

POISON CENTRE NOTIFICATIONS

Cross-sector solution for companies using interchangeable or highly variable components

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General outline of the document

This document intends to provide practical advice on how to make use of the interchangeable components group (ICG) solution in the preparation of Poison Centres notifications.

Detailed explanation of the legal provisions underpinning the ICG solution (Section 3.5, Part B of Annex VIII) are provided in the Guidance on Annex VIII, which also explains which are the criteria that have to be met in order for the solution to apply. The Guidance includes also general examples of situations when the notification may include an ICG.

The Guidance is available at <https://echa.europa.eu/guidance-documents/guidance-on-clp>.

This document complements the regulatory Guidance by illustrating the practical aspects of the application of the ICG solution in the dossier preparation.

1. The interchangeable component group solution

The ICG solution was introduced by the second amendment of Annex VIII to address the challenges certain submitters face to meet the obligation of providing the full composition and with the specific concentration ranges allowed by Tables 1 and 2 of Annex VIII. When the ICG solution can be applied (see criteria in section 1.2 below), the submitter does not need to indicate the concentration of each individual component, but only of the “umbrella component” represented by the group.

Situations intended to be address are those, for example, where certain components are used in an unpredictable way in the same production line. This may make virtually impossible to know which exact component is present at each point in time and at which concentration. Alternatively, this may require several updates and new UFI's, with no benefits for the emergency responders. This can be due to different reasons.

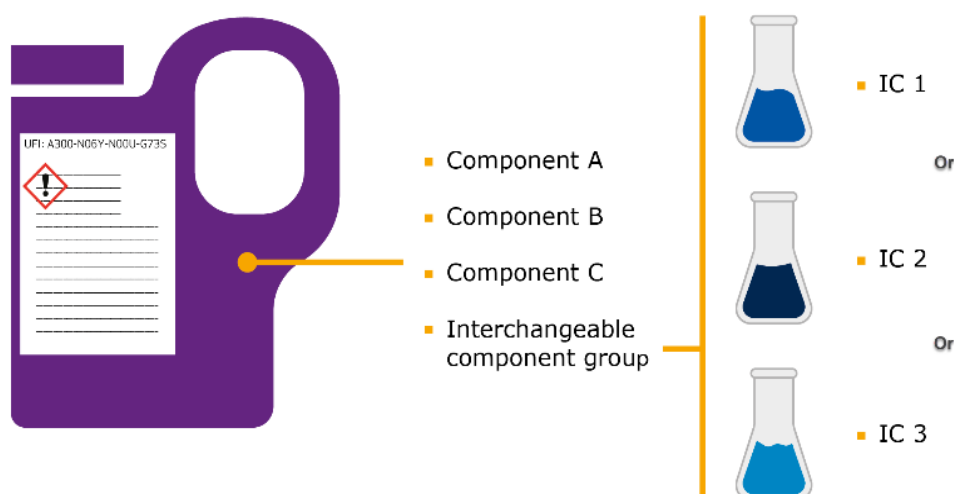
When, for business reasons, different suppliers are used to purchase components with the same function in the final mixture, but not chemically the same, it may be impossible to know which one of these components is present in each batch. Only one or more that one of these components may be present in variable relative percentages, while the total final concentration of these components providing the specific function can be established in accordance to the Annex VIII ranges. In this case, it may not be relevant for the formulator which of these components is present in the final mixture as they are virtually interchangeable, with no impact on the technical specification of the product.

Similar challenges may also be encountered when components with completely different functions are used in the formulation according to their availability or the specific recipe, but still with no relevant impact on the final product from the customer point of view. Here the components are not necessarily used one “instead of” the other (i.e. they are not *interchangeable* with each other), but can be used at the same time and in different percentages, or not used at all in a specific batch.

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In these and other similar cases, the submitter can report a concentration which represents the combination of the individual components grouped in the ICG. This means that while the concentration of each individual component in the mixture can vary, their total can and has still to be reported as exact value or as a range in accordance with Table 1 or 2 of Annex VIII.

