ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on harmonised information relating to emergency health response – Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

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PREFACE

This document is the *Guidance on the harmonised information relating to emergency health responses*. It is a comprehensive technical and scientific document on the implementation of Article 45 and Annex VIII to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP[1]). CLP is based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and is implementing the provisions of the GHS within the EU. CLP now has relevance for European Economic Area (EEA) countries (i.e. it is implemented in the EU countries and in Norway, Iceland and Liechtenstein)[2].

The objective of this document is to provide detailed guidance on the obligation to submit to Member States responsible bodies relevant information on mixtures placed on the market for formulating preventative and curative measures in case of accidents. The guidance is developed to primarily assist companies placing mixture on the market in complying with the obligations. It is also intended to be a support tool for the appointed bodies in the Member States.

This guidance document was developed by ECHA with the support of a dedicated Working Group consisting of experts from Industry, Member State appointed bodies and poison centres. The project started in April 2017 and the working group had meetings and continuous discussions to develop the guidance text until December 2017. Finally the text was consolidated and edited by ECHA and underwent the formal consultation with ECHA Partners during 2018.

[1] Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 [OJ L 353, 31.12.2008, p. 1].
[2] CLP was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 106/2012 of 15 June 2012 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (OJ L 309, 8.11.2012, p. 6–6).

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1. Introduction

1.1 General introduction

A large number of products containing chemical mixtures are used in the EU on a daily basis where the general public and professional users regularly come into contact with them, both in their private lives and occupational environments (e.g. detergents, paints, adhesives).

Chemical products are in general considered to be safe when they are used according to use instructions. Nevertheless, unintentional exposure to chemicals can occur, for example due to inappropriate use or accidents. When this happens, immediate access to relevant information on the chemical product is crucial for medical staff and those who provide emergency responses.

1.2 Legal background

In 1988, Council Directive 88/379/EEC[3] required the Member States to appoint a body for receiving information on dangerous preparations necessary to meet any medical demand by formulating preventative and curative measures, in particular in case of an emergency. In 1999, the Directive was repealed by Directive 1999/45/EC. Many Member States therefore had already in place a system for collecting information from companies that were placing dangerous mixtures on the market and had established bodies called poison centres to provide medical advice in health emergencies. The information collected was only to be used to meet medical demands by the poison centres. Depending on the Member State, physicians and other medical staff, workers and the general public were also able to contact the poison centres to receive recommendations on medical treatment in the event of a poisoning or accidental exposure incident.

Article 45 of the CLP Regulation ((EC) No 1272/2008, which entered into force on 20 January 2009) required the EU Member States[4] to appoint a body for receiving information on the composition of hazardous mixtures to enable the formulation of preventive and curative measures. The absence of harmonised information requirements has led to considerable variation in the national notification systems, data formats and information requirements regarding the requested information in each Member State. Thus companies users placing mixtures on the market in different Member States have needed to submit similar information multiple times and in different formats. This diversity has led to inconsistencies in the information available to medical personnel in cases of poisoning or accidental exposure incidents in different Member States.

The European Commission received a mandate to address the inconsistencies in the information available to poison centres and a review, as foreseen in Article 45 of the CLP Regulation, was carried out in consultation with stakeholders and with the support of the European Association of poison centres and Clinical Toxicology (EAPCCT). Following the review, Commission Regulation (EU) 2017/542 was adopted. The amended Regulation entered into force on 12 April 2017, adding to the CLP Regulation Annex VIII to harmonise, in terms of format and content, the information relating to emergency health responses that certain

[3] Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
[4] Please note that whenever there is a reference to the Union (EU) in this document, the term also covers the EEA countries Iceland, Liechtenstein and Norway. See footnote 1.

companies placing hazardous mixtures on the EU market are required to notify to the bodies appointed by each Member State (i.e. "appointed bodies"). This information includes, for example, the clear identification of the mixture and of the company responsible for the placing on the market, information on the composition and hazardous ingredients and on the intended use through a system of harmonised categories. The information must be submitted by electronic means in a specified format, which enables the appointed bodies to easily retrieve the relevant information. Through a new unique formula identifier ("UFI": this is addressed in detail in section 4), the poison centres would be able to exactly identify the poisoning or hazardous mixture and suggest the appropriate medical treatment. The appointed bodies and poison centres (which are not necessarily the same entity, although in some Member States they are the same; see section 3.2 for more details), need to ensure the confidentiality of the information received.

The information required by Annex VIII is available for use by the poison centres, who have the task to provide medical advice to the general public and medical practitioners in the event of an emergency. The information can, according to Article 45 CLP, also be used to carry out statistical analysis to improve risk management measures (the allowed use of the submitted information is discussed in section 7).

The European Chemicals Agency (ECHA), as foreseen by the amended CLP Regulation, provides the format and tools to facilitate both the preparation and submission of information in a harmonised format. The format and tools aim to facilitate also the management and use of the submitted information by authorities and poison centres.

The deadlines for submitting the information are staggered and depend on the use type of the mixture (see section 3.2.2 for the definition of the different use types). Detailed information about timelines and deadlines is given in section 3.4.

1.3 Aim of this guidance

The aim of this guidance is to clarify and assist companies, appointed bodies and poison centres in the implementation of the new tasks and requirements outlined in Annex VIII to the CLP Regulation.

This guidance provides information on:

- the scope of Annex VIII to CLP, i.e. for which type of mixtures the required information has to be submitted;
- who should submit information in accordance with Annex VIII to CLP and by when;
- issues to consider when preparing for a submission of information;
- the use of the "Unique Formula Identifier" (UFI);
- the use of the harmonised European Product Categorisation System (EuPCS);
- details of the information required to be submitted;
- the use of the common XML harmonised reporting format;
- which changes or new information trigger the need for an update.

Note that, the IT tools provided to prepare and submit the information required by Annex VIII are referred to as the *notification*[5] tools.

[5] This is not to be confused with the notification to the C&L Inventory of **substances** established by ECHA in accordance with Article 42 of CLP.

1.4 Target audience of this guidance

The main target audiences of this guidance are:

- companies placing certain hazardous mixtures on the market (i.e. that are classified as hazardous on the basis of their health or physical effects) and who are required to submit information relevant to poison centre activities.
- the Member States' Competent Authorities and appointed bodies who are responsible for receiving information on such hazardous mixtures which are being placed on the market.
- poison centres who are the end users of the submitted information for the purposes of formulating preventative and curative measures, in particular when providing an immediate health response.

1.5 Overview of the document

This Guidance document is structured to present, after a general introduction, the main concepts which allow setting the scene and the framework for providing the required information. The main elements relevant to all the operators involved are then clarified before going into the details of the specific legal obligations. The obligations are than described by following the same section structure of Annex VIII.

- Section 1, presents the legal background, scope and target of this document in general terms.
- Section 2 provides a list of definitions and clarifies the main terms used throughout the Guidance.
- Section 3 provides relevant information for the reader to understand whether they have obligations under Annex VIII of CLP. Therefore, section 3 clarifies who is required to submit information and to whom, by when and which mixtures fall under the scope of Annex VIII.
- Section 4, presents the need to identify the mixture using a unique formula identifier and the possibility to opt for a limited or a group submission. This section further explains the basic elements and options linked to the submission of information, which should be known before the duty holder starts preparing the submission.
- Section 5 describes in detail the information to be submitted to the appointed body, as required in Annex VIII.
- Section 6 presents the available tools and the system put in place to allow industry and authorities to comply with the legal obligations.
- Section 7 explains what happens after the submission. This includes a description of the possible uses of the information submitted to the appointed bodies, the requirement that the submitter must keep the information up to date, and which changes trigger the obligation to update the submission.
- Section 8 lists the main available additional supporting tools.

1.6 Links to legislation other than CLP

There is a network of EU legislation which relies on CLP classification in one way or another (a detailed list of concerned legislation is available in the *Introductory Guidance on the CLP Regulation*[6]).

1.6.1 REACH Regulation

The provisions of Article 45 and Annex VIII to CLP are indirectly related to certain provisions of the REACH Regulation[7].

In particular the safety data sheets (SDS), which are to be compiled following the requirements in Annex II to REACH, represent one of the main sources of information for the company that is preparing a submission under Article 45 of CLP. The submitted information has to be consistent with the SDS and the SDS itself may need to be part of the submission to the appointed body.

Furthermore, definitions and terminology referring to operators in the supply chain are used in the context of Annex VIII with the same meaning as in REACH (unless specified otherwise).

1.6.2 Other legislation

The EU legislation for biocides, plant protection products, cosmetics[8] and tobacco products are examples of legislation with data submission requirements that are partially overlapping with the harmonised information required under the scope of CLP Article 45 and as specified in Annex VIII.

As part of the biocides and plant protection products authorisation procedures (required before they are placed on the market) under the Biocidal Products Regulation[9] (BPR) and the Plant Protection Products Regulation[10] (PPPR), full information on the identification, composition and hazards of the mixture, including any mixture used in its composition, is required by the authorising Member State Competent Authority (MSCA).

Under the Tobacco Products Directive[11], a notification of information on the identification, composition and hazards of e-liquid mixtures is required before placing on the market.

The Cosmetic Products Regulation[12] requires that responsible persons and, under certain conditions, the distributors of cosmetic products submit some information about the products they place on the market through a dedicated Cosmetic Products Notification Portal (CPNP).

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[6] All ECHA Guidance documents are available in the Support section of the on the ECHA website at: https://echa.europa.eu/guidance-documents/guidance-on-reach.

[7] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[8] Note that mixtures in the finished state intended for the final user and in the form of cosmetic products are exempted from CLP (Art. 1(5)(c)).

[9] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

[10] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[11] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

[12] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

It remains at the discretion of each MSCA, for some of the respective legislative processes (i.e. where the legal text allows the competent authorities to do so), to asses and decide whether a procedure can be established in order to make information supplied under different EU legislations (as part of an obligatory authorisation or notification procedure) available to the appointed bodies under the scope of CLP, Article 45. However, information required by Annex VIII of CLP must be submitted to the appointed body/bodies by the duty holder regardless of whether the appointed body/bodies can use relevant existing information received through other EU laws. Furthermore, the submission of the information under CLP must be provided in the harmonised format as outlined in Annex VIII.

1.6.3 National legislation

It is also to be noted that legislation at national level in each EU Member State may establish conditions complementary to Annex VIII CLP, defining aspects left to the discretion of Member States. This could include the acceptance of information in languages other than official language(s), the application of fees before processing the submissions, reference to submission systems, etc. Nevertheless, Member States cannot ask for anything more than that under the application of CLP; however, they could do so through national legislation.

Note that in this Guidance Document the reference to specific Parts and Sections of Annex VIII to CLP is provided within squared brackets […].

2. Abbreviations/definitions

Standard term / Abbreviation	Explanation
BPR	Biocides Product Regulation. Regulation (EU) No 528/2012.
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
CPNP	Cosmetic Products Notification Portal
Distributor	Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties (Article 2(20) of CLP).
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities (Article 2(19) of CLP).
EAPCCT	European Association of Poisons Centres and Clinical Toxicologists
ECHA	European Chemicals Agency
EEA	European Economic Area

EU	European Union
EuPCS	European Product Categorisation System
Importer	Any natural or legal person established within the EU who is responsible for import (Article 2(17) of CLP), where the latter means the physical introduction into the customs territory of the EU (Article 2(16) of CLP).
LD_{50}	Median lethal dose
MiM	Mixture in a mixture
Mixture	A mixture or solution composed of two or more substances (Article 2(8) of CLP).
MSCA	Member State Competent Authority
PCN	Poison Centre Notification
PPPR	Plant Protection Products Regulation. Regulation (EC) No 1107/2009.
REACH	Registration, Evaluation, Authorisation of Chemicals. Regulation (EC) No 1907/2006.
SDS	Safety data sheet (see *Guidance on the compilation of safety data sheets* for more details)
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (Article 2(7) of CLP).
UFI	Unique Formula Identifier (see section 4.2 of this Guidance)
XML	eXtensible Markup Language

3. Obligations

This section of the Guidance defines the general framework of the provisions of Article 45 of CLP and Annex VIII. It clarifies who may play a role or has potential obligations related to these provisions. It therefore explains which activities may trigger the obligation to submit information under Article 45, which mixtures are affected and which bodies receive the submitted information.

3.1 Who is required to submit information?

According to Article 45 of the CLP Regulation and as further specified in Annex VIII, importers and downstream users placing hazardous mixtures (meeting certain criteria, see section 3.3) on the market, are responsible for complying with the requirements established in Annex VIII to the CLP. These duty holders are required to submit information as specified in the same

Annex, that is relevant for formulating preventative and curative measures in the event of an emergency health response.

Therefore, the responsibility for submitting the information falls on the importers and downstream users. These are also referred to as duty holders or, in the context of CLP Article 45 and Annex VIII as "submitters". The definitions of 'downstream user', 'importer' and other operators potentially part of the supply chain are given in Article 3 of the CLP Regulation and are consistent with the REACH Regulation. The same definitions are reported in section 2 of this Guidance. The *Guidance for Downstream Users* provides more information on the different roles and operators along the supply chain.

As it will be clarified in this section, it is possible for a submission to be physically prepared and submitted by a third party. The use of a third party does not relieve the duty holder (importer or downstream user) from his obligations and responsibilities and his role of submitter.

In the sections below it is clarified which activities carried out by the different operators may confer to them the obligations to submit information to the appointed bodies according to Article 45.

3.1.1 Activities leading to the obligation to submit information according to Annex VIII

The following activities carried out by a company confer on the operator the obligation to submit information related to an emergency health response:

IMPORT ACTIVITIES

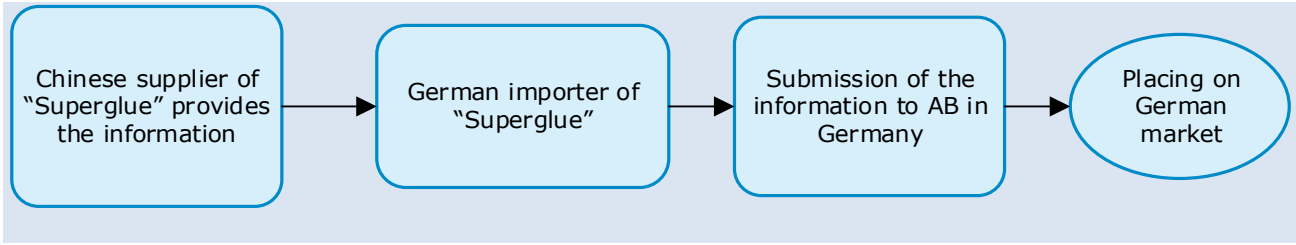
A company that imports a hazardous mixture into the European Union, is an importer and therefore, if they place the mixture on the market in one or more Member State, they have the obligation to submit the information required by Annex VIII in all the Member States where the mixture is placed on the market and in their national language. CLP (and REACH) applies to the European Economic Area (EEA), i.e. the 28 EU Member States and Iceland, Liechtenstein and Norway. This means that imports from Iceland, Liechtenstein and Norway and placing it on an EU Member State market does not constitute import for the purposes of REACH (unlike import from, e.g., Switzerland). Companies importing mixtures from outside the EU must ensure that they have all the available information required for the submission of the harmonised information requirements.

Details on the definition of importer are provided in section 2.1 of the *Guidance on Registration*[13].

Example 1: EU operator importing from outside the EU, placing on one EU market

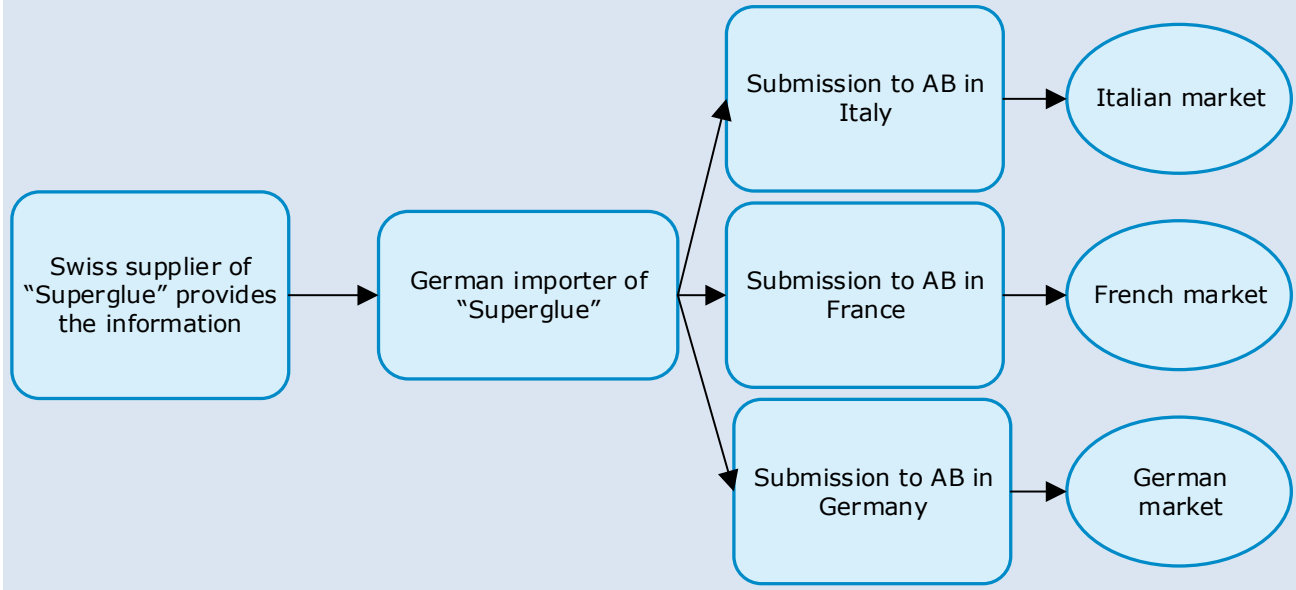
A German company imports from Switzerland (a non-EU supplier) a mixture called Superglue and places it on the German market. This mixture is hazardous for health effects and has to be labelled according to CLP. The German company needs to obtain from the Swiss supplier all the information needed to fulfil the Annex VIII requirements. The German importer will have to submit the information to the German appointed body.

[13] Note that this section refers specifically to the obligations under the REACH Regulation. Nevertheless the definition of importer and the examples provided are relevant for the purposes of Annex VIII to CLP.



Example 2: EU operator importing from outside the EU, placing on several EU markets

If Superglue (see example above) is then intended to be placed on the market in multiple countries, the German importer (from example 1) will have to submit the information to the appointed bodies of the relevant EU countries before being allowed to start the business activities on those markets.



