



European Paediatric Formulation Initiative



Eu – US PFI

Safety and **T**oxicity of **E**xcipients for **P**aediatric [STEP]

User Guide

European Paediatric Formulation Initiative (EuPFI)

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1 Introduction

1.1 Overview

European Paediatric Formulation Initiative (EuPFI) is a consortium working in a pre-competitive way on paediatric drug formulations. Members are from academia, hospital pharmacies, pharmaceutical industry (Innovators, Generics, Contract Research Organizations (CRO), Specials and Excipient Manufacturers) with European Medicine Agency (EMA) as an observer.

Its main aim and objective is to identify/scope issues and challenges in paediatric formulation development in order to raise awareness and facilitate preparation of better/safe medicines for children.

As there is no central repository in public domain that resides all the information on safety and toxicity of Excipients for the paediatric drug development. The Eu-US PFI has established that there is a pressing need for a single authoritative comprehensive database of adverse effects of excipients for paediatrics.

STEP **S**afety and **T**oxicity of **E**xcipients for **P**aediatric [STEP] Database holds all the animal toxicity and human health data, regulatory information and toxicological reviews of excipients. STEP acts as repository for all the scientific communities to share the data for better understanding and paediatric drug development.

1.2 Scope

STEP database is intended to provide the data availability for the paediatric formulation development by the implementation of freely accessible online source which will provide easy access to authoritative comprehensive database of adverse effects of excipients for paediatrics from a key resource. Its main compass is to provide all the regulatory information and toxicological reviews of excipients.

STEP accomplishes a high-level scientific literature review of the pharmacology, toxicology and safety data of a prioritized group of excipients likely to be used in paediatric formulations.

1.3 Purpose

STEP main rationale is to afford the public access of an evidence database of safety and toxicity of excipients for the pharmaceutical industry academics, clinicians and regulators to make informed decisions. This also enhances the prospects of identifying potential safety issues at earlier stages of the development process when excipients are being screened and selected.

STEP also establishes a fine relationship between exposure and evidence of clinically significant toxicity in the paediatric subpopulations and also assists in need of generating new data for paediatric medicines.

2 Getting started

Currently most of the existing databases are focusing in providing Safety and Toxicity related information related only to adults and animals. But very few include the paediatric information related to children. Consequently, there is an acute need for a single repository to capture, archive, validate, manage, maintain and provide access to safety, tolerability and toxicity data that have been generated for excipients available world-wide for paediatric drug development.

In order to address this need, the European (Eu) and United States (US) Paediatric Formulation Initiatives (PFIs) are working together to create and maintain a database of Safety and Toxicity of Excipients for Paediatrics (STEP).

2.1 Log in

Enter the user credentials in the login page and click “Login” as shown below.

EUPFI **STEP database** **uspfi**
European Paediatric Formulation Initiative Database of safety and toxicity of excipients for paediatrics United States Paediatric Formulation Initiative

Revision Date: 10/29/2012

Existing User Login
If you already have an account, please login below

User Guide

Login Email * venkata.bodhanapu@gvkbio.com
Password *
Log In Forgot Password ?
(Your login session will expire after 30 minutes of inactivity)

* Indicates mandatory field(s). Need help? Click [Here](#)

New User - [Register User](#)

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“Search BY Excipients” page appears as shown below.

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate. Options: -- Select --, Acesulfame K, Alcohol, Aspartame, Benzalkonium Chloride.

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate. Options: -- Select --, 1,2-Dihydroxypropane, 1,2-Propanediol, 1,2-Propylene Glycol, 1,2-Propyleneglykol (German).

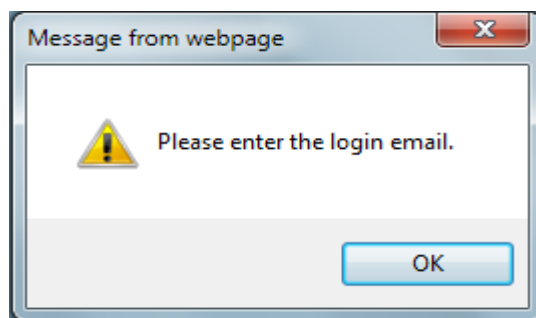
CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate. Options: -- Select --, 100-51-6, 120-47-8, 22839-47-0, 532-32-1.

Function: Select from drop down or enter minimum of 3 characters to populate. Options: -- Select --, Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant.

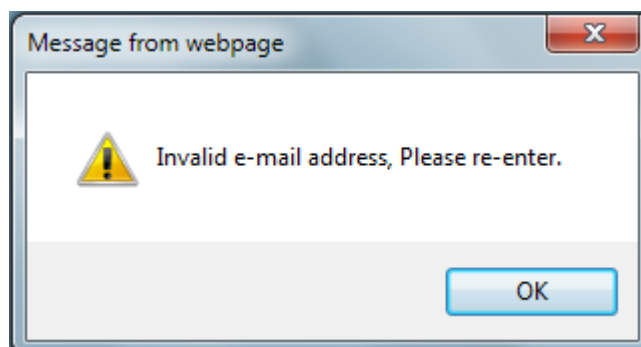
Buttons: Submit, Reset, Search FOR Excipients.

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 27-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box, try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

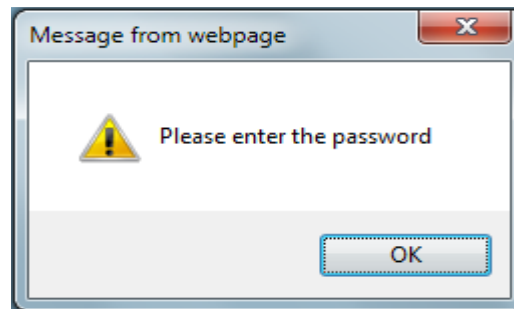
When user clicks “Log in” without entering the email id then the below alert message appears.



When user enters invalid email address then the below alert message appears



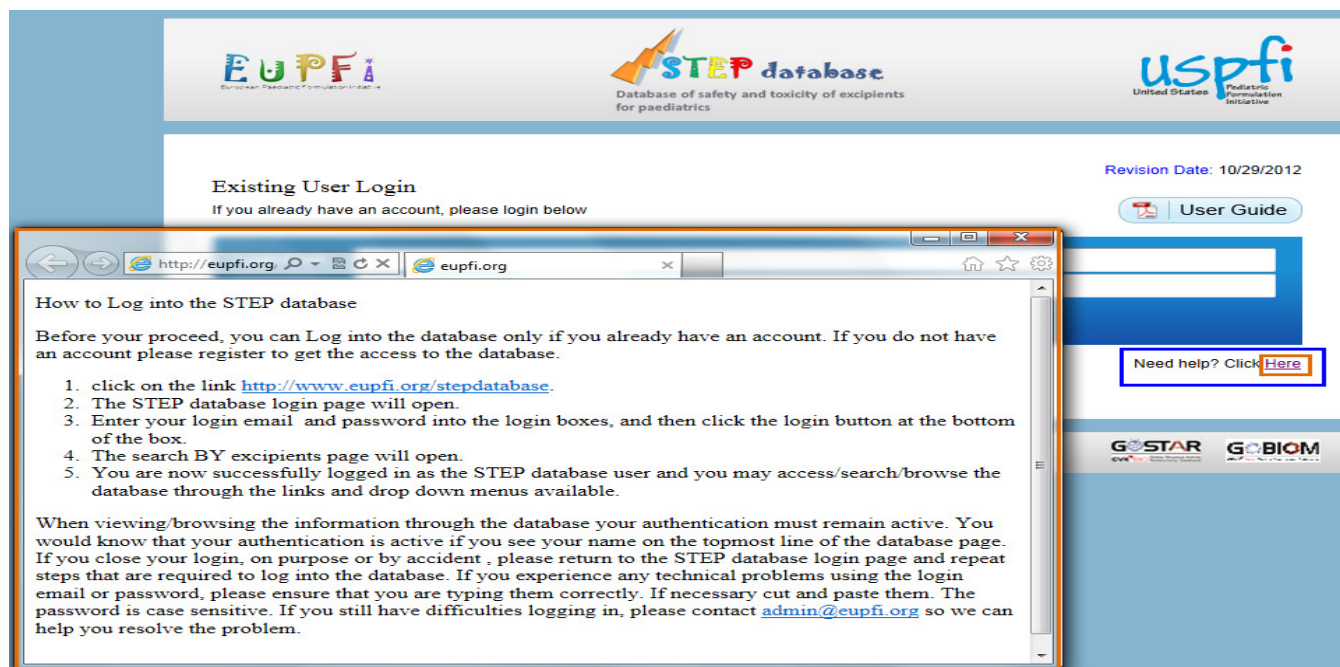
When user clicks “Log in” without entering password, the below alert message appears



If user logs in with unregistered Login Email then the message appears as shown below.

If user is already registered and trying to login with the incorrect credentials then the message appears as shown below.

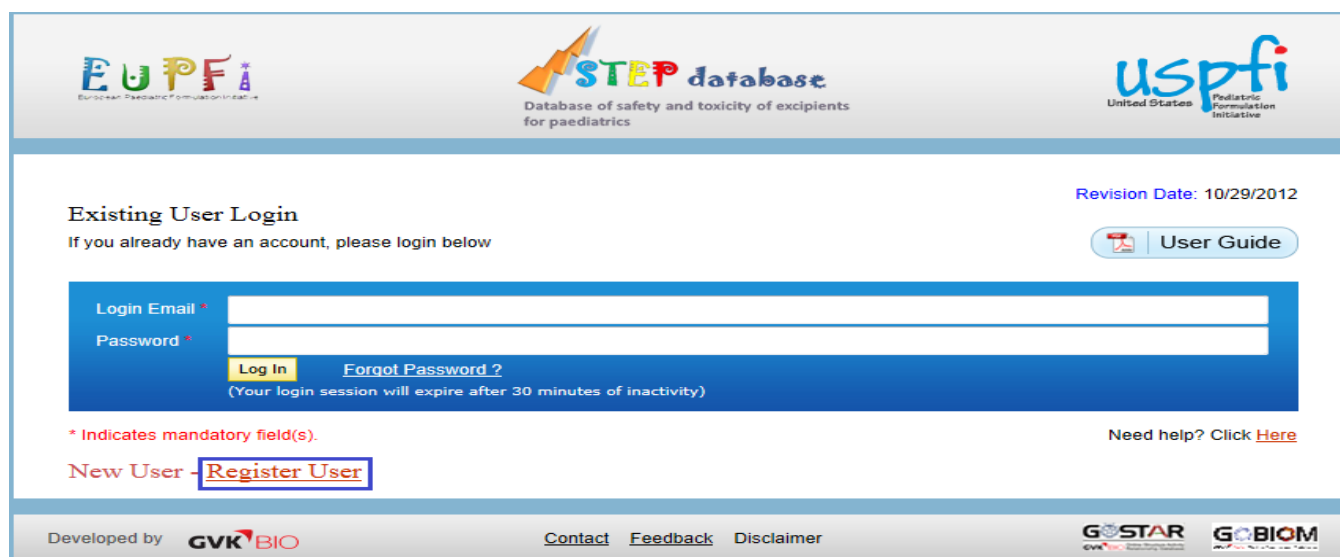
If user needs any help in STEP Database login process then, clicks on Need help? Click Here (Link), it will displays one window with the details,



In Login page, the Revision Date indicates that the recent/last database updation (addition/deletion of data) date in 'MM/DD/YYYY' format.

2.2 New user registration

STEP facilitates user to create a new user in a simple way by using the "Register User" link from the login page. Click "Register User" link from the login page as shown below.



Note: “New User - Register User” page appears, here “I’ve read the Disclaimer and accepted the Terms & Conditions” checkbox appears in selected mode by default and cursor is at first name field by default.

Click “Why Registration?” link then the benefits for registration information appears as shown below.

New User Registration ([Why Registration?](#))

Use of the STEP database is subject to the STEP database Terms of Use and the disclaimer

STEP DATABASE - DISCLAIMER & TERMS OF USE

- This End User License Agreement shall be governed by the United Kingdom laws, without giving effect to principles of conflict of laws. You hereby consent to the exclusive jurisdiction and venue of the courts sitting in London, United Kingdom to resolve any disputes arising under this End User License Agreement.
- This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EuPFI to exercise any of its rights under this End User License Agreement or upon any breach of this End User License Agreement

☒ I've read the Disclaimer and accept the Terms & Conditions

First Name * Last Name

Login Email* Your email address is your username Confirm Login Email*

Contact Number Country*

Organization/Sector

* Indicates mandatory field(s).

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If user clicks on Why Registration (Link) then it will display one window like below,

The screenshot shows the 'New User Registration' page of the STEP database. A pop-up window titled 'Benefits of registration –apart from the access to the database, help and literature search requests.' is overlaid on the registration form. The pop-up lists two main benefits: 1. Providing an opportunity for users to test new data and features before full release, and 2. Giving users an opportunity to provide requirements for an ideal safety and toxicity database and software application. It also mentions support, training, and feedback, including help and support, training/tutorials, and the ability to submit requirements and feedback. A note states that personal information is collected for various purposes, including registration, and is kept confidential. The background registration form includes a disclaimer, a checkbox for accepting terms, and input fields for first name, login email, contact number, and organization/sector, followed by 'Register' and 'Reset' buttons.

New User Registration [Why Registration?](#)

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- This End User License Agreement shall be governed by the laws of the United States of America. You hereby consent to the exclusive jurisdiction of the courts of the United States of America to resolve any disputes arising under this End User License Agreement.
- This End User License Agreement contains the complete and exclusive terms and conditions of use of the STEP DATABASE. It supersedes all prior or contemporaneous agreements, and any varying or additional terms contained in any other document, in relation to The ONLINE STEP DATABASE. You agree to exercise any of its rights under this End User License Agreement.

☒ I've read the Disclaimer and accept the **Terms & Conditions**

First Name *

Login Email* Your email address is your user name

Contact Number

Organization/Sector -- Select --

Need help with this process? Click [Here](#) for more information

Benefits of registration –apart from the access to the database, help and literature search requests.

1. Provide an opportunity for the users to test new data & new features of database and applications prior to full release.
2. Give users an opportunity to provide your requirements on what you need and want in an ideal safety and toxicity database and software application.

Support, Training and Feedback:

- a. Help and support available.
- b. Training /Tutorials available.
- c. Ability to submit database and software requirements and feedback for future enhancements to the STEP database.

Please note that the personal information (such as name, email addresses, contact number, organization and country) that you knowingly choose to disclose, is collected for various purposes. These purposes include registering to get the access to the database, requesting further information from us about the STEP database or simply asking a question. Your information is privileged and confidential and will not be shared or released to any organization or business entity other than those affiliated with or working in conjunction with the STEP database development.

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To get help on user creation click on link “Here”. Help page is displayed as shown below.

The screenshot shows the 'New User Registration' page of the STEP database. A pop-up window titled 'How to Register to get access to the STEP database' is overlaid on the registration form. The pop-up explains that the final step in the registration process is confirming registration and that all registrations must be personal. It provides a list of steps to follow for registration: 1. Read the disclaimer and terms and conditions, 2. Check the box - I have read the disclaimer and terms and conditions, 3. Fill in the registration form (noting mandatory fields), 4. Click the register button, 5. Click the register button again, and 6. Click 'OK' to be sent back to the login page. The background registration form is the same as in the previous screenshot, with the 'Here' link in the footer highlighted by a blue box.

New User Registration [Why Registration?](#)

Use of the STEP database is subject to the STEP database T

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- This End User License Agreement contains the complete and exclusive terms and conditions of use of the STEP DATABASE. It supersedes all prior or contemporaneous agreements, and any varying or additional terms contained in any other document, in relation to The ONLINE STEP DATABASE. You agree to exercise any of its rights under this End User License Agreement.

☒ I've read the Disclaimer and accept the **Terms & Conditions**

First Name *

Login Email* Your email address is your user name

Contact Number

Organization/Sector -- Select --

Need help with this process? Click [Here](#) for more information

How to Register to get access to the STEP database

The final step in the registration process is the page to confirm your registration is successfully completed. You will then be sent back to database login page.

All registrations must be personal registrations using your email address. Generic group or company accounts, or use thereof, are not permitted. Improper, inaccurate or duplicate registrations may be removed without notice.




Please do not re-register yourself if you have previously registered, unless you are not able to retrieve your previous registration email. If you have forgotten your password, use the forgot password link on to reset it.

For registration follow the steps below:

1. Read the disclaimer and terms and conditions.
2. Check the box - I have read the disclaimer and terms and conditions
3. Fill in the registration form. Please note that the fields marked as * in the registration form are mandatory and need to be completed.
4. Click the register button and you will forwarded to confirmation page.
5. Click the register button and you will forwarded to confirmation page.
6. Click "OK" and you will then be sent back to database login page.

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Fill the required information for new user creation in the “New User Registration” page, click on “Register” button.



New User Registration ([Why Registration?](#))

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- This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EuPFI to exercise any of its rights under this End User License Agreement or upon any breach of this End User License Agreement

☒ I've read the Disclaimer and accept the **Terms & Conditions**



First Name *	<input type="text" value="Mounika"/>	Last Name	<input type="text" value="Dugyala"/>
Login Email*	<input type="text" value="mounika.dugyala@gvkbio.com"/>	Confirm Login Email*	<input type="text" value="mounika.dugyala@gvkbio.com"/>
Contact Number	<input type="text" value="9966623713"/>	Country*	<input type="text" value="India"/>
Organization/Sector	<input type="text" value="Patients and Carers"/>		

* Indicates mandatory field(s).




Need help with this process? Click [Here](#) for more information

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After successful creation, below page appears containing user information.



New user registered successfully (Registration details are also mailed to you)

Login Email :	mounika.dugyala@gvkbio.com
Password :	Mounika@123
First Name :	Mounika
Last Name :	Dugyala
Organization/Sector :	Professional Society
Country :	India
Contact Number :	9553114252

This confirms you understand and agree that use of the STEP Database is subject to the STEP database Terms of Use and disclaimer.

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An email is sent to user containing registration details.

Close Reply Reply to All Forward Delete Spam Actions ▾

Eupfi Registration Details

From: donotreply@eupfi.com

To: mounika dugyala

Dear Mounika,

You are successfully registered. Please find your login credentials below,

Login Email : mounika.dugyala@gvkbio.com

Password : Mounika@123


Thank you,

The STEP database Support Team

Disclaimer: *This is a system generated mail. Please do not reply to this email ID*

2.3 Existing User

When user tries to register with already registered email ID, then an error message displayed as show below.


New User Registration ([Why Registration?](#))

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- This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EuPFI to exercise any of its rights under this End User License Agreement or upon any breach of this End User License Agreement.

☒ I've read the Disclaimer and accept the **Terms & Conditions**

First Name *	Venkata	Last Name	Reddy
Login Email*	venkata.bodhanapu@gvkbio.com	Confirm Login Email*	venkata.bodhanapu@gvkbio.com
Contact Number	9966623713	Country*	India
Organization/Sector	Professional Society		

* Indicates mandatory field(s).

[Register](#) [Reset](#)

Need help with this process? Click [Here](#) for more information

Email ID (venkata.bodhanapu@gvkbio.com) already registered. Use some other email address.

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2.4 Forgot Password

User can retrieve the password using “Forgot Password” in the “Login” page by clicking on “Forgot Password” link as shown below

Revision Date: 10/29/2012

Existing User Login

If you already have an account, please login below

[User Guide](#)

Login Email *

Password *

[Log In](#)

[Forgot Password ?](#)

(Your login session will expire after 30 minutes of inactivity)

* Indicates mandatory field(s).

Need help? Click [Here](#)

New User - [Register User](#)

“Forgot Password” page appears as shown below.

EUPFI
European Paediatric Formulation Initiative

STEP database
Database of safety and toxicity of excipients for paediatrics

uspfi
United States Paediatric Formulation Initiative

Forgot Password:

* Indicates mandatory field(s).

- Please enter the Login Email you registered with.
- Your account information will be emailed to you.
- If you can't remember your login email, please re-register or if you have any further problems please contact us at admin@eupfi.org

Login Email:*

Submit Go Back to Login

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Enter the registered login email id and click on “Submit” button to get the password details as shown below.

Forgot Password:

* Indicates mandatory field(s).

- Please enter the Login Email you registered with.
- Your account information will be emailed to you.
- If you can't remember your login email, please re-register or if you have any further problems please contact us at admin@eupfi.org

Login Email:*

venkata.bodhanapu@gvkbio.com

Submit Go Back to Login

Then a message appears indicating the password has been sent to your login email as shown below.

Forgot Password:

* Indicates mandatory field(s).

- Please enter the Login Email you registered with.
- Your account information will be emailed to you.
- If you can't remember your login email, please re-register or if you have any further problems please contact us at admin@eupfi.org

Login Email:*

Your password has been sent to your login email.

Use the received password to login into the STEP Database application.

Example mail content:

Close Reply Reply to All Forward Delete Spam Actions

Eupfi Password Details

From:

To:

Dear bodhanapu,

Please find your login details below.

Login Email :

Password : venkat

Thank you,
The STEP database Support Team

Disclaimer: This is a system generated mail. Please do not reply to this email ID

If entered email id in 'Login Email' field is not yet registered, then the application will display an error message like below.

Forgot Password:

* Indicates mandatory field(s).

- Please enter the Login Email you registered with.
- Your account information will be emailed to you.
- If you can't remember your login email, please re-register or if you have any further problems please contact us at admin@eupfi.org

Login Email:*

Email Id not registered, Please try again.

