Information

UFI, EuPCS and PCN

DR Software
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**Administration of UFI and EuPCS**

**Introduction:**

According to Article 45 of the CLP Regulation, Importers and Downstream Users are required to report the chemical composition, and the chemical identity and concentration of the contents of products to the responsible national authority (i.e. BfR in Germany, NPIS in Great Britain). The national authorities transmit this data to the Poison Centers, so that in case of emergency, the emergency personnel have immediate access to the necessary information.

In order to standardize this process EU-wide, the CLP Regulation has been revised and the new Appendix VIII ("Harmonised information relating to emergency health response and preventative measures") was added.

In addition to a harmonized format for the notification of the information to the responsible authorities, a 16-digit **UFI-Code (Unique Formula Identifier)** has been implemented. This is an unambiguous, alphanumeric code, that is used to precisely identify products and is to be stated on labels and in certain situations on SDSs. This code connects the product on the market with the information transmitted to the poison centres and thus facilitates the fast transfer of information to emergency personnel, in case of emergency. As the name implies, UFIs can only exist for formulations. No UFIs are calculated for raw materials.

Products classified in class 2.5 (Gases under Pressure) and class 2.1 (Explosives), are exempt from this change.

**EuPCS** stands for *European Product Categorisation System* and describes the intended uses of a product, for which a submission, according to Article 45 and Annex VIII (Submission to the European Poison Centers) of the CLP, has to be done.
**Settings:**

The settings for the **UFI Codes** and the **EuPCS** can be found in the following screen *(Maintenance programs – Program adjustments – Settings for UFI, EuPCS and PCN notification)*:

![Settings Screen](image)

**UFI:**

**100% formulations:**
Some users use preparations consisting of 100% of a preparation, instead of variants, as they allow for the input of specific data. For such instances, in order to minimize the amount of UFIs, you can activate the option **When a preparation is 100% of another preparation, use the same UFI**. Please note, that the UFI will only be copied when the company stated in the preparation in the formulation is the same as that of the preparation itself. Thus, if the company was manually changed in one of the two preparations, two separate UFIs will be calculated.

**Variants:**
Some companies sell variants of their products under different names. If desired, it is also possible to activate that a UFI is calculated for each variant. This is not a necessity, as it is not possible to identify from a UFI that it belongs to a different substance name, as different UFIs only must be generated when the classification is different or when the ingredients are different. Therefore, it is necessary to take into consideration the extra efforts that will be required regarding notifications, new labels and changed SDSs.

If the calculation of a UFI is activated for variants, then you can immediately see in the overview screen whether UFIs are available and what type of UFIs they are.
If you hover the mouse over one of the check boxes, then the UFI is shown.

If UFIs are not activated for variants, then you can activate this in the Administration of Variants via the button `Ctrl`+`F9` Activation of UFI for variants.

Please note that via this button, both options in the Options for UFI, EuPCS and PCN notification regarding UFIs for variants, are activated. If you do not wish this to happen, you need to go to the corresponding settings screen.

Logically, the UFIs can only be taken over from the main substance, when no VATIN (VAT number or Value Added Tax identification number) was calculated for the variant. For this to happen, the highlighted option needs to be deactivated.

In the screen for the variant you can enter the VATIN (VAT number or Value Added Tax identification number) for the individual customer, just as for the main substance, and of course also change the UFI manually.

Please note that for variants only customers can be selected for which a phrase exists in the SDS.
No recalculation of UFI after alterations:

If this option is activated, then the UFI of a preparation is not recalculated after changes, until this setting is deactivated.

**EuPCS (European Product Category System):**

ChemGes provides different ways for automating EuPCSs.

**Flags** are used by some users. Here you can allocate various flags to one EuPCS. With this, it should be possible to cover just about everything.

**Variants** do not have an option for assigning flags. This is not an oversight in the program, but was left out intentionally, as the use of flags for variants would lead to such extreme complexity due to the various levels of impact, that it becomes no longer manageable by the user. If your ERP or other system does have flags or equivalent markings, ChemGes also has a solution for that; further information can be found below (Option Transfer of flags / article groups).

**Note:** When hovering the mouse over the various fields, you can access additional information.

*Example:*
Article groups can be used for the main substance as well as for variants.

Customer allocations are only available for Variants. These customer allocations are mainly used for variants in order to sell special product groups under a different company name.

If an SDS has been created, then it is possible to pull information from there.

As there exist many more Uses than PC Codes, it is possible to also make allocations for these.