The imported mixture may be used at the first place of import by the importer themselves and may not necessarily be incorporated in any other mixture further down the supply chain. Also in this case the submission obligation applies to the importer according to the use type of the mixture (industrial, professional or consumer use, as it will be explained later in section 3.3.2).

Ideally, the non-EU supplier of the hazardous mixture discloses the entire mixture formulation information to their customer (the EU importer), so that the latter can do their submission. Nevertheless, there may be cases where complete information is not available or not given because of confidentiality reasons. Alternative ways to work around this problem are the following:

(a) If the non–EU supplier (the non-EU exporter to the EU) has a legal entity based in the EU (or a contractual agreement with an EU-based legal entity), then a submission through this legal entity can be made to the Member States where the EU importer intends to place the mixture on the market, although the non-EU entity or the corresponding EU-based legal entity are not legally required to do so under CLP. The non-EU company (or the corresponding EU-based legal entity) creates a UFI for their mixture which is included in the submission made by their EU based legal entity. Then they need to inform their customer (the EU-importer) about this UFI and confirm that the submission is done. Subsequently, the importer can do their own

submission/notification with a reference to this UFI in relation to the compositional information.

(b) The non EU-company does the submission via the EU-based legal entity on behalf of the EU importer so that does not need to disclose compositional information.

(c) The non-EU supplier (the non-EU exporter to the EU) does the submission, including the generation of a UFI, on behalf of their customer (EU importer) via the PCN portal, in which case they become a representative[14]. It must still be emphasised that the responsibility for the submission remains with the EU importer. Operators entering into such an agreement should be reminded about the need to exchange all the information which is necessary for the submission (e.g. end uses and relevant Member States) and to consider the need for future updates.

In all cases EU importer and non EU supplier should enter in a contractual agreement to cover the details of the submission approach chosen.

It is ultimately the responsibility of the EU importer to demonstrate that it complies with Annex VIII and thus to gather and submit the information required by Annex VIII. Therefore, it may be necessary to put additional effort in the communication with the non-EU supplier in order to obtain the necessary information. The duty holder may want to document such efforts for enforcement purposes to justify cases where the provided information is limited to the information obtained in an SDS.

FORMULATION ACTIVITIES

A company that produces a mixture is a formulator, and is covered by the definition of downstream user under the CLP and REACH Regulations.

Therefore, any company that formulates and places on the market a hazardous mixture meeting certain criteria (see section 3.3) has the obligation to submit the information in accordance with Annex VIII. The submission has to be made in all the Member States where the mixture is placed on the market by the formulator and their distributors in the official language of the relevant Member State (see below for more details).

A company formulating a mixture on behalf of another company/brand name is also a formulator (a toll formulator) and thus a downstream user. A toll formulator in the EU is the entity that first supplies and makes the mixture available on the market, even though the toll formulator does not itself own the product or the intellectual property rights.

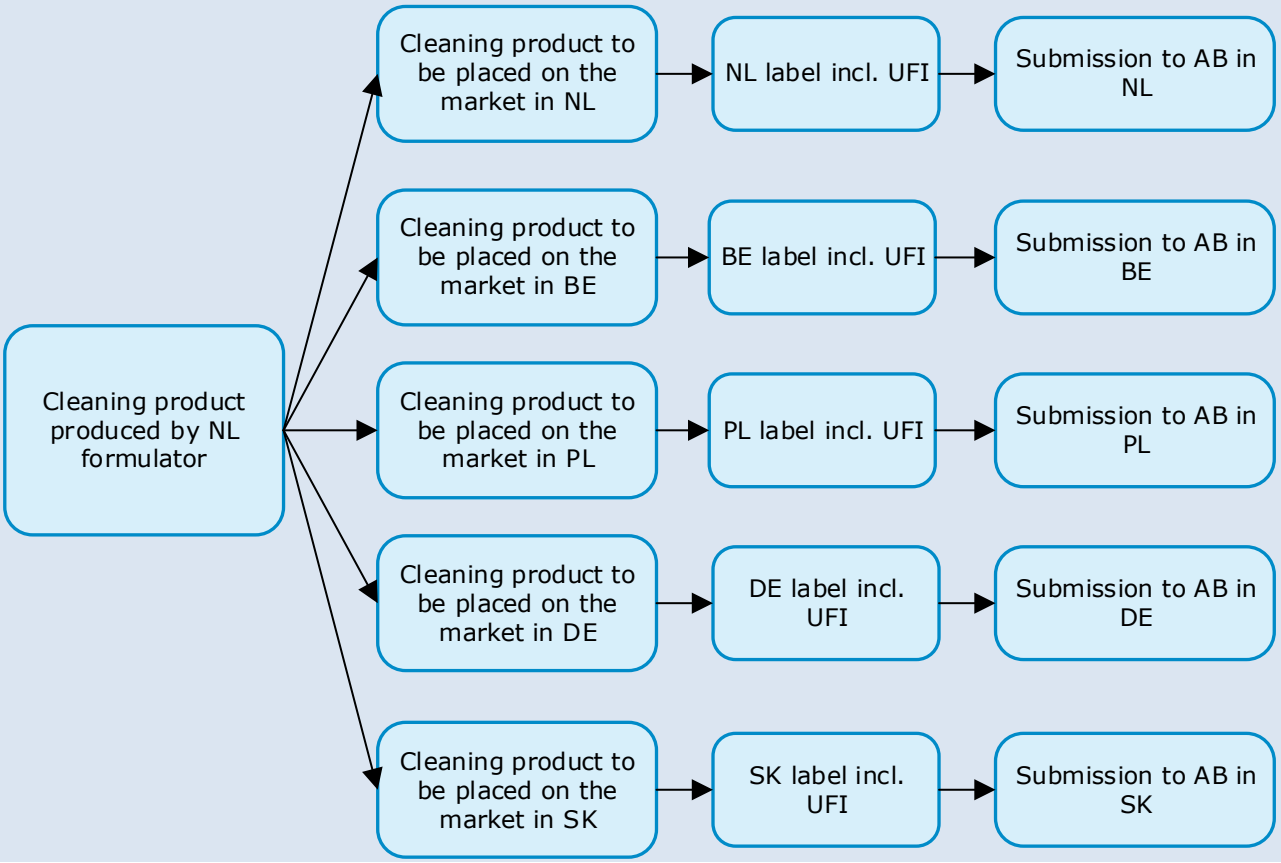
The toll formulator thus has the obligations associated with CLP Article 45. However, whether it is the toll formulator formulating the mixture or the company owning the mixture, (it may depend on contractual arrangements between the two parties) who submits information to the relevant appointed bodies. In practice, the company which actually produces the mixture should have the relevant compositional information required by Annex VIII. This is the company in the position to respond to any request for additional information from the authorities (in the cases foreseen by the legislation, see section 7). If the company owning the mixture produced by the toll formulator submits the information on behalf of the toll formulator, the toll formulator retains the responsibility for the submission. The company owning the mixture does not have obligations itself, as they would simply place on the market a mixture formulated by a supplier with, possibly, a different trade name (acting as re-

[14] To be noted that the use of the PCN portal provided by ECHA is not mandatory and it is up to each Member State to agree on the tools to be used.

branders, see below).

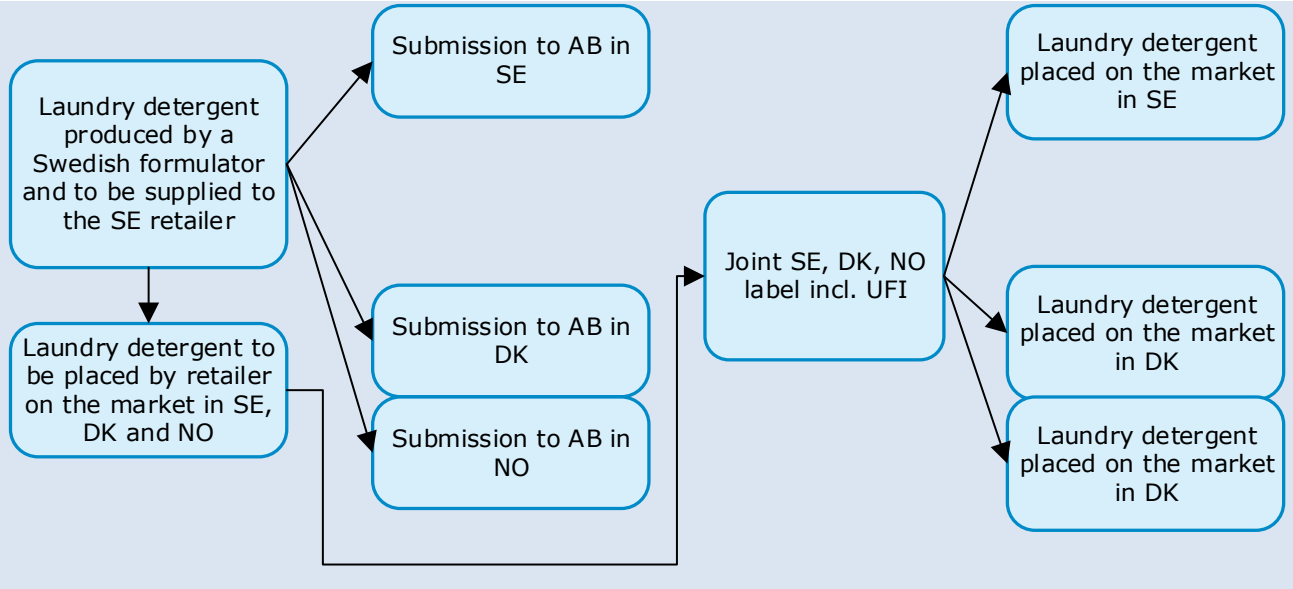
Example 3: Mixture placed on the market in several Member States

A company in the Netherlands formulates a cleaning product under the company brand name. The cleaning product is classified and labelled as flammable and irritating to the skin; it is sold in the Netherlands as well as to distributors in Belgium, Poland, Germany and Slovakia. The Dutch formulator must thus submit information in accordance with CLP Article 45 and Annex VIII to the appointed bodies in these five countries in their official language. In case the mixture is placed on the market in different packaging in the different member states, the information of the packaging relevant in each member state must be given in the specific submissions.



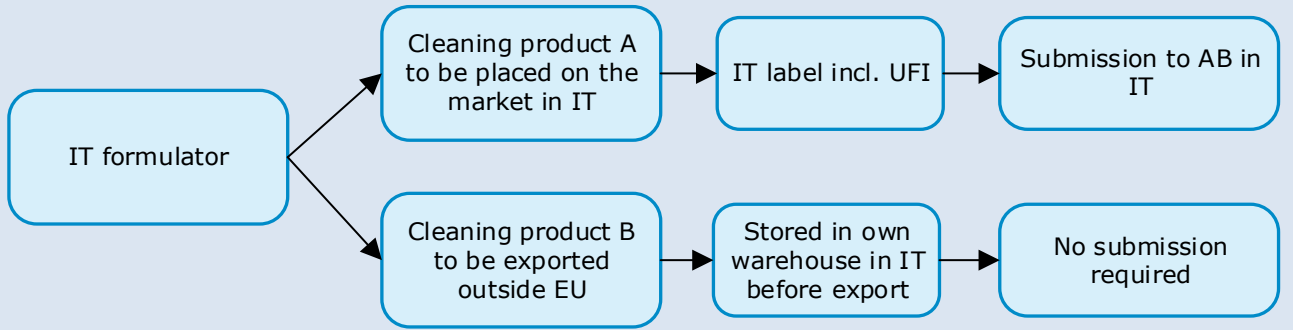
Example 4: Formulation, mixture placed on the market in several Member State

A formulator in Sweden formulates a laundry detergent for consumer use and sells it to a large Swedish-owned retailer selling the product in Sweden, Denmark and Norway. The laundry detergent is classified and labelled as causing severe eye damage. The relevant information must be submitted by the formulator to the appointed body in Sweden. Additionally, a submission needs to be done by the formulator in those Member States where the retailer intends to sell the product (as Norway has also implemented the CLP Regulation though the EEA agreement, the information must also be submitted to the appointed body in Norway). The label for the laundry detergent includes (in this example) all three languages.



A company that formulates a mixture but does not place it on the European Union market and only formulates with the intention of exporting does not have the obligation to do the submission[15]. For example, a formulator in Greece formulates a lubricant which is classified for aspiration toxicity. The lubricant is exported to Turkey, i.e. out of the EU. As the data submission requirements under the scope of CLP Article 45/Annex VIII only applies in the EU member states (and in countries under the EEA agreement) there are no obligations to submit data. If the product is stored in a temporary warehouse before being exported outside the EU, this may qualify as placing on the market and therefore the obligations according to Annex VIII apply. This would be the case if, for example, the formulator sells to a third party which stores the mixture in the warehouse before delivering it to a non-EU company.

Example 5: Formulation, mixture to be placed on the market outside EU



REPACKAGING ACTIVITIES

A company that repacks/refills (transfers from one container to another) a mixture and either keeps or modifies the content of the original label is performing activities that qualify as downstream user activities according to CLP (and REACH). This company is therefore a duty holder for the purposes of Annex VIII. This is the case even if the company does not perform any other activity with the mixture (e.g. no changes in the composition). As the company is placing a mixture on the market which is chemically identical to the one of their supplier, it could be requested from the supplier to do the submission on their behalf, by including the packaging and size in their submission. Alternatively the company that repackages mixtures

[15] Please, note that other obligations under CLP and REACH may also apply.

should do a separate submission. In both cases the company placing the mixture on the market (i.e. in the new package) remains responsible for the submitted information (i.e. the duty holder) even if in the first case the entity doing the actual submission would be a different party (i.e. the supplier).

3.1.1.1 Obligations and supply chain

The fulfilment of the obligation on importers and downstream users to submit the information in all the Member States where the mixtures is placed on the market requires consideration of the full supply chain, i.e. any distribution step is to be taken into account. Distributors normally supply the product further down the supply chain possibly in different Member States and changing trade names and/or labels.

It is the legal responsibility of the importer or downstream user as duty holder to submit the information in all the Member States where the product is placed on the market, either directly by the importer or downstream user or by the distributor. The duty holder has also to make sure that all trade names under which the mixture is placed on the market are covered by a submission to the relevant Member State. In practical terms this limits the possibility of data gaps and is beneficial for the poison centre, the trade name often being the most straightforward means of identification of a product.

It is to be noted that the formulator should expect collaboration from their distributors to receive information on where the product is placed on the market. In order to cover for potential distribution steps in the supply chain, it is strongly advised for duty holders to set up a contractual agreement with their distributors specifying that the distributor will inform their upstream supplier of the Member States where they place the product on the market, potential product name changes and any other relevant information. The upstream supplier (duty holder) can then include this information in their submission. Alternatively, if the distributor does not want to disclose this information, for example for reasons of confidentiality, the contract may stipulate that the distributor will submit the relevant information themselves.

3.1.2 Activities not leading to submission obligation according to Annex VIII

Companies in the supply chain of a mixture may have roles other than a downstream user or an importer role and may not be required to submit the information according to Article 45 and Annex VIII. An example of an activity which does not lead to such obligation is one that involves distribution only. If a company only stores and places on the market a mixture, without undertaking any other activity on the mixture, it is considered a distributor and does not need to submit the information.

However, distributors may also play an important role in the obligation placed on DUs and importers to make information available to poison centres for the purposes of their work (please see Appendix 1 to the *Guidance for Downstream Users* for more information on the role of the distributor). This is relevant, in particular, for distributors that sell the mixture in Member States other than the Member State where the downstream user or importer has supplied it. In this case, distributors are encouraged to communicate with their supplier to inform about the Member States where the mixture will be placed on the market in order to facilitate the duty holders in fulfilling their obligations. The supplier can then submit the information to the respective appointed bodies in the required language. Alternatively, the distributor may voluntarily decide to submit the information as requested by Annex VIII to the appointed body of the Member State where they place the mixture on the market, but there is no obligation for them to do so.

Please note, however, that in the case of distribution the upstream supplier is still a duty holder for the distribution step, as the distributor performs their activity on behalf of the upstream supplier. As stated above, in order for upstream suppliers to be able to fulfil their

legal obligations it is strongly advised that a contractual agreement is set up between the upstream supplier and the distributor stipulating any requirements for information sharing or submission of information by distributors themselves.

RE-BRANDING/RE-LABELLING ACTIVITIES

A company which re-brands and re-labels a mixture and places it on the market without performing any other activities, is not a downstream user according to CLP (and REACH) and therefore does not have the obligation to submit the Annex VIII information. Such activities fall under the definition of distributor's activity[16] and hence the legal obligation to submit information for this step in the supply chain falls again on the upstream duty holder as explained in sections 3.1.1.1. and 3.1.2.

The company which re-brands or re-labels is recommended to communicate with the supplier in order to facilitate the submission of the information to the relevant appointed bodies in accordance with Annex VIII by the duty holder (the upstream downstream user or importer). The rationale behind this is that if a product name changes and no new submission is made, the poison centre may not be able to retrieve information based on the product name given by a caller or the poison centre might be confused by the difference between the UFI and the trade name that it has on record.

As with re-packaging activities, the re-branding company could alternatively agree via contractual agreement with their supplier and do themselves a submission containing the additional product names/brands under which the product will be placed on the market.

Example 6: Formulation and re-labelling and placing on a new market
A company in France formulates and intends to sell "Super Wash" on the French market. The mixture is labelled hazardous for human health and the formulator has submitted all relevant information to the appointed body in France.

The company decides to open up markets and to sell the same product in Spain and Germany. The company re-labels the product, keeping the brand name "Super Wash", and submits the relevant information to the Spanish and German appointed bodies.

A customer (distributor) in Spain decides to sell this product (with no changes in the composition) with their own brand "Ultra Clean". As the distributor does not want to disclose to their upstream supplier the fact that they place the same chemical on the market under a different name, the distributor submits the required information to the Spanish appointed body. This is in line with the contractual agreement drawn up between the distributor and the formulator.

[16] See the *Guidance for downstream users* for more details.

