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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LEGAL NOTICE

Guidance on harmonised information relating to emergency health response

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Version	Comment	Date
	- Editorial changes and typos corrections.	

PREFACE

This document is the *Guidance on the harmonised information relating to emergency health response*. 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 hazardous mixtures placed on the market for formulating preventative and curative measures in case of accidents. The guidance is developed to primarily assist companies placing hazardous mixtures on the market in complying with their obligations. It is also intended to be a support tool for the appointed bodies in the Member States.

The first version of 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 and beginning of 2019.

[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 chemical products (e.g. detergents, paints, adhesives) are placed on the EU market and used both by the general public in their everyday lives as well as by professionals in their working environments.

Chemical products are in general considered to be safe when their use instructions are followed. 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 responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous. This information was to be used to meet any medical demand by formulating preventative and curative measures, in particular in emergencies. In 1999, the Directive was repealed by Directive 1999/45/EC[4], which provided for a similar obligation.

Therefore, many Member States already had in place a system for collecting information from companies that were placing dangerous mixtures on the market and have established bodies, called poison centres, to provide medical advice in health emergencies. The information collected has been used to meet medical demands of 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 advice on medical treatment in the event of a poisoning or accidental exposure incident.

The existing requirement for the EU Member States[5] to appoint a body for receiving this information, was incorporated in Article 45 of the CLP Regulation ((EC) No 1272/2008) which entered into force on 20 January 2009, repealing Directive 1999/45/EC.

Under the previous legislative regime and under the CLP, the absence of harmonised information requirements led to considerable variation in the existing national notification systems, data formats and information requirements. Thus companies placing mixtures on the market in different Member States needed to submit similar information multiple times and in different formats. This diversity 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 was assigned the obligation to carry out a review, as foreseen in Article 45 of the CLP Regulation, to assess the possibility of harmonising the information. The review was carried out in consultation with stakeholders and with the support of the European

[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] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
[5] 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.

Association of Poison Centres and Clinical Toxicologists (EAPCCT). Following the review, Commission Regulation (EU) 2017/542 was adopted. The new Annex VIII entered into force on 12 April 2017. The provisions of the Annex will apply to mixtures for consumer use from 1 January 2020, to mixtures for professional use from 1 January 2021, and to mixtures for industrial use from 1 January 2024.

Annex VIII sets provisions to harmonise, in terms of format and content, the information relating to emergency health responses that companies placing hazardous mixtures, as specified in the Annex, on the EU market are required to submit to the bodies appointed by each Member State (i.e. the "appointed bodies"). The required information includes, among other things, the clear identification of the mixture and of the economic operator responsible for the placing on the market[6], information on the composition and hazardous ingredient substances 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. A unique formula identifier ("UFI": addressed in detail in section 4) will allow the poison centres to unambiguously identify the composition of the mixture and propose the appropriate medical treatment in the event of poisoning.

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, where requested by the Member State (the allowed use of the submitted information is discussed in section 7). 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 amended CLP Regulation, provides that ECHA specifies the harmonised format (i.e. Poison Centres Notification (PCN) format) for the preparation of information by economic operators. The PCN format also aims to facilitate the management and use of the submitted information by authorities and poison centres, who will receive the information and make it available in a database serving the emergency health response purpose.

Additionally, Annex VIII foresees ECHA to facilitate the submission of information. For this purpose, ECHA has made available a centralised Submission Portal, which is a submission system that could be used as an alternative to the national submission systems where available (it is at the discretion of each Member State to indicate which system is to be used). More details are provided in section 6.

The deadlines for submitting the information are staggered and depend on the use type of the mixture (see section 3.4 for the definition of the different use types). Detailed information about timelines and deadlines is given in section 3.5.

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.

[6] According to Article 2(18) of CLP *"placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market."*

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 *submission* tools.

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 the 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[7].

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 then 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 according to 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, the harmonised European categorisation system (EuPCS) and the possibility to opt for a limited or a group submission. This section further explains the basic elements and

[7] It is to be noted that not in all Member States poison centres exist. Emergency service may be provide via different systems (see section 3.2.1 for further details).

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 (a detailed list of concerned legislation is available in the *Introductory Guidance on the CLP Regulation*[8]).

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[9].

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 economic operator 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 be part of the submission to the appointed body[10].

1.6.2 Other legislation

The EU legislation for biocides, plant protection products, cosmetics[11] and tobacco products are examples of EU 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 (and which is required before they are placed on the market), under the Biocidal Products Regulation[12] (BPR)

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[8] All ECHA Guidance documents are available in the Support section of the ECHA website at: https://echa.europa.eu/guidance-documents/guidance-on-reach.
[9] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
[10] Please note, even when it is technically possible to attach the SDS to the submitted information, this will not replace the obligation to provide the information on the mixture. Nevertheless the SDS may be required for components of the mixture in certain cases (section 5.3 provides the details).
[11] Note that CLP does not apply to cosmetic products that are in the finished state intended for the final user (Article 1(5)(c)).
[12] 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).

and the Plant Protection Products Regulation[13] (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[14], 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[15] 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).

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 assess 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 requirements under other EU laws. In addition, information submitted according to Article 45 cannot be used for purposes other than those specified therein. 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 to be noted that Annex VIII CLP is exhaustive, meaning that no additional information can be required under national legislation to that specified in Annex VIII for the purposes provided for under Article 45. However, certain aspects are left to the discretion of Member States, such as the establishment of acceptance criteria for submissions, 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 may have in place submission requirements for substances or mixtures outside the scope of Article 45 for purposes other than those defined in that same Article. This can be regulated by national legislation and in general under a legal framework which is different from Article 45 and Annex VIII. For more information it is recommended to contact the responsible authority in the specific Member State.

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

[13] 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.
[14] 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.
[15] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

2. Abbreviations/definitions

Standard term / Abbreviation	Explanation
Annex VIII	Regulation (EU) 2017/542 amending CLP by adding an Annex on harmonised information relating to emergency health response
Article 45	Article 45 of CLP
BPR	Biocides Products 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 mixture, 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 mixture, in the course of his industrial or professional activities (Article 2(19) of CLP).
EAPCCT	European Association of Poisons Centres and Clinical Toxicologists
EC	European Community
ECHA	European Chemicals Agency
EEA	European Economic Area
EU	European Union
EuPCS	European Product Categorisation System
Formulator	Company that produces a mixture. A formulator established in the EU is a downstream user.
GPI	Generic Product Identifier
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).
IUCLID	International Uniform Chemical Information Database

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
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)
SME	Small and medium enterprise
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)
VAT	Value added tax
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. The section clarifies also obligations which may need to be fulfilled by operators perfrming certain activities and not directly bound by Article 45, but following other provisions in the CLP (in particular Art. 4(9) and (10)).

