture of the 'Appeal of Denial of Exemption Application' pop-up screen:

Exhibit 1-21 Appeal of Denial of Exemption Application Pop-Up

Check the appropriate option(s) below:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

APPEAL OF DENIAL OF EXEMPTION APPLICATION

Please enter below the basis for the request for reconsideration:

Check here if you wish to request a hearing:

Additional Information / User Requests (populated)

The 'Additional Information/User Requests' screen allows user to input additional information and documents to address issues such as exemptions, exemption appeals, time extensions, etc. This screen capture displays how a submitted 'Appeal of Denial of Exemption Application,' 'Submission of Equivalence Data,' and 'Amendment to the Study Plan' will display.

The following exhibit shows a screen capture of the 'Additional Information / User Requests' pop-up screen after it is populated:

Exhibit 1-22 Additional Information/User Requests (populated)

The screenshot shows the GSPP web application interface. At the top, the user is logged in as 'John Doe, Primary Authorized Official'. The navigation menu includes 'Home', 'Forms', 'Resources', 'User Management', and 'Log Out'. The breadcrumb trail indicates the current path: 'Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Letter Of Intent > Additional Information/User Requests (D)'. The main content area is titled 'SECTION D - ADDITIONAL INFORMATION/USER REQUESTS' and features an 'Add New Document' button. Below this is a table with three columns: 'Document Type', 'File Name', and 'Actions'. The table contains three rows of data. At the bottom of the screen, there is a toolbar with buttons for 'Validate', 'Save', 'Preview', and 'Submit', along with an 'Add Federal Register Notice' button. The footer contains links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk (888) 890-1995'.

Document Type	File Name	Actions
Appeal of Denial of Exemption Application	N/A	X
Submission of Equivalence Data		X
Amendment to the Study Plan		X

Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Study Plan Document Management

The ‘Study Plan Document Management’ screen allows users to upload and identify study plans. The following exhibits show screen captures of the ‘Study Plan Document Management’ screen:

Exhibit 1-23 Study Plan Document Management Screen

Section 4 Test Rules, ECAs, and MOU > 75 FR 773 January 6, 2010 > Study Plan > Document Management

STUDY PLAN DOCUMENT MANAGEMENT

Identify the Study Plan from the document type drop-down menu and browse for the appropriate Study Plan document. Click Upload to attach.

Document Type: Phase I Browse Upload

File Name	Document Type	Attachment Date	Actions
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Exhibit 1-24 Study Plan Document Management Screen (populated)

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STUDY PLAN DOCUMENT MANAGEMENT

Identify the Study Plan from the document type drop-down menu and browse for the appropriate Study Plan document. Click Upload to attach.

Document Type: Phase I CBI: Coordination Notes 10111 Browse Upload

File Name	Document Type	Attachment Date	Actions
Meeting Minutes - Internal Team Meeting Template v3.0.doc	Phase II	12/01/2010	✗
Coordination Notes 101111.docx	Phase I	12/01/2010	✗

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Results Document Management

The 'Results Document Management' screen allows users to submit the results of a study. Users may identify and upload documents to perform this task.


Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

The following exhibits show screen captures of the 'Results Document Management' screen:

Exhibit 1-25 Results Document Management Screen

This screen capture displays how submitted 'Results and 'Equivalence' information will display:

Exhibit 1-26 Results Document Management Screen (populated)


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RESULTS DOCUMENT MANAGEMENT


Select the document type from the document type drop-down menu and browse for the document. Click upload to attach.


Document Type:


File Name	Document Type	Attachment Date	Actions
TDD 0921 OPPT MTS Phase II Monthly Status Meeting.doc	Results	12/01/2010	✖
OPPT Monthly Status Meeting 04.docx	Equivalence Data	12/01/2010	✖

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Screen mock-ups are approximations and may change. Each optional field is outlined by a red text box.

Test Rule Substantiation Part 1

The ‘Test Rules Substantiation Part 1’ screen allows users that have asserted claims of confidentiality for certain information submitted to EPA to provide the appropriate substantiation for those claims.

The following exhibit shows the screen capture of the ‘Test Rule Substantiation Part 1’ screen:

Exhibit 1-27 Test Rule Substantiation Part 1 Screen

Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

Contact Information

- Submitting Official Information
- Submitting on Behalf of Information
- Submitting on Behalf of Consortium
- Technical Contact
- Sponsoring Firms

Letter of Intent

- Chemical Identification and Test Rules
- Additional Information/Submitter Requests
- Remove

Study Plan

- Document Management
- Additional Information/Submitter Requests
- Remove

Results

- Document Management
- Remove

Test Rule Substantiation Part 1

Test Rule Substantiation Part 2

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TEST RULE SUBSTANTIATION PART 1

1. Has the information been disclosed in a patent?
 Yes No

2. Would disclosure of the study plan information disclose processes used in the manufacture or processing of a chemical substance or mixture?
 Yes No
 Describe how this would occur.

3. Would disclosure of the study plan information disclose the portion of a mixture comprised by any of the substances in the mixture?
 Yes No
 Describe how this would occur.

4. Has this information been disclosed to the public in any forms?
 Yes No
 Describe the circumstances.

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Test Rule Substantiation Part 2

The ‘Test Rules Substantiation Part 2’ screen allows users that have asserted claims of confidentiality for certain information submitted to EPA to provide the appropriate substantiation for those claims.

The following exhibits shows the screen captures of the ‘Test Rule Substantiation Part 2’ screen:

Exhibit 1-28 Test Rule Substantiation Part 2 – Scroll 1

GSPP Logged in as: John Doe, Primary Authorized Official

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TEST RULE SUBSTANTIATION PART 2

Primary Authorized Official

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- Contact Information
 - Submitting Official Information
 - Submitting on Behalf of Information
 - Submitting on Behalf of Consortium
 - Technical Contact
 - Sponsoring Firms
- Letter of Intent
 - Chemical Identification and Test Rules
 - Additional Information/Submitter Requests
 - Remove
- Study Plan
 - Document Management
 - Additional Information/Submitter Requests
 - Remove
- Results

5. For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently?

Event

Date

Permanently

Why should confidential treatment be given?

6. What harmful effects to your competitive position, if any, do you think would results from disclosure of this information? How would a competitor use such information? How substantial would the harmful effects be? What is the causal relationship between disclose and the harmful effects?

7. What measures have you taken to guard against disclosure of this information to others?

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Exhibit 1-29 Test Rules Substantiation Part 2 – Scroll 2

GSPP
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Section 4 Test Rules, ECAs, and MOU

Primary Authorized Official

75 FR 773 January 6, 2010

- Contact Information**
 - Submitting Official Information
 - Submitting on Behalf of Information
 - Submitting on Behalf of Consortium
 - Technical Contact
 - Sponsoring Firms
- Letter of Intent**
 - Chemical Identification and Test Rules
 - Additional Information/Submitter Requests
 - ✖ Remove
- Study Plan**
 - Document Management
 - Additional Information/Submitter Requests
 - ✖ Remove
- Results**

7. What measures have you taken to guard against disclosure of this information to others?

8. To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?

9. Has EPA, another Federal Agency, or any Federal court made any pertinent confidentiality determination regarding this information?

Yes No

Click the Browse button and search for the appropriate document(s). Click the Upload button to attach copies of such determinations.

TDD 9.21 OPPT MTS Ph: Browse Upload

File Name	Attachment Date	Actions
TDD 9.21 OPPT MTS Phase II IUR Web Design Document v1.1.docx	12/01/2010	✖

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