Note:

- If user enters incorrect Login Email and clicks “Submit” button then the application prompts the below message.
- If user clicks on ‘Go back to Login’ button, application will navigate to login page.

2.5 Regular User

STEP provides a new option for the regular user who ever are visited more than 10 times can provide Feedback on the application using feedback form

Whenever user logs into the application for 10th time then feedback appears. User is recommended to fill the feedback form with the relevant information and click “Submit” as shown below.



Note: Once if the user **Closes** this sub window/iframe, then it indicates that the user is entered feedback and this feedback form will be displays for the next 10th time.

And the application will navigates to Search BY Excipients page as shown below.

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate

-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate

-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate

-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate

-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box , try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use " + " icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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Note:

- When user skips the “Feedback Form” and continues the work and logged out of the application and login to the application again then again this Feedback Form page will not appears.
- It is user responsibility (choice) to fill the Feedback Form this “Feedback Form” will appear for every 10th login.

2.6 Website links

In the STEP application user can access the related websites using the icons in the page throughout the application. When user clicks required logo then the corresponding website appears as shown below

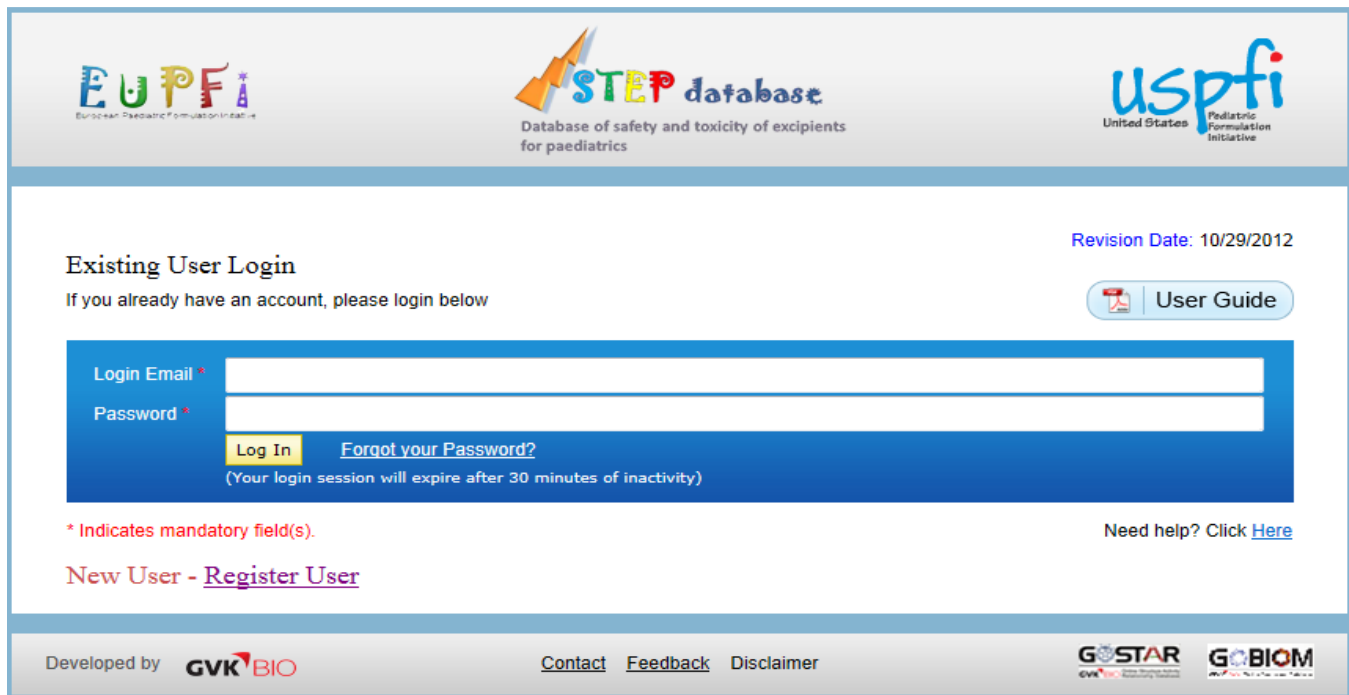
The screenshot shows the EuPFI website interface. At the top, there are logos for EuPFI, STEP database, and uspfi. Below the logos, a yellow banner contains the text "Search BY Excipients | Search FOR Excipients | User Guide | Help | Logout". The main content area is divided into a sidebar on the left and a main panel on the right. The sidebar has a "Search BY Excipients" section with filters for Excipient Name, Synonyms, CAS Registry Number, and Function. The main panel displays the EuPFI logo and a "Welcome to EuPFI" message. A "RECENT NEWS" section mentions the "EuPFI 6th conference 'Formulating Better Medicines for Children'".

3 Session expiration

If the user keeps the application idle/inactive for more than 30 minutes then the session automatically gets expired and displays the below message/page.

The screenshot shows a session expiration message on the EuPFI website. The message is displayed in a yellow box and reads: "Session expired due to 30 minutes inactivity. Please login again." Below the message is a button labeled "Click Here to login." The button is highlighted with a blue border. The background of the page is white, and the EuPFI logo is visible in the top left corner.

To login to the application click “Here” link which automatically opens the application’s login page.



The screenshot shows the 'Existing User Login' section of the application. At the top, there are logos for EUPFI, STEP database, and uspfi. The main heading is 'Existing User Login' with a subtext 'If you already have an account, please login below'. To the right, there is a 'Revision Date: 10/29/2012' and a 'User Guide' button. The login form has two input fields: 'Login Email *' and 'Password *'. Below the password field is a 'Log In' button and a 'Forgot your Password?' link. A note states '(Your login session will expire after 30 minutes of inactivity)'. Below the form, there is a red asterisk indicating mandatory fields and a link to 'Need help? Click Here'. At the bottom, there is a 'New User - Register User' link. The footer contains logos for GVK BIO, GOSTAR, and GBIOM, along with links for 'Contact', 'Feedback', and 'Disclaimer'.

Existing User Login

If you already have an account, please login below

Revision Date: 10/29/2012

User Guide

Login Email *

Password *

Log In

Forgot your Password?

(Your login session will expire after 30 minutes of inactivity)

* Indicates mandatory field(s).

Need help? Click [Here](#)

New User - [Register User](#)

Developed by GVK BIO

[Contact](#) [Feedback](#) [Disclaimer](#)

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4 Logout

Click Logout link as shown below



The screenshot shows the application header with logos for EUPFI, STEP database, and uspfi. Below the logos, there is a yellow bar containing the user's name 'bodhanapu venkata reddy' and a session expiration notice. To the right of the bar are links for 'Search BY Excipients', 'Search FOR Excipients', 'User Guide', 'Help', and 'Logout'.

EUPFI

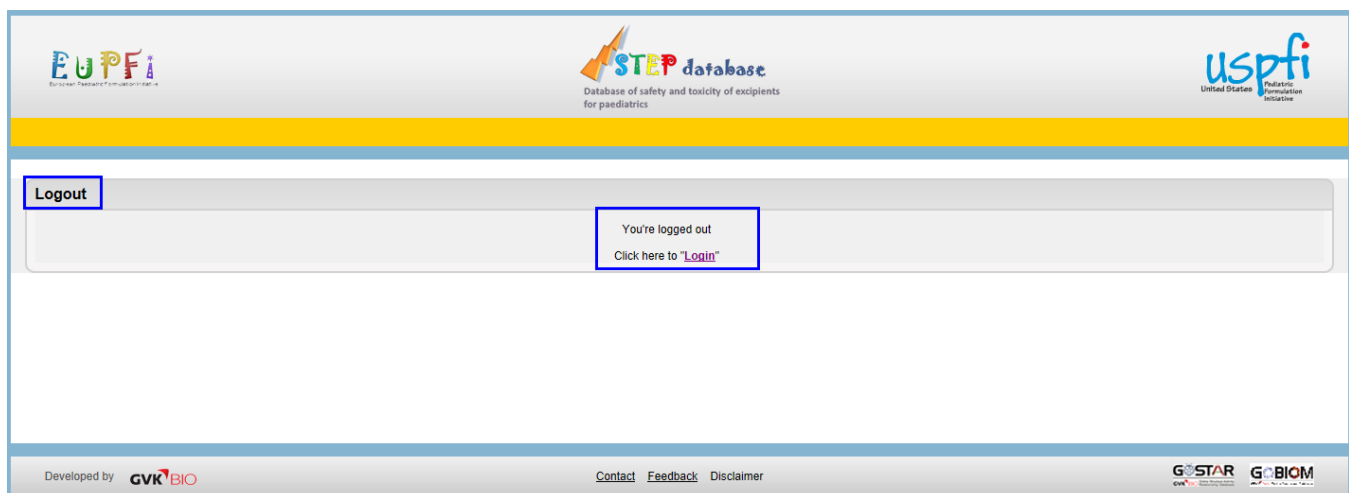
STEP database

uspfi

bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)

[Search BY Excipients](#) | [Search FOR Excipients](#) | [User Guide](#) | [Help](#) | [Logout](#)

Then the application logs out and navigates to the below page, If user desires to login to the application can click "Login" link as shown below



The screenshot shows the application after a successful logout. The header remains the same, but the yellow bar now displays 'Logout' and 'You're logged out'. Below the bar, there is a button labeled 'Click here to "Login"'. The footer is identical to the previous screenshot.

EUPFI

STEP database

uspfi

Logout

You're logged out

Click here to "Login"

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Then the application's login page appears as shown below

Existing User Login

Revision Date: 10/29/2012

If you already have an account, please login below

User Guide

Login Email *

Password *

Log In [Forgot your Password?](#)

(Your login session will expire after 30 minutes of inactivity)

* Indicates mandatory field(s).

Need help? Click [Here](#)

New User - [Register User](#)

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5 Search BY Excipients

Enter the valid user credentials in the “Login” page and click “Login” as shown below.

Existing User Login

Revision Date: 10/29/2012

If you already have an account, please login below

User Guide

Login Email * venkata.bodhanapu@gvkbio.com

Password *

Log In [Forgot your Password?](#)

(Your login session will expire after 30 minutes of inactivity)

* Indicates mandatory field(s).

Need help? Click [Here](#)

New User - [Register User](#)

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Then click “Login” button, application navigates user to “Search” page as shown below

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Acesulfame K
 Alcohol
 Aspartame
 Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 1,2-Dihydroxypropane
 1,2-Propanediol
 1,2-Propylene Glycol
 1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 100-51-6
 120-47-8
 22839-47-0
 532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Antimicrobial agent
 Antimicrobial preservative
 Antiseptic
 Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
 There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
 Select from drop down or enter minimum of 3 characters to populate suggestions.
 If you don't find the excipient in the excipient name box, try searching in synonyms.
 For Multiple Excipient/Function Selection:
 Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
 Progressive search will be based and filtered on the values already selected in dropdowns.
 If you've selected a large dataset the results could take some time to load.
 Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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In the STEP application by default “Search BY Excipients” page appears wherein user is allowed to select the required data and view the results. Search page provides results based on “Excipient Name, CAS Registry Number, Synonyms and Function.”

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Acesulfame K
 Alcohol
 Aspartame
 Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 1,2-Dihydroxypropane
 1,2-Propanediol
 1,2-Propylene Glycol
 1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 100-51-6
 120-47-8
 22839-47-0
 532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Antimicrobial agent
 Antimicrobial preservative
 Antiseptic
 Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
 There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
 Select from drop down or enter minimum of 3 characters to populate suggestions.
 If you don't find the excipient in the excipient name box, try searching in synonyms.
 For Multiple Excipient/Function Selection:
 Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
 Progressive search will be based and filtered on the values already selected in dropdowns.
 If you've selected a large dataset the results could take some time to load.
 Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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5.1 Search BY Excipients

Excipients in medicines are ingredients other than the active drug that are essential for their manufacture, stability and function. Superlatively, an excipient is pharmacologically inactive, non-toxic, and does not interact with the active ingredients or other excipients. However, in practice few excipients meet these criteria.

5.1.1 Excipient Name

STEP endow with Excipient based search functionality for the end users to attain relevant results.

In the “Search BY Excipients” page user can select the required excipient name from the “Excipient Name” drop down as shown below.

Search BY Excipients

Search BY Excipients

Excipient Name:

Synonyms (as per the Handbook of Excipients):

CAS Registry Number:

Function:

[Search FOR Excipients](#)

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

User can get the suggestions after entering minimum of 3 characters in Excipient Name text box. If the data is available then it will display like below,

Search BY Excipients

Search BY Excipients

Excipient Name: ben
-- Select --
Benzalkonium Chloride
Benzoic Acid
Benzyl Alcohol
Benzylparaben

Synonyms (as per the Handbook of Excipients):
Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propylenglykol (German)

CAS Registry Number:
Select from drop down or enter minimum of 3 characters to populate
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function:
Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
Select from drop down or enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box, try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients

Search BY Excipients

Excipient Name: test
Sorry No Matches, try searching by synonyms

Synonyms (as per the Handbook of Excipients):
Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propylenglykol (German)

CAS Registry Number:
Select from drop down or enter minimum of 3 characters to populate
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function:
Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
Select from drop down or enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box, try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

5.1.1.1 Multiple Excipient selection

Use “CTRL” key from the keyboard to select the excipients from the drop down either continuously or randomly as shown below

Search BY Excipients

Excipient Name: (Dropdown menu open showing: Acesulfame K, Aspartame, Benzalkonium Chloride)

Synonyms (as per the Handbook of Excipients): (Dropdown menu open showing: 3-Amino-N-(alpha-Carboxyphenethyl)Succinamic Acid N-Methyl Est, Alkyl Dimethyl Benzyl Ammonium Chloride, Alkyl Dimethylbenzyl Ammonium Chloride, Alkyl dimethyl (Phenylmethyl) Quaternary Ammonium Chlorides, Alpha Aspartame)

CAS Registry Number: (Dropdown menu open showing: 22839-47-0, 8001-54-5)

Function: (Dropdown menu open showing: Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant)

Buttons: Submit, Reset, Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

5.1.1.2 Excipient selection based on the category

In the basic search page user only has the privilege of selecting “Excipients” of one category at a time but there is an another option of selecting multiple category related excipients at a time using “+” symbol. When user clicks “+” symbol besides the “Excipient Name” text box then the below pop up window appears.

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES

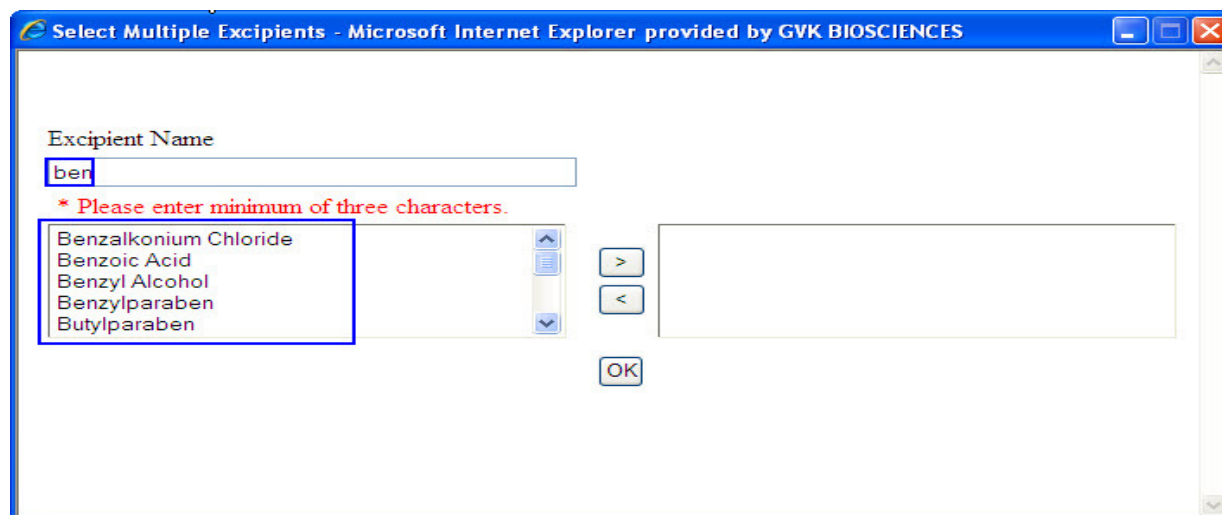
Excipient Name:

* Please enter minimum of three characters.

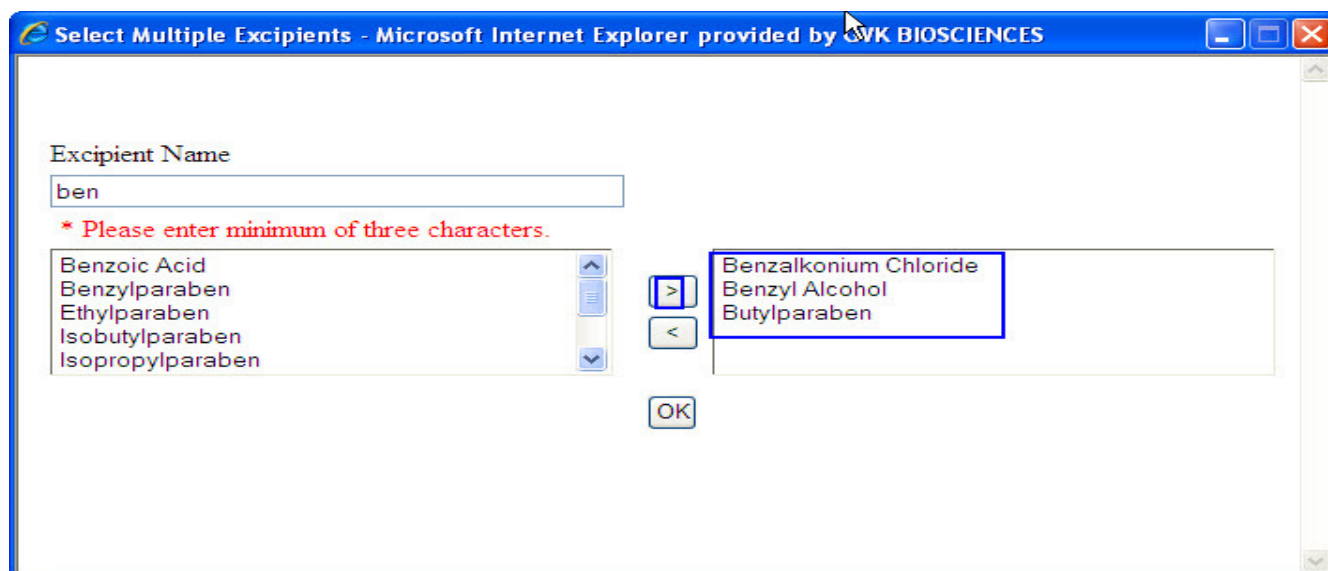
Dropdown menu open showing: Acesulfame K, Alcohol, Aspartame, Benzalkonium Chloride, Benzoic Acid

Buttons: >, <, OK

Auto search is available in the pop-up window, when user specifies 3 or more characters in the excipient name then the relevant excipient names appears as shown below.



Then user is allowed to select the required excipients from the list and can click ">" button then the selected excipient name appears in the empty text box as shown below to



If user needs to select any other excipient from another category can again enter the excipient name then the relevant excipients list appears as shown below

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES

Excipient Name
pro

* Please enter minimum of three characters.

Isopropylparaben
Propylene Glycol
Propylparaben

>
<
OK

Benzalkonium Chloride
Benzyl Alcohol
Butylparaben

Then user can select the required excipient from the list and click “>” button to add it then it appears along with the earlier selected excipient as shown below

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES

Excipient Name
pro

* Please enter minimum of three characters.

Isopropylparaben
Propylparaben

>
<
OK

Benzalkonium Chloride
Benzyl Alcohol
Butylparaben
Propylene Glycol

Click “Ok” button then the selected search criteria appears in the “Search BY Excipients” page as shown below

Search BY Excipients

Search BY Excipients

Excipient Name Benzalkonium Chloride|Benzyl Alcohol|Butylparaben|Propylene Glycol Benzalkonium Chloride Benzoic Acid Benzyl Alcohol Benzylparaben Butylparaben

Synonyms
(as per the Handbook of Excipients) Select from drop down or enter minimum of 3 characters to populate 1,2-Dihydroxypropane 1,2-Propanediol 1,2-Propylene Glycol 1,2-Propyleneglykol (German) 2-Hydroxypropanol

CAS Registry Number Select from drop down or enter minimum of 3 characters to populate 100-51-6 57-55-6 8001-54-5

Function Select from drop down or enter minimum of 3 characters to populate -- Select -- Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

User can select "CAS Registry Number and Synonyms" also along with the selected "Excipient Name" to retrieve the results as shown below

Search BY Excipients

Search BY Excipients

Excipient Name Benzalkonium Chloride|Benzyl Alcohol|Butylparaben|Propylene Glycol Benzalkonium Chloride Benzoic Acid Benzyl Alcohol Benzylparaben Butylparaben

Synonyms
(as per the Handbook of Excipients) Alkyl Dimethylbenzyl Ammonium Chloride|Alkyldimethyl (Phenylmethyl) Alkyl Dimethyl Benzyl Ammonium Chloride Alkyl Dimethylbenzyl Ammonium Chloride Alkyldimethyl (Phenylmethyl) Quaternary Ammonium Chlorides Ammonyx Arqua

CAS Registry Number 8001-54-5 100-51-6 57-55-6 8001-54-5

Function Select from drop down or enter minimum of 3 characters to populate -- Select -- Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Then click "Submit" button to retrieve the search results considering the search criteria.