ECHA did not assign allocations for all PC Codes and some of the allocations are not definitive. Therefore, you can define your own allocations, which will take precedence.

If none of these definitions lead to a result, then the field Otherwise, and if no code from the SDS could be determined, can be used to define a default setting for all other cases.

Note that the EuPCS is determined dynamically if it is not locked. This means that every change of the above stated fields can lead to an immediate change of the EuPCS.

Information on the order of the EuPCS selection:

- If special flags with EuPCS assignments have been defined, the allocation of the first occurrence of a flag is taken from the respective preparation. Since variants do not have a flag, these allocations cannot be used for variants.
- If no allocation could be made for a flag, then the allocated article groups are searched. This works both for the main substance and for variants, since article groups can also be defined for variants.
- The next level is the assignment of suppliers, which is only used for variants, in case that address allocations have been made there.
- If nothing is found there as well, existing SDSs will be searched. The procedure is two-stage, whereby in the first stage all selected PC codes (REACH product categories) are checked as to whether there is a self-selected allocation to an EuPCS. Only if nothing is found, will the second pass use an ECHA allocation (from the ECHA conversion guide). If the ECHA has more than one allocation to a specific PC code, the self-created table of preferred EuPCS codes is searched. If there is a matching entry within the multiple selection of the ECHA, then this one is used, otherwise the first entry in the multiple entries of the ECHA is used.
- If this could not be done, then the 'else' code will be used.
- For variants, if no special code for the variant could be determined, the code of the main substance is used. However, the 'else' code for variants is only used if it would also be allocated to the main substance.

As there are 240 codes, and the selection can thus not be overly clear, you can define in the field Preferred codes, which EuPCSs are to be used in your company. Via the option Only the preferred codes should be displayed, you can additionally define whether only the reduced list (activated), or the complete list with the preferred codes (deactivated), is to be displayed in the beginning.

Button Transfer of flags / article groups:

For users that use flags or equivalent identifiers, but have not entered these into ChemGes, or have the flags for variants in their main system, we have created a function to transfer these via a file import. Detailed information regarding this import can be found after clicking on this option (see next image):
UFI Generation:

Company Data:

The VATIN (Value Added Tax identification number) is required for generating a UFI. There are two options for entering this number in ChemGes. It is possible to create companies that are only used for the calculations of UFIs or to use companies created for output on the SDS (Heading 1.40.10). For both of these options, the VATINs need to be entered.

There are various setting options in the maintenance for the individual companies:
An important point here is that a default company can be defined. The company that is defined as the default company, will be used automatically, when no other company has been assigned to a preparation. If no default company is defined, or a company is allocated that does not have a VATIN (VAT number or Value Added Tax identification number) entered, then the UFI will not be generated until the necessary information is manually allocated.

The VATIN must comply with the regulations of the corresponding country and the logical structure of the VATIN is also checked.

**Entering UFIs:**

It is also possible to manually enter UFIs, that remain locked until the lock is manually removed. This is useful for applying the UFI of a supplier.

In addition, via the button [F1], it is possible to calculate a new UFI at any time.

**Output of UFIs:**

**Labels:**

Additional information for the UFI code – CLP (2017/542, Paragraph 5.2.):

5.2. The submitter shall print or affix the UFI on the label of a hazardous mixture. The UFI shall be preceded by the acronym “UFI” in capital letters and it shall be clearly visible, legible and indelibly marked.

For labels, you can define a variable which is automatically filled with the UFI for a preparation. Please note that the field length needs to be at least 19 characters in order to output a complete UFI. If the field description is not automatically adopted, then the word UFI will be output automatically and the field length needs to, of course, be 23 characters (which is the default definition by the program).
**Safety Data Sheets:**
To output UFI in SDSs, allocate the heading in the screen *Allocation of headings* (Maintenance programs – Safety Data Sheets – Options – Allocation of headings):
**Individual File Creation:**

In the **Individual File Creation**, the UFI Code is output via the following option (**Ins** Selection of fields – **Other classifications**):