3.1 Who is required to submit information?

The information required by Annex VIII has to be made available to the relevant appointed body, for each hazardous mixture (meeting certain criteria, see section 3.3) placed on the market. This is the information which is relevant for formulating preventative and curative measures in the event of an emergency health response.

'Placing on the market' according to Article 2(18) of CLP '*means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market*.'

Article 45 and Annex VIII to the CLP Regulation, identify importers and downstream users placing certain hazardous mixtures on the market, as responsible for complying with the requirements established in the same Annex VIII. These are also referred to as duty holders under Article 45 or, in the context of CLP Article 45 and Annex VIII, as "submitters". They have therefore the responsibility of submitting the information according to Article 45.

Companies in the supply chain of a mixture may have roles other than a downstream user or an importer 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 an obligation is one that involves distribution. If a company only stores and places on the market a mixture, without undertaking any other activity on the mixture, it is considered as a distributor and does not need to submit the information to the appointed body following Article 45.

However, distributors may also play an important role in the obligation placed on downstream users and importers to make information available to appointed bodies, which are eventually used by poison centres for the purposes of their work. This is relevant, in particular, for distributors that change the product identifiers of the mixture and/or sell the mixture in Member States other than the Member State where the downstream user or importer has supplied it.

Art. 4(10) of CLP[16] requires all substances and mixtures placed on the market to be compliant with CLP, conferring on all actors in a supply chain (i.e. also distributors, including re-branders and re-labellers) the obligation for the mixtures they place on the market to be compliant with Annex VIII to CLP. A national appointed body shall have at its disposal emergency health information for mixtures supplied in its Member State. A distributor placing on the market a mixture, which would jeopardise an appointed body's access to that information, would therefore run the risk to be in breach of Art 4(10).

The definitions of 'downstream user', 'importer' and other operators potentially part of the supply chain are given in Article 2 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

[16] Art. 4(10): "*Substances and mixtures shall not be placed on the market unless they comply with this Regulation*".

supply chain (including distributors).

As it will be clarified in this section, it is possible for a submission to be physically prepared and submitted by a party other than the one who has the legal duty to notify. The use of a third party does not relieve the duty holder under either Article 45 (i.e. importer or downstream user) or Article 4(10) (i.e. any actor placing certain hazardous mixtures[17] on the market) from their 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 in order to be compliant with CLP.

Note: The tool provided by ECHA to prepare and submit the information, called ECHA Submission portal (more details are provided in section 6) also allows the submission of the information by a third party on behalf of the duty holder[18], i.e. by outsourcing the preparation and submission of the information[19]. This could apply in various scenarios, for example:

- mother company/head-quarter submitting on behalf of a subsidiary,
- consultant on behalf of the duty holder.

3.1.1 Activities leading to submission obligation according to Article 45

The following activities carried out by an economic operator confer on them the obligation to submit information related to an emergency health response directly from Article 45 of CLP:

IMPORT ACTIVITIES

An economic operator that imports a hazardous mixture into the European Union, is an importer and therefore, they place the mixture on the market according to Article 2 of CLP and have the obligation to submit the information required by Annex VIII. The information must be submitted in the official language/s or any other language allowed by the Member State/s where the mixture is placed on the market. CLP 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 does not constitute import for the purposes of CLP (unlike import from, e.g. Switzerland). Companies importing mixtures from outside the EEA must ensure that they have all the available information required for the submission of the harmonised information.

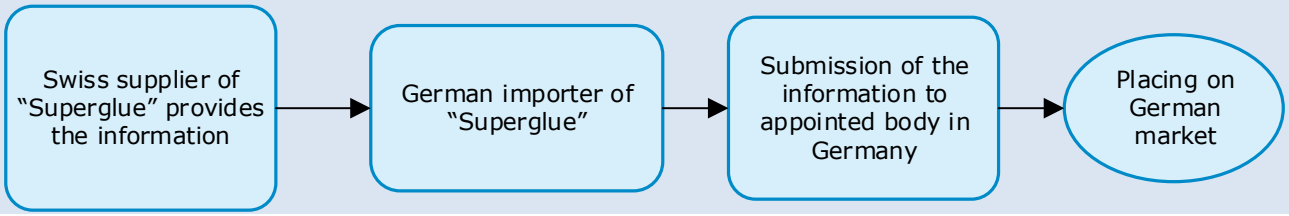
Details on the definition of importer are provided in section 2.1 of the *Guidance on Registration*[20].

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

A German company imports from Switzerland (a non-EU supplier) a mixture called Superglue and places it on the German market. This mixture is classified as hazardous for health effects.

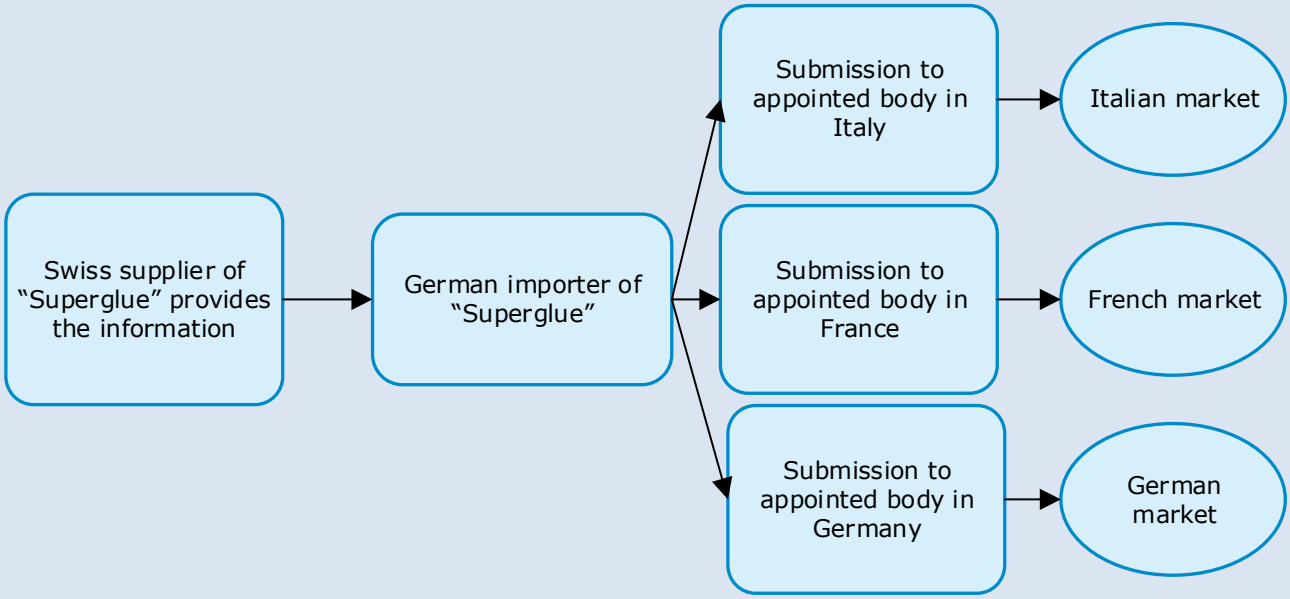
[17] When referring to hazardous mixtures in the context of Article 45, it is meant as classified for physical or human health hazards. This is explained in section 3.3.
[18] The availability of this option in case of national submission systems is to be checked with the relevant authorities.
[19] More information on ECHA accounts management is available in the ECHA accounts Manual. The possibility to assign a "foreign user" is included.
[20] Note that the *Guidance on Registration, and its section* 2.1, refer 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.