The screenshot shows the search results for "Benzalkonium Chloride" in the EUPFI/USPFI database. The interface includes a header with logos for EUPFI, STEP database, and USPFI. A yellow banner at the top displays the user's login information: "bodhanapu venkata reddy" and a session expiration notice. Navigation links for "Search BY Excipients", "Search FOR Excipients", "Export", "User Guide", "Help", and "Logout" are provided.

The main content area is titled "Search Results" and shows "Total References: 15" and "Record 1 of 1". It includes a "General Information" section with details such as "Excipient Chemical Name: Benzalkonium Chloride" and "CAS Registry Number: 8001-54-5". Below this, there are expandable sections for "Excipient Category/Function", "Pharmacopoeial Status", "Regulatory Status", "Synonyms", "Acceptable Daily Intake", and "Revision Date".

A table of clinical data is displayed, with tabs for "Clinical Data (3)", "Non Clinical Data (3)", "Invitro Data (1)", "Regulatory and other information (5)", and "Reviews (3)". The table columns include Ref ID, Excipient Name, Study Type, Age Category, Age, Age Units, Gender, Route of Exposure or Administration, Dose, Dose Units, Duration of Treatment, and Duration. The table shows three entries for Benzalkonium Chloride, with the first entry (Ref ID 121) highlighted in blue.

The footer of the page includes the text "Developed by GVK BIO" and links for "Contact", "Feedback", and "Disclaimer". Logos for "GOSTAR" and "G-BIOM" are also present.

But here based on the selected “Excipient Name” the “CAS Registry Number and Synonyms” gets progressively filtered. User is allowed to select the combination of the “CAS Registry Number” and “Synonyms”.

In search results count of the references appears as shown below.

EUPFI Database of safety and toxicity of excipients for paediatrics

uspfi United States Pediatric Formulation Initiative

Search BY Excipients | Search FOR Excipients | Export | User Guide | Help | Logout

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) Non Clinical Data (3) In vitro Data (1) Regulatory and other information (5) Reviews (3)

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hours
171	Benzalkonium Chloride	Other study type - Lab/Drug de (v,More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hours
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48	Hours

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Note:

- Based on the selected “Excipient Name” remaining data in the “CAS Registry Number”, “Synonyms” appears.
- When user selects “Excipient Name” and “CAS Registry Number” then based on both those values data in the “Synonyms” appears.
- The progressive filtering will populate the data by ‘Contains’ search, with that particular entered search string in the respective text fields.
- The above functionality is applicable when user selects any of the value among “Excipient Name, CAS Registry Number, Synonyms” based on that remaining data appears. If user selects any other value in addition to the initially selected one then considering both those values remaining data appears.

5.1.2 Synonyms

Synonyms includes other chemical names, trade names, common or general names, foreign language names (with the language in parentheses), or codes. Only the key synonyms would be displayed and for details it would be linked to other source

Example: The privilege of selecting the required synonyms using the Synonyms is also facilitated. When user selects synonyms using “Synonyms” then based on that selected synonyms remaining data in the “Excipient Name, CAS Registry Number” appears as shown below

Search BY Excipients page before selecting the Synonyms

Search BY Excipients page after selecting the Synonyms

User can get the suggestions after entering minimum of 3 characters in Synonyms text box. If the data is available then it will display like below,

Search BY Excipients

Search BY Excipients

Excipient Name Select from drop down or enter minimum of 3 characters to populate

-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms
(as per the Handbook of Excipients)

ben
-- Select --
4-Hydroxybenzoic Acid Methyl Ester
4-Hydroxy- Ethyl Ester Benzoic Acid
4-Hydroxy- Methyl Ester Benzoic Acid
4-Hydroxy- Propyl Ester Benzoic Acid

CAS Registry Number Select from drop down or enter minimum of 3 characters to populate

-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function Select from drop down or enter minimum of 3 characters to populate

-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box , try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use " + " icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients

Search BY Excipients

Excipient Name Select from drop down or enter minimum of 3 characters to populate

-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms
(as per the Handbook of Excipients)

test
Sorry No Matches,try searching by excipients name

CAS Registry Number Select from drop down or enter minimum of 3 characters to populate

-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function Select from drop down or enter minimum of 3 characters to populate

-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box , try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use " + " icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
Propylene Glycol

Synonyms (as per the Handbook of Excipients): 1,2-Propanediol || 1,2-Propylen glykol (German) || 2-Hydroxypropanol
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propylen glykol (German)
2-Hydroxypropanol

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
57-55-6

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

After selecting the entire required values click “Submit” button then the search results page appears as shown below.

Search Results [Back](#) Total References: 316 Record 1 of 1

Excipient Navigation

General Information
Excipient Chemical Name: Propylene Glycol
CAS Registry Number: 57-55-6

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (98) Non Clinical Data (158) In vitro Data (95) Regulatory and other information (55) Reviews (16) Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
2	Propylene Glycol	Unspecified	Adult	18 to 83	Years	Male/Female	Parenteral	128 (cumulative)	g	36
10	Propylene Glycol	Unspecified	Paediatric age group and adult ...More	6 to 66	Years	Male/Female	Topical	20	%	1
15	Propylene Glycol	Case study	Adult	49	Years	Male	Unspecified	Unspecified	Unspecified	Unspecified
18	Propylene Glycol	Unspecified	Unspecified	Unspecified	Unspecified	Unspecified	Topical	100	%	1

5.1.3 CAS Registry Number

CAS Registry Number is a numeric designation assigned by the “Chemical Abstracts Service” of the American Chemical Society that uniquely identifies a specific chemical compound, regardless of the name or nomenclature system used.

Example:

57-55-6 for propylene glycol) only a single excipient may be associated with a single CAS registry number

The privilege of selecting the required CAS numbers using the CAS Registry number is also facilitated. When user selects CAS registry number using “CAS Registry Number” then based on that selected CAS Registry Number remaining data in the “Excipient Name, Synonyms” appears as shown below

Search BY Excipients before selecting the CAS Registry Number

The screenshot displays the EUPFI STEP database search interface. At the top, there are logos for EUPFI, STEP database, and uspfi. Below the logos is a navigation bar with links: Search BY Excipients, Search FOR Excipients, User Guide, Help, and Logout. The main content area is titled 'Search BY Excipients' and contains four search criteria: Excipient Name, Synonyms, CAS Registry Number, and Function. Each criterion has a dropdown menu with a search icon and a placeholder text 'Select from drop down or enter minimum of 3 characters to populate'. The dropdowns are populated with suggestions: Excipient Name (Acesulfame K, Alcohol, Aspartame, Benzalkonium Chloride), Synonyms (1,2-Dihydroxypropane, 1,2-Propanediol, 1,2-Propylene Glycol, 1,2-Propyleneglykol (German)), CAS Registry Number (100-51-6, 120-47-8, 22839-47-0, 532-32-1), and Function (Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant). At the bottom of the form are buttons for Submit, Reset, and Search FOR Excipients. To the right of the form is a box with instructions on how to use the search interface.

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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Search BY Excipients after selecting the CAS Registry Number

User can get the suggestions after entering minimum of 3 characters in CAS Registry Number text box. If the data is available then it will display like below,

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: 900
-- Select --
9001-32-5
9005-64-5
9005-65-6
9005-66-7

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: 999
Sorry No Matches

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
Ethylparaben

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
4-Hydroxy- Ethyl Ester Benzoic Acid
4-Hydroxybenzoic Acid, Ethyl Ester
4-Hydroxybenzoic Acid, Ethyl Ester, Sodium Salt
Ben
Benzoic Acid, 4-Hydroxy-, Ethyl Ester

CAS Registry Number: 120-47-8
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent).
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Click "Submit" then the search results appears as shown below.

Search Results Back Total References: 21 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Ethylparaben
CAS Registry Number: 120-47-8

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (4) Non Clinical Data (14) Invitro Data (13) Regulatory and other information (0) Reviews (0)

Clear All Filters on Clinical Data Export Filtered Clinical Data

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
14	Ethylparaben	Case study	Adult	67	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	47	Years	Female	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	56	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp

5.1.4 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

Search BY Excipients before selecting the Function

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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Search BY Excipients after selecting the Function

User can get the suggestions after entering minimum of 3 characters in Function text box. If the data is available then it will display like below,

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
-- Select --
Acesulfame K
Alcohol
Aspartame
Benzalkonium Chloride

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
-- Select --
1,2-Dihydroxypropane
1,2-Propanediol
1,2-Propylene Glycol
1,2-Propyleneglykol (German)

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
-- Select --
100-51-6
120-47-8
22839-47-0
532-32-1

Function: ant
-- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:
There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Select from drop down or enter enter minimum of 3 characters to populate suggestions.
If you don't find the excipient in the excipient name box , try searching in synonyms.
For Multiple Excipient/Function Selection:
Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use "+" icon to open excipients list box for selection.
Progressive search will be based and filtered on the values already selected in dropdowns.
If you've selected a large dataset the results could take some time to load.
Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

The screenshot shows the 'Search BY Excipients' interface. It has four main input fields: 'Excipient Name', 'Synonyms (as per the Handbook of Excipients)', 'CAS Registry Number', and 'Function'. Each field has a dropdown menu with a search icon. The 'Function' field is highlighted with a blue box and contains the text 'test'. Below the 'Function' field, the text 'Sorry No Matches' is displayed. At the bottom, there are three buttons: 'Submit', 'Reset', and 'Search FOR Excipients'. On the right side, there is a section titled 'Instructions on Search BY Excipients page:' which provides detailed guidance on how to use the search functionality.

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate

Function: test

Sorry No Matches

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box , try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

The screenshot shows the 'Search BY Excipients' interface. It has four main input fields: 'Excipient Name', 'Synonyms (as per the Handbook of Excipients)', 'CAS Registry Number', and 'Function'. Each field has a dropdown menu with a search icon. The 'Function' field is highlighted with a blue box and contains the text 'Antiseptic|Disinfectant'. Below the 'Function' field, a list of related terms is displayed: 'Antiseptic', 'Disinfectant', 'Antimicrobial agent', and 'Antimicrobial preservative'. At the bottom, there are three buttons: 'Submit', 'Reset', and 'Search FOR Excipients'. On the right side, there is a section titled 'Instructions on Search BY Excipients page:' which provides detailed guidance on how to use the search functionality.

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate

Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate

CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate

Function: Antiseptic|Disinfectant

Antiseptic
Disinfectant
Antimicrobial agent
Antimicrobial preservative

Submit Reset Search FOR Excipients

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box , try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Click "Submit" then the search results appears as shown below.

Search Results [Back](#) Total References: 21 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Ethylparaben
CAS Registry Number: 120-47-8

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (4) Non Clinical Data (14) In vitro Data (13) Regulatory and other information (0) Reviews (0)




[Show/Hide Clinical Columns](#) [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
14	Ethylparaben	Case study	Adult	67	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	47	Years	Female	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	56	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp

Note: Progressive filtering functionality is available for Excipient Name, CAS Registry Number and Synonyms fields. And Function field is an individual field.

6 Search FOR Excipients

Search FOR Excipients supports user in selecting the search criteria in an easy manner. User can access the Search FOR Excipients using “Search FOR Excipients” link in the main menu bar or from the “Search FOR Excipients” link in the “Search BY Excipients” page at the bottom as shown below.

bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)

[Search BY Excipients](#) | [Search FOR Excipients](#) | [User Guide](#) | [Help](#) | [Logout](#)

Search BY Excipients

Search BY Excipients

Excipient Name: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Acesulfame K
 Alcohol
 Aspartame
 Benzalkonium Chloride


Synonyms (as per the Handbook of Excipients): Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 1,2-Dihydroxypropane
 1,2-Propanediol
 1,2-Propylene Glycol
 1,2-Propyleneglykol (German)



CAS Registry Number: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 100-51-6
 120-47-8
 22839-47-0
 532-32-1

Function: Select from drop down or enter minimum of 3 characters to populate
 -- Select --
 Antimicrobial agent
 Antimicrobial preservative
 Antiseptic
 Disinfectant

[Submit](#) [Reset](#) [Search FOR Excipients](#)

Instructions on Search BY Excipients page:
 There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).
 Select from drop down or enter minimum of 3 characters to populate suggestions.
 If you don't find the excipient in the excipient name box, try searching in synonyms.
 For Multiple Excipient/Function Selection:
 Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.
 Progressive search will be based and filtered on the values already selected in dropdowns.
 If you've selected a large dataset the results could take some time to load.
 Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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Click “Search FOR Excipients” link either from main menu bar or from the “Search BY Excipients” page
“Search FOR Excipients” page appears as shown below.

The screenshot displays the 'Search FOR Excipients' web application. At the top, there are logos for EUPFI, STEP database, and usptfi. A yellow banner shows the user 'bodhanapu venkata reddy' and a session expiration notice. The main content area has a 'Search FOR Excipients' header with two tabs: 'Clinical Data' (selected) and 'Non Clinical Data'. Below the tabs, there are five dropdown menus for search criteria: 'Study Type' (options: A block randomization procedure, A single-blind crossover, ADME/Pharmacokinetics studies, Blocked parallel randomised trial), 'Age Category' (options: Adolescents (12 to 16-18 years), Adult, Children (2 to 11 years), Infants and toddlers (28 days to 23 months)), 'Route of Exposure / Administration' (options: Inhalation, Nasal, Oral, Parenteral), 'Function' (options: Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant), and 'Effect by Organ / System' (options: Appetite, Cardiovascular System, Digestive System, Endocrine System). At the bottom of the form are 'Submit', 'Reset', and 'Search BY Excipients' buttons. The footer includes 'Developed by GVK BIO', 'Contact Feedback Disclaimer', and logos for GOSTAR and GBIOM.

Search FOR Excipients facilitates user to select the search criteria based on the below aspects

- ✓ Clinical Data
- ✓ Non- Clinical Data

6.1 Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Clinical Data. This provides complete optional environment depending on the “Clinical Data” attributes.

Clinical Data attributes listed in the STEP database under “Search FOR Excipients” are

1. Search FOR Excipients

- ✓ Study Type
- ✓ Age Category
- ✓ Route of Exposure / Administration
- ✓ Function
- ✓ Effect by Organ / System

6.1.1 Search FOR Excipients

Search FOR Excipients includes all the data related to the excipient related to the Study Type, Age Category, Route of Exposure/Administration and Function. Based on the data selected under the above categories then relevant Excipients and its related data appears in the search results.

6.1.1.1 Study Type

“Study Type” provides the nature of investigations like randomized controlled, cohort, case studies etc. Depending on the Study Type selected the results page data appears.

The screenshot displays the 'Search FOR Excipients' web application. At the top, there are two tabs: 'Clinical Data' and 'Non Clinical Data', with 'Non Clinical Data' currently selected. Below the tabs, the title 'Search For Excipients' is shown. The main area contains five dropdown menus for filtering search results:

- Study Type:** A dropdown menu with a blue border. The selected option is 'A randomized crossover study'. Other visible options include '-- Select --', 'A block randomization procedure', 'ADME/Pharmacokinetics studies', and 'Blocked parallel randomised trial'.
- Age Category:** A dropdown menu with options: '-- Select --', 'Adolescents (12 to 16-18 years)', 'Adult', 'Children (2 to 11 years)', and 'Infants and toddlers (28 days to 23 months)'.
- Route of Exposure / Administration:** A dropdown menu with options: '-- Select --', 'Inhalation', 'Nasal', 'Oral', and 'Parenteral'.
- Function:** A dropdown menu with options: '-- Select --', 'Antimicrobial agent', 'Antimicrobial preservative', 'Antiseptic', and 'Disinfectant'.
- Effect by Organ / System:** A dropdown menu with options: '-- Select --', 'Appetite', 'Cardiovascular System', 'Digestive System', and 'Endocrine System'.

At the bottom of the form, there are three buttons: 'Submit' (yellow), 'Reset' (orange), and 'Search BY Excipients' (purple).

6.1.1.2 Age Category

“Age Category” indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated here a few group names are

- ✓ Adolescents (12 to 16-18 years; dependent on the region)
- ✓ Adults
- ✓ Children (2 to 11 years)
- ✓ Infants
- ✓ Pre-school Children
- ✓ School Children
- ✓ Unspecified

All the above appears in the “Age Category” drop down based on the selected “Age Category” corresponding excipients and the data appears in the search results page.

Search FOR Excipients

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
A block randomization procedure
A single-blind crossover
ADME/Pharmacokinetics studies
Blocked parallel randomised trial

Age Category: -- Select --
Adolescents (12 to 16-18 years)
Adult
Children (2 to 11 years)
Infants and toddlers (23 days to 23 months)

Route of Exposure / Administration: -- Select --
Inhalation
Nasal
Oral
Parenteral

Function: -- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Effect by Organ / System: -- Select --
Appetite
Cardiovascular System
Digestive System
Endocrine System

[Submit](#) [Reset](#) [Search BY Excipients](#)

6.1.1.3 Route of Exposure / Administration

“Route of Exposure/ Administration” indicates the part of the body through or into which, or the way in which, the excipient is introduced.

Example: Cutaneous, IV, Oral, Inhalation, Dermal, Implantation, Parenteral, Topical, Ocular, rectal, Intranasal.

Considering the selected Route of Exposure/Administration values the search results appears.

Search FOR Excipients

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
A block randomization procedure
A single-blind crossover
ADME/Pharmacokinetics studies
Blocked parallel randomised trial

Age Category: -- Select --
Adolescents (12 to 16-18 years)
Adult
Children (2 to 11 years)
Infants and toddlers (28 days to 23 months)

Route of Exposure / Administration: -- Select --
Inhalation
Nasal
Oral
Parenteral

Function: -- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Effect by Organ / System: -- Select --
Appetite
Cardiovascular System
Digestive System
Endocrine System

[Submit](#) [Reset](#) [Search BY Excipients](#)

6.1.1.4 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

The screenshot shows the 'Search FOR Excipients' form. At the top, there are two tabs: 'Clinical Data' and 'Non Clinical Data', with 'Non Clinical Data' selected. Below the tabs is a header 'Search For Excipients'. The form contains five dropdown menus: 'Study Type' (options: A block randomization procedure, A single-blind crossover, ADME/Pharmacokinetics studies, Blocked parallel randomised trial), 'Age Category' (options: Adolescents (12 to 16-18 years), Adult, Children (2 to 11 years), Infants and toddlers (28 days to 23 months)), 'Route of Exposure / Administration' (options: Inhalation, Nasal, Oral, Parenteral), 'Function' (options: Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant), and 'Effect by Organ / System' (options: Appetite, Cardiovascular System, Digestive System, Endocrine System). The 'Function' dropdown is highlighted with a blue border. At the bottom, there are three buttons: 'Submit', 'Reset', and 'Search BY Excipients'.

6.1.1.5 Effect by Organ / System

Indicates on which organ or system the effects are observed

The screenshot shows the 'Search FOR Excipients' form. At the top, there are two tabs: 'Clinical Data' and 'Non Clinical Data', with 'Non Clinical Data' selected. Below the tabs is a header 'Search For Excipients'. The form contains five dropdown menus: 'Study Type' (options: A block randomization procedure, A single-blind crossover, ADME/Pharmacokinetics studies, Blocked parallel randomised trial), 'Age Category' (options: Adolescents (12 to 16-18 years), Adult, Children (2 to 11 years), Infants and toddlers (28 days to 23 months)), 'Route of Exposure / Administration' (options: Inhalation, Nasal, Oral, Parenteral), 'Function' (options: Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant), and 'Effect by Organ / System' (options: Appetite, Cardiovascular System, Digestive System, Endocrine System). The 'Effect by Organ / System' dropdown is highlighted with a blue border. At the bottom, there are three buttons: 'Submit', 'Reset', and 'Search BY Excipients'.

Based on the selected data the search results appears

6.2 Non-Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Non-Clinical Data. This provides complete optional environment depending on the “Non-Clinical Data” attributes.

Below are the Non-Clinical Data attributes

- Search by Excipients
 - Study Type
 - Species
 - Age Category
 - Route of Exposure/Administration
 - Function
 - Organ/System

6.2.1 Search FOR Excipient

Search FOR Excipients includes all the data related to the excipient related to the Study Type, Species, Age Category, Route of Exposure/Administration and Organ/System. Based on the data selected under the above categories then relevant Excipients and its related data appears in the search results.

6.2.1.1 Study Type

Study Type helps in providing the nature of investigations like Acute Toxicity, Experimental Animal Study, Eye Irritation, Ocular Toxicity etc;

The screenshot shows the 'Search FOR Excipients' form with the 'Non Clinical Data' tab selected. The 'Study Type' dropdown menu is open, showing the following options: ADME/Pharmacokinetics/Toxicokinetics, Acute toxicity (0-14days), Carcinogenicity, and Developmental toxicity / teratogenicity. The other dropdown menus (Species, Age Category, Route of Exposure / Administration) are closed.

6.2.1.2 Species

Species indicates the animal species used in the experiment.

Example: rabbit, rat, sheep, cat, cattle, dog, gerbil, guinea pig, hamster, monkey, mouse, pig and other

The screenshot shows the 'Search FOR Excipients' form with the 'Non Clinical Data' tab selected. The 'Species' dropdown menu is open, showing the following options: Cat, Cattle, Chicken, and Chinchilla. The other dropdown menus (Study Type, Age Category, Route of Exposure / Administration) are closed.