<table>
<thead>
<tr>
<th>Field</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC-Disposal key numbers</td>
<td>No, One</td>
</tr>
<tr>
<td>Waste hazards</td>
<td></td>
</tr>
<tr>
<td>Austrian disposal key number</td>
<td></td>
</tr>
<tr>
<td>Type of water hazard class</td>
<td>Germany, Netherlands</td>
</tr>
<tr>
<td>VOC</td>
<td>Only your country, EU, USA</td>
</tr>
<tr>
<td>EU (in %)</td>
<td></td>
</tr>
<tr>
<td>USA/Exempt solvent</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td></td>
</tr>
<tr>
<td>Danish MAL-Code</td>
<td></td>
</tr>
<tr>
<td>German Arbeitsämterverordung</td>
<td></td>
</tr>
<tr>
<td>German Stärkeverordung</td>
<td></td>
</tr>
<tr>
<td>Only your country</td>
<td></td>
</tr>
<tr>
<td>EU</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td></td>
</tr>
<tr>
<td>TAI-Lift</td>
<td>Type, Creation date, Germany</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Last alteration date</td>
<td>REACH pre-registration, Austria</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Storage class (LGW) acc. to TRGS 010 (Germany)</td>
<td></td>
</tr>
<tr>
<td>ECHA notification - Reference Number</td>
<td>Chemical Safety Assessment available</td>
</tr>
<tr>
<td>Seveso III</td>
<td>Qualified quantities, Categories</td>
</tr>
<tr>
<td>UFI Code</td>
<td>X</td>
</tr>
<tr>
<td>EU-PECS</td>
<td>X</td>
</tr>
<tr>
<td>Text for EU-PECS</td>
<td>X</td>
</tr>
<tr>
<td>Annex XVII REACH</td>
<td>X</td>
</tr>
<tr>
<td>Is subject to annex 2 of the ChemVerordung</td>
<td>X</td>
</tr>
</tbody>
</table>
PCN – Notification


Status 11.11.2019:

With the current version of the PCN portal, ECHA only allows the submission of standard individual notifications, which you can generate with ChemGes. Currently, ECHA does not support the submission of group notifications or a bulk upload of individual notifications. These functions can only be offered in ChemGes, once the PCN portal supports them.

Even though the possibility of a direct upload of dossiers via S2S, has been announced on their website, ECHA has not yet provided on this website or after direct contact, any specifications for the technical implementation of the interface. This direct interface for the upload via S2S can, thus, only be implemented as soon as ECHA provides the necessary documentation.

Creation of the PCN Dossier:

In order to create your PCN dossier, it is first necessary to enter the additional data needed. This can be done for a preparation, in the screen Country specific classifications by clicking on the PCN Button.

Please note: If all default values are entered accordingly in the Options for UFI, EuPCS and PCN notification screen as described below, it is usually not required to enter any further product specific data here.
The following fields are available in this screen:

**PCN number** – If you have a PCN number from a previous notification, then you can enter it here. If this is the first time this preparation is being notified, then leave the field blank. Once the notification is completed, you will be provided with a unique PCN number for your preparation, which is then used in the future for identifying the preparation. ChemGes fills this field in automatically after you have completed the notification.

**Emergency contact** – The emergency contact information is only necessary for *Limited Submissions*. It can be set up by clicking into the line and creating a new contact. You must fill in all fields marked with a * (see below).

After creating a contact, you choose it for output and then you can activate the **Limited submission**.

**Market placement** – For the PCN notification it is necessary to identify the markets on which the product will be placed. The notification must be generated in the official language(s) of the country to which it is going. You can either identify the markets in this field, or ChemGes will identify them by looking for which EU country an SDS has been generated for your preparation.

**Packaging** – The packaging must also be identified. This can be done manually each time, or default packaging, based on the terminology provided by ECHA, can be assigned via the **Options for UFI, EuPCS and PCN notification**.

This can be accessed here:
Here you can assign a default packaging dependant on the state of aggregation and you can set whether these defaults are only to apply to variants.

When assigning packaging, it is possible to provide a number of different types, define the units of measurement for each type, as well as define one or more amounts.

Manual override of the reasons for the update notification – If the dossier has already been generated, and you attempt to run it again, ChemGes automatically verifies whether and what changes have occurred that would merit a new notification. Here you can manually force reasons for a change, when creating a
changed dossier. If no changes are found or forced, ChemGes will provide an error message (see below), since ECHA does not accept update dossiers without change reasons.

Please note: If the notification was successful then a message appears stating this and the output directory (the standard export directory – by default the sub-folder “export” in the program directory) is automatically opened.

In the PCN data screen there is no need for fields for product specific data, as this data is taken directly from your preparation and its SDS. Where ECHA requires specific terminology, as in the colour, ChemGes provides an option for converting the ChemGes used term to an ECHA used term.