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.



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 by the German importer (from example 1), this company will have to submit the information to the appointed bodies of the relevant EU countries before placing the mixtures on the market in those countries.



The imported mixture may be used at the first place of import by the importer themselves, or may be imported in Member State A and subsequently placed on the market also in Member State B. A submission is required in both Member States A and B since import is deemed to be "placing on the market" (Member State A), and the mixture is placed subsequently on the market in Member State B. 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 3.4).

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 make their submission. Nevertheless, there are cases where complete information pursuant to Annex VIII is not available or not given because of confidentiality reasons (normally, as a minimum, information from the SDS should be available to the EU importer). An alternative way to work around this problem is described in section 4.2.5.

In any case it is ultimately the responsibility of the EU importer to demonstrate that they comply with Annex VIII (and other obligations under CLP) 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 EU importer may want to document such efforts for enforcement purposes to justify cases where the provided information on components of a mixture 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 Regulation.

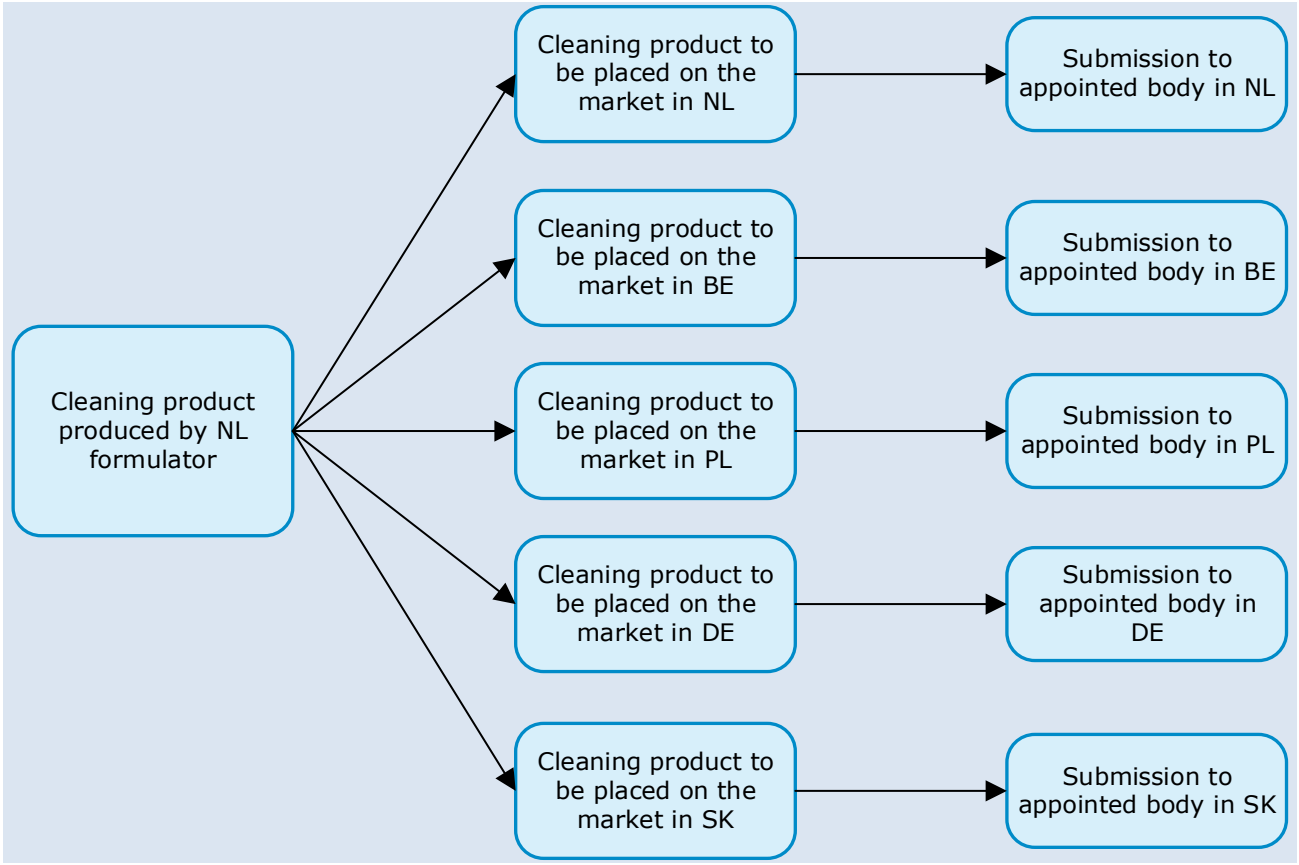
Therefore, any economic operator that formulates and places on the market a hazardous mixture meeting certain criteria (see section 3.3) has the obligation to submit the information in accordance with Annex VIII. The submission has to be made in all the Member States where the mixture is placed on the market in the official language of the relevant Member State (unless the Member State concerned provides otherwise, see section 3.2 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. In practice, the company which actually produces the mixture (in this case the toll formulator) 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 simply stores and places the mixture on the market they would be a distributor. If the owning company subsequently themselves uses that mixture, for example in the formulation of another one, they would be a downstream user and would have submission obligations under Article 45 for the newly formulated mixture.

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 or in the language(s) as requested by the Member State in which the mixture is placed on the market. In case the mixture is placed on the market in different packaging in the different Member States (it is assumed that the repackaging is still done by the original Dutch formulator), the information of the packaging relevant in each Member State must be given in the specific submissions.