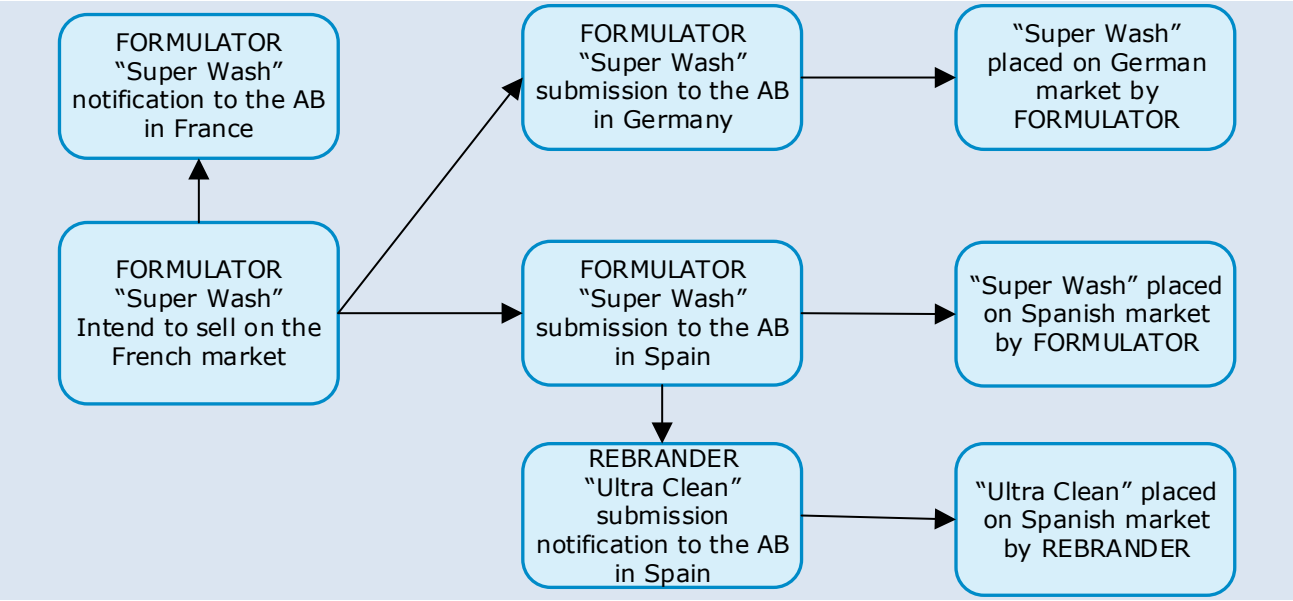

FORMULATOR
"Super Wash"
notification to the AB
in France
FORMULATOR
"Super Wash"
Intend to sell on the
French market
FORMULATOR
"Super Wash"
submission to the AB
in Germany
"Super Wash"
placed on German
market by
FORMULATOR
FORMULATOR
"Super Wash"
submission to the AB
in Spain
"Super Wash" placed
on Spanish market
by FORMULATOR
REBRANDER
"Ultra Clean"
submission
notification to the AB
in Spain
"Ultra Clean" placed
on Spanish market
by REBRANDER

Table 1: Overview of operators and activities triggering or not obligations under Article 45 and Annex VIII

Operator	Category	Legal obligation to submit? (duty holder/submitter)?	Why?	Obligations along the supply chain	Options
Importer	Importer	Yes	Legal text	The mixture may be placed on the market in different Member States by distributors, who may possibly rebrand or relabel the product. It is the DU/I's obligation to submit the information in each Member State where their distributors place the mixture on the market and to cover the different brands/trade names.	A company may rely on their supplier (e.g. mother company) or other company to do the submission on their behalf - this submission would include their product details. They remain duty holder (if applicable, i.e. re-packager and re-filler) but they are not the legal entity submitting of the information in the submission system. Contractual agreement may be needed between the duty holder and the company preparing the submission on its behalf. This should address all possible scenarios: update responsibilities, access to the file, etc…
Formulator	DU	Yes	Legal text		
Re-packager	DU	Yes	Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA *Guidance for downstream users*.		
Re-filler (see also above for re-packager)	DU	Yes	Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA *Guidance for downstream users*.		

Toll formulator	DU	Yes	Toll formulators are downstream users. See ECHA *Guidance for downstream users*.		
Distributors	Distributors	No	Legal text	n/a	Advice to set up contractual agreement between distributor and supplier stipulating that the distributor shall either: - inform the supplier of the change of name and Member State(s) where the product is placed on the market. - submit the information on behalf of the supplier (who remains the duty holder).
Retailer	Distributor	No	Storage/placing on the market of mixtures to consumers without performing any activity qualifying as DU activity. See also ECHA *Guidance for downstream users.* The distributor uses the same UFI as the supplier/duty holder.	n/a	
Re-brander	Distributor	No	Actor who applies his own brand to a product that somebody else has manufactured and places the product on the market. The activity is not considered as a DU activity. See also ECHA *Guidance for downstream users*.	n/a	

Re-labeller	Distributor	no	Actor that affixes the label to a mixture that somebody else has already labelled. The activity is not considered as a DU activity. See also ECHA *Guidance for downstream users*.	n/a	
Commercial representative (=consultant)	The commercial representative is assigned the task to submit in the name and on behalf of the duty holder (DU, importer).	No	Legal text	Need for a contractual agreement (mandate).	

3.2 Who receives the information?

The company that is required to submit the information according to Annex VIII, has to make sure that this information is submitted to the appointed bodies of all the Member States where they place the mixture on the market. Additionally they should make sure these include the Member States where their mixture is sold via, e.g. distributors.

The information will eventually be made available to the poison centres and the personnel dealing with emergency responses in the Member State where the mixture is placed on the market.

3.2.1 Member States' appointed bodies

Article 45(1) of CLP establishes that each Member State must appoint a body (or bodies) responsible for receiving the information supplied by importers and downstream users about mixtures placed on the market that are classified as hazardous based on their health and physical effects (excluding explosives and gases under pressure). The national appointed body or bodies may be a Member State Competent Authority on CLP (MSCA), a poison centre, a National Health Authority or another body appointed by the MSCA. The appointed body or bodies in a given Member State must have access to all the submitted information from the importers and downstream users placing mixtures on the market in that Member State in order to carry out their tasks related to emergency health response. In those cases where the appointed body is not the poison centre, the national appointed body or bodies make the submitted information available to the poison centres.

A list of national appointed bodies is available at the ECHA Poison Centre website: https://poisoncentres.echa.europa.eu/

The appointed bodies must ensure that the information received is kept confidential and is only used for the purpose of Article 45(1) and (2) of CLP. Furthermore, Member States may wish to undertake statistical analyses of information supplied to the national appointed bodies in order to identify where further or improved risk management measures may be necessary. See section 7.2 for further information about the use of the submitted information.

3.3 About what information has to be submitted?

This subsection provides guidance on the scope of Article 45 and Annex VIII to CLP. It clarifies for which mixtures there is an obligation to submit information to the appointed bodies according to the legal text, which mixtures are exempted from the obligation and which information could be submitted on voluntary basis.

It is important to clarify that Article 45 and Annex VIII apply to *mixtures*. Substances[17], either classified or not, are excluded from the obligation to submit information according to Article 45 of CLP.

Sections 4 and 5 below provide more information on the content of the submission as well as special situations including reduced information requirements.

[17] Definitions in Article 2 of CLP (and Article 3 of REACH) apply. See Section 2 of this Guidance for a full list of relevant terms and definitions.

3.3.1 For which mixtures information has to be submitted?

Annex VIII to Regulation (EC) No 1272/2008 requires the submission of information about mixtures that are placed on the EU market and classified as *hazardous* based on their *health* or *physical* effects. It means that all mixture meeting the criteria defined in Part 2 and Part 3 of Annex I to CLP fall under the scope of Article 45 and Annex VIII. The CLP Regulation and Annex VIII provides for few exemptions from the requirements of the CLP Regulation as specified in Article 1:

- radioactive mixtures;
- mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- mixtures used in scientific experimentation, analysis or chemical research, provided they are not placed on the market and they are used under controlled conditions in accordance with EU workplace and environmental legislation;
- waste; and
- certain mixtures in the finished state, intended for the final user:
    - medicinal products,
    - veterinary medicinal products,
    - cosmetic products,
    - medical devices which are invasive or used in direct physical contact with the human body, and in vitro diagnostic medical devices (Directive 98/79/EC27), and
    - food or feeding stuffs.

Among the mixtures which fall under the scope of the CLP Regulation, those classified for environmental hazards *only* are outside the scope of Article 45 and information according to Annex VIII does not need to be submitted. Also mixtures which are subject to supplemental labelling requirements according to Part 2 of Annex II to CLP but are not themselves classified for health or physical hazards are not subject to submission requirements.

3.3.1.1 Exemptions from the obligation to submit information

The following mixtures, even if falling under the scope of the CLP Regulation and classified for health and/or physical hazards, are exempted from the obligation to submit information. This is specified in section 2, Part B of Annex VIII:

- mixtures for scientific research and development (as defined in Article 3(22) of Regulation (EC) No 1907/2006),
- mixtures for product and process oriented research and development (as defined in Article 3(22) of Regulation (EC) No 1907/2006),
- mixtures classified only for one or more of the following physical hazards:
    - (1) gases under pressure;
    - (2) explosives (unstable explosives and Divisions 1.1 to 1.6) (as defined in Annex I, 2.4 and 2.1 respectively, of Regulation (EC) No 1272/2008).

3.3.1.2 Voluntary submission of information

For mixtures which are not subject to submission obligations (see sections 3.3.1 and 3.3.1.1), submission may be done on a voluntary basis.

In fact, although it is not mandatory, submission of relevant information about mixtures not classified on the basis of their health or physical effects is encouraged, to facilitate the appointed bodies and poison centres activities. The availability of information even on such mixtures would significantly decrease possible uncertainties in case of emergency calls and therefore it would reduce incorrect medical advice and/or overtreatment.

Mixtures for which submission is not required can be also used in the formulation of other classified mixtures (mixture in a mixture or MiM) generating potential gaps in the knowledge of mixture composition. When the duty holder does not know the composition of the MiM, it would rely on the SDS of that mixture, which does not provide all the relevant information. The supplier could, following a voluntary submission, communicate the compositional information to the customer via the UFI while ensuring the protection of confidential business information. Lack of detailed compositional information could hamper the medical advice in the event of an emergency or in the establishment of risk management measures by authorities. In cases where the appointed body and poison centre does not have access to the full composition of the mixtures, the response in case of an emergency could potentially lead to incorrect medical advice and /or overtreatment. A voluntary submission of the mixture to be used in another mixture would allow the emergency responder to retrieve all the necessary information.

3.3.2 Use types

The identification of the correct use type for the mixture for which submission is done is important as it defines the information requirements and the deadline by which the obligations have to be fulfilled. Annex VIII, Part A, Section 2.4 defines three types of use as follows:

- **Mixture for consumer** use means a mixture intended to be used by consumers;
- **Mixture for professional** use means a mixture intended to be used by professional users but not at industrial sites;
- **Mixture for industrial** use means a mixture intended to be used at industrial sites only.

The use types are based on the concept of *end-use* which is defined in ECHA Guidance R.12 on *Use Description*[18]. This Guidance also includes considerations on whether a use if professional or industrial. In applying this approach to mixtures, this means that the use of a mixture continues when it is incorporated in another mixture until it reaches its end-of-life stage.

Therefore, if a mixture formulated to be used in an industrial setting ("original mixture") is subsequently also integrated by a downstream user into a mixture for consumer or professional use ("final mixture"), the original mixture should be considered to be for professional or consumer use and the corresponding information requirements must be fulfilled (see section 3.4). When exposed to the final mixture, professionals or consumers come into

[18] "End-use" means the use of a substance as such or in a mixture, as a last step before the end-of-life of the substance, namely before the substance is consumed in a process by reaction during use (including intermediate use), is emitted to waste streams or the environment or is included into an article. The ECHA Guidance R.12 belongs to the full *Guidance on Information Requirements and Chemical Safety Assessment* which is available at https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

contact with the original mixture which is contained in the final mixture. For poison centres to be able to provide an appropriate emergency health response, sufficiently detailed information on the final mixture and its components needs to be available.

Figure 1 below illustrates by means of an example how to identify information requirements and the applicable deadline on the basis of the use type.

While upstream formulators may not always have a complete and detailed overview to what end their original mixtures are used, they often do have the general knowledge whether their mixtures are incorporated in mixtures for professional/consumer use. The company preparing the submission should make an effort to gather all the relevant information about the final use of their mixtures. If new information about the use of the mixture becomes available after the submission, the information submitted under Annex VIII needs to be updated accordingly if needed.

A different approach to the above interpretation on the use of original mixtures may be followed when the original mixture ends up in a final mixture, which is not subject to submission obligations (e.g. the final mixture is a cosmetic product, or the final mixture is not hazardous). In this case, the standard submission for the original mixture is not necessary. Instead, fulfilling the information requirements for mixtures for industrial use suffices.

3.4 Timelines

3.4.1 Dates of application

The deadline for the submission of the new information requirements set by the amended CLP Regulation[19] will apply in a stepwise manner, according to the intended use of the mixture (see section 3.3.3). Importers and downstream users placing mixtures on the market not already notified under national legislation must comply with Annex VIII of the Regulation from the following dates:

- Mixtures for consumer use: from 1 January 2020.
- Mixtures for professional use: from 1 January 2021.
- Mixtures for industrial use: from 1 January 2024.

By 1 January 2025 for all mixtures on the market submission must be done under the harmonised Annex VIII requirements (see also section 3.4.2).

If a mixture has several types of use, the earlier corresponding deadline applies and related requirements must be met. For instance, in the case of a glue classified as hazardous for health effects, and placed on the market for both consumer and professional use, the earlier deadline of 1 January 2020 will apply.

Before these dates, mixtures continue to be subject to existing national requirements. Duty holders should contact the appointed body in the country of interest to check their requirements during the transitional period. A list of national appointed bodies is available at the ECHA Poison Centre website: https://poisoncentres.echa.europa.eu/

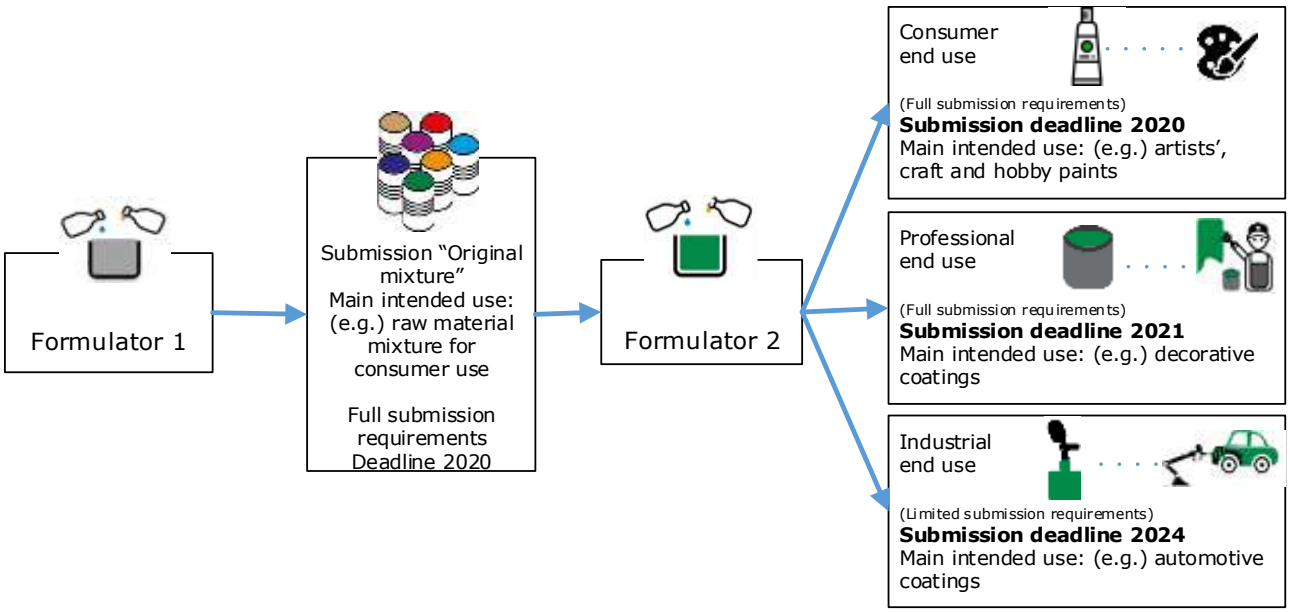
Companies can decide to do a submission in accordance with Annex VIII before the dates mentioned above. However, in that case it should be verified with the relevant appointed body whether it already accepts submissions in the new format and whether this releases from the

[19] It is amended by Commission Regulation (EU)2017/542 by adding Annex VIII.

duty to make a parallel submission according to national provision being in force until the date of applicability of Annex VIII.

Independently from any obligation under Annex VIII, obligations at national level may also remain valid and may still need to be fulfilled regardless of the submission of a done under the new format.

Figure 1: Identification of information requirements and deadline according to the use type



3.4.2 Transitional period

If a company has already submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the relevant date of applicability (i.e. according to the notification requirements existing at that time in any given Member State), there is no obligation to comply with Annex VIII until 1 January 2025 (transitional period), except in case of changes to their mixture (see below).

If the company intends to keep placing the same product on the market after 1 January 2025, they will have to provide a new submission in full accordance with Annex VIII of the Regulation by that date. As of 1 January 2025 'old' submissions will be considered as 'archived' and not relevant with regards to Annex VIII. Thus, operators must ensure that a new submission is done in due time to allow them to continue placing the mixture on the market.

However, as soon as the mixture composition, product identifier or toxicological properties change during the transitional period (i.e. before 1 January 2025), the duty holder is required to do a submission for the changed mixture in accordance with Annex VIII before it is placed on the market (relevant information is provided in section 7 of this Guidance, where the needs for an update are discussed).

A submission done under the existing national system(s) according to the existing definition of end use remains valid. The company does not need to comply with Annex VIII before the end

of the transitional period for the only reason that a new definition of end use applies, i.e. without actual change of use.

4. General submission requirements

This section of the Guidance introduces the obligations under Article 45 and the main elements concerning the submission of information as required by Annex VIII. Once the duty holder and their need to fulfil the obligations are identified as explained in section 3, certain concepts and possible ways forward should be understood before starting to prepare the submission. These are explained in this section.

4.1 Overview

A company placing a mixture on the market and subject to obligations under Article 45, has to provide the information required by Annex VIII to the appropriate appointed body in the Member States where the mixture is placed on the market. The submission must be made either directly to the national appointed body or using the PCN portal at ECHA, and must be submitted by electronic means in a harmonised XML format provided by ECHA (see section 6 for the details on the available submission tools).

In order to improve the emergency response and facilitate the work of poison centres in general, a new more specific means for the unique identification of a mixture has been introduced by Annex VIII. Labels for mixtures placed on the market will generally be required to carry a Unique Formula Identifier (UFI)[20]. A UFI enables rapid and unambiguous identification of the information submitted on the mixture by any poison centre called upon to provide advice on dealing with a poisoning incident. Information on the generation and use of UFIs is provided in section 4.2.

