



TIP OF
THE
MONTH



CREATION OF POISON CENTRE NOTIFICATION DOSSIERS

Creating a Poison Centre Notification Dossier

Did you know Formpak has additional functionality to create PCN dossiers for submission into the ECHA Poison Centre Portal?

As you may be aware Article 45 Annex VIII of the CLP regulation includes a provision to submit Poison Centre Notifications and this applies only in the EU. EU companies that supply hazardous CLP goods must make a Notification and provide a UFI (Unique Formula Identifier) on Safety Data Sheets and labels.

GB adopted CLP and accidentally included the regulation on mandatory Poison Centre Notifications, but this regulation is going to be reversed. Therefore GB companies do not have to make a mandatory PCN submission (unless they are in NI in which case a EU Notification .i6z is required).

Companies selling into the EU have no legal responsibility under CLP because it does not apply to 'outside the EU', however, if you want to sell in the EU, you must provide sufficient information to the Importer (i.e. the first link in the supply chain that is in the EU). Companies can give the Formulation to the EU Importer (not an ideal business practice) or alternatively make a voluntary Notification and pass on the UFI for the Importer to use.

Making a valid EU Notification from outside the EU is not possible, therefore, it is required for a company outside the EU to use an EU Legal Entity (OR Only Representative) to act on their behalf and submit any required dossier. Some Formpak Users based outside the EU use a third party to submit Formpak generated dossiers on their behalf.

Formpak Poison Centre Notification generation is an additional module and if you require further information on implementation, please contact us via the support email address support@formpak-software.com

PCN Initial set up

Importing a Legal Entity File to the Default TO.

Excluding non-hazardous accumulator Items with Property PCNEXCLUDECOMP.

Creating a Template Formulation to copy 'standard' PCN requirements.

For more information on initial set up please click [here](#).

Generate a Dossier for a Formulation.

Navigate to 'Add a New Cross Reference'.

Select a Company.

Select an Item.

Select Code Cross Reference Sequence (Automatic, or Manual if you wish to add your own code).

Add Cross Reference Name.

Add a UFI – Unique Formula Identifiers may be generated free-of-charge from the ECHA website.

Save.

Add a New Cross Reference

On this page you can add a new cross reference.

Add a New Cross Reference

Company
 C/SNI001 Sniffs UK

Item
 PCN-TEST01 PCN Formulation - Spicy R

Code Cross Reference Sequence
 Fragrance Division XR

Code Cross Reference

Name Cross Reference
 Fruity Rose Spice

Last Sale Date
 E.g. d/m/yyyy

Last Sample Date
 E.g. d/m/yyyy

Application
 %

UFI
 90SQ-79AA-N10V-X784

PCN Number

Notes

Navigate to 'Generate a Poison Centre Notification for an Item'.

Select the Item.

Enter the same Company that was used in the Cross Reference.

Select the Cross Reference you added (and not a previous Cross Reference).

Do not change the TO or the Language (Default is the only TO with Legal Entity uploaded, and language is automatically selected).

Click Generate.

Generate a Poison Centre Notification for an Item

On this page you can generate a Poison Centre Notification for an item.

Generate a Poison Centre Notification for an Item

Item
 PCN-TEST01 PCN Formulation - Spicy Rose Gerani

Company
 C/SNI001 Sniffs UK

Cross Reference
 PS000014 Spiced Rosy Geranium

TO
 DEFAULT

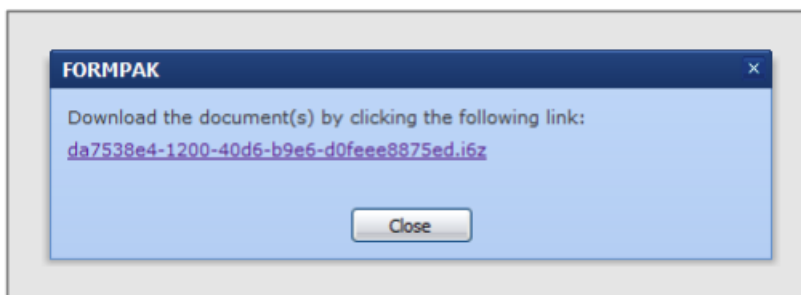
Language
 Default

Notification Type
 Initial Update Composition Update

Resend Update

Update Justification
 Change in the mixture classification

In just a few seconds the dossier should be generated.



By clicking the link, it may be saved and then submitted to the ECHA Portal or viewed in a third-party application.

Once a dossier has been successfully submitted to the ECHA Portal it may not be re-submitted as an initial submission, however, it may be submitted with a different Cross Reference.

Mini Tip

How to generate a UFI (Unique Formula Identifier)

Generating a UFI and providing the UFI number on the Safety Data Sheet and Labels is an obligation for companies in Europe and additionally non-EU companies may have an obligation to provide information within the supply chain.

The aim of the UFI is to establish an unambiguous link between the information you provide to the poison centre and the product you place on the market.