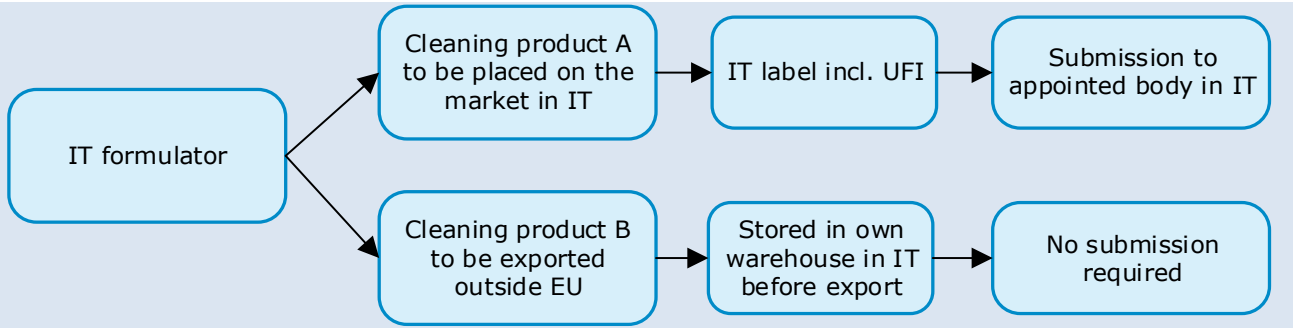


A company that formulates a mixture but does not place it on the European Union market and only formulates with the intention of exporting does not have the obligation to make the submission[21]. If the product is stored in a temporary warehouse before being exported outside the EU, this may qualify as placing on the market and therefore the obligations according to Annex VIII apply. This would be the case if, for example, the formulator makes available the mixture, whether in return for payment or free of charge, to a third party which stores the mixture in the warehouse before delivering it to a non-EU company. If the mixtures are stored by the same downstream user that formulates them in a warehouse, there would be no obligations to submit information[22].

Example 4: Formulation, mixture to be placed on the market outside EU

A formulator in Italy formulates two lubricant products (product A and product B) which are classified for aspiration toxicity. The lubricant B is stored in a warehose own by the same formulator before being 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 for product B.

[21] Please, note that other obligations under CLP may also apply.
[22] Please note that CLP does not apply to 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 (Article 1(2)(b).



REPACKAGING ACTIVITIES

A company that repacks/refills a mixture by transferring it from one container to another (and either keeps or modifies the content of the original label) is performing activities that qualify as downstream user activities according to CLP. This re-packaging company is therefore a duty holder for the purposes of Annex VIII under Article 45. This is the case even if the re-packaging 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, they may decide to request that their supplier makes a submission on their behalf (a contractual agreement would be needed). This will not only alleviate the administrative burden for the repackager, but it will also resolve the issue of repackagers often not having access to the full compositional and related hazard information.

If the supplier does not take up in his notification the re-packager's information, the repackaging company must make a separate submission. The repackaging company can use the same UFI as the supplier, or alternatively, they can generate their own UFI. In both cases, the composition of the product can be specified as consisting for 100% of the supplier's UFI (final mixture = 100% supplier's UFI as MiM).

In both cases (re-packager's information submitted by the formulator or submitted separately), the re-packaging company placing the mixture on the market (i.e. in the new package) remains responsible for the submitted information (i.e. the duty holder under Article 45).

3.1.2 Activities leading to submission obligations according to Article 4(10)

All distributors, including re-branders and re-labellers, have to comply with Art. 4(10) and can thus only place CLP-compliant mixtures on the market. That compliance requirement includes compliance with Article 45, which provides that a national appointed body shall have at its disposal emergency health information for mixtures supplied in its Member State. A distributor placing on the market a mixture, which would jeopardise an appointed body's access to that information, would therefore run the risk to be in breach of Art 4(10). The distributor, in order to be CLP-compliant, needs to consider the full supply chain. This is particularly crucial when a distributor supplies the product in different Member States than the Member State(s) where the supplier has placed the product on the market (and therefore made a submission) or changes trade/brand names, and/or labels.

Distributors (e.g. re-branders) must make sure to only place CLP compliant products on the market and ensure that all product identifiers (in particular trade/brand names and UFIs) under which the mixture is placed on the market are covered by a submission to the relevant appointed body.

This means that a distributor cannot place a mixture on the market where the appointed body:

- has not received the corresponding Annex VIII submission; or

- has received a submission by the supplier, but not all the relevant distributor's product identifiers, including e.g. trade names and UFIs, have been indicated.

It is to be noted that the requirement to comply with Article 4(10) does not necessarily lead to an obligation for distributors to make a submission under Article 45. Rather, if a distributor has the knowledge that certain information is not included in the original notification because it is not known to the original notifier (e.g. the fact that he is distributing in different Member States), he has the duty to make sure that this information becomes available to the appointed body. This can be done either by informing the upstream notifier or by making a notification themselves.

The objective of ensuring that the relevant appointed body will have at its disposal the emergency health response information for all mixtures supplied in its Member State can be ultimately achieved in the following ways:

- The distributor communicates upstream to their supplier(s) all the relevant information about the distribution step (e.g. country of placement and/or new identifier if one or both are different from the supplier). In this case the supplier has to include this information in their submission to all the relevant Appointed Bodies.

- Alternatively, if the distributor does not want to disclose the information upstream, or the original submitter refuses to take up the distributor's information in their submission, they will need to make their own submission. In this case the submission will include the full set of information required by Annex VIII, including the composition (who will possibly indicate that its mixture composition is made 100% by the mixture purchased from the supplier; see section 5.3 for more details on information on components)[23].

It is to be noted that importers and downstream users remain responsible for the submission of information under Article 45. For actors other than these, orders or penalties can be imposed by virtue of Article 4(10).