This solution can potentially be applied for any type of mixture and by any industry sector as long as the criteria laid down in the legal text are met.



1.1. ICG criteria

In practice the ICG consists in the possibility to group different components and report them as a group instead of individually. The ICG can be used to group either substances or mixtures in mixture.

Components can be grouped only if they meet one of two sets of criteria identified in Section 3.5, Part B of Annex VIII. The main and common criteria is that for any possible combination of components in the ICG, the classification of the final mixture and the toxicological information has to remain the same. It is important to understand that the purpose of this solution is not to allow a submission covering different mixtures. The dossier and the notification still concern a single mixture, whose composition can vary unpredictably. Therefore, the whole set of information requirements in Part B of the Annex VIII has to remain the same¹.

It is to be noted that not all the criteria are automatically checked by the validation assistant of the Submission portal. Some are in fact based on information which is not legally required and possibly no field exists in the format. The submitter is responsible for complying with the obligations and may be asked by the authorities to provide more information, if needed.

The two sets of criteria are the following:

¹ Note that it is normally possible to notify different product information in the same dossier (e.g. same mixture placed on the market in different packaging and sizes and for different final uses). But, for example, the pH value should not change regardless the specific interchangeable components present.

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Criteria set 1

All components in the same ICG must have identical technical function.

All components in the same ICG must have identical classification for health and physical hazards (same hazard class and category).

All components in the same ICG must have same toxicological properties.

Classification and labelling of final mixture do not change.

Additional information on the final mixture in Section 2.4, Part B of Annex VIII is the same (e.g. pH).

Criteria set 2

Components can be classified only for skin corrosion, skin irritation, eye damage, eye irritation, aspiration toxicity, or respiratory or skin sensitisation.

All components in the same ICG must have identical classification for health and physical hazards (same hazard class and category).

All components classified only for skin corrosion, skin irritation, eye damage or eye irritation, in the same ICG must have similar pH.

The ICG contains maximum 5 components.

Classification of final mixture does not change.

Additional information on the final mixture in Section 2.4, Part B of Annex VIII is the same (e.g. pH).

2. Including an ICG in the notification

ICGs are considered in the PCN format, from a technical point of view, like MiMs. A specific tick box will allow to flag the MiM datasets in order for specific rules to apply and treat them differently from a standard MiM.

Unlike standard MiMs, an ICG can contain both types of components, i.e. substances and mixtures, which will be included in the ICG *composition*.