This is available in the screen Options for UFI, EuPCS and PCN notification, under the option Assignment of colors to PCN codes. These are set by default, using the colours already available in ChemGes. Any self-created colours would, of course, need to be assigned. This can be done, as well as the changing of any already existing assignment, by clicking into the Assigned PCN phrases column.

Beyond the above-mentioned data, you must also enter or generate a UFI as well as the EuPCS.
Finally, it is necessary, to create the company and choose it for the notification. As much as possible, the details are taken from the text phrase of the supplier, and can be adjusted by the user as needed. The fields marked with a "*", must be filled in. The **UUID** must be adopted from the Legal Entity Data from the PCN Portal. Please copy this number, including the prefix (i.e. „ECHA-“ or format „ECHA-xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx“) into the corresponding **UUID Field** in the customer data.

In order to generate the PCN dossier, after all information is entered, simply click the **PCN button** in the **PCN data screen**.
If you create a PCN dossier from the main substance or from the variant, the dossier will contain the main substance and all of its variants. In order to deactivate this default setting, please activate the option **Separate PCN notification per VATIN if different companies are used for variants** (in Maintenance programs – Program adjustments – Settings for UFI, EuPCS and PCN notification). Once this is activated, separate notifications will be created for each variant that has a different VATIN (*VAT number or Value Added Tax identification number*) than the main substance. Any that have the same VATIN will still be contained in one dossier with the main substance.

Alternatively, you can choose, before generating a dossier from the variant settings, whether you wish to generate the **PCN notification for the main substance and all variants**, the **PCN notification for the...**
main substance and all variants with this VATIN, or the PCN notification only for this one variant. Whatever setting is chosen in this screen for the variant, at the time of generating the dossier, takes precedence over the setting in the Options for UFI, EuPCS and PCN notification screen.

**MiM:**
A MiM is a preparation that is an ingredient in another preparation (known in ChemGes as an intermediate). As a UFI notification requires the output of all ingredients of a preparation, a situation might arise where it is not possible to retrieve all of the ingredient information for a MiM, from a supplier. The legislator suggests two options to deal with such a situation:

1. If the MiM has its own UFI Code, then this code can be output instead of the unknown ingredients.
2. If you do not have a UFI Code for the MiM, you can attach the SDS of the MiM to the notification. The legislator describes this option as a last resort, if nothing else can be done.

It is important to note, that it is absolutely necessary to be able to show that you have tried to obtain the relevant data from your supplier. Also, choosing either of these two options will almost certainly lead to you being contacted by auditors wishing to ensure that you have done everything in your power to retrieve this data. Therefore, you can expect auditor visits.

In ChemGes, these options can be activated with the setting **Contains unknown ingredients** (screen Country specific classifications). Once this setting is activated, all known raw materials and the UFI Code of the MiM substance, will be output in the SDS of the preparation containing it.
If no UFI Code is available for this MiM, then the PDF SDS that is linked to this substance, will be output automatically. In this case, the legislators require that information regarding the supplier is output. This data can be entered in ChemGes in the screen *Company Settings*.

A PDF can be attached to a substance entry in ChemGes via the button *(Alt)(F8)* PDF files. Any such PDFs must first be placed into the folder PDF in the folder CHEM/GEFDAT or CHEM/DATA.

For each PDF you can define the language as well as the country, and whether it is a MiM for the PCN notification. This then ensures that the PDF is automatically a part of your notification, if the option *Contains unknown ingredients* is activated in the *Country specific classifications screen* (see first image above).
Some additional information:

- You can create variances concerning the Market placement and the Packaging in the notification information for variants (Alt F3 Variants in Maintenance of preparations). This can be filled in for each variant (see below).

Please note: Whether you run the dossier generation in a variant or in the main substance, makes no difference. The dossier that is generated will always be for a substance and all of its variants.

- Limited submissions are permitted for mixtures that are only for Industrial Use. In the Physical Data screen you can activate the purpose of the substance (‘Public’ or ‘Industry or trade’). Then in the
Options for UFI, EuPCS and PCN notification screen, you can define the meaning behind ‘Industry or trade’ for the purpose of your PCN notifications.

- The generic product identifiers “perfumes”, “fragrances” and “colouring agents”, can be used to identify specific components, as long as these are not classified with any health hazard and they do not cross the total percentages (5% for perfumes/fragrances and 25% for colouring agents). These can be activated in the Country specific classifications screen:

- By clicking on the question mark symbol you can access further details on the required information for the creation of the PCN dossier:
By means of the button [F9] PCN transfer programs in the screen PCN data you can switch to the import and export programs for the PCN notification.