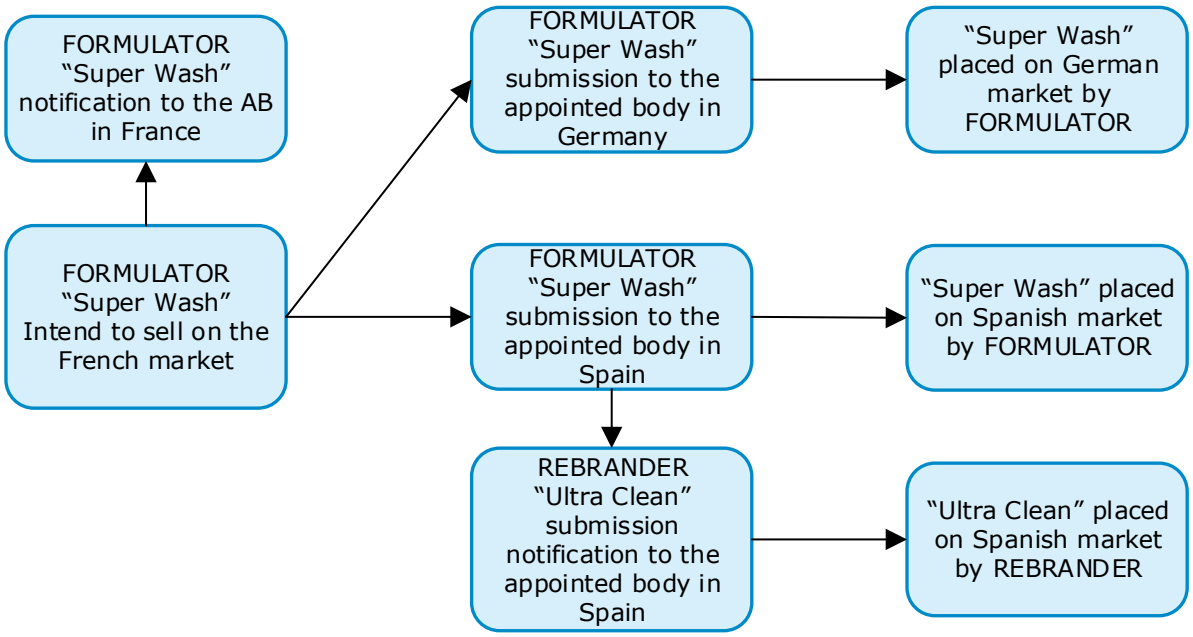
Example 5: Submission made by re-labelling company placing on a new market

A company in France formulates and intends to sell "Super Wash" on the French market. The mixture is classified 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 mixture on the market under a different name, the distributor submits the required information to the Spanish appointed body tehmselves.

[23] Note, that currently the ECHA submission portal does not provide the possibility to indicate the actual duty holder under Article 45. Communication should happen outside the system.



Example 6: Formulation, mixture placed on the market in several Member States

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. In accordance with Article 45 the relevant information must be submitted by the Swedish formulator to the appointed body in Sweden. Additionally, a submission needs to be made 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). Since the retailer is a distributor following Article 2(20) CLP, they do not have direct submission obligations under Art.45. Yet, he has the obligation by virtue of Article 4(10) to ensure that all relevant information is made available to the appointed bodies. The retailer can decide to either provide the information related to the distribution step to the supplier (i.e. the Swedish formulator, who includes the additional information in his submission) or, e.g. for confidentiality reasons, to make a submission to the appointed bodies of Denmark and Norway thmeselves instead. The label for the laundry detergent includes (in this example) all three languages.

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

Activity	Operator	Legal obligation to submit information? (duty holder)?	Why?	Options
Import	Importer	Yes	Legal text (Art.45)	A company may rely on their supplier (e.g. mother company) or other company to make the submission on their behalf - this submission would include their product details. They remain duty holder under Art.45 (if applicable, i.e. re-packager and re-filler) but they are not the legal entity submitting 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…
Formulation	DU	Yes	Legal text (Art.45)	
Re-packaging	DU	Yes	Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA *Guidance for downstream users*. (Art.45)	
Re-filling (see also above for re-packaging)	DU	Yes	Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA *Guidance for downstream users*. (Art.45)	

Toll formulation	DU	Yes	Toll formulators are downstream users. See ECHA *Guidance for downstream users*. (Art.45)	
Distribution	Distributors	Yes, if distributing in Member States other than the ones included in the original submission.	Legal text (Art.4(10))	Distributors cannot place a mixture on the market which is not compliant with CLP in general. Therefore, distributors have to make sure they don't distribute a mixture: - in a Member State where a submission has not been made; or - with a product identifier which was not included in a submission to the relevant appointed body. In case of distribution (including re-labelling and re-branding) in different Member States than the one where the original submission was made or with trade names not included in the submission, the distributor may provide the relevant information to the original submitter for inclusion in the submission. Alternatively they may decide to make their own submission to the relevant appointed body(ies).
Retail	Distributor (retailer)	Yes, if distributing in Member States other than the ones included in the original submission.	Retailers are by definition distributors. Obligations to provide information through Art. 4(10). Storage/placing on the market of mixtures to consumers without performing any activity qualifying as DU activity. See also ECHA *Guidance for downstream users.*	
Re-branding	Distributor	Yes	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*. (Obligations to provide information through Art.4(10)).	

Re-labelling	Distributor	Yes	Actor that adapts corporate colours or identifiers on the label to a mixture or adapts the label in another manner. The activity is not considered as a DU activity. See also ECHA *Guidance for downstream users*. (Obligations to provide information through Art. 4(10)).	
Commercial representative (=consultant)	The commercial representative is assigned the task to submit in the name and on behalf of the duty holder.	No	Legal text. The commercial representative is not an actor for CLP purposes, so not subject to Art.45 or Art. 4(10).	

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 the mixture is placed on the market. This includes the Member States where their mixture is sold via their distributors.

The information should 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)[24] responsible for receiving the information submitted by importers and downstream users related to mixtures placed on the market that are classified as hazardous based on their health or physical effects. 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 in a given Member State must have access to all the submitted information 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 should 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. See section 7.3 for further information about the use of the submitted information.

3.3 What is the scope of Article 45?

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[25] placed on the market on their own, 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 limited information requirements.

3.3.1 Which mixtures require information to be submitted?

Annex VIII 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 mixtures meeting any of the criteria defined in Part 2 and Part 3 of Annex I to CLP fall under

[24] Please note that the legal text (Article 45) foresees the possibility for a Member State to appoint more than one body, although it is not often occurring in practice. In subsequent text of the guidance all references are made to singular appointed body for readability purposes.
[25] Definitions in Article 2 of CLP apply. See Section 2 of this Guidance for a full list of relevant terms and definitions.

the scope of Article 45 and Annex VIII.

3.3.1.1 General exemption from CLP Regulation and Article 45

Pursuant to Article 1(2) of CLP, the Regulation (and therefore Annex VIII provisions) does not apply to:

- "*radioactive substances and mixtures […]*";
- "*substances and 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 research and development , 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, and
    - food or feeding stuffs.