6.2.1.3 Age Category

Age Category” indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated here a few group names are

Example: Adults, Juvenile etc;

Search FOR Excipients

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
ADME/Pharmacokinetics/Toxicokinetics
Acute toxicity (0-14days)
Carcinogenicity
Developmental toxicity / teratogenicity

Species: -- Select --
Cat
Cattle
Chicken
Chinchilla

Age Category: -- Select --
Adult
Adult and Juvenile
Juvenile
Juvenile and Adult

Route of Exposure / Administration: -- Select --
Implantation
Inhalation
Nasal
Ophthalmic

Function: -- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Organ / System: -- Select --
Analgesia
Cardiovascular System
Cellular
Digestive System

6.2.1.4 Route of Exposure / Administration

Route of Exposure/Administration indicates the part of the body through or into which, or the way in which, the excipient is introduced.

Example: Oral, Inhalation, Dermal, Implantation, Parenteral, Topical, Ocular, rectal other.

Search FOR Excipients

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
ADME/Pharmacokinetics/Toxicokinetics
Acute toxicity (0-14days)
Carcinogenicity
Developmental toxicity / teratogenicity

Species: -- Select --
Cat
Cattle
Chicken
Chinchilla

Age Category: -- Select --
Adult
Adult and Juvenile
Juvenile
Juvenile and Adult

Route of Exposure / Administration: -- Select --
Implantation
Inhalation
Nasal
Ophthalmic

Function: -- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Organ / System: -- Select --
Analgesia
Cardiovascular System
Cellular
Digestive System

6.2.1.5 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

6.2.1.6 Organ/System

Effect is any undesired action or effect of an Excipient. User can view the search results based on the effect. Indicates on which organ or system the effects are observed

Example: Kidney, Brain, Cellular System, Renal, Liver, Cardiovascular etc.

Search FOR Excipients

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
ADME/Pharmacokinetics/Toxicokinetics
Acute toxicity (0-14days)
Carcinogenicity
Developmental toxicity / teratogenicity

Species: -- Select --
Cat
Cattle
Chicken
Chinchilla

Age Category: -- Select --
Adult
Adult and Juvenile
Juvenile
Juvenile and Adult

Route of Exposure / Administration: -- Select --
Implantation
Inhalation
Nasal
Ophthalmic

Function: -- Select --
Antimicrobial agent
Antimicrobial preservative
Antiseptic
Disinfectant

Organ / System: -- Select --
Analgesia
Cardiovascular System
Cellular
Digestive System

[Submit](#) [Reset](#) [Search BY Excipients](#)

When user provides any search criteria in the “Non-Clinical Data” page and clicks “Submit” button as shown below

The screenshot shows the 'Search FOR Excipients' web application. At the top, there are logos for EUPFI, STEP database, and USPFI. A yellow navigation bar contains the user's name 'bodhanapu venkata reddy', a session expiration message, and links for 'Search BY Excipients', 'Search FOR Excipients', 'User Guide', 'Help', and 'Logout'. The main content area is titled 'Search FOR Excipients' and has two tabs: 'Clinical Data' (selected) and 'Non Clinical Data'. Below the tabs is a search form with the following fields:

- Study Type: Dropdown menu with options: -- Select --, ADME/Pharmacokinetics/Toxicokinetics (highlighted), Acute toxicity (0-14days), Carcinogenicity, Developmental toxicity / teratogenicity.
- Species: Dropdown menu with options: -- Select --, Cat, Cattle, Chicken, Chinchilla.
- Age Category: Dropdown menu with options: -- Select --, Adult, Adult and Juvenile, Juvenile, Juvenile and Adult.
- Route of Exposure / Administration: Dropdown menu with options: -- Select --, Implantation, Inhalation, Nasal, Ophthalmic.
- Function: Dropdown menu with options: -- Select --, Antimicrobial agent, Antimicrobial preservative, Antiseptic, Disinfectant.
- Organ / System: Dropdown menu with options: -- Select --, Analgesia, Cardiovascular System, Cellular, Digestive System.

At the bottom of the form are buttons for 'Submit', 'Reset', and a link 'Search BY Excipients'.

The footer contains the text 'Developed by GVK BIO', links for 'Contact', 'Feedback', and 'Disclaimer', and logos for 'G-STAR' and 'G-BIOM'.

Then “Search Results” page appears with the corresponding results. But if there are more than one excipient exists for the given search criteria then the below page appears

The screenshot shows the 'Excipient(s) Intermediate Page'. It has a 'Back' link in the top right corner. Below the header, it says 'Number of Excipients found: 2'. There is a list of checkboxes for selecting excipients:

- ☒ All
- ☒ Aspartame
- ☒ Propylene Glycol

At the bottom of the list is a 'Submit' button.

Then the “Search Results” page appears considering the selected excipient as shown below.

The screenshot displays the EuPFI (European Union Pharmacovigilance Initiative) interface. At the top, there are logos for EuPFI, STEP database, and uspfi. Below the logos, a yellow banner contains the user's name 'bodhanapu venkata reddy' and a session expiration notice. Navigation links for 'Search BY Excipients', 'Search FOR Excipients', 'Export', 'User Guide', 'Help', and 'Logout' are provided.

The main content area is titled 'Search Results' and shows 'Total References: 316'. It includes a 'Back' link and 'Excipient Navigation' controls (First, Previous, Next, Last) with a page number '2' and a 'Go' button.

Under 'General Information', the following details are listed:

- Excipient Chemical Name: Propylene Glycol
- CAS Registry Number: 57-55-6
- Excipient Category/Function :
- Pharmacopoeial Status:
- Regulatory Status:
- Synonyms:
- Acceptable Daily Intake:
- Revision Date:

Below this, a tabbed interface shows different data sections: Clinical Data (96), Non Clinical Data (158), In vitro Data (95), Regulatory and other information (55), and Reviews (16). The 'Clinical Data' tab is selected, showing a table of clinical references. The table has columns for Ref ID, Excipient Name, Study Type, Age Category, Age, Age Units, Gender, Route of Exposure or Administration, Dose, Dose Units, and Duration of Treatment. The first four rows of data are highlighted in yellow.

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
1015	Propylene Glycol	Unspecified	Adult	18 to 61	Years	Male	Topical	100 (15)	% (ul/Finn Chamber)	48
186	Propylene Glycol	Cohort (Incidence, Longitudinal, More)	Adult	48	Years	Male	Parenteral	444	g	7
186	Propylene Glycol	Cohort (Incidence, Longitudinal, More)	Adult	35	Years	Female	Parenteral	28	g	2
186	Propylene Glycol	Cohort (Incidence, Longitudinal, More)	Adult	35	Years	Male	Parenteral	490	g	2

At the bottom, there are links for 'Contact', 'Feedback', and 'Disclaimer', along with logos for GVK BIO, G-STAR, and G-BIOM.

Note:

- If user gave the search criteria from Search BY Excipients or Clinical Data section of Search FOR Excipients then the Search Results will display with Clinical Data section by default.
- If user gave the search criteria from Non Clinical Data section of Search FOR Excipients then the Search Results will display with Non Clinical Data section by default.
- User can give the combination of all the fields on sections wise (Clinical and Non Clinical), based on the given inputs the search results will display.
- On each field name mouse hover, the respective field description will be displayed as tool tip.

7 Excipient(s) Intermediate Details:

User can select the search criteria from Search BY Excipients or Search FOR Excipients to get the Multiple Excipients like below,

Excipient(s) Intermediate Details:

Search BY Excipients

Search BY Excipients

Excipient Name:

Synonyms (as per the Handbook of Excipients):

CAS Registry Number:

Function:

[Search FOR Excipients](#)

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 37-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

In search results if more than one Excipients are selected in the 'Search BY Excipients' or 'Search FOR Excipients' then "Excipient(s) Intermediate Page" appears as shown below.

Excipient(s) Intermediate Page [Back](#)

Number of Excipients found: 3

☐ All
☐ Alcohol
☐ Benzalkonium Chloride
☐ Benzyl Alcohol

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Select the required excipients using checkboxes and click "Submit" to retrieve the search results and search results appears as shown below.

Excipient(s) Intermediate Details:

Search Results [Back](#) Total References: 1 Record 1 of 3

General Information

Excipient Chemical Name: Alcohol
CAS Registry Number: 64-17-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Excipient Navigation
 1

Clinical Data (1) Non Clinical Data (0) Invitro Data (0) Regulatory and other information (0) Reviews (0)
Different colors indicates Unique References




Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
126	Alcohol	Other study type - Lab/Drug de (More)	Adult	Unspecified	Unspecified	Male	Topical	1.5; 0.2	ml	5	Minutes

Based on the user selection of Excipients, the search results will be displayed for those Excipients.

8 Search Results

Based on the search criteria given in the “Search BY Excipients or Search FOR Excipients” as shown below.

bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)

[Search BY Excipients](#) | [Search FOR Excipients](#) | [User Guide](#) | [Help](#) | [Logout](#)

Search BY Excipients

Search BY Excipients

Excipient Name:

Synonyms (as per the Handbook of Excipients):

CAS Registry Number:

Function:

[Search FOR Excipients](#)

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)

Select from drop down or enter minimum of 3 characters to populate suggestions.




If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection: Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

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Search results page appears considering the search criteria. STEP provides the Data in the search results page in a user friendly manner. Search Results page is universal when user selects the search criteria either from “Search BY Excipients or from Search FOR Excipients”. Then the Search Results page appears displaying the corresponding information as shown below.

The screenshot shows the 'Search Results' page for 'Benzyl Alcohol' in the STEP database. The page includes a header with logos for EUPFI, STEP database, and uspfi. A yellow banner at the top displays the user 'bodhanapu venkata reddy' and session information. The main content area shows 'General Information' for Benzyl Alcohol, including its CAS Registry Number (100-51-6) and various status fields. Below this, a table of clinical data is displayed, with columns for Ref ID, Excipient Name, Study Type, Age Category, Age, Age Units, Gender, Route of Exposure or Administration, Dose, Dose Units, and Duration of Treatment. The table shows three entries for Benzyl Alcohol, with the first entry highlighted in blue and the others in green. A footer section contains logos for GVK BIO, G-STAR, and G-BIOM, along with contact and disclaimer links.

Search Results [Back](#) Total References: 93 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzyl Alcohol
CAS Registry Number: 100-51-6

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2) Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
64	Benzyl Alcohol	Case study	Adult	Unspecified	Unspecified	Male/Female	Topical	1	%	Unspecified
933	Benzyl Alcohol	ADME/Pharmacokinetics studies	Preterm newborn infants (born More)	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified
933	Benzyl Alcohol	ADME/Pharmacokinetics studies	Term newborn infants (0 to 27 More)	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified

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Search Results provides the result information in a categorical manner for that the information is categorized into the below data

- ✓ General Information
- ✓ Clinical Data
- ✓ Non Clinical Data
- ✓ Invitro Data
- ✓ Regulatory & other information

✓ Reviews

Among those “General Information” and “Clinical Data” information appears by default as shown below.

The screenshot shows a web interface for 'Search Results'. At the top, there is a header bar with 'Search Results' on the left, a 'Back' link, 'Total References: 93' in the center, and 'Record 1 of 1' on the right. Below the header, there is a section titled 'General Information' which is highlighted with a red box. This section contains the following details: 'Excipient Chemical Name: Benzyl Alcohol', 'CAS Registry Number: 100-51-6', and a list of expandable fields: 'Excipient Category/Function:', 'Pharmacopoeial Status:', 'Regulatory Status:', 'Synonyms:', 'Acceptable Daily Intake:', and 'Revision Date:'. To the right of the 'General Information' section, there is a link for 'Excipient Navigation'.

8.1 General Information

In the “Search Results” page considering the search criteria “General Information” provides the information about the corresponding Excipient along with the CAS Registry Number as shown below.

This screenshot is identical to the one above, showing the 'Search Results' page with the 'General Information' section highlighted. It displays the excipient details for Benzyl Alcohol, including its CAS Registry Number and a list of expandable fields for further information.

In the “General Information” along with “Excipient Chemical Name and CAS Registry Number” details regarding “Excipient Category/Function, Pharmacopoeial Status, Regulatory Status, Synonyms, Acceptable Daily intake, Revision Date” data is also available in the Collapsed mode by default in “Search Results” page as shown below.

This screenshot is identical to the previous ones, showing the 'Search Results' page with the 'General Information' section highlighted. It displays the excipient details for Benzyl Alcohol, including its CAS Registry Number and a list of expandable fields for further information.

Whenever user clicks [+] symbol before the fields then the corresponding data appears as shown below.

Search Results [Back](#) Total References: 93 Record 1 of 1

Excipient Navigation

[General Information](#)

Excipient Chemical Name: Benzyl Alcohol
CAS Registry Number: 100-51-6

☐ Excipient Category/Function :

Antimicrobial preservative, Disinfectant, Solvent

☐ Pharmacopoeial Status:

JP XV; USP32?NF27; PhEur 6.5;

☐ Regulatory Status:

Agency	Description	Permitted Functionality	Use limits	Reference	Source URL
Japan	listed in the Japanese Compreh[...More]	-	precedent for use of Benzyl Al[...More]	Japanese Comprehensive Licensi[...More]	-
EU	-	preservative	permitted up to the max. conce[...More]	Ash, Michael, and Irene Ash. H[...More]	http://www.knovel.com/knovel2/ToC.jsp?BookID=2978
US	-	preservative	permitted up to the max. conce[...More]	Ash, Michael, and Irene Ash. H[...More]	http://www.knovel.com/knovel2/ToC.jsp?BookID=2978
FDA	-	Synthetic flavoring substances[...More]	-	Title 21 of the U.S. Code of F[...More]	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfctr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20alcohol

☐ Synonyms:

A-Toluenol	Alpha Hydroxytoluene	Benzenemethanol	Hydroxymethylbenzene
Phenylcarbinol	Phenylmethanol	Phenethylol	Benzyl Alcohol

☐ Acceptable Daily Intake:

General Acceptable Daily Intake

Source	Limit	Year	Reference	Source URL
EC SCF	0-5 mg/kg bw.	2002	SCF (Scientific Committee on F[...More]	http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf
Joint FAO/WHO Expert Committee[...More]	0-5 mg/kg bw ; No safety conce[...More]	2002	Summary of Evaluations Perform[...More]	http://www.inchem.org/documents/keca/keceval/kec_194.htm

Acceptable Daily Intake for Pediatrics

Source	Limit	Year	Reference	Source URL
No Data Found				

☐ Revision Date:

N/A

In the “Search Results” the count of the references for a particular excipient appears as shown below.

Clinical Data (14)Non Clinical Data (2)In vitro Data (7)Regulatory Reference (7)Reviews (1)

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
29	Sodium Benzoate	Case Study	Adult	64	Years	Female	Oral	750	Mg
64	Sodium Benzoate	Case Study	Adult	Unspecified	Unspecified	Male/Female	Topical	5	%
79	Sodium Benzoate	Case Study	Children (2 To 11 Years)	5	Years	Male	Topical	4	%

8.2 Clinical Data

Clinical data provides complete Clinical information of the excipient.

8.2.1 Reference ID

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicates that the records with the unique Reference ID.
- Click “Ref ID”, to get the complete reference information appears in a tabular format as shown below

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Unspecified	Unspecified	120, 150	Mg/Kg

Ref ID	Reference	Title	Author	Reference Type	Year
112	NA, Thomas Vogt, Micheal Landthaler, Wilhelm Stoiz. Sodium benzoate-induced acute leukocytoclastic vasculitis with unusual clinical appearance. Arch Dermatol. 1999 Jun;135(6):726-7, NA, 1999, NA(NA), NA-NA	Thomas Vogt, Micheal Landthaler, Wilhelm Stoiz. Sodium benzoate-induced acute leukocytoclastic vasculitis with unusual clinical appearance. Arch Dermatol. 1999 Jun;135(6):726-7		J	1999

8.2.2 Excipient Name

Based on the search criteria the relevant “Excipient Name” appears in the “Excipient Name” column as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
124	Sodium	Pharmacokinetics	Adult	Unspecified	Unspecified	Unspecified	Oral	130; 150	Mg/Kg

8.2.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant “Study Type” appears in the column types as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
124	Sodium	Pharmacokinetics	Adult	Unspecified	Unspecified	Unspecified	Oral	130; 150	Mg/Kg

8.2.4 Age Category

“Age Category” indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name is indicated. Depending upon the search criteria the corresponding age category information will appear under “Age Category” column

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
124	Sodium	Pharmacokinetics	Adult	Unspecified	Unspecified	Unspecified	Oral	130; 150	Mg/Kg

8.2.5 Age

Age provides numerical entry for age in its corresponding column as shown below

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
124	Sodium	Pharmacokinetics	Adult	Unspecified	Unspecified	Unspecified	Oral	130; 150	Mg/Kg

8.2.6 Age Units

Displays the unit for Age- provides in years, months etc; as shown below

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

8.2.7 Gender

Displays the gender based on the search criteria in the relevant column as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

8.2.8 Route of Exposure or Administration

“Route of Exposure/Administration” indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

8.2.9 Dose

Dose(s) or concentration(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)) will be displayed based on the searched criteria as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

8.2.10 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	
Mg/Kg	Unspecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K(...More)	NA, K. Oyanagi, Kuniya, A. (...More)	
Mg	1	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (...More)	NA, Nettis Colanardi MC, Fe (...More)	
Mg	Unspecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN (...More)	
Unspecified	Unspecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(...More)	NA, Tom E, Raposo	

8.2.11 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	
Mg/Kg	Unspecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K(...More)	NA, K. Oyanagi, Kuniya, A. (...More)	
Mg	1	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (...More)	NA, Nettis Colanardi MC, Fe (...More)	
Mg	Unspecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN (...More)	
Unspecified	Unspecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(...More)	NA, Tom E, Raposo	

8.2.12 Duration Units

Displays duration of the dose in units

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)									
Show/Hide Clinical Columns									
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
Unspecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K(...More)	NA, K. Oyanagi, Y. Kuniya, A. (...More)	J	
Unspecified	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (...More)	NA, Nettis E, Colanardi MC, Fe (...More)	J	
Unspecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN, R. (...More)	J	
Unspecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(...More)	NA, Tomaz-E, Raposo-	J	

8.2.13 Frequency of Administration

This indicates the administration of doses to the test species as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns ⓘ								
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						(...More)	Hsien-Yuan (...More)	
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (...More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjev S (...More)	J
	Hours	Every 3 Hours	Unspecified	Agitation; Confusion; Kussmaul (...More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjev S (...More)	J
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (...More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjev S (...More)	J

8.2.14 System/Organ

Indicates on which organ or system the effects were observed as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns ⓘ								
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						(...More)	MC, Fe (...More)	
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN, R. (...More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge (...More)	NA, Tomaz-E, Raposo-MS, Santos (...More)	J
	Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (...More)	NA, Chien-Han Lai, Hsien-Yuan (...More)	J

8.2.15 Safety / Tolerability / Adverse Effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Clinical Data(10) Non Clinical Data(73) Invitro Data(21) Regulatory and other information(7) Reviews(2)								
Show/Hide Clinical Columns ⓘ								
Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference
--Select--	--Select--	--Select--	--Select--	--Select--		--Select--		--Select--
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec (...More)	NA, Schnuch A, Lessmann H, Gei (...More)
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (...More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (...More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)

When user clicks “More” link then the complete information about the adverse effects appears as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2)										Different colors indicates Unique References	
Show/Hide Clinical Columns										Clear All Filters on Clinical Data Export Filtered Clinical Data	
Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year	
--Select--	--Select--	--Select--	--Select--	--Select--		--Select--			--Select--		
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec (...More)	NA, Schnuch A, Lessmann H, Gei (...More)	J	2011	
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine than in term newborns as hippuric acid formation is deficient in preterm neonates (...Less)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)	J	1988	
					Larger percentages of benzyl alcohol			NA, LeBel			

Mouse hover on “More” link also displays the complete information of the “Adverse Effects” in a tool tip as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2)										Different colors indicates Unique References	
Show/Hide Clinical Columns										Clear All Filters on Clinical Data Export Filtered Clinical Data	
se Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year	
ect--	--Select--	--Select--	--Select--	--Select--		--Select--			--Select--		
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec (...More)	NA, Schnuch A, Lessmann H, Gei (...More)	J	2011	
ified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (...More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)	J	1988	
ified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)	J	1988	

8.2.16 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2)										Different colors indicates Unique References	
Show/Hide Clinical Columns										Clear All Filters on Clinical Data Export Filtered Clinical Data	
se Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year	
ect--	--Select--	--Select--	--Select--	--Select--		--Select--			--Select--		
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec (...More)	NA, Schnuch A, Lessmann H, Gei (...More)	J	2011	
ified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (...More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)	J	1988	
ified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)	J	1988	

8.2.17 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns ⓘ								
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN, R. (...More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(...More)	NA, Tomaz-E, Raposo-MS, Santos (...More)	J
	Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (...More)	NA, Chien-Han Lai, Hsien-Yuan (...More)	J
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (...More)	Injection	Not Applicable	NA, Pranhannhoti	J

Click “More” link then complete comments data appears as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns ⓘ								
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory Flow Rate Of 50% Was Demonstrated With Oral Sodium Benzoate 100 Mg. The Anaphylactoid Reaction Was Due To Sodium Benzoate Given With The Diazepam. (...Less)	NA, D. A. MONERET-VAUTRIN, R. (...More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge Tests Resulted In Urticaria. (...Less)	NA, Tomaz-E, Raposo-MS, Santos (...More)	J

8.2.18 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns ⓘ								
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	NA, D. A. MONERET-VAUTRIN, R. (...More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge Tests Resulted In Urticaria. (...Less)	NA, Tomaz-E, Raposo-MS, Santos (...More)	J
	Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (...More)	NA, Chien-Han Lai, Hsien-Yuan (...More)	J
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (...More)	Injection	Not Applicable	NA, Pranhannhoti	J

Click “More” link then complete reference information appears as shown below.