Duty holders are also requested to provide information on the main intended use of the mixture (e.g. detergent, construction product, plant protection products, etc.) which is important for both emergency response and statistical analysis purposes. In order to facilitate the transmission of such information and its use by the receiving bodies, a European Product Categorisation System (EuPCS) has been developed. Section 4.3 illustrates the concept and provides relevant links.

The company which is required to do the submission should be aware that besides the standard submission, the Regulation allows a limited submission for products intended for industrial use only (see section 3.3.2 on use categories). This option is presented in section 4.4.

Companies can also decide to submit information:

- for **single mixtures** (placed on the market with one or multiple trade names, which can be included in the same submission) or,
- if certain criteria are met, to opt for a **group submission** which brings together multiple similar mixtures (differing for certain specific component types) into one

[20] Part A, point 5.3 of Annex VIII includes derogations for mixtures for industrial use only and mixtures not packaged (see section 4.2 for more details).

submission. Information on the group submission option and the criteria to be met are provided in section 4.5.

The information to be submitted includes the physical, chemical and toxicological properties of the mixture, its composition and its classification. Much of this information should be available in the SDS, however a SDS under REACH usually does not contain all the information required. Duty holders may need to complement information from other own sources or consult their supplier for more specific information, especially regarding composition. The specific information requirements for the different submission types (standard and limited, individual and by group) are listed in Part B of Annex VIII and detailed in the following section 5 of this Guidance document.

It is important to underline that the language used in the submission has to be that of the Member State where the product is being placed on the market, unless the Member State specifies otherwise. Some of the Member States may accept submissions in English as an alternative to their own language. A table listing Member States accepting submissions in English is available on ECHA Poison Centre website at https://poisoncentres.echa.europa.eu/. When the operator places the same mixture on the market in more than one Member State, the individual submissions will need to be made in all the appropriate languages.

The PCN portal developed by ECHA supports multilingualism by allowing the preparation of the submission in the preferred language as well as supporting in the distribution of the information in the language(s) of the relevant Member State(s).

4.2 UFI

4.2.1 What is a UFI?

Poison centres and appointed bodies have reported experiencing problems with the correct identification of the mixture in case of accidental exposure in up to 40 % of the calls they receive. Therefore, as part of the harmonisation of information requirements, a unique alphanumeric code to be printed or affixed to the label was introduced as an additional means of identification of a mixture. This code, or UFI (Unique Formula Identifier) is a unique 16-digit alphanumeric code that unambiguously links the submitted information on a mixture (and hence information relevant for the treatment of patients) to a specific mixture placed on the market. All products labelled and for which submission is done with the same UFI need to share the same composition. However, different UFIs can be used for the same mixture, as long as those UFIs have been submitted to the appointed bodies. The same mixtures may be placed on the market under different trade names and by the same or different operators. In those cases, operators can decide to use the same UFI, as long as the mixture composition does not change or the variation is limited and does not have an impact on the toxicological information (see section 5 for details). For marketing and/or confidentiality reasons, operators may also decide to generate and affix on the label of each product a different UFI although the mixture composition of those products remains the same. In such case, all UFIs assigned to the mixture must be provided as part of the submission for that mixture.

The UFI is meant to complement the other means used by poison centres to identify the poisoning agent, such as the product and/or brand name. When entering the UFI in their databases, appointed bodies or poison centres may find several products and related submissions, but all those products or submissions will have or describe the same composition. Below an example is given of what a UFI looks like:

UFI: E600-30P1-S00Y-5079

The UFI is an information requirement to be submitted to the appointed body according to Annex VIII.

4.2.2 Generation of UFI

Companies are responsible for the generation and management of the UFI for their mixtures. A software application (the UFI generator) has been developed to allow industry to generate UFIs. ECHA provides the tool and the user manual free of charge. Both are available on the Poison Centres website at https://poisoncentres.echa.europa.eu/.

The UFI of a specific mixture is based on the VAT number of a company and a formulation number assigned by the company to this specific mixture. The use of the VAT number is meant to ensure that there is no duplication between UFIs generated by two different companies. Indeed, different companies will use similar formulation numbers, but as long as they use different VAT numbers, the algorithm generates a new UFI each time.

Companies are responsible for generating and managing the UFIs under a specific VAT number. They need to communicate internally and manage properly the formulation numbers used under a specific VAT number to ensure that every mixture composition has its own UFIs – in other words, the same UFIs must never be used for mixtures that have different compositions. A certain degree of flexibility is allowed in the use of the UFIs in order to ensure confidentiality of business information (see examples below in 4.2.3).

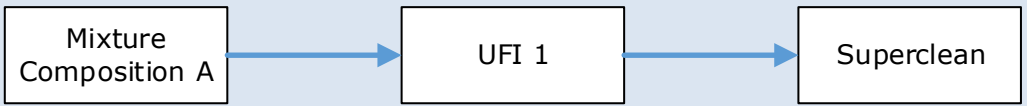
Note that for companies not having a VAT number an alternative method for generating a UFI exists (more information available in the UFI generator Manual).

4.2.3 How to use UFI

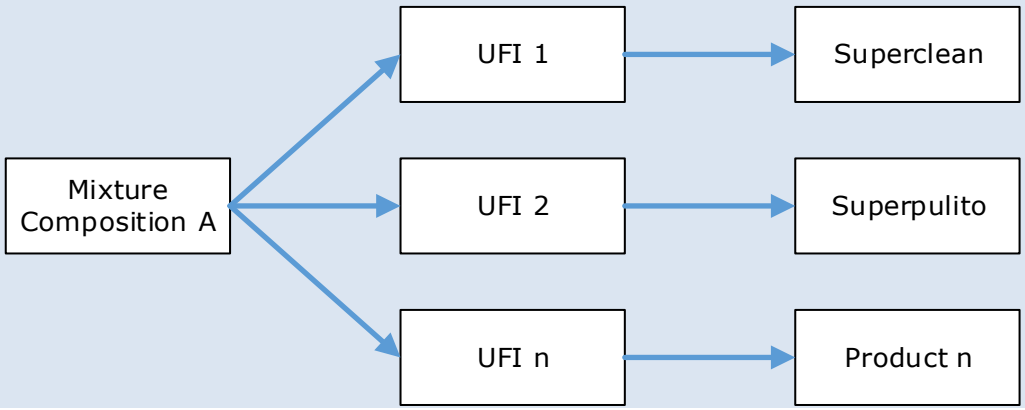
In the following paragraphs a number of examples are presented showing with increasing level of complexity how and when a UFI has to, or can be, generated; graphical representations are also provided to support the reader. The following examples illustrate the flexibility around UFI generation and its use, while ensuring the essential condition is fulfilled: the same UFI(s) can be used for several products only if those products share the same composition (according to concentration ranges defined in Annex VIII).

Note that the same UFIs can be used across the EU market for the same mixtures, providing that for those mixtures submission including the UFIs has previously been done to the relevant Member States.

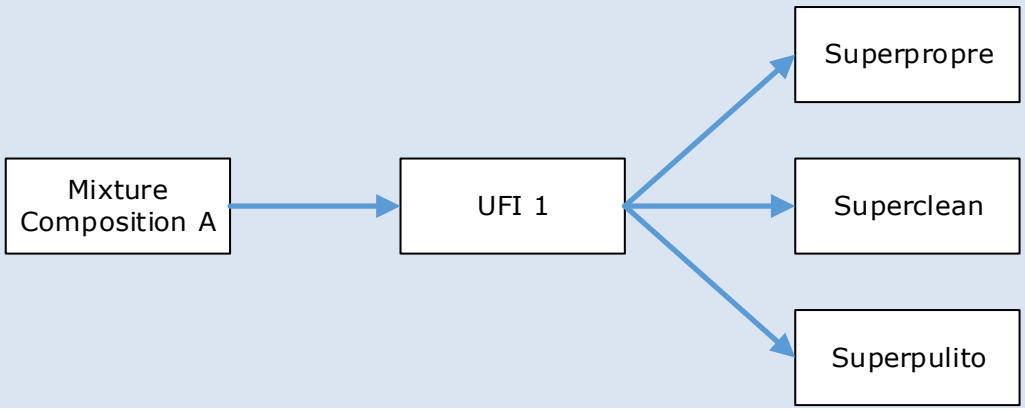
Example 7: 1 Mixture composition– 1 UFI – 1 Product placed on the market ("Superclean")



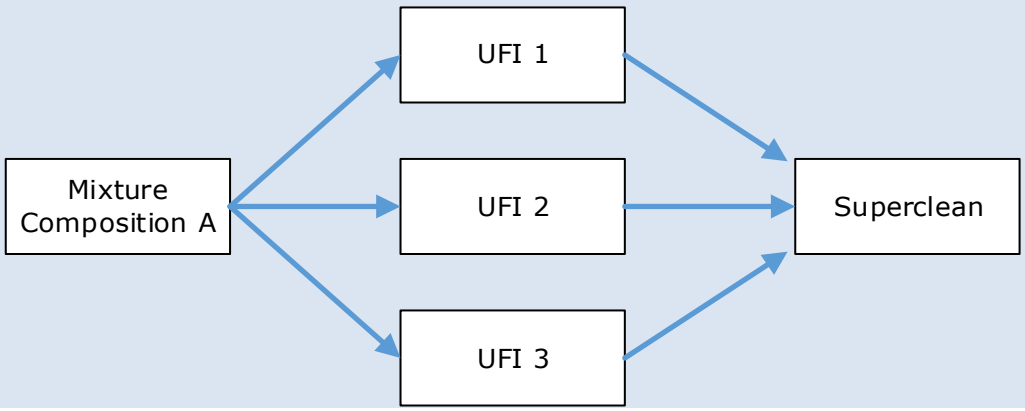
Example 8: 1 Mixture composition– 2 or more UFIs – 2 or more Products placed on the market with same composition



Example 9: 1 Mixture composition – 1 UFI – 3 Products placed on the market



Example 10: 1 Mixture composition – 2 or more UFI – 1 Product placed on the market

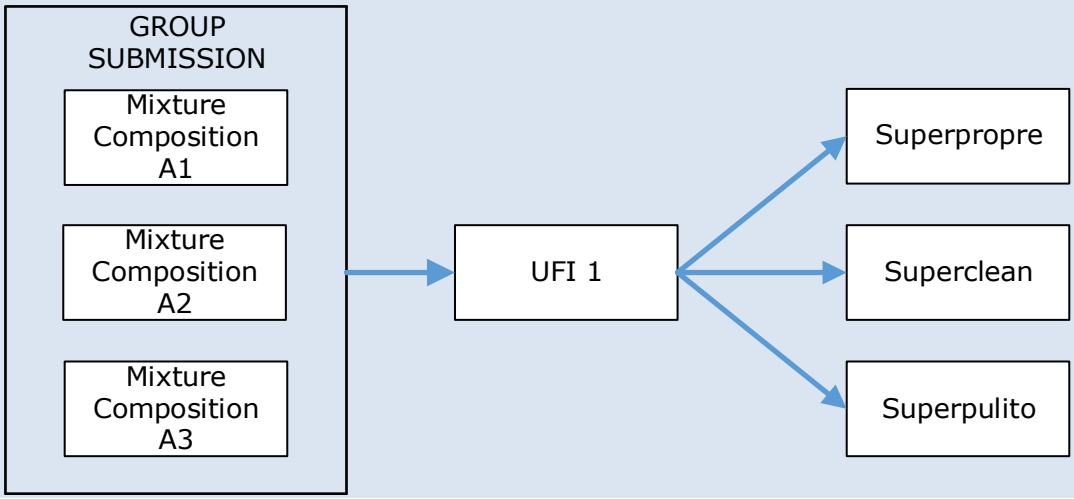


Note to examples 8 to 10: When several UFIs have been generated and assigned to one mixture, all those UFIs need to be included in the submission to the relevant MS and can be submitted individually or in the same submission.

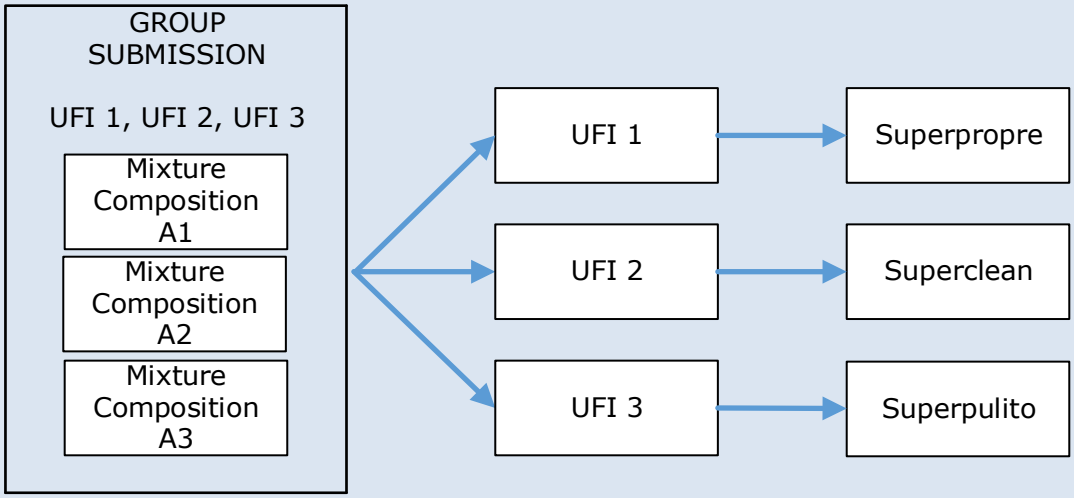
For group submissions (see section 4.5), one UFI can be used to cover the whole group of mixtures (although it is not an obligation). This is illustrated in examples 10 and 11 below. Note that the allowed differences in the composition of mixtures in a group submission are

limited (see section 4.5 and 5.4 for details).

Example 11: Three similar mixtures (1 Group submission) - one UFI, one or more Products placed on the market



Example 12: Three similar mixtures (1 Group submission) – several UFIs, one or more Products placed on the market.

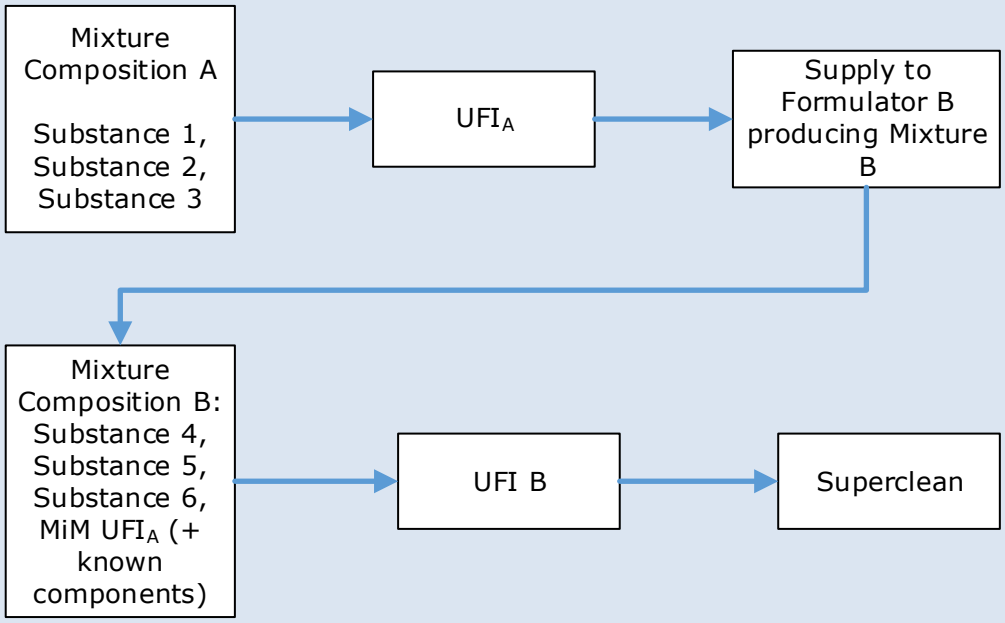


4.2.3.1 UFI and mixtures in a mixture

As defined in Annex VIII, mixture components can include other mixtures, referred to as mixtures in mixtures (MiM). By default, duty holders need to submit information on the full composition of their mixture and therefore include information on the MiM composition. However, when there is no access to the full composition of the MiM supplied, the MiM's UFI can instead be indicated in the submission together with the known MiM's components (at least those found in the SDS). Providing that submission for the MiM has been previously done to the relevant appointed bodies, having the UFI of the MiM will allow appointed bodies (and ultimately the poison centres) to link the mixture submission with the submission of the MiM and retrieve the relevant information in case of an emergency involving the mixture containing such MiM.

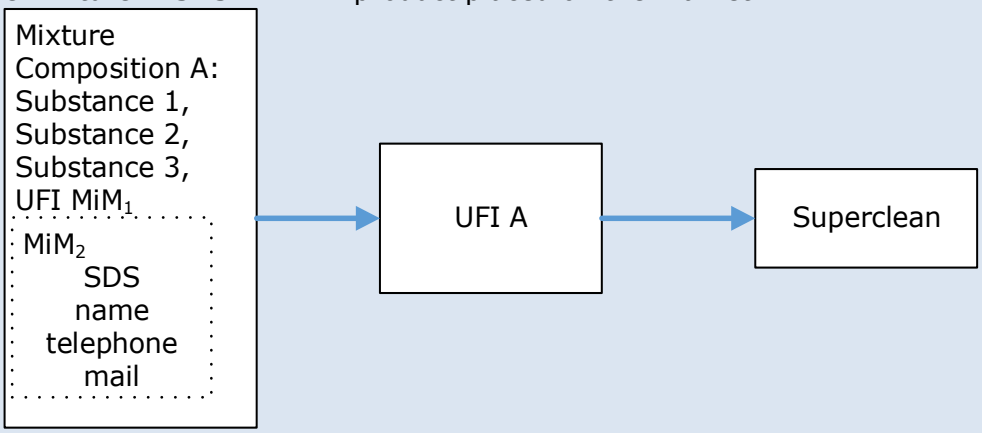
More detailed information about information requirements for mixtures and their components is provided in section 5.

Example 13: 1 Mixture (with 1 MiM identified via its UFI) - 1 UFI for the mixture– 1 product placed on the market



If the MiM does not have a UFI and the composition is not known, as a last resort the safety data sheet of the MiM must be provided as well as the name, email address and telephone number of the MiM supplier (see section 5 for more details on information requirements).