3.3.1.2 Exemptions from the obligation to submit information under Annex VIII

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

- mixtures for scientific research and development (as defined in Article 2(30) of Regulation (EC) No 1272/2008),
- 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 (as defined in Annex I, 2.5 of Regulation (EC) No 1272/2008);
    - (2) explosives (unstable explosives and Divisions 1.1 to 1.6) (as defined in Annex I, 2.1 of Regulation (EC) No 1272/2008).

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.

3.3.1.3 Voluntary submission of information

For mixtures which are not subject to submission obligations (see sections 3.3.1), 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. A mixture, although not classified as hazardous on the basis of health or physical effects, may be harmful in certain poisoning cases (i.e. babies, pre-existing pathological condition, etc.). The availability of information even on such mixtures would significantly decrease possible uncertainties in case of emergency calls and therefore it could support a quicker and more effective identification or curative measures.

Mixtures for which submission of information 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 do 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 might allow the emergency responder to retrieve all the necessary information.

3.4 Use types

The identification of the correct use type for the mixture for which submission is made is important as it defines the information requirements and the deadline (see section 3.5 and Figure 1 below) 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 (e.g. 'Artists' craft and hobby paints', Figure 1);
- **Mixture for professional** use means a mixture intended to be used by professional users but not at industrial sites (e.g. 'Decorative paints, Figure 1);
- **Mixture for industrial** use means a mixture intended to be used at industrial sites only (e.g. Automotive coatings, Figure 1).

The use types are based on the concept of *end-use*. End-use means the use of a mixture, as a last step before the end-of-life of the mixture, namely before the mixture (or each of its components) is emitted to waste streams or the environment, is included into an article or is consumed in a process by reaction during use (including intermediate use as defined by the CLP Regulation)[26]. 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.

[26] Adapted from the ECHA Guidance R.12 *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.

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 professional or consumer use ("final mixture"), then the original mixture should be considered to be also for professional or consumer end-use and the corresponding information requirements must be fulfilled and the deadline met. When exposed to the final mixture, professionals or consumers come into 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.

While upstream formulators may not have a complete and detailed overview of all the final mixtures in which their original mixture (as a MiM) have been incorporated into, they often do have the general knowledge of whether their mixtures are incorporated into mixtures for professional or consumer use. In case of uncertainty, the company preparing the submission for the original mixture should, where possible, make an effort to gather such information. If new information about the use type of the original mixture becomes available after the submission, the information submitted under Annex VIII needs to be updated accordingly if needed.

Note that the submission should reflect the use type of the original mixture as placed on the market by the submitter, as well as the final mixtures where it may end up in (see section 5.2.3). However, when original mixtures end up in final mixtures which are not subject to submission obligations (e.g. the final mixture is a cosmetic product, or the final mixture is not classified for health or physical hazards), the uses of these final mixtures do not need to be considered for submission purposes with regard to the original mixture. For example, if a mixture for industrial use ends up in a final mixture classified for environmental hazards only, a submission for mixtures for industrial use suffices (relevant deadline and option for limited submission).

3.5 Timelines

3.5.1 Dates of application

The deadline for the submission of the information following the new requirements set by the amended CLP Regulation[27] will apply in a stepwise manner, according to the use type of the mixture i.e. consumer, professional or industrial use (see section 3.4). Importers and downstream users placing mixtures on the market not notified already 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.

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

Where 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.

Note that by 1 January 2025 a submission must be made for all mixtures on the market according to the harmonised Annex VIII requirements (see also section 3.5.2).

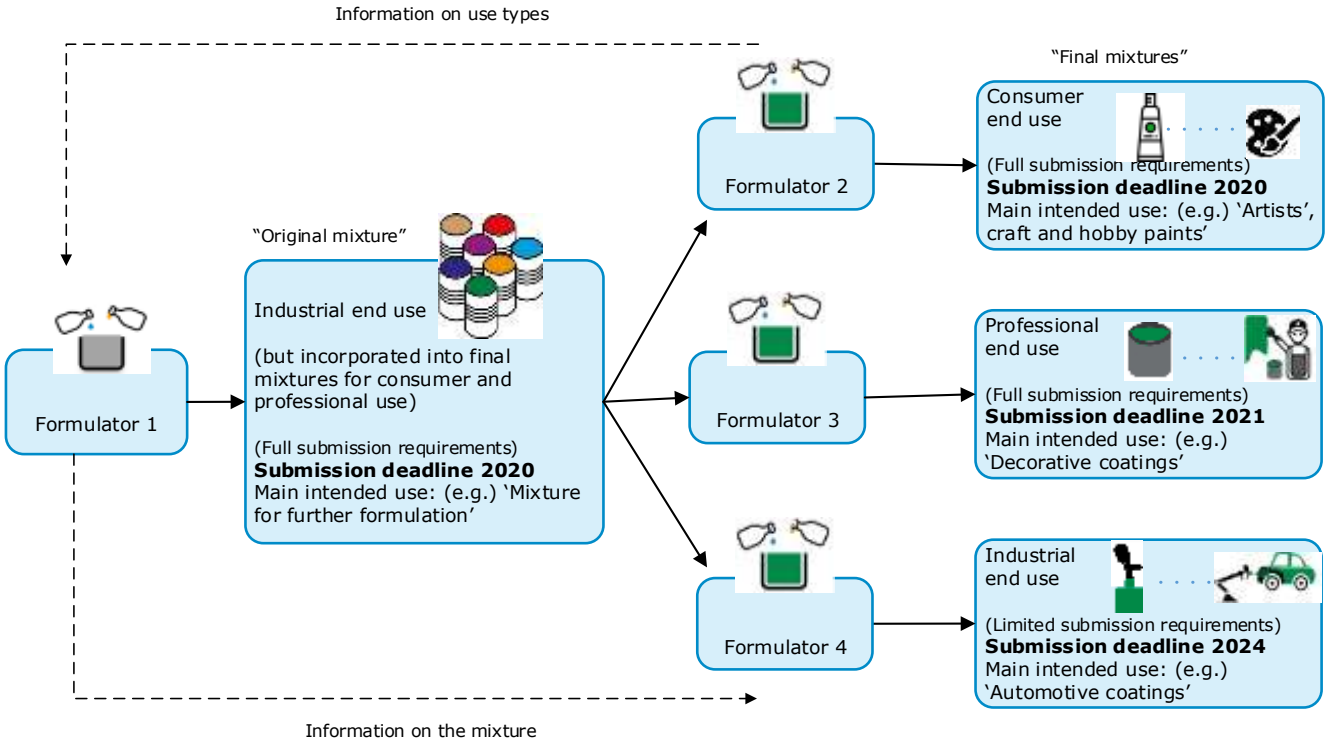
[27] It is amended by Commission Regulation (EU)2017/542 by adding Annex VIII.