UFIs may be generated in multiples using a free to use online generation tool on the ECHA website.

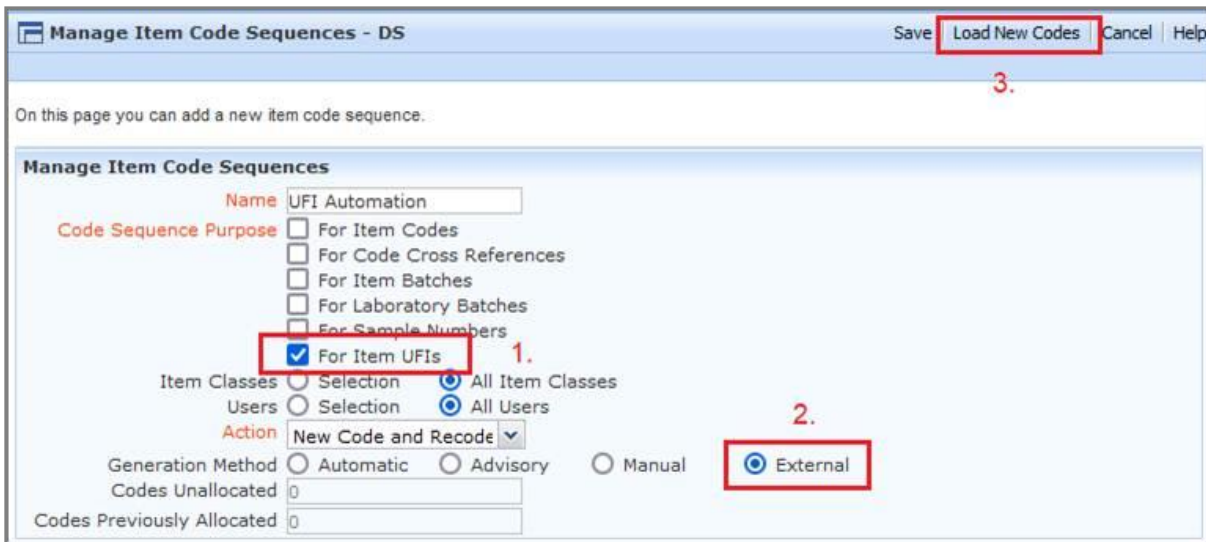
UFIs can be obtained from the ECHA website which you can access by clicking [here](#).

The screenshot shows the ECHA UFI generation tool interface. At the top, there are navigation links: 'CREATE UFIS', 'VALIDATE UFI', and 'GET A COMPANY KEY'. On the right, there are links for 'Support' and 'English'. Below this is a section for 'Company VAT number' with a dropdown menu and an input field. A checkbox below it reads: 'By ticking this box, I declare that the company does not have a VAT number or chose not to use it to generate a UFI.' A purple box contains a note: 'Please note that the generation of a UFI code and its placement on the label are not enough to place your product on the market; you need to also generate a dossier, include this UFI, and submit it to the relevant Appointed body (ies). For further information please see https://poisoncentres.echa.europa.eu/en/steps-for-industry'. Below this is the 'Create single UFI' section, which has a 'Formulation number' input field (with a note 'A number between 0 and 268 435 455') and a 'UFI' output field. There are 'Create' and 'Reset' buttons. The 'Create multiple UFIs' section has two radio buttons: 'From sequential formulation numbers' (selected) and 'From a CSV file (of up to 10 000 formulation numbers)'. The 'From sequential formulation numbers' option has a 'First formulation number' input field (with a note 'A number between 0 and 268 435 455') and a 'Count of formulation numbers' input field (with a note 'A number between 1 and 10 000'). There are 'Create' and 'Reset' buttons. The 'From a CSV file' option has a file upload icon and a greyed-out input field.

The UFIs can be uploaded to Formpak.

Manage Item Code Sequences, Add, Select Item Classes/Users relevant to your requirements.

1. Select For Item UFIs.
2. Select External.
3. Click Load New Codes.



To see previous 'Tip of the Month' articles, please see [here](#).

All of our training and support material can be accessed from our **Support Centre**. The Support Centre is available 24/7 and is a great resource to use at your convenience. It includes:

- Over 100 training and support articles
- Links to training videos
- Quick Start Guides
- The Formpak Training Matrix

The Support Centre can be accessed on the Home screen of Formpak software or via the following link: https://www.formpak-software.com/Support_Centre/Pages/Support_Centre.html

Our **Support Team** are available:

Monday - Thursday: 8:30 - 17:00 (GMT)

Friday: 8:30 - 16:00 (GMT)

Email: support@formpak-software.com

Telephone: +44 (0) 1235 250 020

The Formpak **Help Centre** is included directly in Formpak software, just press the 'Help' button to access it. The Formpak Help Centre offers explanations for each function of the application as well as a glossary of the technical terminology used.

View our **YouTube** channel with lots of helpful guides and information about Formpak

<https://www.youtube.com/user/FormpakSoftware/videos>