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns								
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Unspecified	Integumentary System	Drug Eruption	Patch	No Evidence Of Sodium Benzoate(...More)	NA, J. V ILAPLANA, C. R. OMAGUERA. Fixed Drug Eruption From Sodium Benzoate. Contact Dermatitis. 2003 Dec;49 (5):290-1. NA, 2003, NA (NA), NA-NA (...Less)	J
pecified	Unspecified	Unspecified	Integumentary System	Drug Eruption	Solution	No Evidence Referring To Sodi(...More)	NA, J. V ILAPLANA, C.	J

8.2.19 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

Clinical Data(14) Non Clinical Data(2) Invitro Data(7) Regulatory Reference(7) Reviews(1)								
Show/Hide Clinical Columns								
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Q6h	Multiple Organs/Systems	Impaired Renal Function And H(...More)	Injection	VdD0.145 0.07 L/Kg (0.08670.2(...More)	NA, Green TP, Marchessault RP, (...More)	J
pecified	Unspecified	Q6h	Genitourinary System	Renal Failure	Injection	Use Of sodium Benzoate In Newbo(...More)	Thomas P Green And B L Mirkin (...More)	O
pecified	Unspecified	Unspecified	Integumentary System	Pruritis	Capsule	Sodium Benzoate Induces A Rela(...More)	NA, R. Asero. Sodium Benzoate- (...More)	J
pecified	Unspecified	Unspecified	Integumentary	Acute Leukocytoclastic Vasculi	Capsule	Sodium Benzoate Is	NA, Thomas	J

8.2.20 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2)								
Show/Hide Clinical Columns								
Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference
--	--Select--	--Select--	--Select--	--Select--		--Select--		--Select--
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec(...More)	NA, Schnuch A, Lessmann H, Gei (...More)
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a(...More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine	Solution	Not Available	NA, LeBel M, Ferron L, Masson (...More)

Note: For any field, the data is more than 30 characters in the cell, then the data will display 30 characters and followed by “(...More)”. If user clicks on “More” link then user is able to see the full information for that particular cell. In that case the link will be “(...Less)” as shown above. More over user is able to see the full text of that particular cell as a tooltip (Mouse hover). This is applicable for overall application in the search results page.

8.3 Non Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Non-Clinical Data. This provides complete optional environment depending on the “Non-Clinical Data” attributes.

8.3.1 Ref ID

Non-Clinical data provides complete Non-Clinical information of the excipient.

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicate Unique References.
- Click “Ref ID”, complete reference information appears in a tabular format as shown below

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
5	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other (...More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96	Aspartame	Pharmacokinetics/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg
Ref ID	Reference		Title		Author	Reference Type	Year		
27	NA, Edmundson AB, Manion CV. Treatment of osteoarthritis with aspartame. Clin Pharmacol Ther. 1998 May;63(5):580-93, NA, 1998, NA(NA); NA-NA		Edmundson AB, Manion CV. Treatment of osteoarthritis with aspartame. Clin Pharmacol Ther. 1998 May;63(5):580-93			J	1998		

8.3.2 Excipient Name

Based on the search criteria the relevant “Excipient Name” appears in the “Excipient Name” column as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
5	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other (...More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96	Aspartame	Pharmacokinetics/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg

8.3.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant “Study Type” appears in the column types as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
5	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other (...More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96	Aspartame	Pharmacokinetics/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg

8.3.4 Species

Species displays the information about the species name of the excipient as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
207	Aspartame	Reproductive Toxicity And Deve (...More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

8.3.5 Age Category

“Age Category” indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated. Depending upon the search criteria the corresponding age category information will appear under “Age Category” column as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
5	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other ...More	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96	Aspartame	Pharmacokinetics/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg

8.3.6 Age

Age provides numerical entry for age in its corresponding column as shown below

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
207	Aspartame	Reproductive Toxicity And Deve ...More	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

8.3.7 Age Units

Displays the unit for Age- provides in years, months etc; as shown below

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
207	Aspartame	Reproductive Toxicity And Deve ...More	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

8.3.8 Gender

Displays the gender based on the search criteria in the relevant column as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

8.3.9 Dose/Concentration

Dose(s) or concentration(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)) will be displayed based on the searched criteria as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

8.3.10 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
in	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa(More)
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Expo Aspartame(More)
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam(More)
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wa

8.3.11 Route of Exposure or Administration

“Route of Exposure/Administration” indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
In	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa...
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (...More)	Solution	Lifetime Expo Aspartame...
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam...
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wz...

8.3.12 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
In	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa...
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (...More)	Solution	Lifetime Expo Aspartame...
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam...
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wz...

8.3.13 Duration Units

Displays duration of the dose in units

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
In	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa...
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (...More)	Solution	Lifetime Expo Aspartame...
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam...
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wz...

8.3.14 Frequency of Administration

This indicates the administration of doses to the test species as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
In	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa...
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (...More)	Solution	Lifetime Expo Aspartame...
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam(...)
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wz

8.3.15 System/Organ

Indicates on which organ or system the effects were observed as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
In	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa...
	Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (...More)	Solution	Lifetime Expo Aspartame...
	Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam(...)
	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wz

8.3.16 Adverse effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Clinical Data (10)Non Clinical Data (73)Invitro Data (21)Regulatory and other information (7)Reviews (2)										Different colors indicates Unique References			
Show/Hide Non Clinical Columns										Clear All Filters on Non Clinical Data		Export Filtered Non Clinical Data	
Frequency of Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year			
--Select--	--Select--	--Select--	--Select--	--Select--		--Select--			--Select--				
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(...More)	Solution	Benzyl alcohol, on a dose/body(...More)	NA, McCloskey SE, Gershanik JJ(...More)	J	1986			
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(...More)	Solution	Benzyl alcohol, on a dose/body(...More)	NA, McCloskey SE, Gershanik JJ(...More)	J	1986			
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp (...More)	Gel	Benzyl alcohol did not cause a(...More)	NA, Thomas R Moench, Russell J(...More)	J	2010			
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, (...More)	J	1979			
				Integumentary				NA, Motoyoshi					

8.3.17 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

Clinical Data (10)					Non Clinical Data (73)		Invitro Data (21)		Regulatory and other information (7)		Reviews (2)		Different colors indicates Unique References			
Show/Hide Non Clinical Columns										Clear All Filters on Non Clinical Data		Export Filtered Non Clinical Data				
Duration of Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year						
	--Select--	--Select--	--Select--	--Select--		--Select--		--Select--								
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(More)	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ(More)	J	1986						
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(More)	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ(More)	J	1986						
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp(More)	Gel	Benzyl alcohol did not cause a(More)	NA, Thomas R Moench, Russell J(More)	J	2010						
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, (More)	J	1979						
				Integumentary				NA, Motoyoshi								

8.3.18 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects	Powder	SC-18862 Was Neither Embryotox[...More]	Schroeder R. E, Mitchell A, Ra[...More]	O
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weig [...More]	Powder	Continuous Dietary Administrat[...More]	R. E. Schroeder, K. S. Rao, G. [...More]	O
	Unspecified	Unspecified	Continuous Feeding	Multiple Organs/Systems	Hepatocellular Carcinoma; Alve [...More]	Pellet	Aspartame Is A Carcinogenic Ag [...More]	NA, Morando Soffritti, Fiorell [...More]	J
	4	Weeks	Continuous Feeding	Multiple Organs/Systems	No Adverse Effects- 100% Survi[...More]	Powder	No Adverse Physical/Behavioura [...More]	KS Rao, TB Martinez, And RG Mc	O

Click “More” link then complete comments data appears as shown below.

Clinical Data(98)

Non Clinical Data(102)

Invitro Data(18)

Regulatory Reference(59)

Reviews(21)

Show/Hide Non Clinical Columns

Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects	Powder	SC-18862 Was Neither Embryotoxic Nor Teratogenic To The Albino Rabbit Fetus, When Administered Intragastrically At A Dosage Of 2 G/Kg/Day During The Mid-Portion Of Gestation. Likewise, It Lacked Notable Adverse Effects On The Maternal Animal. ...Less	Schroeder R. E, Mitchell A, Ra(...More)	O
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weiq (...More)	Powder	Continuous Dietary Administrat(...More)	R. E. Schroeder, K. S. Rao, G.	O

8.3.19 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)									
Show/Hide Non Clinical Columns ⓘ									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects	Powder	SC-18862 Was Neither Embryotox (...More)	Schroeder R. E, Mitchell A, Ra (...More)	O
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weig (...More)	Powder	Continuous Dietary Administrat (...More)	R. E. Schroeder, K. S. Rao, G. (...More)	O
	Unspecified	Unspecified	Continuous Feeding	Multiple Organs/Systems	Hepatocellular Carcinoma; Alve (...More)	Pellet	Aspartame Is A Carcinogenic Ag (...More)	NA, Morando Soffritti, Fiorelli (...More)	J
	4	Weeks	Continuous Feeding	Multiple Organs/Systems	No Adverse Effects- 100% Survi(...More)	Powder	No Adverse Physical/Behavioura (...More)	KS Rao, TB Martinez, And RG Mc	O

Click “More” link then complete reference information appears as shown below.

Clinical Data(98)Non Clinical Data(102)Invitro Data(18)Regulatory Reference(59)Reviews(21)

Show/Hide Non Clinical Columns

Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
Unspecified	Unspecified	Reproductive System	A Slight Elevation In Maternal	Solution	Administration Of Aspartame At	Rao KS, McConnell RG. SC-18862: Experiments In Mated And Pregnant Rhesus Monkeys. 1975 May;1-29;	O
Days	OD	Cellular	Chromosomal Aberration	Solution	Aspartame Significantly Induce	NA, AlSuhaibani ES. In Vivo Cytogenetic Studies On Aspartame. Comp Funct Genomics. 2010. Pii: 605921, NA, 2010, NA(NA), NA-NA	J
Days	OD	Not Applicable	Mean Body Weight In The Offspr	Powder	The Study Shows That Levels Of	Lennon HD, Metcalf L, Mares SE, Smith JH. Effects Of SC-18862 On Lactation In Rats. 1973 Sep;1-67;	O
Days	OD	Cellular	No Adverse Effects	Unspecified	No Mutagenic Effects Were Obse	Mutagenic Study In Rats. SC-18	O
Days	OD	Endocrine System	No Adverse Effects	Suspension	Intact Male Rats Have No Male	Mares SE, Berg JR. Effects Of	O

8.3.20 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

Clinical Data(98)

Non Clinical Data(102)

Invitro Data(18)

Regulatory Reference(59)

Reviews(21)

Show/Hide Non Clinical Columns

Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
Unspecified	Unspecified	Reproductive System	A Slight Elevation In Maternal	Solution	Administration Of Aspartame At	Rao KS, McConnell RG. SC-18862	O
Days	OD	Cellular	Chromosomal Aberration	Solution	Aspartame Significantly Induce	NA, AlSuhaibani ES. In Vivo Cy	J
Days	OD	Not Applicable	Mean Body Weight In The Offspr	Powder	The Study Shows That Levels Of	Lennon HD, Metcalf L, Mares SE	O
Days	OD	Cellular	No Adverse Effects	Unspecified	No Mutagenic Effects Were Obse	Mutagenic Study In Rats. SC-18	O
Days	OD	Endocrine System	No Adverse Effects	Suspension	Intact Male Rats Have No Mortal	Mares SE, Berg JR. Effects Of	O

8.3.21 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10)	Non Clinical Data (73)	Invitro Data (21)	Regulatory and other information (7)	Reviews (2)	Different colors indicates Unique References									
Show/Hide Non Clinical Columns											Clear All Filters on Non Clinical Data		Export Filtered Non Clinical Data	
Duration of Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year				
	--Select--	--Select--	--Select--	--Select--		--Select--			--Select--					
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(...More)	Solution	Benzyl alcohol, on a dose/body(...More)	NA, McCloskey SE, Gershanik JJ(...More)	J	1986				
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(...More)	Solution	Benzyl alcohol, on a dose/body(...More)	NA, McCloskey SE, Gershanik JJ(...More)	J	1986				
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp (...More)	Gel	Benzyl alcohol did not cause a(...More)	NA, Thomas R Moench, Russell J(...More)	J	2010				
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, (...More)	J	1979				
				Integumentary				NA, Motoyoshi						

8.4 Invitro data

Invitro Data provides the complete information about the

8.4.1 Ref ID

Invitro provides complete Invitro information of the excipient.

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicate Unique References.
- Click “Ref ID”, complete reference information appears in a tabular format as shown below

Clinical Data(98)

Non Clinical Data(102)

Invitro Data(18)

Regulatory Reference(59)

Reviews(21)

Show/Hide Invitro Columns

Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

Ref ID	Reference	Title	Author	Reference Type	Year
39	NA, Szucs EF, Barrett KE, Metcalfe DD. The effects of aspartame on mast cells and basophils. Food Chem Toxicol. 1986 Feb;24(2):171-4. NA, 1986, NA(NA), NA-NA	Szucs EF, Barrett KE, Metcalfe DD. The effects of aspartame on mast cells and basophils. Food Chem Toxicol. 1986 Feb;24(2):171-4		J	1986

8.4.2 Excipient Name

Based on the search criteria the relevant “Excipient Name” appears in the “Excipient Name” column as shown below.

Clinical Data(98)

Non Clinical Data(102)

Invitro Data(18)

Regulatory Reference(59)

Reviews(21)

Show/Hide Invitro Columns

Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant “Study Type” appears in the column types as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.4 Species

Species displays the information about the species name of the excipient as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.5 Dose

Dose(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)') will be displayed based on the searched criteria as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.6 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.7 Route of Exposure or Administration

“Route of Exposure/Administration” indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.8 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

Clinical Data(98) Non Clinical Data(102) Invitro Data(18) Regulatory Reference(59) Reviews(21)								
Show/Hide Invitro Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
39	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10-5, 10-6, 10-7, (...More)	M		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

8.4.9 Duration Units

Displays duration of the dose in units

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns ⓘ								
Route Of Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (...More)		The Study Performed On Cat Ooc (...More)	NA, Comizzoli P, Wildt DE, Puk (...More)	J
	48 (Pre-Treatment), 48 (Post-T (...More)	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treat (...More)	NA, Sherertz EF, Sloan KB, McT (...More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (...More)	NA, Xiaorong Huang, Ping Zhuan (...More)	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When (...More)	NA, Seki S, Kouya T, Tsuchiya (...More)	J

8.4.10 System/Organ

Indicates on which organ or system the effects were observed as shown below.

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns ⓘ								
Route Of Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (...More)		The Study Performed On Cat Ooc (...More)	NA, Comizzoli P, Wildt DE, Puk (...More)	J
	48 (Pre-Treatment), 48 (Post-T (...More)	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treat (...More)	NA, Sherertz EF, Sloan KB, McT (...More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (...More)	NA, Xiaorong Huang, Ping Zhuan (...More)	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When (...More)	NA, Seki S, Kouya T, Tsuchiya (...More)	J

8.4.11 Safety/Tolerability/Adverse Effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2) Different colors indicates Unique References									
Show/Hide Invitro Columns ⌵									
Exposure or Administration	Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
⌵	--Select-- ⌵	--Select-- ⌵	--Select-- ⌵		--Select-- ⌵			--Select-- ⌵	
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl [...More]	NA, Placzek M, Krosta I, Gaube [...More]	J	2005
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat [...More]		Not Available	NA, Ball JC, FoxallNot Availab [...More]	J	1984
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up [...More]		Not Available	NA, SainteNot AvailableMarie J [...More]	J	1990
	3, 60	Minutes	Reconstructed epidermis ESTNot [...More]	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007;	O	2007

8.4.12 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2) Different colors indicates Unique References									
Show/Hide Invitro Columns ⌵									
Exposure or Administration	Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
⌵	--Select-- ⌵	--Select-- ⌵	--Select-- ⌵		--Select-- ⌵			--Select-- ⌵	
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl [...More]	NA, Placzek M, Krosta I, Gaube [...More]	J	2005
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat [...More]		Not Available	NA, Ball JC, FoxallNot Availab [...More]	J	1984
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up [...More]		Not Available	NA, SainteNot AvailableMarie J [...More]	J	1990
	3, 60	Minutes	Reconstructed epidermis ESTNot [...More]	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007;	O	2007

8.4.13 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns ⌵								
Exposure or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
⌵	⌵	⌵	⌵	⌵				⌵
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M [...More]		The Study Performed On Cat Ooc [...More]	NA, Comizzoli P, Wildt DE, Puk [...More]	J
	48 (Pre-Treatment), 48 (Post-T [...More])	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treate [...More]	NA, Sherertz EF, Sloan KB, McT [...More]	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos [...More]	NA, Xiaorong Huang, Ping Zhuan [...More]	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When [...More]	NA, Seki S, Kouya T, Tsuchiya [...More]	J

Click “More” link then complete comments data appears as shown below.

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns								
Pre Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M ...More		The Study Performed On Cat Ooc ...More	NA, Comizzoli P, Wildt DE, Puk ...More	J
	48 (Pre-Treatment), 48 (Post-T) ...More	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treated With Propylene Glycol And Then Applied With Theophylline In A Diffusion Cell System Shows Increased Theophylline Flux ...Less	NA, Sherertz EF, Sloan KB, McT ...More	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos ...More	NA, Xiaorong Huang, Pinn	J

8.4.14 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns								
Pre Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	24	Hours	Abdominal Skin	No Adverse Effects		Steady State Penetration Rate ...More	NA, Fasano WJ, Ten Berge WF, B ...More	J
	Unspecified	Unspecified	Sperm	No Adverse Effect		The Study Shows That The Combi ...More	NA, Vildiz C, Ottaviani P, Law ...More	J
	30	Minutes	Embryo	Significantly Good Survival Ra ...More		Ethylene Glycol Does Not Appear ...More	NA, Emiliani S, Van Den Bergh ...More	J
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M ...More		The Study Performed On Cat Ooc ...More	NA, Comizzoli P, Wildt DE, Puk ...More	J
	48 (Pre-Treatment), 48 (Post-T) ...More	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treated With ...More	NA, Sherertz EF, Sloan KB, McT ...More	J

Click “More” link then complete reference information appears as shown below.

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns								
Pre Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
							On Sperm Quality, Nuclear DNA Integrity, In Vitro Fertilization, And In Vitro Embryo Development In The Mouse. Reproduction. 2007 Mar;133(3):585-95; NA, 2007, NA(NA), NA-NA ...Less	
	30	Minutes	Embryo	Significantly Good Survival Ra ...More		Ethylene Glycol Does Not Appear ...More	NA, Emiliani S, Van Den Bergh ...More	J

8.4.15 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

Clinical Data(68) Non Clinical Data(96) Invitro Data(65) Regulatory Reference(55) Reviews(16)								
Show/Hide Invitro Columns								
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (...More)		The Study Performed On Cat Ooc (...More)	NA, Comizzoli P, Wildt DE, Puk (...More)	J
	48 (Pre-Treatment), 48 (Post-T) (...More)	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treated With Propylene Glycol And Then Applied With Theophylline In A Diffusion Cell System Shows Increased Theophylline Flux (...Less)	NA, Sherertz EF, Sloan KB, McT (...More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (...More)	NA, Xiaorong Huang, Ping (...More)	J

8.4.16 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2)								
Show/Hide Invitro Columns								
Clear All Filters on Invitro Data Export Filtered Invitro Data								
Exposure Or Administration	Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	--Select--	--Select--	--Select--		--Select--			--Select--
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl (...More)	NA, Placzek M, Krosta I, Gaube (...More)	J
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat (...More)		Not Available	NA, Ball JC, FoxallNot Availab (...More)	J
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up (...More)		Not Available	NA, SainteNot AvailableMarie J (...More)	J
	3, 60	Minutes	Reconstructed epidermis ESTNot (...More)	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007; (...More)	O

8.5 Regulatory & other information

'Regulatory & other information' includes the references to the regulations, and regulatory requirements for a specific substance.

8.5.1 Ref ID

All references will be given a unique Reference ID. This will help users to identify the references where two or more studies are discussed in one reference. When user clicks "Ref ID" link in the "Regulatory & other information" table, entire information of the reference appears as a tabular

separate with the “Ref ID, Reference, Title, Author, Reference Type and Year information as shown below

Clinical Data (10)		Non Clinical Data (73)		Invitro Data (21)		Regulatory & other information (7)		Reviews (2)		Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL				Reference Year			
650	Benzyl Alcohol	Opinion of the Scientific Comm(…More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf				2002			
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(…More)		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?cm=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search							
679	Benzyl Alcohol	Benzyl alcohol regulatory data(…More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294							
513	Benzyl Alcohol	A survey and health assessment(…More)		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm				2007			
543	Benzyl Alcohol	white paper(Source: unknown)(…More)		http://legacy.library.ucsf.edu/tid/khl05c00/pdf				1997			
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(…More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf				2004			
577	Benzyl Alcohol	Scientific Opinion on Flavour(…More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf				2011			

Ref ID	Reference	Title	Author	Reference Type	Year
650	Opinion of the Scientific Committee on Food on Benzyl alcohol(Source: Opinion of the Scientific Committee on Food on Benzyl alcohol)(Year: 2002)(URL: http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf), Opinion of the Scientific Committee on Food on Benzyl alcohol	Opinion of the Scientific Committee on Food on Benzyl alcohol(Source: Opinion of the Scientific Committee on Food on Benzyl alcohol)(Year: 2002)(URL: http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf)		O	2002

8.5.2 Excipient Name

Based on the search criteria the relevant “Excipient Name” appears in the “Excipient Name” column as shown below.