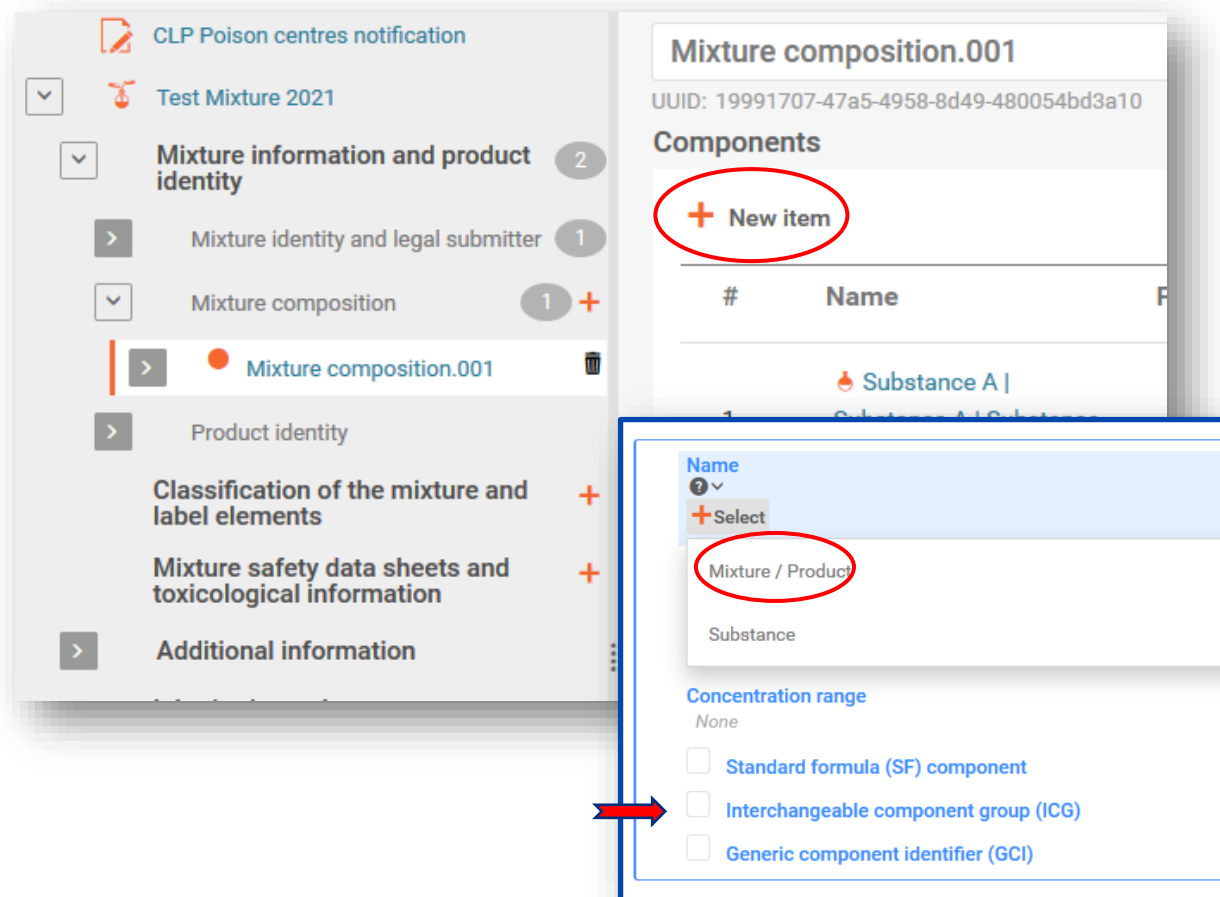
There are two ways to include an ICG, either directly from the final mixture composition document or, alternatively, in advance and retrieve it from the list of existing mixture datasets when including components in the final mixture composition. More than one ICG can be included in the same submission.

2.1. Including an ICG from the mixture composition document

The most convenient way to create and include an ICG is from the navigation tree of the final mixture.

The first step is to include a MIM component from the composition document of the final mixture and flagged it as "Interchangeable component group (ICG)".