Before these dates, mixtures continue to be subject to existing national requirements and duty holders should contact the appointed body in the country of interest for further information. A list of national appointed bodies is available at the ECHA Poison Centre website: https://poisoncentres.echa.europa.eu/

Companies can decide to make 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 duty to make a parallel submission according to national provisions being in force until the date of applicability of Annex VIII.

Independently from any obligation under Annex VIII, obligations at national level (established under different legal frameworks and for purposes other than those defined by Article 45) may also remain valid and may still need to be fulfilled regardless of the submission having been made under the new format.

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



3.5.2 Transitional period

If a company has already submitted information relating to hazardous mixtures to an appointed body 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 cases where there is a need to provide updated information (see below).

If the company intends to keep placing the same mixture 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 made in due time to allow them to continue placing the mixture on the market.

However, if there is a change in the mixture composition, product identifier (including UFI) or toxicological properties during the transitional period (i.e. after the relevant date of application mentioned in section 3.5.1 and before 1 January 2025) the duty holder is required to submit information concerning 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 made under the existing national system(s) according to the existing definition of end use in a specific Member State (definitions of end use types may have been implemented differently in different Member States before the entry into force of Annex VIII) remains valid. The company does not need to comply with Annex VIII before the end of the transitional period if their actual end use type does not change even if the definitions of use for their mixture has changed.

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 (when allowed by the Member State) using the Submission Portal provided by 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 hazardous mixtures (within the scope of Article 45) placed on the market will generally be required to carry a Unique Formula Identifier (UFI)[28]. 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. A mixture being subject to the notification obligation according to Annex VIII CLP may not be placed on the market, if it does not carry a UFI which is linked to a valid submission. This is essential in order to ensure the functioning of the system of providing emergency information. Information on the generation and use of UFIs is provided in section 4.2.

Duty holders are also required 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 make the submission should be aware that besides the standard submission, Annex VIII allows a limited submission for mixtures intended for industrial use only (see section 3.4 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 submission. Information on the group submission option and the criteria to be met are provided in section 4.5.

[28] 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).

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 will thus need to complement information from other sources or consult their supplier for more specific information, especially regarding composition where practical. 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 mixture is being placed on the market, unless the Member State specifies otherwise. Some of the Member States may accept submissions in more than one language or in English as an alternative to their own language(s). A table listing Member States and the language(s) accepted for the submission is available[29] 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 ECHA Submission Portal largely 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) for example by means of a structured format containing standard phrases (see section 6.2).

4.2 The UFI for mixtures and products

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 on or affixed to the label of a product 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 product placed on the market. Here, we refer to a mixture as a formulation containing the chemical components having associated properties for example composition, toxicological properties, colour, and pH, while a product refers to the mixture in the form in which it is supplied to the user and defining the other aspects for example trade name, packaging, and product category (i.e. intended use).

All products for which submission is made with the same UFI need to share the same composition[30]. 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.

[29] The list is, at the time publication of version 1.0 of this Guidance, under preparation. It is planned to be made available soon.
[30] Note, in case of group submission (addressed in sections 4.5 and 5.4) the same UFI could be used to refer to several similar mixture compositions.

The UFI is meant to complement the other means used by poison centres to identify the mixture, 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 (or compositions with very limited differences, see section 5.4 for details). 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 guide free of charge. Both are available on the ECHA Poison Centres website at https://poisoncentres.echa.europa.eu/ufi-generator.

The UFI of a specific mixture is based on the value added tax (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. The VAT number therefore is by no means used for identification or tracking of companies or products.

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, except for group submissions where mixtures may differ in perfume or fragrance components up to 5% (See section 4.5). 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 section 4.2.3).

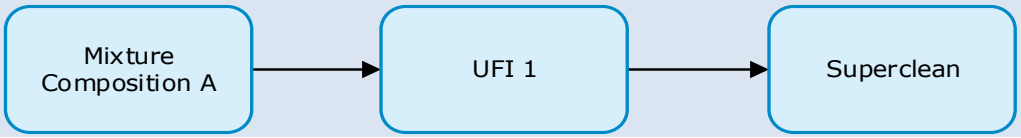
Note that in specific circumstances there is an alternative method for companies to generate UFIs if they do not have a VAT number through the same software application (more information available in the UFI generator user guide).

4.2.3 How to use UFI

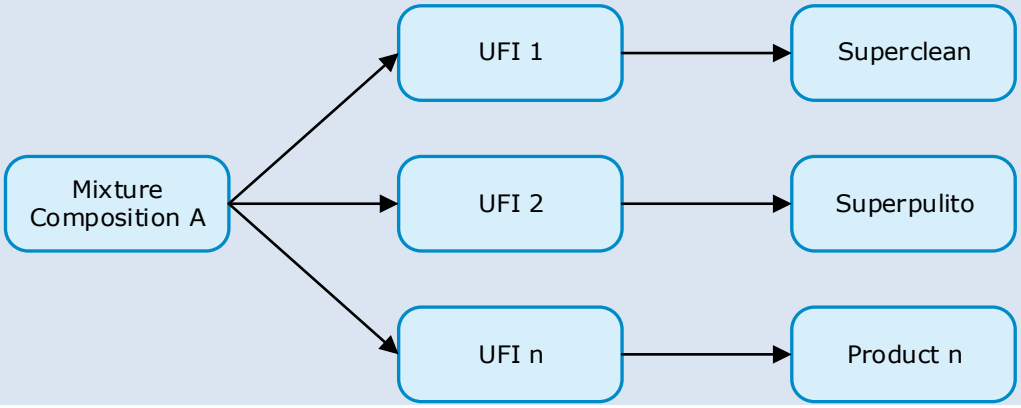
In this section a number of examples are presented showing with increasing level of complexity how and when a UFI has to, or can be, generated; graphical representations are also provided to support the reader. The following examples illustrate the flexibility around UFI generation and its use, while 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 (See section 4.5).

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.