Clinical Data (10)		Non Clinical Data (73)		Invitro Data (21)		Regulatory & other information (7)		Reviews (2)		Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL				Reference Year			
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf				2002			
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?cm=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search							
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294							
513	Benzyl Alcohol	A survey and health assessment(...More)		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm				2007			
543	Benzyl Alcohol	white paper(Source: unknown)(...More)		http://legacy.library.ucsf.edu/tid/khl05c00/pdf				1997			
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(...More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf				2004			
577	Benzyl Alcohol	Scientific Opinion on Flavour(...More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf				2011			

8.5.3 References

References indicate the source from which the information is extracted. Bibliographic source of the study report or publication will be provided. The references would be linked to their original source through DOI. The users who need the details of the study will be able to access the full text, if available with their subscription or will be able to access the abstract.

Clinical Data (10)		Non Clinical Data (73)		Invitro Data (21)		Regulatory & other information (7)		Reviews (2)		Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL				Reference Year			
650	Benzyl Alcohol	Opinion of the Scientific Comm(…More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf				2002			
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(…More)		http://iter.ctonet.net/publicurl/p_report_l2_non.cfm?cm=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search							
679	Benzyl Alcohol	Benzyl alcohol regulatory data(…More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294							
513	Benzyl Alcohol	A survey and health assessment(…More)		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm				2007			
543	Benzyl Alcohol	white paper(Source: unknown)(…More)		http://legacy.library.ucsf.edu/tid/khl05c00/pdf				1997			
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(…More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf				2004			
577	Benzyl Alcohol	Scientific Opinion on Flavour(…More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf				2011			

8.5.4 Source

Source indicates from which the Reference information is extracted.

Clinical Data (10)		Non Clinical Data (73)	In vitro Data (21)	Regulatory & other information (7)	Reviews (2)	Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL		Reference Year	
650	Benzyl Alcohol	Opinion of the Scientific Comm[...More]		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf		2002	
678	Benzyl Alcohol	Benzyl alcohol - Report(Source[...More])		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crn=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search			
679	Benzyl Alcohol	Benzyl alcohol regulatory data[...More]		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294			
513	Benzyl Alcohol	A survey and health assessment[...More]		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm		2007	
543	Benzyl Alcohol	white paper(Source: unknown)([...More])		http://legacy.library.ucsf.edu/tid/khl05c00/pdf		1997	
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses[...More]		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf		2004	
577	Benzyl Alcohol	Scientific Opinion on Flavour[...More]		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf		2011	

8.5.5 Source URL

Source URL indicates from which the Reference information is extracted.

Clinical Data (10)		Non Clinical Data (73)	In vitro Data (21)	Regulatory & other information (7)	Reviews (2)	Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL		Reference Year	
650	Benzyl Alcohol	Opinion of the Scientific Comm[...More]		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf		2002	
678	Benzyl Alcohol	Benzyl alcohol - Report(Source[...More])		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crn=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search			
679	Benzyl Alcohol	Benzyl alcohol regulatory data[...More]		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294			
513	Benzyl Alcohol	A survey and health assessment[...More]		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm		2007	
543	Benzyl Alcohol	white paper(Source: unknown)([...More])		http://legacy.library.ucsf.edu/tid/khl05c00/pdf		1997	
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses[...More]		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf		2004	
577	Benzyl Alcohol	Scientific Opinion on Flavour[...More]		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf		2011	

8.5.6 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10)		Non Clinical Data (73)	In vitro Data (21)	Regulatory & other information (7)	Reviews (2)	Different colors indicates Unique References	
Ref ID	Excipient Name	Reference	Source	Source URL		Reference Year	
650	Benzyl Alcohol	Opinion of the Scientific Comm[...More]		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf		2002	
678	Benzyl Alcohol	Benzyl alcohol - Report(Source[...More])		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crn=100-51-68&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search			
679	Benzyl Alcohol	Benzyl alcohol regulatory data[...More]		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294			
513	Benzyl Alcohol	A survey and health assessment[...More]		http://www2.mst.dk/common/Udqvramme/Frame.asp?http://www2.mst.dk/Udqv/publications/2007/978-87-7052-638-8/html/kap06_eng.htm		2007	
543	Benzyl Alcohol	white paper(Source: unknown)([...More])		http://legacy.library.ucsf.edu/tid/khl05c00/pdf		1997	
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses[...More]		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf		2004	
577	Benzyl Alcohol	Scientific Opinion on Flavour[...More]		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf		2011	

8.6 Reviews

This includes the references to the general safety and toxicological reviews and specific reviews

Ex: IPCS, IARC monograph reviews, ASTDR reviews etc.

8.6.1 Ref ID

All references will be given a unique Reference ID. This will help users to identify the references where two or more studies are discussed in one reference. When user clicks “Ref ID” link in the “Reviews” table, entire information of the reference appears as a tabular separate with the “Ref ID, Reference, Title, Author, Reference Type and Year information as shown below

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J.(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

Ref ID	Reference	Title	Author	Reference Type	Year
704	Benzyl alcohol, In: Editor: J.K. Aronson, Editor(s)-in-Chief, Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions (Fifteenth Edition), Elsevier, Amsterdam, 2006, Pages 444-445, ISBN 9780444510051, 10.(Source: Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions (Fifteenth Edition), Elsevier, Amsterdam, 2006, Pages 444-445, ISBN 9780444510051, 10.)(Year: 2006)(URL: http://www.sciencedirect.com/science/referenceworks/9780444510051); Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions (Fifteenth Edition), Elsevier, Amsterdam, 2006, Pages 444-445, ISBN 9780444510051, 10.	Benzyl alcohol, In: Editor: J.K. Aronson, Editor(s)-in-Chief, Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions (Fifteenth Edition), Elsevier, Amsterdam, 2006, Pages 444-445, ISBN 9780444510051, 10.(Source: Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions (Fifteenth Edition), Elsevier, Amsterdam, 2006, Pages 444-445, ISBN 9780444510051, 10.)(Year: 2006)(URL: http://www.sciencedirect.com/science/referenceworks/9780444510051)		O	2006

8.6.2 Excipient Name

Based on the search criteria the relevant “Excipient Name” appears in the “Excipient Name” column as shown below.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J.(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

8.6.3 References

References indicate the source from which the information is extracted. Bibliographic source of the study report or publication will be provided. The references would be linked to their original source

through DOI. The users who need the details of the study will be able to access the full text, if available with their subscription or will be able to access the abstract.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

8.6.4 Source

Source indicates from which the Reference information is extracted.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

8.6.5 Source URL

Source URL indicates from which the Reference information is extracted.

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

8.6.6 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory & other information (7) Reviews (2) Different colors indicates Unique References					
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
704	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(...More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758	Benzyl Alcohol	Summary data of benzyl alcohol(...More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

8.7 Customization using Filters

In the STEP application user is allowed to customize the excipient selection by selecting more than one excipient using “Search BY Excipients” as shown below using CTRL key

Search BY Excipients

Excipient Name:

Synonyms (as per the Handbook of Excipients):

CAS Registry Number:

Function:

[Search FOR Excipients](#)

Instructions on Search BY Excipients page:

There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg. 1,2 propanediol) or by function (eg. solvent).

Select from drop down or enter minimum of 3 characters to populate suggestions.

If you don't find the excipient in the excipient name box, try searching in synonyms.

For Multiple Excipient/Function Selection:

Please use "Ctrl" or "Mouse click & drag" to select multiple search terms. OR please use "+" icon to open excipients list box for selection.

Progressive search will be based and filtered on the values already selected in dropdowns.

If you've selected a large dataset the results could take some time to load.

Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Then click “Submit” button then below page appears

Excipient(s) Intermediate Page [Back](#)

Number of Excipients found: 4

☐ All

☐ Acesulfame K

☐ Alcohol

☐ Aspartame

☐ Benzalkonium Chloride

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In the above page user is allowed to select one or more than one excipient name using check boxes

As shown below

Excipient(s) Intermediate Page [Back](#)

Number of Excipients found: 4

☐ All
☐ Acesulfame K
☐ Alcohol
☐ Aspartame
☒ Benzalkonium Chloride

[Submit](#)

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Click “Submit” to retrieve the results. Then the “Search Results” page appears as shown below

Search Results [Back](#) Total References: 15 Record 1 of 1

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3) | Non Clinical Data (3) | Invitro Data (1) | Regulatory and other information (5) | Reviews (3)




Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hours
171	Benzalkonium Chloride	Other study type - Lab/Drug de (More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hours
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48	Hours

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Here user can able to filter the data in all 3 (Clinical Data, Non Clinical Data and Invitro Data) tabs in 2 ways.

- Horizontally (Row wise) Filtering.
- Vertically (Column wise) Filtering.

bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)
 Search BY Excipients | Search FOR Excipients | Export | User Guide | Help | Logout

Search Results [Back](#) Total References: 15 Record 1 of 1

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3) Non Clinical Data (3) Invitro Data (1) Regulatory and other information (5) Reviews (3)

Show/Hide Clinical Columns Clear All Filters on Clinical Data Export Filtered Clinical Data

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dosage Form
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamf

A. Horizontal (Row wise) Filtering:

For example user is trying to apply the filters on Clinical Data tab;

- User is applying the filtering criteria on any one of the columns, say Ref ID as shown below.

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3) | Non Clinical Data (3) | Invitro Data (1) | Regulatory and other information (5) | Reviews (3)
 Different colors indicates Unique References

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Unit
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamb

Filter criteria is on 'Ref ID' with '171, 1016' Value.

Based on the filter criteria the corresponding values will be filtered in the Clinical Data table.

b. If user wants to apply the filter on any one of the other fields, say "Age" as shown below.

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) **Non Clinical Data (3)** **Invitro Data (1)** **Regulatory and other information (5)** **Reviews (3)** Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dosage Form
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamb

Filter criteria is on 'Ref ID' with '171, 1016' value and 'Age' with '18 to 61' value.

Based on the filter criteria the corresponding values get progressively filtered in the Clinical Data table.

If the user want to apply the filter on the already filter applied field(s), in the dropdown of the field will contain the distinct values of the visible rows from the data (i.e. Already filter applied value (121) in that respective field (Ref ID) will not be displayed).

User can able to Clear all filters which are applied on that particular tab will be cleared by using "Clear All Filters on Clinical Data" Button as shown below.

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) **Non Clinical Data (3)** **Invitro Data (1)** **Regulatory and other information (5)** **Reviews (3)** Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dosage
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamt

This will be applicable for all the fields in the Clinical Data tabs where ever it is applicable.

The same filtering functionality will be applicable for Non Clinical Data and Invitro Data tabs in the “Search Results” page.

Note:

1. User can identify the filter(s) applied field(s) by observing the filter image(s) beside the field(s) name.
2. Once the filter is applied on the particular filter then again user wants to apply the filter on the same field then the only values which are visible are available in the dropdown to filter the data. (I.e. if user wants to change the filtering criteria then user will clear the filters by clicking on Clear All Filters button on the particular tab/section wise.)

B. Vertical (Column wise) Filtering:

For example user is trying to apply the vertical (Show/Hide) filters on Clinical Data tab;

Proposed functionality is as below.

- a. If User is trying to apply the vertical filter(s) on any one of the columns, say Ref ID as shown below.

Search Results [Back](#) Total References: 15 Record 1 of 1

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data \(3\)](#) [Non Clinical Data \(3\)](#) [Invitro Data \(1\)](#) [Regulatory and other information \(5\)](#) [Reviews \(3\)](#)
Different colors indicates Unique References

Show/Hide Clinical Columns

- ☐ Ref ID
- ☒ Excipient Name
- ☒ Study Type
- ☒ Age Category
- ☒ Age
- ☒ Age Units
- ☒ Gender
- ☒ Route of Exposure or Administration

Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48
Unspecified	Unspecified	Male	Topical	0.5	%	48
18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48

Based on the filter criteria the corresponding Column & Values will be hidden on the Clinical Data table.

If user wants to apply the filters on any one of the other fields, say “Excipient Name” as shown below.

Search Results [Back](#) Total References: 15 Record 1 of 1

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data \(3\)](#) [Non Clinical Data \(3\)](#) [Invitro Data \(1\)](#) [Regulatory and other information \(5\)](#) [Reviews \(3\)](#)
Different colors indicates Unique References

Show/Hide Clinical Columns

- ☐ Ref ID
- ☒ Excipient Name
- ☒ Study Type
- ☒ Age Category
- ☒ Age
- ☒ Age Units
- ☒ Gender
- ☒ Route of Exposure or Administration

Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48
Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48

This will be applicable for all the fields in the Clinical Data tab where ever it is applicable.

The same filtering functionality will be applicable for Non Clinical Data and Invitro Data tabs in the “Search Results” page.

8.8 Show/Hide Columns

User is also allowed to view or to hide the required columns using the “Show/Hide Columns” as shown below

Clinical Data (3) Non Clinical Data (3) Invitro Data (1) Regulatory and other information (5) Reviews (3) Different colors indicates Unique References											
Show/Hide Clinical Columns Clear All Filters on Clinical Data Export Filtered Clinical Data											
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Dur
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--St
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hour
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hour
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	Hour

When user clicks “[+]” besides “Show/Hide Columns” then it displays all the columns in the page as shown below. By default all the columns appears in the checked state.

Clinical Data (3) Non Clinical Data (3) Invitro Data (1) Regulatory and other information (5) Reviews (3) Different colors indicates Unique References											
Show/Hide Clinical Columns Clear All Filters on Clinical Data Export Filtered Clinical Data											
<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type	<input checked="" type="checkbox"/> Age Category	<input checked="" type="checkbox"/> Age	<input checked="" type="checkbox"/> Age Units	<input checked="" type="checkbox"/> Gender	<input checked="" type="checkbox"/> Route of Exposure or Administration	<input checked="" type="checkbox"/> Dose	<input checked="" type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Duration of Treatment	<input checked="" type="checkbox"/> Dur
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--St
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hour
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hour
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	Hour

User is allowed to customize the required columns to display the information using the check boxes as shown below

Clinical Data (3)

Non Clinical Data (3)

Invitro Data (1)

Regulatory and other information (5)

Reviews (3)

Different colors indicates Unique References

Show/Hide Clinical Columns

☒Ref ID

☐Excipient Name

☒Study Type

☐Age Category

☐Age

☒Age Units

☐Gender

☒Route of Exposure or Administration

(...More)

1016

Unspecified

Years

Topical

0.5 (15)

% w/v (µl/Finn Chamber)

48

Hours

Once

Integumentary System

Predominant
(...More)

Route of Exposure or Administration

Dose

Dose Units

Duration of Treatment

Duration Units

Frequency of Administration

System/Organ

Safety / Toxicity

--Select--

--Select--

--Select--

--Select--

--Select--

--Select--

--Select--

--Select--

Topical

0.5; 1

% aq

48

Hours

Unspecified

Integumentary System

Irritant contact dermatitis

Topical

0.5

%

48

Hours

once

Integumentary System

Scaling or flaking

When user selects the required columns then the page gets refreshed and search results page only displays the selected columns as shown below

Clinical Data (3)

Non Clinical Data (3)

Invitro Data (1)

Regulatory and other information (5)

Reviews (3)

Different colors indicates Unique References

Show/Hide Clinical Columns




Clear All Filters on Clinical Data

Export Filtered Clinical Data

Ref ID	Study Type	Age Units	Route of Exposure or Administration	Reference	Reference Year
--Select--	--Select--	--Select--	--Select--		
121	Other study type	Years	Topical	NA, Willis CM, Stephens JM, Wi(More)	1988
171	Other study type - Lab/Drug de(More)	Unspecified	Topical	NA, Willis CM, Stephens CJ, Wi(More)	1992
1016	Unspecified	Years	Topical	NA, Willis CM, Stephens CJ, Wi(More)	1989

8.9 Navigations in Search Results page

Whenever user selects more than one excipient as shown below








bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)
 Search BY Excipients | Search FOR Excipients | User Guide | Help | Logout

Excipient(s) Intermediate Page [Back](#)

Number of Excipients found: 3

☒ All
☒ Benzalkonium Chloride
☒ Benzyl Alcohol
☒ Propylene Glycol

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Then clicks “Submit” button search results page appears displaying the corresponding information along with the navigation links to navigate in between the excipient selected as shown below

Search Results [Back](#) Total References: 15

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) **Non Clinical Data (3)** **In vitro Data (1)** **Regulatory and other information (5)** **Reviews (3)** Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hours
171	Benzalkonium Chloride	Other study type - Lab/Drug de [...More]	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hours
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	Hours

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When user selects multiple excipients then only these navigation links appears using which user can view the search results information of the related excipient.

Based on the selection initially “Benzalkonium chloride” information is displaying as shown below.

Here user is able to navigate among the excipients by using excipients navigation by using respective links (First, Previous, Next and Last) or Giving direct record number in the text field and then clicks on Go button.

Excipients navigation by using respective links like below,

Search Results [Back](#) Total References: 93 Record 2 of 3

General Information

Excipient Chemical Name: Benzyl Alcohol
CAS Registry Number: 100-51-6

Excipient Category/Function :
Pharmacopoeial Status :
Regulatory Status :
Synonyms :
Acceptable Daily Intake :
Revision Date :

Excipient Navigation
2 [Go](#) [First](#) [Previous](#) [Next](#) [Last](#)

Clinical Data (10) Non Clinical Data (73) Invitro Data (21) Regulatory and other information (7) Reviews (2) Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
64	Benzyl Alcohol	Case study	Adult	Unspecified	Unspecified	Male/Female	Topical	1	%	Unspecified
933	Benzyl Alcohol	ADME/Pharmacokinetics studies	Preterm newborn infants (born ...More)	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified
933	Benzyl Alcohol	ADME/Pharmacokinetics studies	Term newborn infants (0 to 27 ...More)	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified

Excipients navigation by giving record number and clicks on Go Button as like below,

Search Results [Back](#) Total References: 316 Record 3 of 3

General Information

Excipient Chemical Name: Propylene Glycol
CAS Registry Number: 57-55-6

Excipient Category/Function :
Pharmacopoeial Status :
Regulatory Status :
Synonyms :
Acceptable Daily Intake :
Revision Date :

Excipient Navigation
3 [Go](#) [First](#) [Previous](#) [Next](#) [Last](#)

Clinical Data (98) Non Clinical Data (158) Invitro Data (95) Regulatory and other information (55) Reviews (16) Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
119	Propylene Glycol	Randomized controlled clinical(...More)	Adult	21-28	Years	Male/Female	Oral	1 : 8 (In water)	Ratio	3
121	Propylene Glycol	Other study type	Adult	34 (Mean age)	Years	Male	Topical	50; 100	% aq	48
122	Propylene Glycol	Randomized controlled clinical(...More)	Unspecified	Unspecified	Unspecified	Unspecified	Parenteral	35	vol %	1
123	Propylene Glycol	Unspecified	Unspecified	Unspecified	Unspecified	Unspecified	Topical	20	%	1

Note:

- If user clicks on Ref ID from any section (Clinical Data, Non Clinical Data, Invitro Data, Regulatory & other information and Reviews), it will display the details about that particular reference. Once if the user moved from one tab/section to another then that reference details will be disappear.

8.10 Filtered Data Export

This application will provide the “Option of exporting only the data that has been filtered by the user”. Filtered data export feature is available for 3 sections (Clinical Data, Non Clinical Data and Invitro Data)

Here user can export the data that has been filtered either horizontally or vertically or combination of both filters. For this user can find the respective button(s) to export the filtered data in the search results page in 4 cases as given below.

The screenshot displays the STEP database search results for Benzalkonium Chloride. The page includes a header with logos for EUPFI, STEP database, and uspfi. The search results section shows a table with columns: Ref ID, Excipient Name, Study Type, Age Category, Age, Age Units, Gender, Route of Exposure or Administration, Dose, and Dosage Form. The table contains three rows of data for Benzalkonium Chloride. The 'Export Filtered Clinical Data' button is highlighted in a red box.

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dosage Form
121	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq
171	Benzalkonium Chloride	Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamb

Case: 1

Filtered Data export by applying Horizontal Filters:

Here user can able to export the filtered data by applying horizontal filters in search results page for clinical data.

Search Results [Back](#) Total References: 15 Record 1 of 1

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3) Non Clinical Data (3) Invitro Data (1) Regulatory and other information (5) Reviews (3)
Different colors indicates Unique References

Show/Hide Clinical Columns [Clear All Filters on Clinical Data](#) [Export Filtered Clinical Data](#)

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dosage Form
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamb

If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

It will display one dialog box, which will contain all the fields available in that respective table like below.