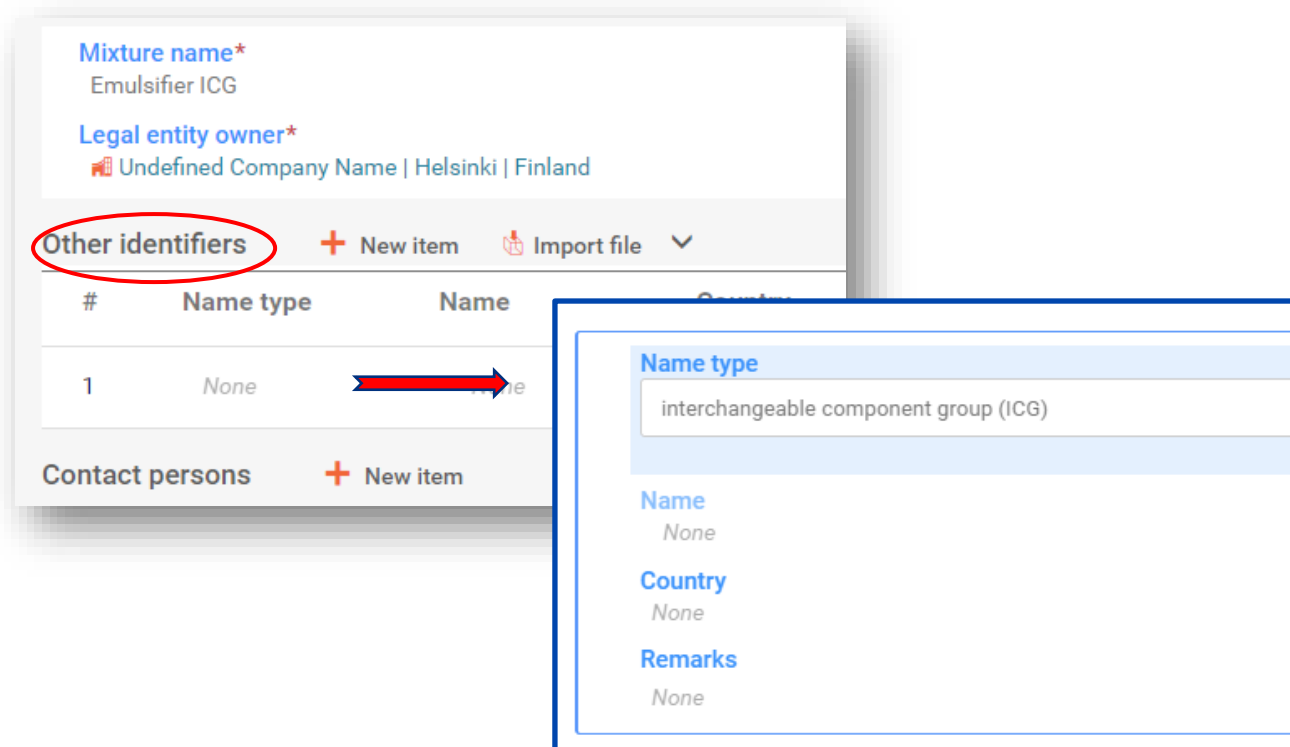
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The name given to this “MiM” is effectively the name of the ICG and should be meaningful and deliver information which allows the user (i.e. PC or appointed body) to understand which type of components could be potentially present in the mixture. The legal text requires that the ICG name reflects the function(s) of the grouped components.

In addition, under “Other identifiers” the format allows the selection of the specific name type “Interchangeable component group (ICG)”. In the “Name” field below, a more detailed description of the ICG can be provided (note the field is multi-language).

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The screenshot shows a software interface for managing chemical information. At the top, there are fields for 'Mixture name*' (Emulsifier ICG) and 'Legal entity owner*' (Undefined Company Name | Helsinki | Finland). Below this is a section titled 'Other identifiers' (circled in red), which includes a table with columns for '#', 'Name type', and 'Name'. A red arrow points from the 'Name type' column to a detailed view of an ICG record. This view shows fields for 'Name type' (interchangeable component group (ICG)), 'Name' (None), 'Country' (None), and 'Remarks' (None).

A Legal entity owner has to be always provided, as per any normal MiM or substance component, even if the details are not checked.

The “Function” of the ICG can be selected from a drop-down list, but this information is not checked.

The concertation of the ICG as a whole has to be provided as exact value or concentration range. The latter has to be provided in accordance to table 1 or 2 of Annex VIII, as applicable. This corresponds to the total concentration of the components covered by the ICG, which individually may vary.

2.1.1. Providing individual components information

Once the ICG record is created, this is visible in the navigation tree, under “Mixture composition”, at the same level as other substance or MiM components.

Interchangeable components can be created and included directly from the “ICG composition” document. It is important to remind that the components in the ICG have to be identified following standard rules for substances or MiMs.

Therefore, each MiM included in an ICG will have to be identified with:

- its name and the full composition (if available); or
- its name and UFI (if available), or
- its name, the composition from the SDS and the supplier’s details.