Example 14: 1 Mixture (with 2 MiMs, the first identified via its UFI, the second via its SDS) - 1 UFI for the mixture + SDS MiM – 1 product placed on the market



4.2.3.2 Use of the UFI along supply chain and for Legal entity changes

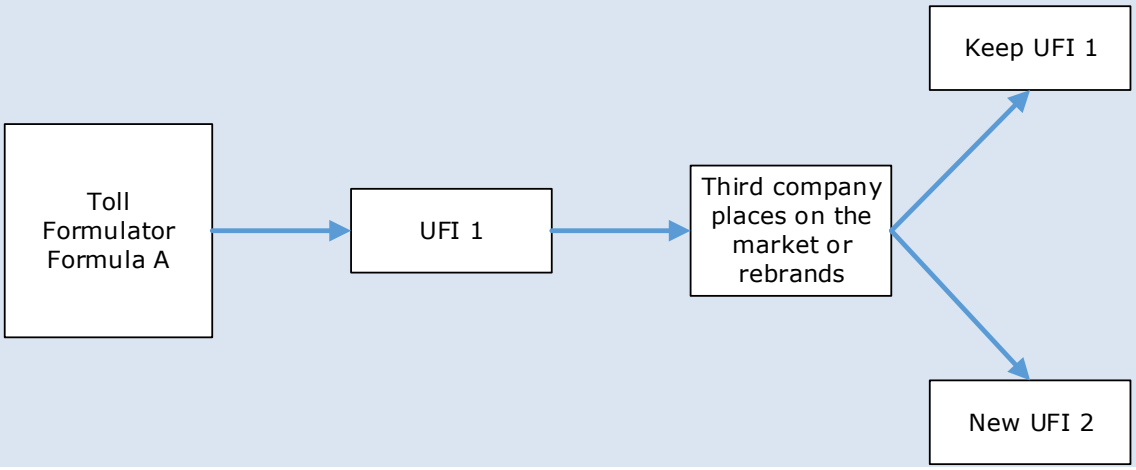
As long as the mixture composition remains the same, the same UFI can (but not necessarily) be used by other downstream users/formulators in the supply chain (in case of formulator, this would become UFI of a MiM). In other words, if a downstream user purchases a product with a UFI and does not modify the mixture, they can choose to use the same UFI for their own products and in their own submission. Alternatively, the downstream user may generate and submit a new UFI .

If the company generating the original UFI changes legal entity or ceases its activity, the UFI already generated remains valid and can continue to be used by the company successor, as long as the mixture composition remains the same (in the allowed concentration ranges defined in Annex VIII).

4.2.4 Toll formulator and UFIs

A toll formulator is a service providing company that formulates a mixture on behalf of another company and often also provides the label with the contact details and brand name of the customer (more details are in section 3.2). With regard to the use of the UFI, the toll formulator has to generate a UFI for the mixture placed on the market, include it in their submission and provide it to the customer. If the latter does not change the formulation, it can use the original UFI provided by the toll formulator. Alternatively, the toll formulator's customer can create a new UFI if desired (e.g. in case of relabelling). The new UFI needs to be included in the submission and printed or affixed to the label.

Example 15: 1 Formula by a toll formulator - 1 UFI for the composition – 1 third company places on the market/rebrands – Original UFI or new UFI



4.2.5 How to manage UFIs

Companies will need to keep an overview in their internal systems of which mixture corresponds to which UFI and keep track of changes and updates (the main reasons being to avoid the use of the same UFI for mixtures with different compositions).

It is strongly recommended that the data management system allows maintaining and recording for internal use the relation between the following values for every mixture:

- The UFI;
- The VAT number used to generate the UFI
- The internal formulation number used to generate the UFI;
- The internal formulation code of this mixture, if different from the formulation number.

As described in the user guide on "UFI generator application" [21] the UFI is generated on the basis of a company VAT number and on an internal formulation number. The latter needs to be a 9 digit number between 0 and 268435455 and therefore companies need to keep their own

[21] Available at https://poisoncentres.echa.europa.eu/ufi-generator.

records/cross referencing and manage an internal mapping of their formulation codes with the internal formulation numbers.

Normally companies identify their products with an internal code; it is highly unlikely that such internal codes can be used directly for the generation of the UFIs since the former often contain letters, special characters or more than 9 digits. Therefore, if the company's internal coding system cannot be adapted to be used directly in the UFI tool, it is necessary to convert the original internal code and generate a new internal company formulation number based on which a UFI can be created.

In addition, if a single existing internal company code is used to represent different mixtures, new internal company formulation numbers could also be necessary in order to ensure different UFIs are assigned to different mixtures (this is likely to be the case when mixture management or SDS generation tools are used by the company).

It is strongly advised to record the information mentioned above. Mapping should be established in the system that companies/submitters will use to manage their submissions in order to guarantee that a correct relation is maintained between the mixture information stored (company, trade name, composition, physic-chemical properties, classification) and its UFI. This will be useful for the efficient management of the current products (e.g. different batches of the same mixture for which labels have to be created) and to keep track in case of updates.

4.2.6 New UFI as a result of composition changes

Since the main purpose of the UFI is to unambiguously link a mixture on the market and the corresponding information relevant for an emergency health response, the UFI is always linked to a specific composition[22]. Annex VIII to CLP requires that a new UFI be created in case the mixture composition changes according to certain criteria. In particular, a new UFI has to be created when there is:

1. ***A change of components (addition, substitution or deletion of one or more components)*** - the addition, substitution or deletion of one or more components is considered a major change requiring the creation of a new UFI. Note that this applies to the components which are required to be indicated in the submission (e.g. the change in a component which is not classified for health or physical effects and present in concentration < 1% would not require a new UFI). A derogation to this principle is provided for mixtures in a group submission containing perfumes or fragrances if the change in the composition only relates to those components.

2. ***A change in concentration beyond the concentration range provided in the original submission*** – For the declaration of the concentration of mixture components it is possible to use concentration ranges (see section 5.3 on information on mixture components). If the new concentration of a particular component exceeds the given range (indicated in the original submission) a new UFI has to be created and an update of the submission has to be provided accordingly. If the change is within the range, there is no requirement to update the UFI but the submission can be voluntarily updated. In case of multiple changes within the ranges followed by voluntary updates, the UFI has to be updated as soon the concentration exceeds the range indicated in the original submission.

3. ***A change in concentration beyond the limits allowed for exactly declared concentrations*** - For the declaration of the concentration of mixture components it is

[22] Note, in case of group submission the same UFI could be used to refer to several similar mixture compositions.

possible to use the exact concentration, in which case concentration changes are allowed within certain limits. If the new concentration exceeds the allowed variation, a new UFI has to be created and therefore an update of the submission has to be provided accordingly. If the new concentration does not exceed the allowed variation, (which is always measured against the initial submission, regardless of the number of possible subsequent voluntary updates), the submission can be voluntarily updated without the need for a new UFI. The same applies in case of further changes as long as the new concentration does not exceeded a total allowed variation.

It should be noted that the changes discussed in this section concern components which are required to be indicated in the original submission, so besides triggering the need to create a new UFI these changes trigger at the same time the need to update the whole submission. More details are provided in section 7.3.

It is also to be noted that changes to the UFI may occur as a result of a commercial decision of the company, even if none of the above conditions are fulfilled (the composition remains the same and a change of the UFI is not legally required). A company may decide to change the UFI voluntarily whenever other changes occur, possibly because of their internal change management system (an example would be a change of packaging which is considered by the company as a new product). For voluntary changes of UFI, an update of the submission is required the same way as for the mandatory change of UFI.

4.2.7 Placement and display of UFI

The UFI must be printed or affixed to the label of the hazardous mixture for which submission obligations apply (see derogations mentioned in section 4.2.7.2). It must be preceded by the acronym "UFI" in capital letters and must be clearly visible, legible and indelibly marked.

The legal text specifies that the UFI must be indicated on the label but it does not cover other requirements that should be taken into account when preparing the label information. The following suggestions are provided to enhance the recognition of the UFI by users and consumers and to assist the communication with appointed bodies and poison centres.

- No additional marker than “UFI” should appear before the actual UFI code.
- The UFI is related to a specific composition, but as it can also be seen as an element of product identification - the UFI (with the “UFI” marker) could be placed in the field used for this purpose. In this part of the label, the UFI would often be most visible and easiest for a user to identify.
- Affixing the UFI to the label is possible instead of printing directly on the label. It is recommended that the sticker is affixed firmly so that it cannot easily be separated from the actual label. Affixing the UFI may seem to be a useful option in the following cases:
    - To avoid wasting labels printed before the applicability of Annex VIII and where still valid (though without UFI printed);
    - To mitigate the need of frequent changes to the label, in case the product changes the composition dynamically (e.g. seasonal changes or frequent changes of suppliers).
- The acronym “UFI” must be used always using the Latin alphabet, independent of the country, language and national alphabet(s).
- To help distinguish the acronym from the beginning of the UFI, notably if the first character of the UFI is “I”, a colon “:” can be used to separate the “UFI” acronym from the UFI code. An optional space may be placed after the colon (e.g. if it can improve the legibility using the selected font).

The three hyphens separating the blocks of the UFI must be printed. Alternatively, the UFI can be printed on two lines and the second hyphen omitted. In the latter case, using a monospaced font is strongly advised to keep the blocks aligned.

This leads to strings such as

UFI:I600-30P1-S00Y-5079
(23 characters)

UFI: I600-30P1-S00Y-5079
(24 characters)

UFI: I600-30P1
S00Y-5079
(23 characters in two lines)

For example, on a light background black is a good option; conversely, a light colour should be used on a dark background. In principle, any colour can be used, notably in order to consider the printing equipment capabilities.

Monospaced fonts have proven to be a good option - especially when printing the UFI on two lines, as shown above as they tend to improve the legibility of individual characters. The size of the font is recommended to be adapted to the style of the font itself to ensure that the UFI is legible for a person with average eyesight (e.g. it can be better to use a slightly larger font size for a bolder font).

4.2.7.1 Multi-component products

Mixtures can be placed on the market not only as products containing a single mixture, but also as part of kits or sets of multiple mixtures. In the latter case, each single mixture bears the label relevant to that mixture, where required[23]. Each mixture that is part of a set or kit and is classified as hazardous regarding human health or physico-chemical properties, has to have its own UFI, which needs to be included on the respective label.

In some products, mixtures are placed on the market as parts of a multi-component product, where each mixture is in a separate container, but the containers are purchased together and a new mixture is created upon the use of the product (e.g. certain glues). The company placing such a product on the market must provide a UFI for each component-mixture in their separate submissions[24]. Information relevant for the emergency response concerning the final mixture should be provided in the submission of the component mixtures (e.g. in the toxicological section).

4.2.7.2 Exemption from labelling requirements

According to Article 29(1) CLP, in cases where the packaging of a mixture is in such a shape or

[23] See *Guidance on Labelling and Packaging in accordance with Regulation (EC) 1272/2008* at https://echa.europa.eu/guidance-documents/guidance-on-clp

[24] The rationale is that the obligation to submit information concerns mixture actually placed on the market, i.e. the single mixtures which are part of the product, and not the mixture created upon use. Furthermore, the label of the product bears the information on the component mixtures (and hence their UFIs) and not of the final mixture.

is so small that labelling requirements are impossible to be met, it is possible to provide the label elements in a fold-out label, on tie-on tags or on outer packaging. In case of multiple-language label, the UFI could be indicated either for each language or, e.g., on the cover page of the fold-out label.

In any case, the UFI will have to be indicated on the fold-out label, tie-on tag or outer packaging, as appropriate. When using a fold-out label, the UFI should be placed on both the top layer and on the layer that is attached to the container.

When a package consists of an outer and an inner packaging, together with any intermediate packaging, the placement of the UFI will follow the general rules in accordance with Article 33 of CLP. UFI is to be considered part of the supplemental labelling information and should appear on the different packaging layers. Detailed information on the general rules and specific cases (e.g. overlapping with transport classification and consolidation packaging) is provided in the *Guidance on Labelling and Packaging*.

For mixtures which are intended for industrial use only, and benefit from the limited submission (see section 4.4), it is not mandatory to include the UFI on the label provided it is indicated in the SDS. The same derogation applies for mixtures which are placed on the market but not packaged.

4.3 EuPCS

A harmonised European product categorisation system (EuPCS) maintained by ECHA[25] is used to describe the main intended use of a mixture to be submitted (section 3.4 of part A of Annex VIII). Examples of product categories include "Hand dishwashing detergents", "Adhesives and sealants for construction", "Decorative paints and coatings"[26]. The product category does not cover toxicological information, composition or type of packaging, which should be provided in other sections of the submission format.

Information on a mixture's product category may serve to support poison centres and appointed bodies in a harmonised approach to statistical analyses and reporting of poisoning cases between EU member states. In addition, the EuPCS may serve as an additional aid to poison centres in the identification of the product in a poisoning case where no other information for identification is available.

When submitting a submission for a hazardous mixture, duty holders must assign a product category which best defines the intended use of the product it corresponds to. The same principle is followed in the case of dual use products that may fit multiple product categories, for example, a 2-in-1 laundry detergent also containing a stain removal agent: in this case, the main intended use would be a laundry detergent. In the specific case where a mixture has a dual use, one of which has either a biocidal use or a plant protection product use (e.g. a detergent that is also a biocide), the main intended use must always be categorised according to the corresponding biocidal or plant protection product category.

It should be noted that the main intended use referred to in this section is different from the intended use types, i.e. a mixture for consumers uses, professional uses or industrial uses, as described in section 3.3.2. The 'use type' is based on the final end user of the mixture (and

[25] The current EuPCS is based on the system originally developed by the Commission following the "Study on a Product Category System for information to be submitted to poison centres" available at http://ec.europa.eu/growth/sectors/chemicals/poison-centres/.

[26] Note that the EuPCS is still under refinement and categories may be subject to modification.

determines the information requirements) while the 'main intended use' is based on the user next in the supply chain. To illustrate this, consider an 'original mixture' e.g. raw material fragrance mixture, which is eventually incorporated into a 'final mixture' e.g. a detergent that is subsequently placed on the consumer market. As the raw material has a consumer end use, the submission will need to be done fulfilling the information requirements for mixtures for consumer use and its intended use must be categorised as the appropriate raw material.

The EuPCS has been published on the ECHA Poison Centres website along with a practical manual to support categorising products according to their intended use.

ECHA is responsible for the maintenance and any changes to the EuPCS. Requests for updates or adaptations can be made by accredited stakeholders following the procedure detailed on the ECHA Poison Centre website.

4.4 Limited submission

The importers and downstream users of hazardous mixtures placed on the market for industrial use only, have the possibility to opt for a 'limited submission' as an alternative to the general submission requirements [A.2.3].

In such cases, information on the composition of their industrial mixtures submitted to the appointed body may be limited to the information contained in the safety data sheet ('SDS'). However, it must be ensured that additional detailed information on the composition of such mixtures is rapidly available on request, in the event of an emergency health incident [A.2.3 and B.3.1.1]. The rationale for this specific regime is provided in Recital 11 of Regulation (EU) 2017/542,[27] which specifies that *"on industrial sites there usually is a greater knowledge of the mixtures used and medical treatment is generally available. Therefore, importers and downstream users of mixtures for industrial use should be allowed to fulfil limited information requirements."* The regulatory burden for the industry is thus tailored proportionally upon the specific needs of the 'industrial use'.

Companies which intend to do a limited submission are invited to consult *ECHA's Guidance on the compilation of safety data sheets*,[28] providing comprehensive guidance on the compilation and handling of SDSs.

Typically, an SDS is less detailed than what is required in a 'full submission' pursuant to Annex VIII to the CLP. See section 5.4 for more information.

4.4.1 Contacts for rapid access to 'additional detailed product information'

The submitters who have chosen the 'limited submission' must, according to section 2.3 of Part A and section 1.3 of Annex VIII, provide in the submission the contact's details for rapid access to 'additional detailed product information'.

These contact details must include as a minimum:

- the name of the submitter, responsible for the placing on the market of the hazardous industrial mixture;

[27] Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response

[28] *Guidance on the compilation of safety data sheets*, in particular section 3.3 'Composition/ information on ingredients'.

- a telephone number accessible 24 hours per day and 7 days per week, where 'additional detailed product information', which are not included in the SDS but would be requested by Annex VIII, can be obtained by a responsible authority and/or [any] medical personnel, dealing with a poisoning/ health incident;
- an email address for follow-up exchange of information between the submitter and the responsible authority or medical personnel.

4.4.2 Availability and content of the additional information and rapid access

The 'additional detailed product information' within the meaning of Annex VIII must be such to allow a responsible authority or medical personnel dealing with a poisoning/ health incident, to formulate adequate preventative and curative measures. The information on the composition required for a 'full submission' pursuant to section 3.4 of part B of Annex VIII, is considered sufficient for this purpose. It must be kept readily accessible to be supplied on request to the responsible authority or medical personnel dealing with a poisoning/ health incident.

As it is not possible to safely define "rapid" access, the information is expected to be provided without delay, which means as soon as practically possible. This is also justified by the impossibility to pre-empt the severity of the poisoning.

Note that rapid access must be provided in a language(s) of a Member State where product is placed on the market. Additionally, the telephone number should not generate disproportionate cost to the Member State (e.g. 'premium' phone numbers or numbers located outside of the EU).

Pursuant to Article 45.2 of the CLP the requested information can be used by the responsible authorities exclusively to meet a medical demand by formulating preventative and curative measures in the event of an emergency. The importers and downstream users of mixtures are thus legitimate in any verification of the credentials of any medical personnel requesting product information from them.

If, following receipt of the 'additional detailed product information', the responsible authority or medical personnel dealing with a poisoning/ health incident makes a 'reasoned request' to the submitter that further additional information or clarification is necessary, the submitter must provide the necessary information or clarification requested without undue delay.

It should be noted that the 'limited submission' is optional. Operators dealing with hazardous mixtures for industrial use and who are required to do the submission, can also decide to comply with the general (full) submission requirements, thus being exempted from the obligation to provide 24/7 contact details for additional information.

4.5 Group submission

Companies may sometimes have in their product portfolio, a high number of similar mixtures, which may only slightly differ in certain elements. Therefore the Regulation allows to submit, under certain conditions, information for several mixtures with a single submission, which is called 'group submission'.

A group submission can be made when:

- all mixtures in the group contain the same composition except for certain perfumes and/or fragrances under specific condition, and for each of the components, the reported concentration or concentration range is the same.
- all mixtures in the group have the same classification for health and physical hazards; and
- all mixtures in the group belong to the same product category.

Section 5.4 provides more details on the information required for a group submission.

5. Information contained in the submission

The company that is placing on the market a mixture for which a submission under Article 45 has to be made (as clarified in section 3), is required to submit the information specified in Part B of Annex VIII to CLP.