Export Filtered Clinical Data

Clinical Data Fields

- ☒ All
- ☒ Ref ID
- ☒ Excipient Name
- ☒ Study Type
- ☒ Age Category
- ☒ Age
- ☒ Age Units
- ☒ Gender
- ☒ Route of Exposure or Administration
- ☒ Dose
- ☒ Dose Units
- ☒ Duration of Treatment
- ☒ Duration Units
- ☒ Frequency of Administration
- ☒ System/Organ
- ☒ Safety / Tolerability / Adverse Effects
- ☒ Dosage Form
- ☒ Conclusion / Comments
- ☒ Reference
- ☒ Reference Type
- ☒ Reference Year

[Export to Excel](#) [Export to PDF](#)

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

Ref ID	Excipient	Study Type	Age Category	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
1016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Firm Chamber)	48	Hours	Once	Integumentary System	Patch	The patch tests of benzalkonium chloride on human skin produced predominantly mild reactions	NA, Willis CM, Stephens CJ, Wilkinson JD. Epidermal damage induced by irritants in man: a light and electron microscopic study. J Invest Dermatol. 1989 Nov 93(5):695-9(ul. http://www.ncbi.nlm.nih.gov/pubmed/2794552); NA, 1989, NA(NA), NA NA	J	1989

Clinical Data:	
Record No: 1	
Ref ID	1016
Excipient Name	Benzalkonium Chloride
Study Type	Unspecified
Age Category	Adult
Age	18 to 61
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5 (15)
Dose Units	% w/v (µl/Firm Chamber)
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Once
System/Organ	Integumentary System
Safety / Tolerability / Adverse Effects	Predominantly mild in reactions with three negative reactions: mild and patchy spongioidosis with exocytosis of small number of predominantly mononuclear cells, occasional foci of necrotic damage in the upper stratum spinosum, ultrastructurally the affected keratinocytes were characterized by shrunken pyknotic nuclei, disrupted organelles and membrane and considerable intracytoplasmic vacuolation, lipid accumulation within keratinocytes was rarely observed
Dosage Form	Patch
Conclusion / Comments	The patch tests of benzalkonium chloride on human skin produced predominantly mild reactions
Reference	NA, Willis CM, Stephens CJ, Wilkinson JD. Epidermal damage induced by irritants in man: a light and electron microscopic study. J Invest Dermatol. 1989 Nov 93(5):695-9(ul. http://www.ncbi.nlm.nih.gov/pubmed/2794552); NA, 1989, NA(NA), NA NA
Reference Type	J
Reference Year	1989

Case: 2:

Filtered Data export by applying Vertical Filters:

Here user can able to export the filtered data by applying vertical filters in search results page for clinical data.

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3)
Non Clinical Data (3)
Invitro Data (1)
Regulatory and other information (5)
Reviews (3)
Different colors indicates Unique References

[Show/Hide Clinical Columns](#)

[Clear All Filters on Clinical Data](#)
[Export Filtered Clinical Data](#)

Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48
Other study type - Lab/Drug de (...More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48

If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

It will display one dialog box, which will contain all the fields available in that respective table and user can identify that the columns which are **hidden** in search results page are in uncheck mode like below.

Export Filtered Clinical Data

Clinical Data Fields

- ☐ All
- ☐ Ref ID
- ☐ Excipient Name
- ☒ Study Type
- ☒ Age Category
- ☒ Age
- ☒ Age Units
- ☒ Gender
- ☒ Route of Exposure or Administration
- ☒ Dose
- ☒ Dose Units
- ☒ Duration of Treatment
- ☒ Duration Units
- ☒ Frequency of Administration
- ☒ System/Organ
- ☒ Safety / Tolerability / Adverse Effects
- ☒ Dosage Form
- ☒ Conclusion / Comments
- ☒ Reference
- ☒ Reference Type
- ☒ Reference Year

Export to Excel **Export to PDF**

Search Results: [Back](#)

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) **Non Clinical Data (3)** **Invitro Data (3)**

Show/Hide Clinical Columns

Study Type	Age Category	Age	Age units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48
Other study type - Lab/Drug development	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Unit	Duration	Duration Unit	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Hours	once	Integument	Integument Irritation Patch	The patch NA, Willis J		1988		
Other study type - Lab/Drug development	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hours	once	Integument	Integument Irritation Patch	The study NA, Willis J		1992		
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48	Hours	once	Integument	Integument Irritation Patch	The patch NA, Willis J		1989		

Clinical Data:	
Record No: 1	
Study Type	Other study type
Age Category	Adult
Age	34 (Mean age)
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5; 1
Dose Units	% aq
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Unspecified
System/Organ	Integumentary System
Safety / Tolerability / Adverse Effects	Irritant contact dermatitis
Dosage Form	Patch
Conclusion / Comments	The optimum concentration of benzalkonium chloride to induce mild to moderate skin reactions is estimated to be 0.5% using patch tests
Reference	NA, Willis CM, Stephens JM, Wilkinson JD. Experimentally-induced irritant contact dermatitis. Determination of optimum irritant concentrations. Contact Dermatitis. 1988 Jan;18(1):20-4, NA, 1988, NA(NA), NA-NA
Reference Type	J
Reference Year	1988
Record No: 2	
Study Type	Other study type - Lab/Drug development studies
Age Category	Adult
Age	Unspecified
Age Units	Unspecified
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5
Dose Units	%
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	once
System/Organ	Integumentary System
Safety / Tolerability / Adverse Effects	Scaling or faint, patchy erythema, erythema with mild edema, erythema with moderate edema, marked erythema with vesiculation, keratinocyte proliferation
Dosage Form	Patch
Conclusion / Comments	The study in healthy non atopic male subjects indicates that the cellular changes like proliferation in keratinocytes were related to chemical nature of irritants like benzalkonium chloride and its specific biochemical interactions on the skin rather than being the consequence of a generalized inflammatory response
Reference	NA, Willis CM, Stephens CJ, Wilkinson JD. Differential effects of structurally unrelated chemical irritants on the density of proliferating keratinocytes in 48 h patch test reactions. J Invest Dermatol 1992 Oct;99(4):449-53, NA, 1992, NA(NA), NA-NA
Reference Type	J
Reference Year	1992
Record No: 3	
Study Type	Unspecified
Age Category	Adult
Age	10 to 61
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5 (15)
Dose Units	% w/v (µl/Finn Chamber)
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Once
System/Organ	Integumentary System
Safety / Tolerability / Adverse Effects	Predominantly mild in reactions with three negative reactions, mild and patchy spongiosis with exocytosis of small number of predominantly mononuclear cells, occasional foci of necrotic damage in the upper stratum spinosum, ultrastructurally the affected keratinocytes were characterized by shrunken pyknotic nuclei, disrupted organelles and membrane and considerable intracytoplasmic vacuolation, lipid accumulation within keratinocytes was rarely observed
Dosage Form	Patch
Conclusion / Comments	The patch tests of benzalkonium chloride on human skin produced predominantly mild reactions
Reference	NA, Willis CM, Stephens CJ, Wilkinson JD. Epidermal damage induced by irritants in man: a light and electron microscopic study. J Invest Dermatol. 1989 Nov;93(5):695-9(url: http://www.ncbi.nlm.nih.gov/pubmed/2794552), NA, 1989, NA(NA), NA-NA
Reference Type	J

Case: 3:

Here user can export the data by applying both (Horizontal & Vertical) filters the search results page will looks like below.

Search Results [Back](#) Total References: 15 Record 1 of 1

Excipient Navigation

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data (3)
Non Clinical Data (3)
Invitro Data (1)
Regulatory and other information (5)
Reviews (3)
Different colors indicated Unique References

[Show/Hide Clinical Columns](#)

[Clear All Filters on Clinical Data](#)
[Export Filtered Clinical Data](#)

Study Type	Age Category	Age <input checked="" type="checkbox"/>	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48

If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

It will display one dialog box, which will contain all the fields available in that respective table and user can identify that the columns which are **hidden** in search results page are in uncheck mode like below.

Export Filtered Clinical Data

Clinical Data Fields

- ☐ All
- ☐ Ref ID
- ☐ Excipient Name
- ☒ Study Type
- ☒ Age Category
- ☒ Age
- ☒ Age Units
- ☒ Gender
- ☒ Route of Exposure or Administration
- ☒ Dose
- ☒ Dose Units
- ☒ Duration of Treatment
- ☒ Duration Units
- ☒ Frequency of Administration
- ☒ System/Organ
- ☒ Safety / Tolerability / Adverse Effects
- ☒ Dosage Form
- ☒ Conclusion / Comments
- ☒ Reference
- ☒ Reference Type
- ☒ Reference Year

Export to Excel **Export to PDF**

Search Results [Back](#)

General Information

Excipient Chemical Name: Benzalkonium Chloride
CAS Registry Number: 8001-54-5

Excipient Category/Function :
Pharmacopoeial Status:
Regulatory Status:
Synonyms:
Acceptable Daily Intake:
Revision Date:

Clinical Data (3) **Non Clinical Data (3)** **Invitro Data (3)**

Show/Hide Clinical Columns

Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--	--Select--
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48

Export Filtered Clinical Data

Different colors indicates Unique References

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
Other study type - Lab/Drug development	Adult	34 (Mean ± SD)	Years	Male	Topical	0.5, 1	% aq	48	Hours	Unspecified	Integument	Integument	Integument	The patch	The patch	NA, Willis J	1989
Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48	Hours	Once	Integument	Integument	Integument	The patch	The patch	NA, Willis J	1989

The Same data will be export in PDF format also.

Case: 4:

In addition to that, there is a provision to add/delete the columns to export the filtered data. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
Years	Male	Topical	0.5 (15)	% w/v (ul/Finn Chamber)	48 hours	Once	Integumentary Patch	The patch NA, Willis J					1909

The Same data will be export in PDF format also.

User can also identify the same criteria as specified for the Clinical Data, is available with Non Clinical Data and Invitro Data tabs/sections.

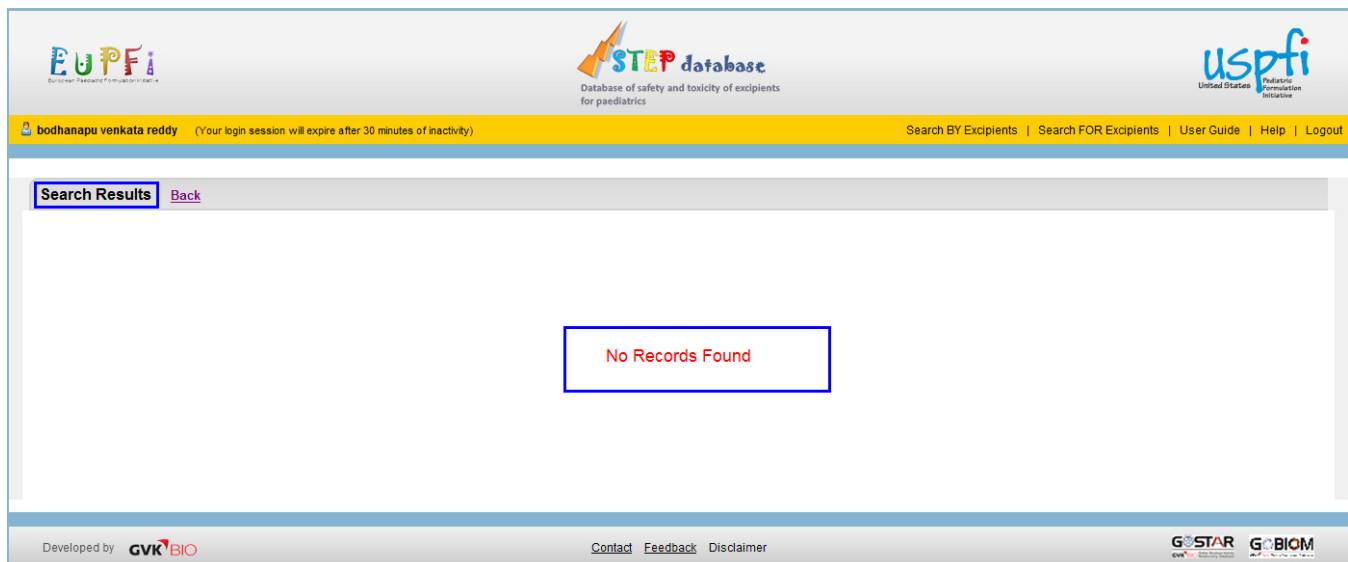
Note:

- Filtered data export is applicable for Clinical Data, Non Clinical Data and Invitro Data.
- The file names are
 1. Excel - “EupfiFilteredResults_ <Section Name>”
 2. PDF – “EupfiFilteredResults_ <Section Name>”

The Section Names for Clinical Data, Non Clinical Data and Invitro Data will be ClinicalData, NonClinicalData and InvitroData respectively.

8.11 No records found

If there is no data available for the given search criteria, then the below failure (No Records Found) page will appear.



8.12 Back Link Functionality

In the application “Back” link is provided to navigate to the previous page, when user clicks “Back” link from any page then application navigates to the previous page.

Example: If user clicks “Back” from the “Search Results” page as shown below.

Search Results Back		Total References: 292	Record 1 of 1
Excipient Navigation			
General Information			
Excipient Chemical Name:	Aspartame		
CAS Registry Number:	22839-47-0		
<input type="checkbox"/> Excipient Category/Function : <input type="checkbox"/> Pharmacopoeial Status: <input type="checkbox"/> Regulatory Status: <input type="checkbox"/> Synonyms: <input type="checkbox"/> Acceptable Daily Intake: <input type="checkbox"/> Revision Date: N/A			

Then application navigates to the previous page (Excipient(s) Intermediate Page) as shown below.

Excipient(s) Intermediate Page Back
Number of Excipient found: 3 <input type="checkbox"/> All <input checked="" type="checkbox"/> Acesulfame K <input checked="" type="checkbox"/> Aspartame <input type="checkbox"/> Benzalkonium Chloride <input type="button" value="Submit"/>

Note:

- Back link functionality will be available for Excipients Intermediate Page, Search Results Page and Export Pages.
- If user clicks Back link in Export page then application will redirect to Search Results page by default and will not consider any filters (if applied).
- If user clicks Back link in Search Results page then application will redirect to Search BY Excipients or Search FOR Excipients or Excipients Intermediate page by default (if more than one excipient is found for the given search criteria).
- If user clicks Back link in Excipients Intermediate page then application will redirect to either Search BY Excipients or Search FOR Excipients page depends up on the Search criteria.
- Where ever the "Source URL" field is available in the Search Results page, there will be 2 conditions in displaying of data.
 1. If Source URL value starts with 'http://' then that will be displayed as direct **hyperlink** and if user clicks on that link that will redirect to that particular link.
 2. If Source URL value does not start with 'http://' then that content will be displayed as it is in that particular cell (if that content is less than 30 characters)
 3. If Source URL value does not start with 'http://' and the value is more than 30 characters then 'More' and 'Less' functionality will be applicable with that particular record.

For the above both the cases the whole content will be displayed as title for that particular cell for all the sections of Search Results page.

- Color coding is applicable for Clinical Data, Non Clinical Data and Invitro Data sections in the results page.

- On each field name mouse hover, the respective field description will be displayed.

9 Export




STEP is also accommodating users to export the required information using the “Export” link from the main menu bar from the “Search Results” page as shown below.



When user clicks “Export” link from the main menu bar “Select to Export” page appears. By default “General Information fields” appears in expanded mode, remaining fields in collapsed mode as shown below.

The screenshot shows the 'Select to Export' page. At the top, there's a header with 'Select to Export' and a 'Back' link. Below this, there's a large table of fields organized into categories. The 'General Information' category is expanded, showing fields like 'Excipient ID', 'CAS Registry Number', 'Excipient Name', etc. Other categories like 'Regulatory Status', 'General Acceptable Daily Intake', and 'Acceptable Daily Intake for Pediatrics' are collapsed. At the bottom, there are buttons for 'Export to Excel', 'Export to PDF', and 'Cancel Export'. A red box highlights the 'Clinical Data' section on the left sidebar, which includes 'Non Clinical Data', 'Invitro Data', 'Regulatory and other information', 'Reviews', and 'Reference'.

Click “[+]” symbol besides the name to expand the fields and select the required fields using check boxes and click “Export to Excel / Export to PDF” as shown below.

Database of safety and toxicity of excipients for paediatrics

United States Pediatric Formulation Initiative

bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)
Search BY Excipients | Search FOR Excipients | User Guide | Help | Logout

Select to Export [Back](#)

General Information

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Excipient ID	<input checked="" type="checkbox"/> CAS Registry Number	<input checked="" type="checkbox"/> Excipient Name
<input checked="" type="checkbox"/> Excipient Category/Function	<input checked="" type="checkbox"/> Pharmacopoeial Status	<input checked="" type="checkbox"/> Synonyms	<input checked="" type="checkbox"/> Revision Date

Regulatory Status

<input type="checkbox"/> All	<input type="checkbox"/> Agency	<input type="checkbox"/> Description	<input type="checkbox"/> Permitted Functionality
<input type="checkbox"/> Use limits	<input type="checkbox"/> Source URL	<input type="checkbox"/> Reference	

General Acceptable Daily Intake

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Source	<input checked="" type="checkbox"/> Limit	<input checked="" type="checkbox"/> Year
<input checked="" type="checkbox"/> Reference	<input checked="" type="checkbox"/> Source URL		

Acceptable Daily Intake for Pediatrics

<input type="checkbox"/> All	<input type="checkbox"/> Source	<input type="checkbox"/> Limit	<input type="checkbox"/> Year
<input type="checkbox"/> Reference	<input type="checkbox"/> Source URL		

Clinical Data

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Age Category	<input checked="" type="checkbox"/> Age	<input checked="" type="checkbox"/> Age Units	<input checked="" type="checkbox"/> Gender
<input checked="" type="checkbox"/> Route of Exposure or Administration	<input checked="" type="checkbox"/> Dose	<input checked="" type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Duration of Treatment
<input checked="" type="checkbox"/> Duration Units	<input checked="" type="checkbox"/> Frequency of Administration	<input checked="" type="checkbox"/> System/Organ	<input checked="" type="checkbox"/> Safety / Tolerability / Adverse Effects
<input checked="" type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input checked="" type="checkbox"/> Reference	<input checked="" type="checkbox"/> Reference Type
<input checked="" type="checkbox"/> Reference Year			

Non Clinical Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input checked="" type="checkbox"/> Age Category	<input checked="" type="checkbox"/> Age	<input checked="" type="checkbox"/> Age Units
<input type="checkbox"/> Gender	<input type="checkbox"/> Dose / Concentration	<input checked="" type="checkbox"/> Dose Units	<input type="checkbox"/> Route of Exposure or Administration
<input type="checkbox"/> Duration of Treatment	<input type="checkbox"/> Duration Units	<input type="checkbox"/> Frequency of Administration	<input checked="" type="checkbox"/> System/Organ
<input checked="" type="checkbox"/> Adverse Effect	<input type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference
<input checked="" type="checkbox"/> Reference Type	<input checked="" type="checkbox"/> Reference Year		

Invitro Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input type="checkbox"/> Route of Exposure or Administration
<input type="checkbox"/> Duration of Treatment	<input type="checkbox"/> Duration Units	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability / Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type
<input type="checkbox"/> Reference Year			

Regulatory and other information

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Reference
<input checked="" type="checkbox"/> Source	<input checked="" type="checkbox"/> Source URL	<input checked="" type="checkbox"/> Reference Year	


Reviews

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Reference
<input type="checkbox"/> Source	<input type="checkbox"/> Source URL	<input checked="" type="checkbox"/> Reference Year	



Reference

<input checked="" type="checkbox"/> Reference			
---	--	--	--

Export to Excel
Export to PDF
Cancel Export

Developed by 

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Note: Excipient name appears in selected mode by default and in disable mode as shown below.