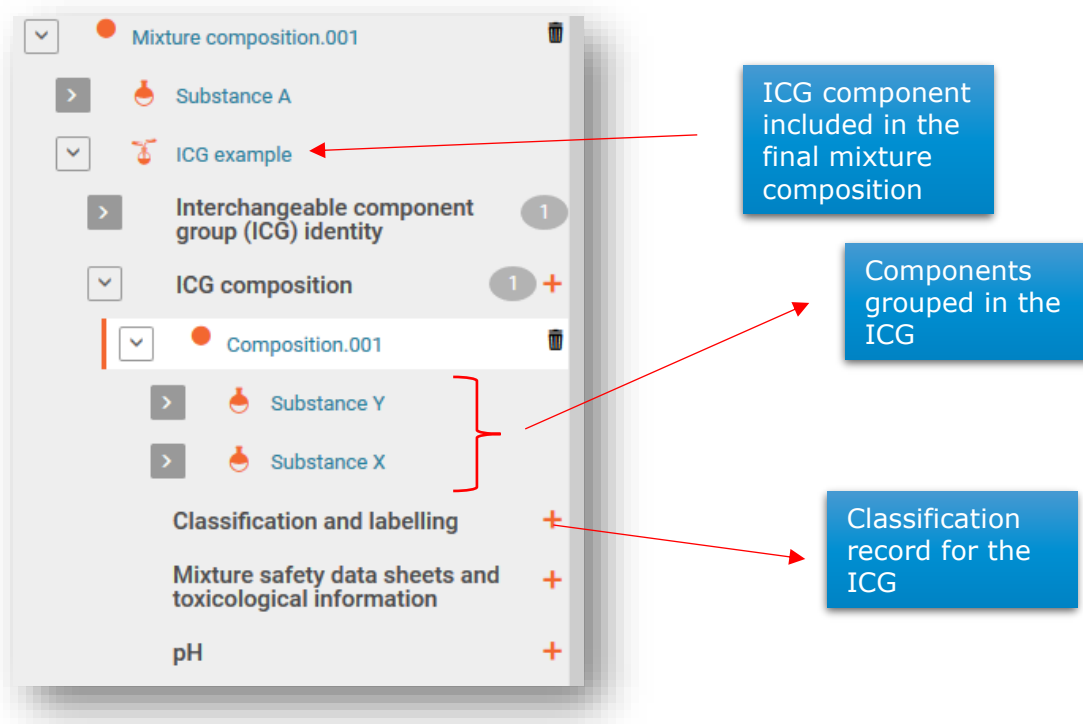
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Each substance included in an ICG has to be identified as per any other substance, and normally as precisely as possible. Note that each substance included in an ICG requires a link to a reference substance.

The components included in an ICG do not require concentration information.

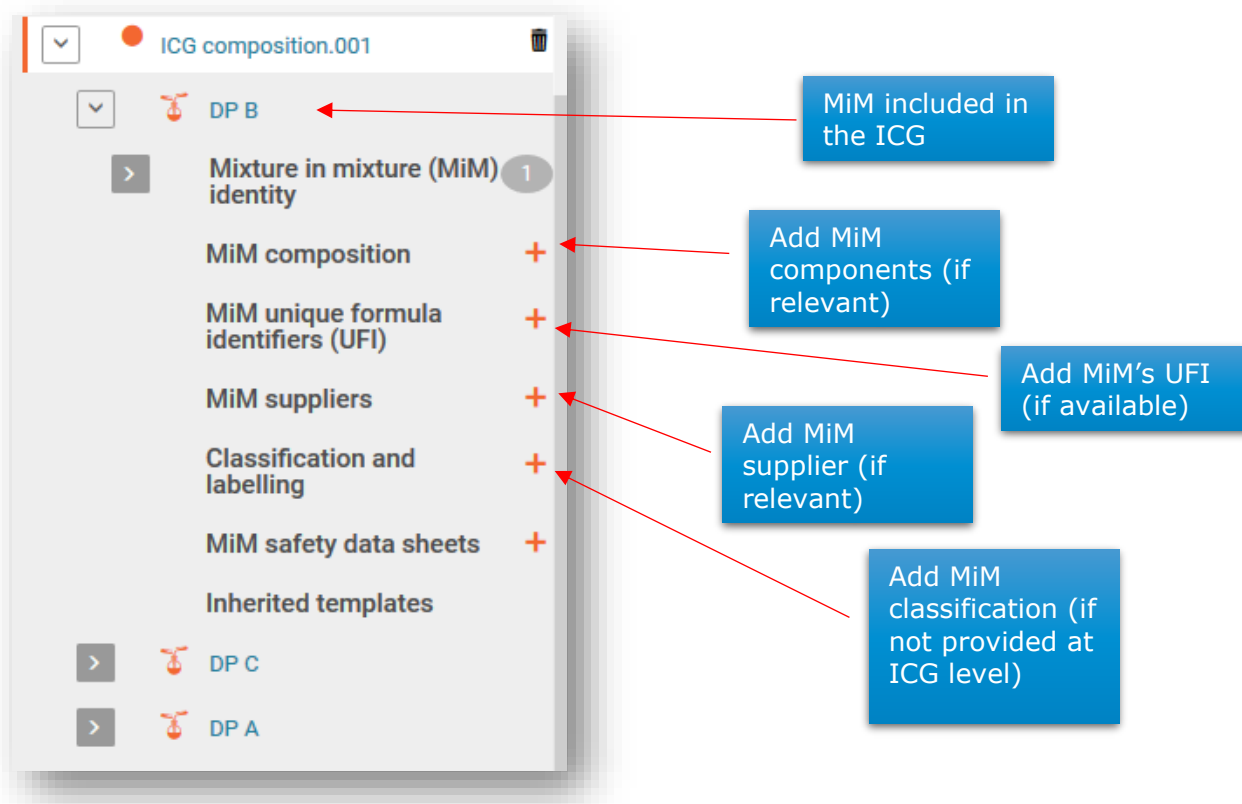
The information on classification can be provided for the ICG as a whole, in particular when all the components have exactly the same composition. When small differences exist (possible at subcategory level), the classification should be provided for each component individually.