This section provides guidance on which information is needed according to the legal text in the case of a full submission as well as in the case of limited (see section 4.4) and group (see section 4.5) submissions. The reference to the relevant section of the legal text is indicated in brackets next each heading.

5.1 Identification of mixture and submitter [Part B.1]

5.1.1 Product identification [B.1.1]

Poison centre operators must receive information to enable them to rapidly and accurately identify the responsible product in the event of a poisoning incident. Following a poisoning accident, this information is normally provided by the person making the call, who ideally should have the relevant product identifiers at hand on the label of the product itself. The product identifiers needed for the purposes of Article 45 and the poison centre work are laid out in Annex VIII to CLP in accordance with Article 18(3)(a) of the same Regulation. The Unique Formula Identifier (UFI) code is one of the main product identifiers on the label (as already mentioned in the previous sections) that a caller should relay to the poison centre operators to allow the identification of the poisoning agent (see section 4.1).

In addition to this, there are other elements from the label which are important to poison centre operators such as the trade name or names of a product, including any other names as they appear on the product (e.g. brand names and variant names). The same mixture could be placed on the market under several trade names and for different intended uses. As long as the composition doesn't change, all these trade names can be included in the same submission[29]. The provision of all the exact names in the submission as they appear on the label is necessary for the poison centres as there are cases where many products exist with the same name but differ in other aspects such as the chemical composition or product category.

5.1.2 Submitter details [B.1.2]

The responsibility for submitting information on hazardous mixtures in the context of CLP Article 45 and Annex VIII is considered to be that of the duty holder who is referred to as the "submitter" (see section 3.1). Annex VIII requires that the details of the submitter, such as their name, full address, telephone number and email address are to be provided in the submission and must be consistent with those on the label of the product (as indicated in Article 17(1)(a) CLP).

A distinction must be made between the submitter, who bears the legal obligation to provide the necessary information in a submission in a consistent manner with the product label, and another natural person acting as a third party or representative of the submitter, but who may

[29] Note that a limited variability may exist if generic product identifiers are used. See following subsections for more details.

physically prepare and make the submission (see section 3.1).

5.1.3 Details for rapid access to additional product information [B.1.3]

Submissions made for industrial mixtures which qualify for reduced information requirements, i.e. a limited submission, require additional contact elements for the purpose of providing an emergency responder with more information if required in case of emergency. In order to provide rapid access to this information, the submission must contain a telephone number and email address and be accessible 24 hours a day, seven days a week. This service must be provided in the national language(s) of where the product is placed on the market (see section 4.4).

5.2 Hazard identification and additional information [Part B.2]

5.2.1 Classification of the mixture and label elements [B.2.1 and B.2.2]

The classification of the mixture for health and physical hazards has to be provided in the submission. There is no requirement for providing information regarding the possible classification of the mixture as hazardous to the environment. Environmental hazards are not related to the information needed for an emergency health response.

The classification for health and physical hazards needs to indicate the hazard classes and associated hazard categories relevant for the mixture (e.g. "Acute Tox. 4", "Flam. Liq. 2").

The labelling elements associated with the classification for health and physical hazards according to the rules set in Annex I to CLP must be provided. This includes the hazard pictogram code (e.g. GHS07), the signal word (danger/warning), the hazard statement codes (e.g. H302) and precautionary statement codes (e.g. P264).

Information about the mixture classification and the associated labelling elements has to be consistent with the information provided in Sections 2.1 and 2.2 of the safety data sheet (SDS) of the mixture as specified in Annex II to the REACH Regulation, (EC) No 1907/2006.

5.2.2 Toxicological information [B.2.3]

Annex VIII part B, section 2.3, specifies that the submission has to include the information on the toxicological effects of the mixture or its components that is required in Section 11 of the SDS of the mixture. The information requirements for an SDS are specified in Annex II to the REACH Regulation. The information to be included in the submission thus has to include as a minimum all the relevant and available information on the toxicological health effects related to each of the health hazard classes covered by Annex I to CLP:

(a) acute toxicity;
(b) skin corrosion/irritation;
(c) serious eye damage/irritation;
(d) respiratory or skin sensitisation;
(e) germ cell mutagenicity;
(f) carcinogenicity;
(g) reproductive toxicity;
(h) STOT-single exposure;
(i) STOT-repeated exposure;
(j) aspiration hazard

For each of the above hazard classes the submission should include the information from Section 11 of the SDS, which will allow the poison centres to provide adequate advice in case of exposure to the mixture. This could include, when available, the result of the study,

reference to the species and test method used, and possibly information on the exposure period. Examples are illustrated below:

- Acute toxicity, oral: LD50 1310 mg/kg (rat)
- Skin corrosion/irritation: Corrosive (rabbit, OECD 404, 20h)
- Skin sensitisation: Not sensitising (guinea pig, OECD 406)

Annex VIII does not prescribe any specific structure for reporting such information. Considering that it is not possible to define in general terms what information is needed for the purposes of this Annex, the full content of Section 11 of the SDS could be considered potentially relevant for the poison centres and emergency responders. The full content of Section 11 of the SDS may, e.g., contain information on toxicokinetics, metabolism and distribution as well as more elaborate information on the toxicological effects and test methods.

The submitter, nevertheless, has to make sure that the required toxicological information is provided, in order for the poison centre to have access to the relevant information. Information included in the submission should not contain cross-references to other sections of the SDS.

This information could be integrated, if needed, with relevant information concerning the final mixture generated upon use in case of multi-constituent products (see section 4.2.7.1).

5.2.3 Additional information [B.2.4]

Additional information about the packaging, physical appearance, intended use and use types of the mixture has to be provided in the submission. Some of the information below is normally contained in Section 9 of the SDS of the mixture, as specified in Annex II to REACH. In some cases, the submission covers multiple trade names under which the mixture is placed on the market (which may differ for various product's characteristics). The information and the specific trade name/product should be adequately linked to ensure that the emergency responders can properly identify the risks.

The additional information is specified in Part B, Section 2.4, and includes the following:

- *The type(s) and size(s) of the packaging used to place the mixture on the market for consumer or professional use*. The type relates to the form of the packaging as supplied, e.g. a bottle, a box, a tube, a dispenser etc. The type does not relate to the nature/composition of the packaging material. The size has to be given as the nominal volume(s) or weight(s) of the packaging(s). If a mixture is supplied in different types and sizes of packaging in any given Member State, information of all the relevant types and sizes placed on the market in that Member State has to be contained in the submission. Information about the specific type of packaging linked to each trade name is useful information, for both a emergency response and statistical analysis purposes.

- *The colour(s) and the physical state(s) of the mixture, as supplied.* This information relates to the general appearance of the mixture (see section 9 of the SDS, e.g. "colourless/clear liquid"). In case the submission covers a mixture where the colouring agent(s) relevant to a specific trade name varies [30], it is not necessary to indicate the specific colour of each trade name but basic generic colour names can be used. It is important that colour information is provided taking into account its purpose, i.e. for an

[30] For a standard submission this is possible only if the colouring agents meet specific criteria which allow use of the same generic identifier, see section 5.3 for more details on information on mixture's components.

emergency health response and under the consideration that this information may be provided by a caller to the poison centre operator who needs to identify the mixture. It is advised that colour names are as simple as possible. The PCN provided by the Agency supports the identification of colours by providing the list of colours identified as appropriate in this context.

- *The pH, where applicable.* (See section 9 of the SDS).

- *Product categorisation.* The product category according to the EuPCS describing the intended use of a mixture must be provided. In case the same mixture is placed on the market under different trade names with different intended uses, an appropriate product category can be allocated to each of them. Support for selecting the most suitable product category can be found in the EuPCS practical manual available on the ECHA website https://poisoncentres.echa.europa.eu/tools. See also section 4.3 in this document on the EuPCS.

- *Use types (consumer, professional, industrial).* The relevant end-user group of the mixture as supplied by the submitter has to be indicated in the submission. Nevertheless since the final end-use of the mixtures determines the deadline for submission and information requirements, in case the mixture is supplied e.g. for professional use but it can be reasonably expected that consumers can purchase the same mixture, then consumer use has to be reflected in the submission. The use types are defined in section 3.3.2 of this document.

5.3 Information on mixture components [Part B.3]

This section provides guidance on which components contained within the mixture have to be indicated in a submission, and on the information to be provided for each component.

The information to be provided on the components of a mixture varies according to the type of submission the operator has to or has decided to prepare, e.g., whether it is a standard submission, a group submission or a limited submission for industrial use only. It can to a certain extent vary also depending on the knowledge the submitter has on the mixture content. This section provides guidance on the information required in each case.

5.3.1 General requirements [B.3.1]

Ideally, the full composition of the mixture should be indicated. Both hazardous and non-hazardous components may manifest adverse effects after, for example, unintended uses. Therefore, poison centres and emergency response personnel may potentially need information on all components.

Nevertheless, for practical reasons components do not legally need to be indicated when present in the mixture below certain concentration thresholds. Furthermore, in the case of a mixture for industrial use only, for which a limited submission is done (see section 4.4 of this guidance), information on composition may be limited to the information available in the safety data sheet for that mixture (see section 5.3.4).

For each component that is required to be listed (see section 5.3.2), the following is to be specified in the submission:

- Its chemical identity (see 5.3.3 below), and
- Its concentration (exact concentration or range – see 5.3.3)

Furthermore, the classification of the component may be required under certain conditions (see section 5.3.3).

It is not allowed in a submission to list a component which is not present in the mixture, or in at least one mixture in a group of mixtures in the case of a group submission (except for the specific derogation for perfume or fragrance components under section 5.4).

5.3.2 Components subject to submission requirements [B.3.3]

A component of a mixture can be one of the following:

- A **substance,** as defined in Article 2(7) of CLP (see section 2)*;*
- A **mixture in mixture (MiM)** – i.e. a mixture (as defined in Article 2(8) of CLP; see section 2) used in the formulation of a second mixture that is placed on the market and the subject of the current submission.

Normally, the substances contained in a MiM should be reported individually, as for all other substances. When the composition of the MiM is fully known, its components should be considered as components of the final mixture and indicated accordingly. However, if the submitter does not have access to information on the full composition of the MiM, it is possible to report the MiM as such in the submission, together with the known components. For further information, see section 5.3.3 below.

A component, whether a substance or a MiM, must be included in the submission when it is:

1. Classified as hazardous on the basis of physical or health effects, and either
   - Present in a concentration equal to or greater than 0.1%; or
   - Identified and present at concentrations below 0.1% - unless the submitter can demonstrate that it is irrelevant for the purposes of emergency health response and preventative measures;
2. Not classified as hazardous on the basis of physical or health effects, when identified and present at concentrations equal to or greater than 1%. This includes components not classified or classified for environmental hazard only.

'*Identified'* means that the submitter knows the component is present, e.g., because he has added it intentionally or it has been communicated to him by a supplier in, e.g., a safety data sheet. Submitters are not legally required to analyse their mixtures to determine the presence of components, nor to request additional information from their suppliers on the identity of mixture components for which there is no legal obligation to communicate information in an SDS. Nevertheless, it is recommended to make an effort in actively seeking missing information, as it may be important for the activities of the emergency responders.

There is no specific scientific method to demonstrate the irrelevance of a substance or mixture for an emergency health response. The decision not to indicate a component, which is present below 0.1%, should be based on considerations which include the hazard type (e.g., none of the hazard classes considered to be of major concern), relevance of the route of exposure (e.g., physical state does not allow inhalation), concentration (e.g., trace levels can normally be disregarded), and possible interaction with common treatments. When a Specific Concentration Limit exists (SCL)[31] for a substance, this may be used as a basis to conclude on the irrelevance of the substance (e.g. substance to be considered as relevant when the SCL < 0.1). There is no obligation to include the justification in the submission. This can be the object

[31] SCL are assigned to substances according to Article 10 of CLP and are available in Annex VII or/and in the C&L Inventory.

of a "reasoned request" by the appointed body if it decides so (see section 7.1).

5.3.3 Information required on components

A) Identification of the components [B.3.2]

Substances in a mixture must be identified in accordance with Article 18(2) of the CLP Regulation:

- name and an identification number as given in Part 3 of Annex VI to CLP;
- if the substance is not included in Part 3 of Annex VI to CLP, a name and an identification number as they appear in the Classification and Labelling (C&L) Inventory;
- if the substance is neither included in Part 3 of Annex VI to CLP nor in the C&L Inventory database, the CAS number and the IUPAC name, or the CAS number and another international chemical name, e.g. the name in INCI nomenclature, where applicable; or
- if no CAS number is available and none of the above apply, the IUPAC name or another international chemical name, e.g. the name in INCI nomenclature where applicable.

An INCI name, a colour index name or another international chemical name may also be used, provided the chemical name is well known and unambiguously defines the substance identity. The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 of CLP must be provided as well.

As regards **mixtures in mixtures (MiMs),** information on the substances contained in a MiM must be provided:

- As a rule, in accordance with what is stated about substances above. Substances components of a MiM (when the composition of the MiM is fully known) should be regarded as components of the final mixture. Information regarding same substances (originating from MiM and/or on their own) should be presented in aggregated form.
- Alternatively, if the submitter does not have access to information on the full composition of the MiM, this must be identified by means of its product identifier i.e. trade name or designation (according to Article 18(3)(a) of CLP), together with its concentration (range) and UFI, when available (see point C below for information about concentration and classification). Also all known MiM components shall be provided (e.g. based on the SDS). Enforcement authorities may enquire about the efforts made towards accessing the information on full composition of MiM.
- As a last resort, in absence of a UFI and of the possibility to obtain it from the supplier, the safety data sheet of the MiM must be provided, as well as the name, email address and telephone number of the MiM supplier. This scenario was envisaged to address temporarily the issues that may occur during the transition period until 2025, when it comes to communication in the supply chain. It is expected that after 2025, all compositional information is provided within two above scenarios. If a submitter does not receive the UFI of the MiM from their supplier, this does not discharge the notifier from their legal obligations as regards information provision on (known) components. Duty holders should make a reasonable effort to obtain a UFI from their MiM suppliers. Enforcement authorities may enquire about the efforts made towards accessing the information on full composition of MiM.

A **generic product identifier –** "perfume", "fragrance" or "colouring agents" - can be used to identify one or several components of the mixture, if they are used exclusively to add perfume, fragrance or colour, respectively, to the mixture. The generic product identifier is used instead of the actual chemical identity of the relevant component(s), and may be used where the following conditions are met:

- The relevant component(s) is/are not classified for any health hazard, and
- The total concentration of the components covered by the generic product identifier does not exceed:
    - 5% for the sum of perfumes and fragrances;
    - 25% for the sum of colouring agents

Mixtures whose composition differs only in components which can be identified by the same generic product identifier, can be included in the same submission. Such mixtures may be placed on the market under multiple trade names which can be also indicated in the same submission.

Note: using generic product identifiers is optional and at the discretion of the submitter.

For the purposes of Annex VIII, the term "component" with reference to the mixture subject of the submission, is used in this guidance to indicate any of the following: a substance, a MiM or a substance or mixture indicated with a GPI.

B) Concentration and concentration ranges of the mixture components [B.3.4]

The regulation provides different provisions for mixture components (substances and MiM) that are considered of 'major' concern and 'other' components. This distinction is defined in section 3.4 of Part B of Annex VIII. The submitter is required to provide the concentration or concentration ranges of each component according to the hazard class as described below.

In case of MiM for which the composition is fully known, the concentration of its components should refer to the final mixture. In case the same components comes from different sources (e.g. as component of a MiM and as single substance), the information should be provided in aggregated form.

B.1) Hazardous components of major concern for emergency health response and preventative measures

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in a mixture must be expressed as exact percentages, in descending order by mass or volume:

— acute toxicity, Category 1, 2 or 3

— specific target organ toxicity (Single exposure, Category 1 or 2)

— specific target organ toxicity (Repeated exposure, Category 1 or 2)

— skin corrosion, Category 1, 1A, 1B or 1C

— serious eye damage, Category 1

As an alternative to providing concentrations as exact percentages, a range of percentages may be submitted in accordance with Table 1 in Part B of Annex VIII (reported in Table 2 below), in descending order by mass or volume.

Where the exact concentration is higher than 1%, the upper and lower limits of the concentration bands could be rounded to a maximum of one decimal; where the exact concentration is lower than or equal to 1%, a maximum of two decimals could be used.

Table 2: Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MIM) - Table 1 in Part B of Annex VIII

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	5% units
≥ 10 - < 25	3% units
≥ 1 - < 10	1% unit
≥ 0,1 - < 1	0,3% units
> 0 - < 0,1	0,1% units

Example 16: Concentration ranges for components of "major" concern

In the case of a substance (hazardous component of "major" concern) in a mixture with an exact concentration of 26%, the submitter can choose among different ranges to report, provided that the exact concentration is comprised within this range and the maximum width of the concentration range is 5% units: 21-26%, 22-27%, 23-28%, 24-29%, 25-30%, 26-31%. Also narrower ranges can be applied such as 25-27% etc.

B.2) Other hazardous components and components not classified as hazardous

The concentration of components classified for hazard classes not listed above or components not classified as hazardous should be expressed, in accordance with Table 2 in Part B of Annex VIII (reported in Table 3 below), as concentration ranges in descending order by mass or volume. As an alternative, the exact concentration can be provided.

The upper and lower limits of the concentration bands should be rounded to a maximum of one decimal for components with an exact concentration > 1% and to a maximum of two decimals for components with an exact concentration ≤ 1%.

The reason for the interval >0-<1 in Table 2, is that all components classified as hazardous on the basis of their health or physical effects, also those not of major concern have to be included in the submission if present at concentrations equal to or greater than 0.1 %. Furthermore, they may need to be included in the submission even if present in concentrations below 0.1% if hazardous and identified, unless demonstrated to be irrelevant for emergency health response and preventative measures (see section 5.3.2 above).

Table 3: Concentration ranges applicable to other hazardous components and components not classified as hazardous (substances or MiM) – Table 2 in Part B of Annex VIII

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	20% units
≥ 10 - < 25	10% units

≥ 1 - < 10	3% units
> 0 - <1	1% unit

Example 17: Concentration ranges for components not of "major" concern

In the case of a substance (not classified or classified as hazardous but not of major concern) in a mixture with an exact concentration of 6%, the submitter can choose among different ranges provided that the exact concentration is comprised within this range and the maximum width of the concentration range is 3% units: 3-6%, 4-7%, 5-8% or 6-9%. Also narrower ranges can be applied such as 5-6%.