Select to Export [Back](#)

General Information

☐ All ☐ Excipient ID ☐ CAS Registry Number ☒ **Excipient Name**

☐ Excipient Category/Function ☐ Pharmacopoeial Status ☐ Synonyms ☐ Revision Date

Regulatory Status

☐ All ☐ Agency ☐ Description ☐ Permitted Functionality

☐ Use limits ☐ Source URL ☐ Reference

General Acceptable Daily Intake

☐ All ☐ Source ☐ Limit ☐ Year

☐ Reference ☐ Source URL

Acceptable Daily Intake for Pediatrics

☐ All ☐ Limit ☐ Year

☐ Reference ☐ Source URL

Clinical Data

☐ All ☐ Ref ID ☒ **Excipient Name** ☐ Study Type

☐ Age Category ☐ Age ☐ Age Units ☐ Gender

☐ Route of Exposure or Administration ☐ Dose ☐ Dose Units ☐ Duration of Treatment

☐ Duration Units ☐ Frequency of Administration ☐ System/Organ ☐ Safety / Tolerability / Adverse Effects

☐ Dosage Form ☐ Conclusion / Comments ☐ Reference ☐ Reference Type

☐ Reference Year

Non Clinical Data

☐ All ☐ Ref ID ☒ **Excipient Name** ☐ Study Type

☐ Species ☐ Age Category ☐ Age Units ☐ Gender

☐ Duration of Treatment ☐ Dose / Concentration ☐ Dose Units ☐ Route of Exposure or Administration

☐ Adverse Effect ☐ Duration Units ☐ Frequency of Administration ☐ System/Organ

☐ Reference Type ☐ Dosage Form ☐ Conclusion / Comments ☐ Reference

Invitro Data

☐ All ☐ Ref ID ☒ **Excipient Name** ☐ Study Type

☐ Species ☐ Dose ☐ Age Units ☐ Route of Exposure or Administration

☐ Duration of Treatment ☐ Duration Units ☐ System/Organ ☐ Safety / Tolerability / Adverse Effects

☐ Dosage Form ☐ Conclusion / Comments ☐ Reference ☐ Reference Type

☐ Reference Year

Regulatory and other information

☐ All ☐ Ref ID ☒ **Excipient Name** ☐ Reference

☐ Source ☐ Source URL ☐ Reference Year

Reviews

☐ All ☐ Ref ID ☒ **Excipient Name** ☐ Reference

☐ Source ☐ Source URL ☐ Reference Year

Reference

☐ Reference

[Export to Excel](#) [Export to PDF](#) [Cancel Export](#)

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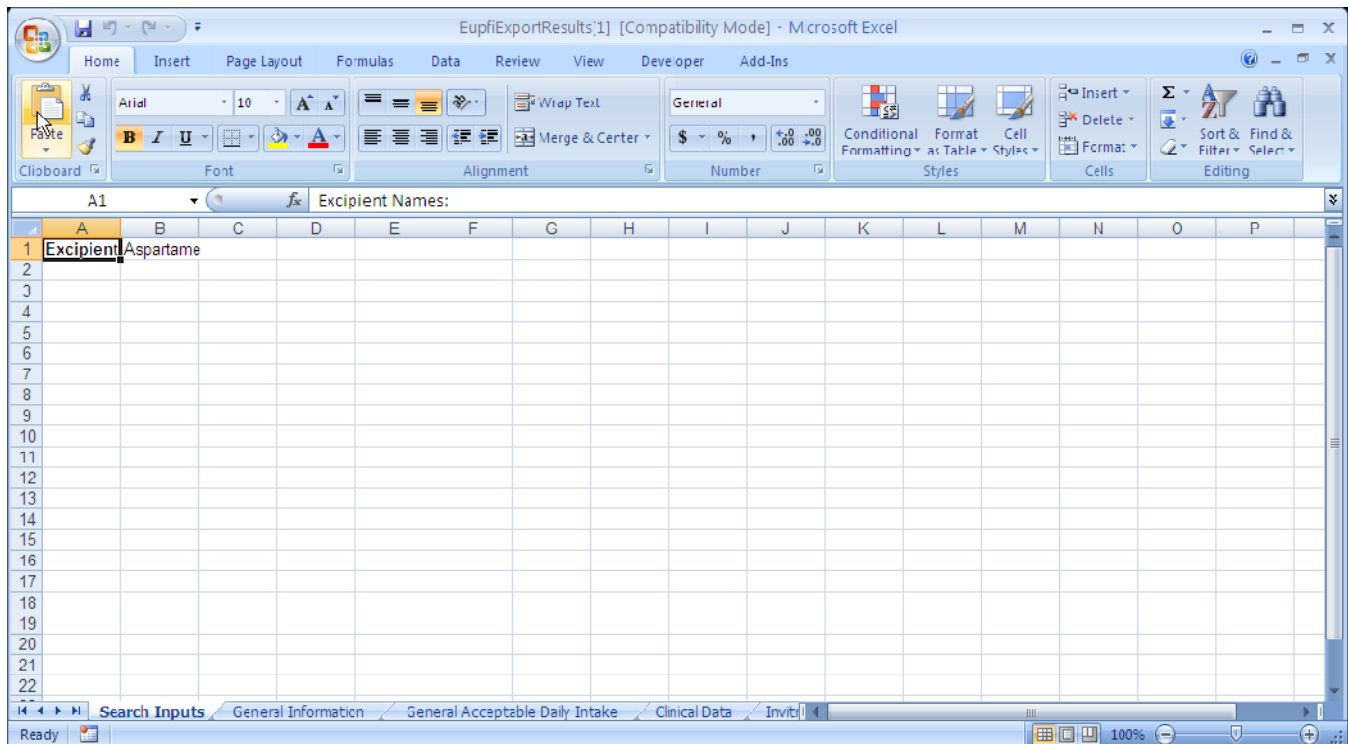
9.1 Export to Excel

Click “Export to Excel” from the “Select to Export” page, then the “File Download” window appears as shown below.

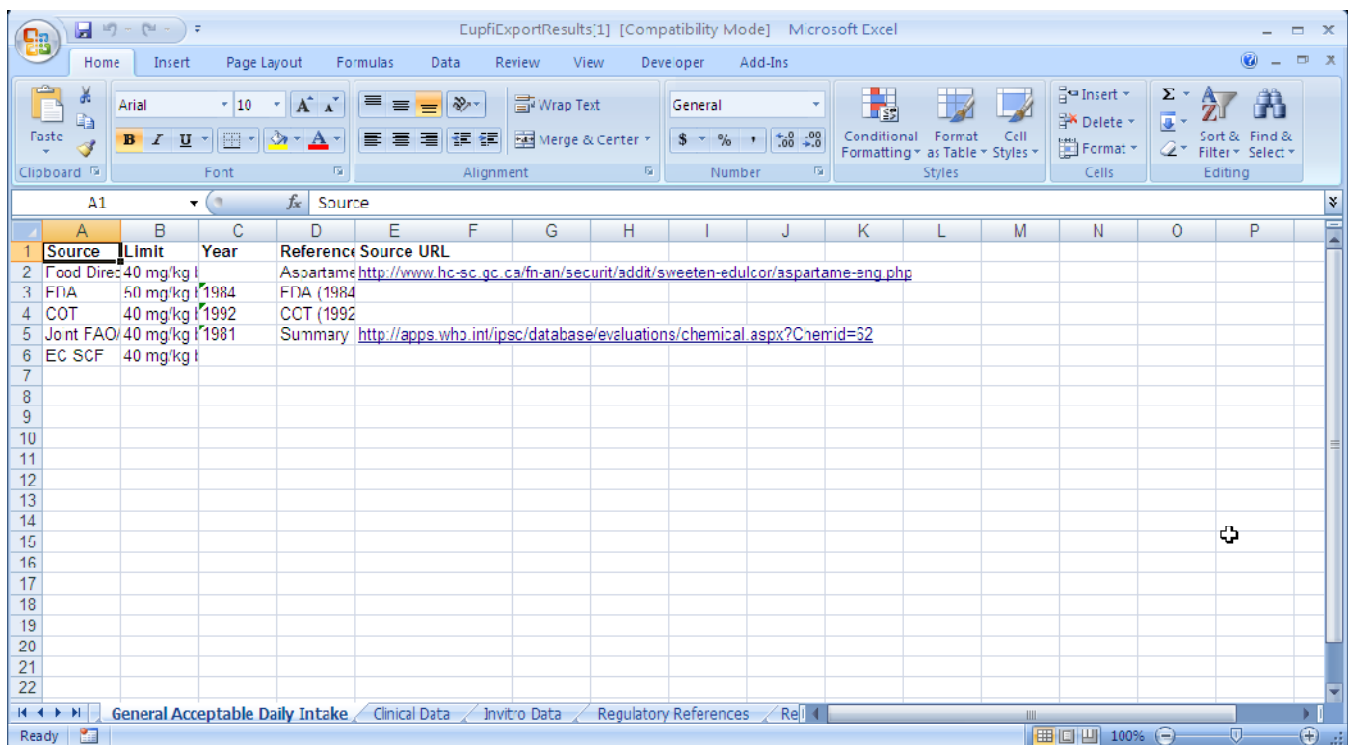
Do you want to open or save EupfiExportResults.xls from localhost?

[Open](#) [Save](#) [Cancel](#) [X](#)

Click “Open” to open the excel file or save it using “Save”. Otherwise cancel the download using “Cancel” on the file download window. First page “Search Inputs” provides the information about the search criteria given by the user.



Then the excel file appears with the selected data and based on the categorization data in the excel sheets appears in separate sheets as shown below.



Note: Click “Source URL” from the excel, as shown below corresponding website appears in a new window as shown in the below figures respectively.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
	Source	Limit	Year	Reference	Source URL											
1	Food Direc	40 mg/kg l		Aspartame	http://www.hc-sc.gc.ca/fn-an/secure/addit/sweeten-edulcor/aspartame-eng.php											
2	FDA	50 mg/kg l	1904	FDA (1904												
3	COT	40 mg/kg l	1992	COT (1992												
4	Joint FAO/	40 mg/kg l	1981	Summary	http://apps.who.int/ipsc/database/evaluations/chemical.aspx?Chemid=62											
5	EC SCF	40 mg/kg l														

WHO | Evaluations of Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Microsoft I...

http://apps.who.int/ipsc/database/ev... Delta Search

File Edit View Favorites Tools Help

★ Favorites Suggested Sites Get more Add-ons

Zimbra: I... EUPFI - ... WHO... x

The International Programme on Chemical Safety (IPCS)

WHO UNEP

Publications | About IPCS | Events

International Programme on Chemical Safety > Chemicals in food > Joint FAO/WHO Expert Committee on Food Additives

Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) ASPARTAME

General Information

Synonyms: ASPARTYL PHENYLALANINE METHYL ESTER

Internet 100%

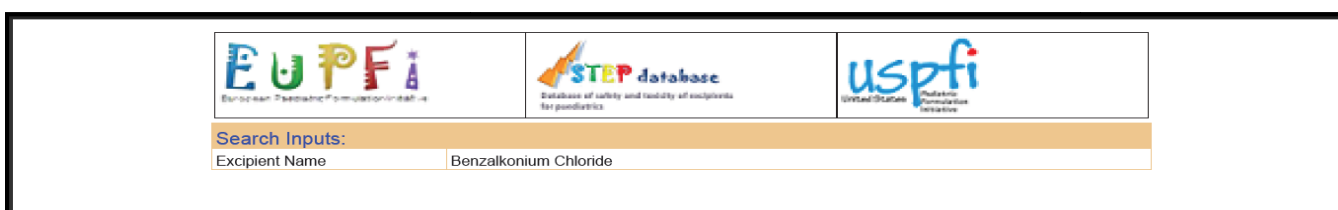
9.2 Export to PDF

Click “Export to PDF” from the “Select to Export” page, then the “File download” window appears as shown below.

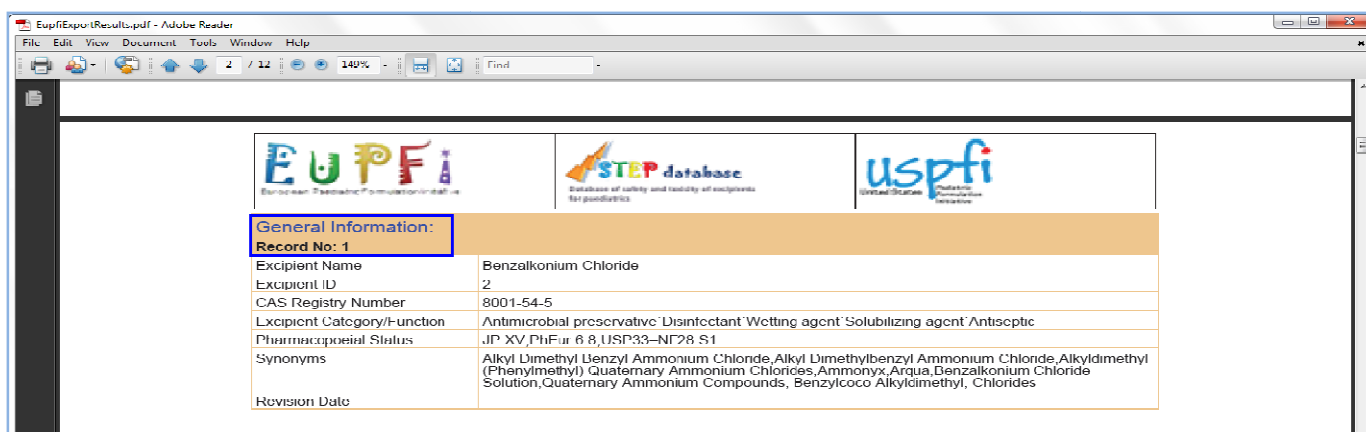


Click “Open” to open the PDF file or save it using “Save”. Otherwise cancel the download using “Cancel” on the file download window.

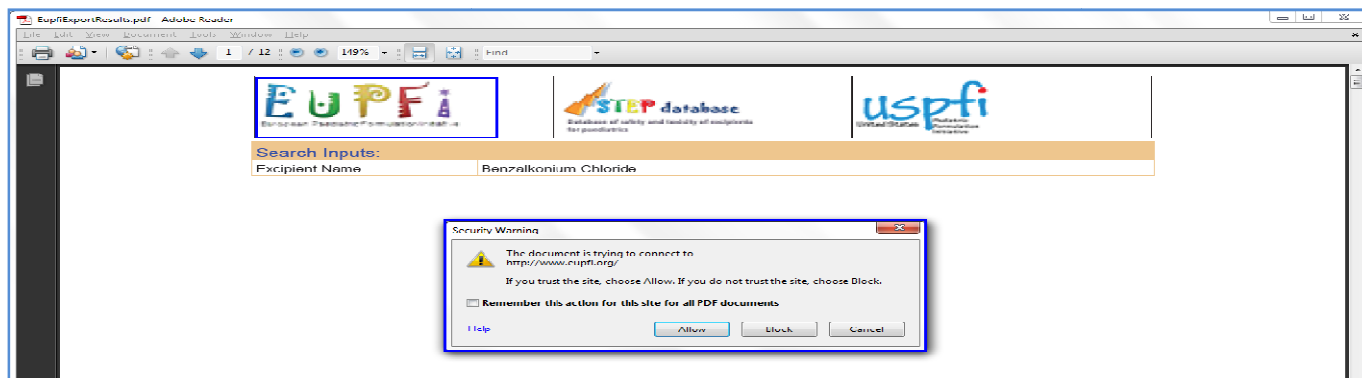
Then the PDF appears with First page as “Search Inputs” with the information about the search criteria given by the user as shown below.



Based on the categorization data in the PDF appears in separate pages as shown below.



In PDF export format, user can find the header with application logs. And if user clicks on those header images, the respective/appropriate link will be displayed like below



If user clicks on the Allow button then it will display like below.



Note:

- Only the selected sections with selected fields will be exported (i.e. If none of the fields are selected in any section then that particular section will not be exported and will not create any separate sheet or page with those details).

- Only PDF export will have the logos (as a header for all pages) and if user clicks on any logo, that respective link will display on the browser.
- The export file names will be like below
 1. Excel - “EupfiExportResults.xls”.
 2. PDF – “EupfiExportResults.pdf”.
- Source URL in both the exported formats (excel & PDF) will be displayed as **hyperlink**. On click of that particular link, the respective page will be opened by default.
- Due to MS-Office excel limitation (I.e. Sheet name can’t exceed 31 characters); Sheet name will be displayed as “ADI for Pediatrics” instead of ‘Acceptable Daily Intake for Pediatrics’ only in Excel export. Whereas all the other places where ever ‘Acceptable Daily Intake for Pediatrics’ name occurs, the same name will be displayed.

9.3 Cancel Export

User can cancel the “Export” page using “Cancel Export” link as shown below

Select to Export [Back](#)

General Information

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Excipient ID	<input checked="" type="checkbox"/> CAS Registry Number	<input checked="" type="checkbox"/> Excipient Name
<input checked="" type="checkbox"/> Excipient Category/Function	<input checked="" type="checkbox"/> Pharmacopoeial Status	<input checked="" type="checkbox"/> Synonyms	<input checked="" type="checkbox"/> Revision Date

Regulatory Status

<input type="checkbox"/> All	<input type="checkbox"/> Agency	<input type="checkbox"/> Description	<input type="checkbox"/> Permitted Functionality
<input type="checkbox"/> Use limits	<input type="checkbox"/> Source URL	<input type="checkbox"/> Reference	

General Acceptable Daily Intake

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Source	<input checked="" type="checkbox"/> Limit	<input checked="" type="checkbox"/> Year
<input checked="" type="checkbox"/> Reference	<input checked="" type="checkbox"/> Source URL		

Acceptable Daily Intake for Pediatrics

<input type="checkbox"/> All	<input type="checkbox"/> Source	<input type="checkbox"/> Limit	<input type="checkbox"/> Year
<input type="checkbox"/> Reference	<input type="checkbox"/> Source URL		

Clinical Data

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Age Category	<input checked="" type="checkbox"/> Age	<input checked="" type="checkbox"/> Age Units	<input checked="" type="checkbox"/> Gender
<input checked="" type="checkbox"/> Route of Exposure or Administration	<input checked="" type="checkbox"/> Dose	<input checked="" type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Duration of Treatment
<input checked="" type="checkbox"/> Duration Units	<input checked="" type="checkbox"/> Frequency of Administration	<input checked="" type="checkbox"/> System/Organ	<input checked="" type="checkbox"/> Safety / Tolerability / Adverse Effects
<input checked="" type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input checked="" type="checkbox"/> Reference	<input checked="" type="checkbox"/> Reference Type
<input checked="" type="checkbox"/> Reference Year			

Non Clinical Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input checked="" type="checkbox"/> Age Category	<input checked="" type="checkbox"/> Age	<input checked="" type="checkbox"/> Age Units
<input type="checkbox"/> Gender	<input checked="" type="checkbox"/> Dose / Concentration	<input checked="" type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Route of Exposure or Administration
<input checked="" type="checkbox"/> Duration of Treatment	<input checked="" type="checkbox"/> Duration Units	<input type="checkbox"/> Frequency of Administration	<input checked="" type="checkbox"/> System/Organ
<input checked="" type="checkbox"/> Adverse Effect	<input checked="" type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference
<input checked="" type="checkbox"/> Reference Type	<input checked="" type="checkbox"/> Reference Year		

In Vitro Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input checked="" type="checkbox"/> Dose	<input checked="" type="checkbox"/> Dose Units	<input type="checkbox"/> Route of Exposure or Administration
<input type="checkbox"/> Duration of Treatment	<input type="checkbox"/> Duration Units	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability / Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type
<input type="checkbox"/> Reference Year			

Regulatory and other information

<input checked="" type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Reference
<input checked="" type="checkbox"/> Source	<input checked="" type="checkbox"/> Source URL	<input checked="" type="checkbox"/> Reference Year	

Reviews

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Reference
<input type="checkbox"/> Source	<input type="checkbox"/> Source URL	<input checked="" type="checkbox"/> Reference Year	

Reference

<input checked="" type="checkbox"/> Reference

[Export to Excel](#) [Export to PDF](#) [Cancel Export](#)

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Then the export page gets cancelled and the application navigates to the “Search Results” page.

Note:

- If user clicks on the “Cancel Export” link in Export page, by default it will displays the Search Results page (without considering any filter criteria, if any applied).

10 Help

Help link from the main menu bar facilitates the help information about the application to the user. When user clicks “Help” from any page in the application, then the current page information appears in new window.

Example: When user clicks “Help” from “Export” page as shown below.

The screenshot displays the Eu – US PFI User Guide interface. At the top, there are logos for EUPFI, STEP database, and usptfi. Below the logos, a yellow banner contains the user's name 'bodhanapu venkata reddy' and a session expiration message. The main navigation bar includes links for 'Search BY Excipients', 'Search FOR Excipients', 'User Guide', 'Help', and 'Logout'. The 'Help' link is highlighted with a red box. The main content area shows the 'Select to Export' page, which is divided into two columns. The left column lists various data categories for export, including 'General Information', 'Regulatory Status', 'General Acceptable Daily Intake', 'Clinical Data', 'Non Clinical Data', 'Invitro Data', 'Regulatory and other information', 'Reviews', and 'Reference'. The right column contains a list of fields to be exported, including 'Excipient Name', 'Revision Date', 'Permitted Functionality', and 'Year'. The 'Export' link is highlighted with a red box in the top right corner of the 'Select to Export' page.

Note:

Help link is available for over all application. (I.e. Search BY Excipients, Search FOR Excipients, and Excipients Intermediate, Search Results and Export pages)

11 Glossary

Attribute: In data modeling, specific items of data that can be collected for a class.

Availability - The degree to which a system (or system component) is operational and accessible when required for use.

Capacity - A measure of the amount of input a system could process and/or amount of work a system can perform; for example, number of users, number of reports to be generated.

Document - Written and/or graphical information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, reviews, or results.

End user: The ultimate consumer of a product, especially the one for whom the product has been designed. End-users for STEP database application include Pharmaceutical Scientists, Regulators, Toxicologists, physicians, nurses, epidemiologists, health care providers etc.

Entity - Represents data attributes about which data are collected and maintained.

Functional Requirement: A description of what a system should be able to do—a function it should perform.

Life Cycle: All the steps or phases a project passes through during its system life; from concept development to disposition.

Methodology: A set of methods, procedures, and standards that define the approach for completing a system development or maintenance project.

Non-functional Requirements: Software design requirements related to the efficiency, reliability, portability, and usability of the system. Also known as supplementary requirement.

Process: A set of activities that produces products and services for customers.

Process Flow: The set of steps or working states in a documented standard process.

Requirement: A requirement describes a condition or capability to which a system must conform; either derived directly from user needs, or stated in a contract, standard, specification, or other formally imposed document. A requirement is a desired feature, property, or function to be met by the application.

Scope - The established boundary (or extent) of what must be accomplished; during planning, This defines what the project will consist of (and just as important, what the project will not Consists of.

Software Requirements Specifications (SRS): A project artifact that defines the complete system requirements through use cases and supplementary specifications.

Web-based: A set of interconnected web pages, usually including a homepage, generally located on the same server, and prepared and maintained as a collection of information by a person, group, or organization. Web-based applications are usually accessed with a web browser (e.g., Microsoft Internet Explorer, Netscape).

User interface: The programming that controls a display for the user (usually on a computer monitor) and that allows the end user to interact with the system with commands and mechanisms to control system operation and input data.

User Manual - A formal document that contains all essential information for the user to make Full use of the new or upgraded system.