Information about pH and toxicological properties for the ICG as a whole (i.e. relevant to all the components included in the ICG) can be provided but it is not legally required.



The information needed is included directly from the navigation tree, by adding a new item and expanding the relevant arrow. The figure below illustrates the fields present in the navigation tree when a MiM is included in an ICG.

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2.2. Creating an ICG in advance: ICG working context

An ICG dataset can be created in advance, and not necessarily only from the final mixture composition document.

To create an ICG in advance, the specific working context "CLP Interchangeable Component Group (ICG)" is to be selected when creating a new mixture/product dataset.



A meaningful name should be provided to the new dataset to identify the ICG. Also in case the name type "Intrechangeable component group (ICG)" can be indicated and a infomative description provided.

From the navigation tree of the newly created ICG dataset, you can add all the

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necessary information about the grouped components and the ICG itself.

The ICG will be included in the mixture list available to be reused in the creation of final mixtures composition.

3. Tips and hints for the notification of ICG components

Specific validation rules apply when a mixture data set is flagged as "ICG". These will allow certain standard information requirements to be waived and at the same time to ensure the required information for the ICG is correctly provided.

Firstly, the ICG has to be reported as MiM, and not as substance. Substance records cannot include further components.

The identification of the ICG requires a name only. This has to be meaningful and to reflect the type of components it covers, but there is no UFI for the ICG and no supplier's details. UFI and suppliers details should be provided, if relevant, for the MiMs included in the group.

The ICG composition record cannot be empty and has to contain minimum two components (any type, substances or MiMs). This because the ICG is not a component itself, but it is used to group components. Furthermore, an ICG can be used only to group more than one component.

The concentration has to be provided for the ICG as a whole, and not for each of the grouped components. If the precise concentration of a components can be established, this should be rather notified separately, at main mixture composition level.

Components can be added or deleted from an existing ICG via updates, without the need to change the UFI. But if an ICG is created when it was not present in the initial submission, a new UFI is needed. The submitter is recommended to consider in advance the possibility of the need to use interchangeable components (e.g. different suppliers).

An ICG could, in principles, represent 100% of a final mixture composition (i.e. this means that the ICG is the only "component"). This is possible only when the individual components grouped in the ICG are actually used for the formulation of the same mixture. It is not possible to group, for instance, MiMs which are placed on the market separately. In this case different submissions (and UFIs) would be needed.