Special case: perfume or fragrance components
In the case of perfume or fragrance components that are not classified as hazardous or are classified only for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, submitters are not obliged to provide information on their concentration, as long as the total concentration of such perfume or fragrance component does not exceed 5%.
For colouring agents with a generic product identifier, Table 3 above applies.

C) Classification of mixture components (substances and MiM) [B.3.5]

The classification for health and physical hazards of the mixture components must be provided. This includes hazard classes, categories and statements of, at least, all the identified substances which are referred to in Point 3.2.1 of Annex II to the REACH Regulation (requirements for the compilation of SDSs). Point 3.2.1 lists the criteria for identifying the component substances that have to be indicated in the SDS of a mixture itself classified as hazardous[32].

In other words, at least for all the component substances that would need to be indicated on the SDS of the mixture, their classification is to be provided in the submission. Annex II to REACH also includes an obligation to provide information on substances classified for environmental hazards only. For the purposes of Annex VIII, for components classified for environmental hazards only, the classification does not need to be indicated (although it can be indicated on a voluntary basis).

In the cases where the mixture for which submission needs to be done contains one or more MiM(s) (for which full composition not known), the notifier should provide the classification of the MiM itself. In this case, the classification of the components of the MiM(s) is not required. In case the MiM composition is fully known, the classification for health and physical hazards of the substances contained in the MiM should be indicated following the rules above.

Information on classification for environmental hazards is not required.

Components identified via a generic product identifier may present physical hazards. Nevertheless the classification of such components (even when the same generic product identifier covers several components) does not need to be indicated.

Example 18: Use of Generic Product Identifiers

In option A, all components are included in the submission with the 'chemical name', health classification and concentration in the mixture (either a concentration range or an exact concentration). There are eight fragrance components (1-8) and three other components (A,B,C).

The use of generic product identifiers is illustrated in the option B below where

[32] See ECHA's *Guidance on the compilation of safety data sheets*.

fragrance/perfume components are grouped. Note: the indicated concentrations, classifications and number of components are chosen with the sole purpose of explaining the requirements.

OPTION A – ALL COMPONENTS INDICATED WITH A 'CHEMICAL NAME'		
Components	**Classification**	**Concentrations**
Chemical name component A	not classified	60-80%
Chemical name component B	not classified	13%
Chemical name component C	major concern	11-14%
Fragrance chemical name 1	not classified	1-4%
Fragrance chemical name 2	not classified	1%
Fragrance chemical name 3	not classified	0.5%
Fragrance chemical name 4	acute toxicity, cat 1	0.3-0.6%
Fragrance chemical name 5	skin corrosion, cat 1C	2-3%
Fragrance chemical name 6	skin sens. cat. 1	2%
Fragrance chemical name 7	aspiration toxicity	3-6%
Fragrance chemical name 8	not classified	4%

This composition can alternatively also be submitted as presented in option B (below). Fragrance components 1 to 3 are indicated with a generic product identifier. This is allowed since these components are not classified for a health hazard and the total concentration of the components covered by the given generic product identifier does not exceed 5% [B.3.3]. 'Fragrance chemical name 4 to 7 cannot be indicated with a generic product identifier because these components are classified for a health hazard.

OPTION B – SOME COMPONENTS INDICATED WITH A GENERIC PRODUCT IDENTIFIER		
Components	**Classification**	**Percentage**
Chemical name component A	not classified	60-80%
Chemical name component B	not classified	13%
Chemical name component C	major concern	11-14%
Fragrances	not classified	3%, 2-5% or 'not indicated'
Fragrance chemical name 4	acute toxicity, cat 1	0.3-0.6%
Fragrance chemical name 5	skin corrosion, cat 1C	2-3%
Fragrance chemical name 6	skin sens. cat. 1	2% or 'not indicated'
Fragrance chemical name 7	aspiration toxicity	3-6%
Fragrance chemical name 8	not classified	4%

Additional notes to the example:

- 'Fragrance chemical name 1' was indicated in option A with a concentration range of 1-4%. The actual concentration apparently was 1.5% (only known to the submitter) so the total concentration is 1.5+1+0.5=3%.

- Not all non-classified fragrances can be grouped within the same generic product identifier because if 'fragrance chemical name 8' is included, the total concentration is 7%. Other non-classified fragrance component must be indicated individually with their chemical name.
- It would also have been possible to, for example, indicate 'fragrance chemical name 2' and 'fragrance chemical name 8' with a generic product identifier "fragrances" since the total concentration does not exceed 5%. In that case the other non-classified fragrance components (1 and 3) must be indicated individually with their chemical name.
- On the indicated concentration:
  The generic product identifier can be indicated with an exact concentration (the sum of the components covered by the same generic identifier, 3% in the example) or a range according to table 2, for example 2-5% (3% units bandwidth allowed; with a maximum of 5%). Alternatively it is allowed to not indicate the concentration at all. For fragrance components that are not classified or only classified for skin sensitisation or aspiration hazard, this is not required provided that the total concentration does not exceed 5% [B.3.4.2]. Since the actual concentration of the generic product identifier is 3%, it is possible to additionally not indicate the concentration of 'Fragrance chemical name 6' to reach the maximum of 5%.

5.3.4 Limited submission [B.3.1.1]

When a company decides to opt for a limited submission (possible for mixtures intended for industrial use only) the list of components to be provided may be limited to that included in Section 3.2 of the SDS. Also the information to be provided on the concentrations of such components may be limited to that contained in the SDS.

Detailed information on the compilation of the SDS, and in particular of Section 3, is available in the ECHA's *Guidance on the compilation of safety data sheets*[33].

In practice, the information provided in this case will be less detailed than a standard submission and the poison centre will not have access to the full composition of the mixture. For example, Annex II to REACH (on the compilation of SDS) does not require the indication of non-hazardous components, and sets for the hazardous components to be indicated concentration thresholds which are less strict than Annex VIII to CLP (e.g. hazardous components may need to be included in a standard submission even if present in concentration <0.1%).

5.4 Group submission

Information on multiple mixtures with limited differences in the composition can be provided in the same submission: this is referred to as a 'group submission'. The general conditions under which such a 'group submission' is allowed are specified in Section 4, part A of Annex VIII.

Mixtures can be grouped in the same submission if they:

- have the same classification for health and physical hazards (this means that a difference in classification for environmental hazard is allowed);
- belong to the same product category (link to the EuPCS – see section 4.3 for details on the EuPCS);
- have very similar composition (see section 5.4.2 for details);

[33] Available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

- the same components are reported in the same concentration or concentration range.

Besides substances indicated with their own chemical name, as explained in section 5.3, the mixtures' components can include substances, 'mixtures in mixtures', and components which are allowed to be indicated with 'generic product identifiers' (see section 5.3.3).

All mixtures in the group must contain the same components, except for perfume or fragrance components, as referred to in point B.4.3 of Annex VIII. The components can differ between mixtures in the group under certain conditions (see section 5.4.2 below).

Under the conditions described above, group submission is possible for:

- Similar mixtures that are marketed under different trade names. Those might be intended for a different user group, e.g. 'consumer use' and 'professional use'.
- Mixtures with compositions that differ, under certain conditions, in fragrances and/or perfumes. These would be 'product variants' (possibly marketed under different trade names), for example detergents with a difference in fragrances.

Note: the grouped mixtures all have to be placed on the market by the same importer or downstream user. A group submission can only refer to one 'legal submitter'. It is not possible to group mixtures that are placed on the market by different companies, for example by private label customers.

Ultimately, the difference between a standard and a group submission concerns the possibility to group mixtures with variation in fragrances and/or perfumes which cannot be indicated with a generic product identifier. As explained earlier in this section, also in a standard submission multiple trade names can be included, as long as the composition of the mixture remains the same.

Note: The decision whether to provide a standard or group submission (when the conditions are fulfilled) lays with the duty holder and could be based on the specific portfolio. Group submission is an option: the duty holder may always decide to submit a standard submission for each product without grouping it with other products.

5.4.1 Information to be provided in a group submission

Information described in part B of Annex VIII should be provided for each of the mixtures in the group.

The information provided on mixture components in a group submission should apply to all the mixtures in the group, except for perfumes or fragrances that may only apply to some mixtures in the group under certain conditions (see section 5.4.2 below).

Most of the information will be the same but there might be a difference in:

- 'Product identifiers of the mixture': a group submission (as well as a standard submission) may cover mixtures placed on the market with different trade names and/or to which different UFIs could be assigned.
- 'Additional information' items listed in Part B, Section 2.4, of Annex VIII:
  - Colour and physical state of the mixture;
  - pH;
  - Types and sizes of the packaging;
  - Use types (consumer, professional, industrial) as described in section 3.2.2 of this Guidance.

Trade names, colour(s) and UFIs should be indicated for every individual product in the group. This information is important for the emergency responders in order to promptly identify the relevant information for the specific product. Nevertheless for the colour, a limited range of standard types can be used (no need to indicate the exact shade). Exceptionally and for practical reasons, a generic indication "various" in the colour field can be accepted for paints, where high numbers of products with great colour variability can be included in the same group submission.

The pH value can be indicated for the group as a whole; a range applicable to the whole group can be used. Where the pH value is particularly low or high (i.e. <3 or >10), the range to be indicated should not be bigger than one unit (e.g. 2.5 – 3.5).

Regarding the packaging, the specific type is potentially relevant to identify the appropriate emergency response measures. This information should be provided for each mixture of the group placed on the market with a specific trade name.

5.4.2 Mixture components in a group submission

Mixtures in a group submission should contain the same components in the same concentration or concentration range, except for perfumes and fragrances components. Those components may only differ between the mixtures of the group under the conditions described below (point A.4.3 and B.3.1 of Annex VIII). The total concentration of perfumes and fragrances in each mixture of the group cannot exceed 5%. In case the concentration of fragrances or perfumes in a mixture is above this threshold, the mixture cannot be included in the same group submission.

The intention of this rule is to allow grouping of the mixtures only if their compositions are very similar (and hence the toxicological information does not vary). This means that for a maximum of 5% of the composition, the mixtures' compositions may differ in perfumes or/and fragrances content.

It is to be underlined that the 5% must include all the fragrances/perfumes in the mixture (i.e., regardless of whether they are present in all the mixtures or the group, or are those differing between the mixtures).

The perfumes and fragrances contained in each mixture of the group must be specified.

The information required on the mixture composition in a group submission is illustrated by examples 19 and 20. References to the relevant legal text are made in the notes to the examples (in square brackets) to indicate compliance with the requirements on group submission as well as with requirements on component identification/information where relevant for grouping. For detailed guidance on component identification and information requirements, please see section 5.3 of this guidance document.

It is important to note that these examples are presented in a simplified form with the sole purpose of illustrating the requirements for group submission. In the examples different formats are used to present the information, but the same principles apply.

Example 19: Grouping of mixtures with difference in perfume/fragrance components

Mixtures in the group have a difference in some fragrance/perfume components that are classified for a health hazard (therefore those components cannot be indicated with a 'generic product identifier').

GROUPING OF MIXTURES WITH DIFFERENCE IN PERFUME/FRAGRANCE COMPONENTS		
UFIs: - C4P7-GHVS-ED8M-42DH - AB45-GD45-K908-0987 - DEF5-UH78-482D-1234 Classification: # Product Category: #	Product names: - Trade name 1 - Trade name 2	
Components	**Percentage**	**Classification***
Chemical name component A	60-80%	not classified
Chemical name component B	7-10%	other
Chemical name component C	11-14%	major concern
Chemical name component D	1-2%	major concern
Perfumes (Generic product identifier)	not applicable (but <5%)	not classified
Fragrance chemical name 1	1-4%	other
Fragrance chemical name 2	0.3-0.6%	major concern
Fragrance chemical name 3	2-3%	major concern
Fragrance chemical name 4	1-3%	other
'Perfume MiM' UFI: A67T-VHG2-DMM4-NH2A **MIM's known components:** MIM component A MIM component B	1-4% 2-4 % 8-12 %	Other Other Not classified

Information about fragrances and perfumes included in each mixture:

Name	Fragrance or perfume	Classification*
Trade name 1	Fragrance chemical name 1	other
UFIs: C4P7-GHVS-ED8M-42DH AB45-GD45-K908-0987	Fragrance chemical name 3	major concern
	'Perfume MiM' A67T-VHG2-DMM4-NH2A	other
Trade name 2	Fragrance chemical name 2	major concern
UFI: DEF5-UH78-482D-1234	Fragrance chemical name 4	other (skin sens. cat. 1)
	Perfumes	not classified

* In this example classifications are indicated with three categories: 'major concern' (list of classifications in B3.4.1), 'other' (all other hazard classifications) and 'not classified'.

Compliance with Annex VIII requirements:

- All mixtures in the group have the same components in the same concentration or concentration ranges [A4.2], except for the components 'fragrance chemical name 1 - 4', 'Perfume MiM' and the perfumes indicated with the generic product identifier "perfumes" that are at least present in one of the mixtures [A4.3].
- The difference between the mixtures concerns only perfumes or fragrances and 'the total concentration of perfumes and fragrances contained in each mixture does not exceed 5%'. This concerns the sum of 'actual concentrations' (which are known to the submitter) of these components while a concentration range is indicated in the submission.
- If the composition of a MIM is only partially known, the UFI has to be provided together with the known components.
- Since the MiM composition is not fully known, information on the concentration of known MiM components refers to the MiM itself.

Trade name 1:
Fragrance chemical name 1 - indicated 1-4% - actual concentration 1.2%.
Fragrance chemical name 3 - indicated 2-3% - actual concentration 2.1%.
Perfume MiM - indicated 1-4% - actual concentration 1%.
The actual concentration of fragrance and perfume components in the mixture is 4.3%.

Trade name 2:
Fragrance chemical name 2 - indicated 0.3-0.6% - actual concentration 0.4%.
Fragrance chemical name 4 - indicated 1-3% - actual concentration 1.4%.
Perfumes – not indicated – actual concentration 2%
The actual concentration of fragrance and perfume components in the mixture is 3.6%.

Note that there are two separate '5% rules':

- The one described above for perfume/fragrance components differing between mixtures in the group [A4.3] and
- A maximum concentration of 5% for the generic product identifier 'Fragrances/Perfumes' [B3.2.3].

- Since fragrances and perfumes vary between the mixtures contained in the group, a list must be provided of the mixtures and the perfumes or fragrances they contain, including

their classification. This information is contained in the additional list [B3.1.]. Note in this example that:

- A 'Perfume MiM' is included as fragrance/perfume component that differs between the mixtures.
- The concentration of the generic "Perfumes" does not have to be indicated since for 'perfume or fragrance components that are not classified or only classified for skin sensitization cat. 1, 1A or 1B or aspiration toxicity, submitters are not required to provide information on their concentration, provided that the total concentration of those perfumes or fragrances does not exceed 5%' [B.3.4.2]. This applies to every individual fragrance/perfume component.

Example 20: Grouping of mixtures with difference in perfume/fragrance components

GROUP SUBMISSION
UFI: C4P7-GHVS-ED8M-42DH
Product category: All-purpose cleaners, non-abrasive
CLP classification: Serious eye damage cat.1 + Skin sensitiser cat.1
Product trade names: ABC, BCD, CDE

	Product- trade name ABC + Product- trade name BCD + Product-trade name CDE		
	Components	**Classification**	**Concentration**
COMMON INGREDIENTS	Surfactant 123	Serious eye damage cat.1	5-6%
	Surfactant 456	Serious eye damage cat.1	8-9%
	Soap xyz	Not classified	2-5%
	Sodium carbonate	Eye cat. 2	7-10%
	Processing aid xxx	Not classified	1-2%
	Water	Not classified	66-76.4%
	Perfumes	As attached or not classified	up to 5%

Variant in perfumes:

Product- trade name ABC				
Components	**Classification**	**UFI and known components**	**SDS**	**Concentration**
Perfume mixture a	MIM: Skin sens. Cat. 1 Known component 1: # Known component 2: #	UFI A67T-VHG2-DMM4-NH2A + known component 1+known component 2 + …etc	-	MIM: 0.1-0.5% Known component 1 # Known component 2 #
Perfume mixture b	Skin sens. Cat 1B + asp. tox.	Not available	Provided	0.5-1.5%

Product- trade name BCD				
Components	**Classification**	**UFI**	**SDS**	**Concentration**
« Perfume » (Generic Product Identifier)	Not classified	Not applicable	-	0.6-2%

Product- trade name CDE				
Components	**Classification**	**UFI**	**SDS**	**Concentration**
Perfume mixture b	Skin sens. Cat 1	Not available	Provided	0.5-0.9%
« Perfume » (Generic Product Identifier)	Not classified	Not applicable	-	0.1- 1.1%

Notes to the tables of example 20:

- Total perfume a + perfume b in product- trade name ABC should not exceed 5% [A.4.3].
- Total perfume b + "perfume" (GPI) in product-trade name CDE should not exceed 5% [A.4.3].
- Components of perfume a are included in the submission of this perfume a by a supplier upstream (link with UFI).
- "Perfume" (GPI) does not contain any hazardous component [B.3.2.3].
- The concentration of known MiM components refers to the MiM itself (MiM composition not fully known).

List of perfumes in GS		
Perfume name	**Classification**	**Products of the GS where the perfume is present**
Perfume mixture a	Skin sens. Cat 1	Product- trade name ABC
Perfume mixture b	Skin sens. Cat 1 + asp. tox.	Products- trade names ABC+CDE
« Perfume » (Generic Product Identifier)	NC	Products- trade names BCD+CDE

6. Preparation and submission of information: available tools

The submission of the required information has to be done electronically and using the XML format provided by ECHA. The tools developed and maintained by ECHA assists both the submitters and the Member States appointed bodies in fulfilling their obligations and perform their tasks. They support with preparing the submission in the correct format, allow the submission of the information and facilitate the distribution of the submitted information to the relevant Member State(s).

6.1 UFI generator

The generation of the UFI(s) can be done at any time before the actual submission. It should be preferably done during the mapping and analysis of the portfolio while preparing the submission strategy. Generation and use of UFI is explained in section 4 (in particular subsection 4.2) which addresses the general submission requirements.

6.2 XML format

Annex VIII to CLP mandates ECHA to specify, maintain and update the electronic XML-based format that must be used for the submission of the harmonised information.

The use of this format is mandatory and alternatives (e.g. paper submissions or other electronic formats) are not allowed. The format is harmonised and it applies in all Member States.

ECHA, being strongly engaged with the OECD in international initiatives aiming to promote the definition and use of commonly agreed formats for the electronic exchange of information on chemicals, developed the XML format under the IUCLID (International Uniform Chemical Information Database) project.

The format is available for download from ECHA Poison Centre website and its use is free of charge. The usage of the format and creation of submission files containing required information can be executed offline using the IT systems available to duty holders.

6.3 PCN editor for generating IUCLID XML files

ECHA aims at providing the companies with an online editor that allows insertion of data and creation of XML files using an ECHA web-based application. The online editor does not require a company to develop IT data management systems which would be synchronised with format.

6.4 Submission of information

The IUCLID XML files, once prepared and containing the required information, must be submitted to the appointed bodies, as stipulated by Article 45(2) CLP. Submissions must be done to the appointed bodies by electronic means endorsed by them for that purpose. It is at the discretion of each Member State to define technical means of submission, including the possibility to 'outsource' this task and allow the submission of information centrally via the PCN portal provided by the Agency.

The PCN portal envisages for industry that:

- submissions can be prepared and submitted online using the PCN editor integrated in the portal;

- submissions prepared offline using the XML format can be uploaded to the PCN portal (also in bulk);

- submission are integrated system-to-system between PCN portal and company IT systems.

The PCN portal envisages for Member States that:

- submissions can be downloaded and integrated into local databases;

- submissions can be stored at the database coupled with PCN portal and hosted by the Agency.

Whether the submissions are done by industry and received by Member States centrally via PCN portal or locally via Member States submission systems, it is still the Member States that are responsible for any enforcement related to the submission of information, including compliance with submission deadlines, content, quality and update of the submissions etc. Appointed bodies remain responsible for the verification of the quality of the information submitted.

6.5 Fees

The usage of XML formats, UFI generator and PCS provided by the Agency is free of charge.

However it needs to be noted that a fee may be levied in each Member State for each submission. It is at the discretion of the competent authority of the Member State where the submission is to be made to decide whether fees are applicable for submission to the national appointed body/bodies.

7. Post-submission

7.1 General introduction

Successful submission of the information to the appointed body is the basic requirement to allow placing the product containing the mixture on the market of the relevant Member State. This requires the submission to be compliant with the requirements of Annex VIII requested by the Member State.

It is to be noted that some of the Member States currently require additional information that goes beyond the scope of Article 45 and Annex VIII to be submitted before placing the product on their market. This information is normally requested within different legal frameworks and for purposes potentially different from those described in this guidance (see section 7.2). The XML format defined for the purpose of Annex VIII implementation does not foresee such additional requirements.

Submitters have to make sure that the submitted information is constantly up-to-date in order to ensure that the poison centres have the relevant information at their disposal. Changes which trigger a mandatory update of the submission are detailed in section 7.4.

7.2 Additional requests by appointed bodies

Appointed bodies may perform, either on a regular basis or following specific criteria or "alerts" (e.g. under indication of the poison centre), a quality check of the submitted information. Should the appointed bodies identify areas that are deficient, unclear or maybe considered conflicting, they could contact the company who did the submission and request clarification or justification for any open or conflicting areas.

According to point A.3.2 of Annex VIII, an appointed body can make a "reasoned" request for additional information or clarification if this is necessary to carry out its tasks under Article 45. This request may concern a submission at any point in time. The information that could possibly be requested should not trigger requirements going beyond Annex VIII given that the information to be submitted is harmonised and set in the legal text. Therefore, requests for additional information should be limited to information required under Annex VIII and other information necessary to perform activities under Article 45 besides the emergency health response. An example of a reason for requesting additional information could be an inconsistency detected between the classification and the information provided in Section 11 of the SDS.

7.3 Use of submitted information

As indicated in Article 45 of CLP, appointed bodies have to ensure that the submitted information is used only to:

(a) meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; and

(b) where requested by the Member State, undertake statistical analysis to identify where improved risk management measures may be needed.

Appointed bodies or poison centres may undertake statistical analysis of the submitted information to identify where improved risk management measures may be needed. This data can help to identify particular trends in incidents or to adjust the focus of preventative actions.

7.3.1 Security and confidentiality

Information submitted to appointed bodies may contain sensitive and confidential data which are handled in systems designed to follow strict security standards and by personnel authorised by the appointed bodies.

Appointed bodies and poison centres provide all requisite guarantees for maintaining the confidentiality of the information received. In the event of emergency they are required to provide health response without disclosing directly confidential business information.

7.4 Keeping information up to date

7.4.1 Introduction

This section provides guidance on when the information submitted has to be updated and covers in particular Section 4, Part B of Annex VIII. This section of the guidance covers also voluntary updates following changes not listed under B.4.1. After a submission, changes may be made to the submitted mixture or new information about it may become available. It is necessary to ensure that the information submitted to the appointed body is relevant and up-to-date for every product being and having been placed on the market. This will make sure that adequate advice can be given in poisoning accidents by poison centres and medical services. The legal text indicates which changes trigger specific actions from the submitter.

7.4.2 Update rules

The updating rules apply to both new submissions in the harmonised format and to mixtures already notified in accordance with the existing national rules before the entering into force of Annex VIII (see section 3.4.1 above).

According to Section B.4.1 of Annex VIII, a submission update is required when:

- the name of the mixture (the product identifier, e.g. trade name/brand/identification of the mixture) or the UFI is changed, or
- the classification for health or physical hazards changes, or
- relevant new toxicological information that is required in Section 11 of the safety data sheet becomes available on the hazardous properties of the mixture or its components,
- the composition of the mixture is changed through addition, substitution or deletion of

one or more of the components that needs to be indicated[34], or

- concentration ranges are provided in the original submission; and the concentration of a component of the mixture is changed beyond the concentration range provided in Table 1 and 2 Annex VIII, or
- the exact concentration is provided in the original mixture; and the concentration of a component in the mixture is changed beyond the limits indicated in Table 3 of Annex VIII and reported in table 4 below (exemplified further down).

Table 4: Variations of the concentration of components requiring a submission update (Table 3 of Annex VIII)

Exact concentration of the component contained in the mixture (%)	Variations (±) of the initial component concentration requiring a submission update
> 25 - ≤ 100	5%
> 10 - ≤ 25	10%
> 2,5 - ≤ 10	20%
≤ 2,5	30%

Some changes not listed in Section 4.1 Part B of Annex VIII may take place and may be relevant for the purposes of the regulation, in particular for an emergency health response (e.g., a change in the contact details of the submitter or in the physical parameters of the mixture). Furthermore the submitter may want to correct information for different reasons (e.g. spelling mistakes, which became particularly relevant when affecting mixture identifiers).

In any case, a submission update (or a new submission) containing the most recent information about a product is always recommended without undue delay.

While all the changes described above require (either for legal or voluntary reasons) an update of the information submitted, they may be handled differently at a technical level in order to respond to the need of the ultimate user, i.e. the poison centre.
Changes (either listed under Section B.4.1 of Annex VIII or not) may trigger different scenarios which have different consequences for the end user (i.e. the appointed bodies and poison centres):

(i) addition of information (e.g. new additional trade name, new additional packaging) or

(ii) replacement of old, no longer relevant information with new relevant information (e.g., new classification due to changes in the criteria; the original classification is not relevant anymore), or

(iii) creation of a new record as a change in composition leads *de facto* to two different products on the market; the two sets of information (referring to the original and new composition) remain relevant (both products may remain on the market for a long time).

To be noted that the existing submissions done in accordance to the pre-Annex VIII rules, are valid until 1 January 2025 (see section 3.4). However, if a change described in Part B, 4.1 of

[34] To be noted that the substitution of one component with another with identical composition and hazard profile (possibly following a change of supplier) does not trigger the need for an update or a new submission.

Annex VIII (and illustrated below) takes places before that date, a submission update has to be submitted in accordance with Annex VIII. The same need for update applies to mixtures for professional use and mixtures for industrial use, for which submission was done following the respective requirements, which afterwards begin being used in a consumer product.

Examples and clarifications

Below are some examples of changes and the associated scenarios, (i), (ii) and (iii) above, (table 5), which in most cases apply to both single and group submissions. When there are differences, this is indicated and information on updates of group submissions, when different from single submissions, can be found in the next section (7.3.1).

Table 5: Examples of possible changes requiring an update under B.4.1 and related scenarios

Changes	Relevance	Scenario triggered
Addition of a new trade name only[(a)].	Standard, limited and group submission	Scenario (i).
Addition of a new UFI only[(a)].	Standard, limited and group submission	Scenario (i).
Modification of the classification for health or physical hazard[(c)] following change in classification criteria.	Standard, limited and group submission	Scenario (ii).
Addition of new toxicological information (e.g. results from new tests on the mixture become available). The existing information remains valid.	Standard, limited and group submission	Scenario (i)
Addition, substitution[(b)] , deletion of component(s). (for group submissions with perfumes, fragrances or generic product identifiers, see below 7.3.1).	Standard, limited and group submission	Scenario (iii) Note that a new UFI must be provided.
Modification of reported concentration ranges, **beyond** the indicated range[(d)].	Standard, limited and group submission	Scenario (iii) Note that a new UFI must be provided.
Modification of reported exact concentration **beyond** the indicated range[(e)]	Standard, limited and group submission	Scenario (iii) Note that a new UFI must be provided

Notes to the table:

(a) Rationale: products with the old identifier may still be on the market for an unspecified period of time.

(b) Substitution is in this case intended with a component which is chemically different. If a component is replaced by another one which is chemically the same (i.e. same composition and hazard profile) but (e.g.) from a different supplier, it is not considered to be substitution.

(c) The classification of a mixture may change when a new harmonised classification of a component in the mixture or when new information becomes available. In that case, an update is required no later than when the new classification becomes applicable.

(d) When declaring mixture component concentrations, it is allowed to use concentration ranges. For instance, for a hazardous component of major concern (see Table 1 in Part B of Annex VIII) present at a concentration of 16%, the concentration can be reported using a range of 3% (for instance 14-17%). If the new concentration does not fall within the range (e.g. the new concentration is 19%), a new UFI has to be created (see example 21 below). On the contrary, if the change in the concentration stays in the mentioned range (e.g. the new concentration is 15%), there is no obligation to update the submission. However, it is advised to do so voluntarily.

(e) When declaring the concentration of mixture components, it is possible to use exact concentrations. Limited changes to the exact value are allowed within a certain variation without the need to update. Allowed variations are listed in Table 3 of Annex VIII. If the new concentration exceeds the allowed variation (see example 22 below), an update is required and a new UFI has to be created.

Example 21: Mixture components with classification of major concern

MIXTURE COMPONENTS WITH CLASSIFICATION OF MAJOR CONCERN			
Component	**Exact concentration in the mixture (%)**	**Concentration ranges provided in the original submission (%)**	**New concentration requiring a submission update (%)**
Comp A	3.5	3.2-4.2	<3.2 or >4.2
Comp B	20.5	19.9-22.9	<19.9 or >22.9
Comp C	76	71-76	<71 or >76

Example 22: Mixture submitted with exact concentrations of classified components

MIXTURE SUBMITTED WITH EXACT CONCENTRATIONS OF CLASSIFIED COMPONENTS			
Component	**Exact concentration provided in the submission (%)**	**Variations (±) of component concentration requiring a submission update (%)**	**New concentration requiring a new submission (%)**
Comp D	1	30	<0.7 or >1.3
Comp E	5	20	<4 or >6
Comp F	22	10	<19.8 or >24.2

Comp G	72	5	<68.4 or >75.6

The use of table 3 of Annex VIII deserves some clarification: the reference concentration to define whether a UFI change is required should be always the original one. This allows avoiding the situation where many small changes (followed by voluntary updates) not requiring a UFI update lead to the situation where eventually the concentration has changed significantly from the original one, yet the UFI remains the same.

Generic product identifiers

When ingredients covered by the generic product identifiers "perfumes", "fragrances" or "colouring agents" are included (see section 5.3), an update is not required if a perfume, fragrance or colouring agent for which a generic product identifier can be used is added, substituted or removed from the mixture. This applies as long as the total concentration of ingredients covered by the generic product identifier remains below the allowed maximum level (5% for perfumes/fragrances and 25% for colouring agents) and none of those ingredients is classified for any health hazard.

In addition, it should also be mentioned that for "perfumes" or "fragrances" components, with a total concentration below 5% and not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, there is no need to provide the concentration (exact or range) of the single components. This means that variations in the components' concentration within the limits mentioned above do not require to update the submission.

7.4.3 Update – special cases with group submissions

Examples and clarifications

Addition, substitution, deletion of perfumes and fragrances (covered and not covered by generic product identifiers) in a group submission

When the perfumes or fragrances in a group submission change (if added, substituted or removed) in one or more of the mixtures in the group, the list of mixtures and the fragrances or perfumes they contain as required in Annex VIII Section 3.1 must be updated. If the change of perfumes or fragrances is the only change, a new UFI is not required. It is to be reminded that if the change leads to an increase in the content of perfumes or fragrances in a certain mixture above 5%, this cannot be part of the same group submission and a new submission is required.

Note: The rules for updates are one of the factors to be taken into consideration when it is possible to decide between standard and group submission. The decision needs to take into account not only the convenience of preparing the initial submission, but also the consequences for the updates in the future.

Examples and clarifications

Example 23: Changes in a group submission for two mixtures with a difference in perfume/fragrance components, submitted to an appointed body

GROUP SUBMISSION OF TWO MIXTURES WITH DIFFERENCE IN PERFUME/FRAGRANCE COMPONENTS			
UFI: C4P7-GHVS-ED8M-42DH	Product names: - Trade name 1		

Classification: # Product Category: #	- Trade name 2		
Components	**Percentage**	***Actual conc.*[a]**	**Classification[b]**
Chemical name comp. A	60-80%		not classified
Chemical name comp. B	7-10%		other
Chemical name comp. C	11-14%		major concern
Chemical name comp. D	1-2%		major concern
Fragrances (Generic Product Identifier)	not applicable (but <5%)	2	not classified
Chemical name fragrance 1	1-4%	1.5	other
Chemical name fragrance 2	0.3-0.6%	0.4	major concern
Chemical name fragrance 3	1-2%	1.1	major concern
Chemical name fragrance 4	not applicable (but <5%)	0.5	other (skin sens. cat. 1)
'Perfume MiM' UFI: A67T-VHG2-DMM4-NH2A	1-4%	1.8	other

The total concentration of perfumes/fragrances in each mixture cannot exceed 5% in order to qualify for a group submission [A.4.3].

The total concentration of fragrances identified with a given generic product identifier in each mixture cannot exceed 5% [B.3.2.3].

Fragrances not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity do not need information on concentration if the total concentration of such fragrances (i.e. not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity) in each mixture does not exceed 5% [B.3.4.2].

LIST OF PERFUMES/FRAGRANCES IN THE MIXTURES TRADE NAME 1 AND TRADE NAME 2		
Name	**Fragrance or perfume**	**Classification[b]**
Trade name 1	Fragrance chemical name 1	other
	Fragrance chemical name 3	major concern
	'Perfume MiM' A67T-VHG2-DMM4-NH2A	other
Trade name 2	Fragrance chemical name 2	major concern
	Fragrance chemical name 4	other (skin sens. cat. 1)
	Fragrances (Generic Product Identifier)	Not classified

Notes to the tables:

(a) Actual concentrations are reported for internal calculation purposes only; they are not necessarily required to be indicated in the submission.

(b) Classifications are indicated in this example with three categories: 'major concern' (list of classifications in B3.4.1], 'other' (all other hazard classifications) and 'not classified'.

The following changes may occur affecting the information included in the submission exemplified above:

• *Change of concentration of generic product identifiers*

If the concentration of *fragrances* is changed, but still remains <5 %, no update is required.

• *Change of concentration of classified perfume/fragrance component*

If the concentration of *Chemical name fragrance 2* is changed to <0,3 % or >0,6 % an update with a new concentration interval for *Chemical name fragrance 2* is required, but an updated list is not.

• *Addition of classified perfume/fragrance to a mixture in a group submission*

- If *Chemical name fragrance 1* is added to Trade name 2, but the concentration is still within the interval 1-4 %, only an updated list is required.
- If a classified perfume/fragrance, not declared among the components, is added to either of the mixtures, Trade name 1 or Trade name 2, an update of the components is required, as well as an updated list.
- If a perfume/fragrance not classified for any health hazards is added, but the total concentration of the generic product identifiers remains <5 %, no update is required.

• *Deletion of a classified perfume/fragrance in a mixture in a group submission*

- If *Chemical name fragrance 3* is removed from Trade name 1 an update of the components is required as well as an updated list.

Note that the total concentration of perfumes and fragrances contained in each mixture of the group should not exceed 5%. Otherwise the mixtures cannot be grouped and separate standard submissions are required.

7.4 Validity of the submission

In practice, many products may remain on the market (on shelves, in storehouses or in households) for years after a company has ceased marketing those products. Information may still be needed by poison centres in case of accidental exposure to those products. Therefore, submissions related to those products cannot just be retracted or deleted upon the cease of marketing or after the last placing on the market.

It is not possible to establish for every product – based on the type, use and market – a specific deadline after which the possibility of exposure to a mixture by consumers, professionals and even industrial users can reasonably be excluded. For this reason, deletion or removal of the submitted information from the databases has not been foreseen and, in principle, the information remains available to appointed bodies and poison centres (and in general for the personnel dealing with emergency response) indefinitely.

It is at the discretion of the appointed bodies to decide whether to apply a cut-off date to 'clean' information from their databases for practical reasons, e.g. after 20-25 years (diminishing the likelihood of an incident), or after, for example, 10 years if there has been no incident involving the mixture during that period.

It is the responsibility of the importer/downstream user to make sure that the submission is correct at any time and keep it up to date until the last date of placing on the market. The companies will have the possibility to indicate via the PCN to authorities the ceasing of their activity. In case new relevant information becomes available to the company after the last placing on the market, it is recommended that the information submitted for the purposes of Annex VIII is voluntarily updated in order to facilitate the emergency response work. It should be noted that after the last placing on the market, appointed bodies and/or poison centres can still request additional information from submitters, if needed for emergency reasons in the context of 3.2. of Part A of Annex VIII.

8. Additional support

Below is a list of additional sources of information and support tools, which may be relevant and is currently available:

ECHA Poison Centres Website (https://poisoncentres.echa.europa.eu/)

- For 'News' updates on the ECHA poison centre project
- Frequently asked Q&As which are regularly updated on a range of topics
- UFI generator and the user guide in all EU languages
- Tools for the preparation and submission of information
- European product categorisation system and manual
- Targeted support pages e.g. for industry

ECHA Website, support section (https://echa.europa.eu/support), which contains a range of support material besides the Guidance, including:

- Webinars
- Animations
- Publications e.g. 'In brief' material
- Helpdesk support

National Helpdesks

National Helpdesks have been established as the first point of contact for questions regulatory advice in your own language. You can find more details on your National Helpdesk here: https://echa.europa.eu/support/helpdesks

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