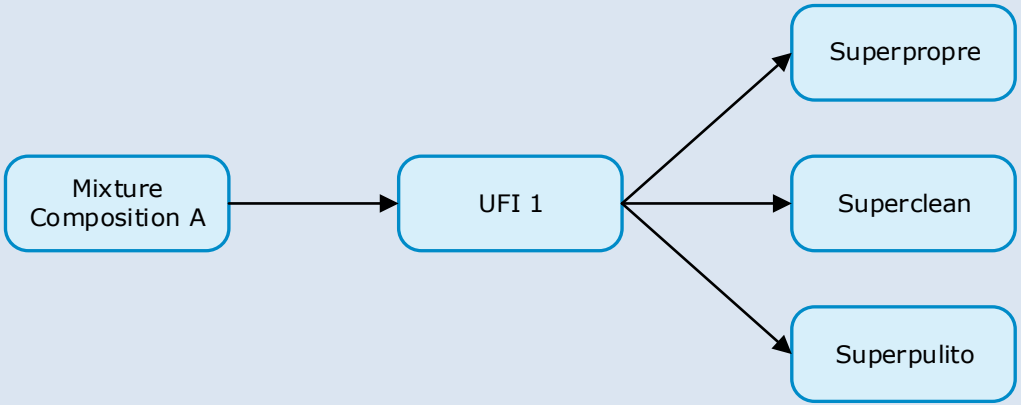
Example 7: 1 Mixture composition– 1 UFI – 1 product placed on the market ("Superclean")



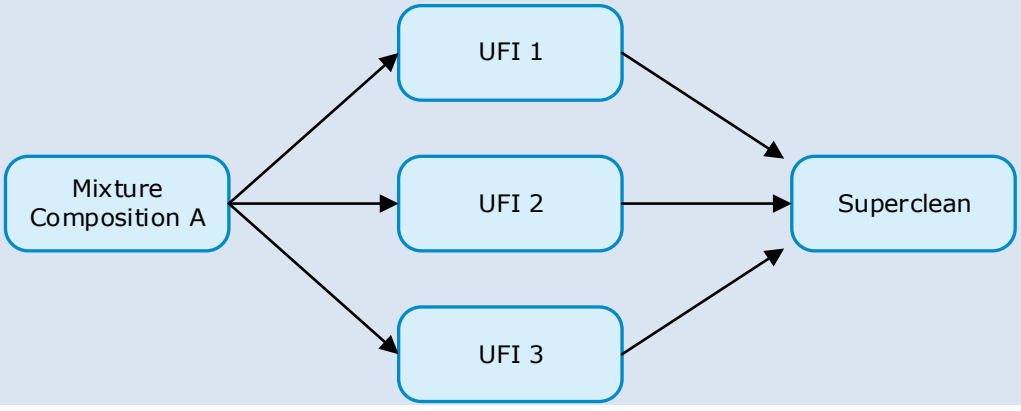
Example 8: 1 Mixture composition– 2 or more UFIs – 2 or more products placed on the market with same composition



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



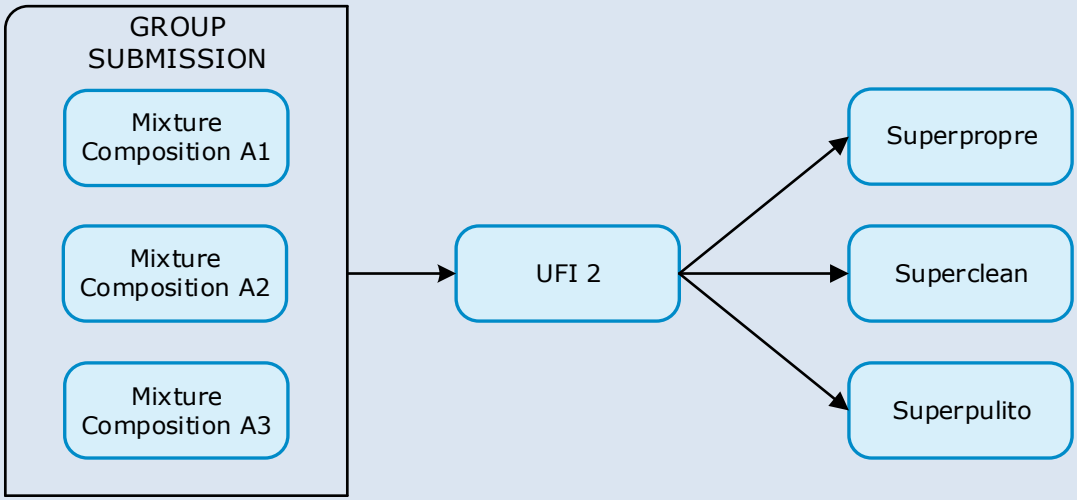
Example 10: 1 Mixture composition – 2 or more UFI – 1 product placed on the market



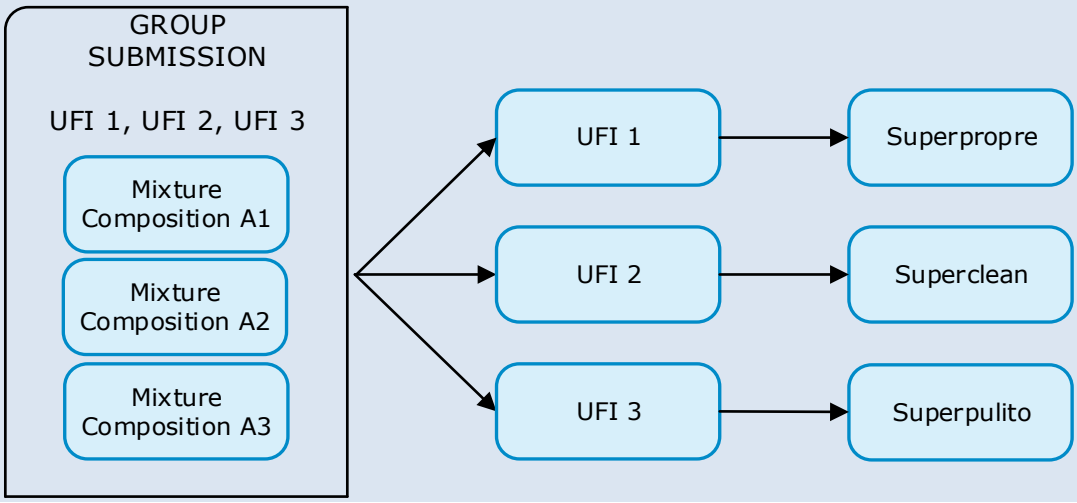
Note to examples 7 to 9: When several UFIs have been generated and assigned to one mixture, all those UFIs need to be included in the submission to the relevant Member State and can be submitted individually or in the same submission. When more than one UFI is assigned to the same product (containing the same mixture), it is sufficient to include only one UFI on the label of the product (example 9) while all UFIs should be indicated on the SDS.

For group submissions, one UFI can be used to cover the whole group of mixtures (although it is not an obligation) even though the mixtures in a group do not necessarily have the exact same composition. 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.



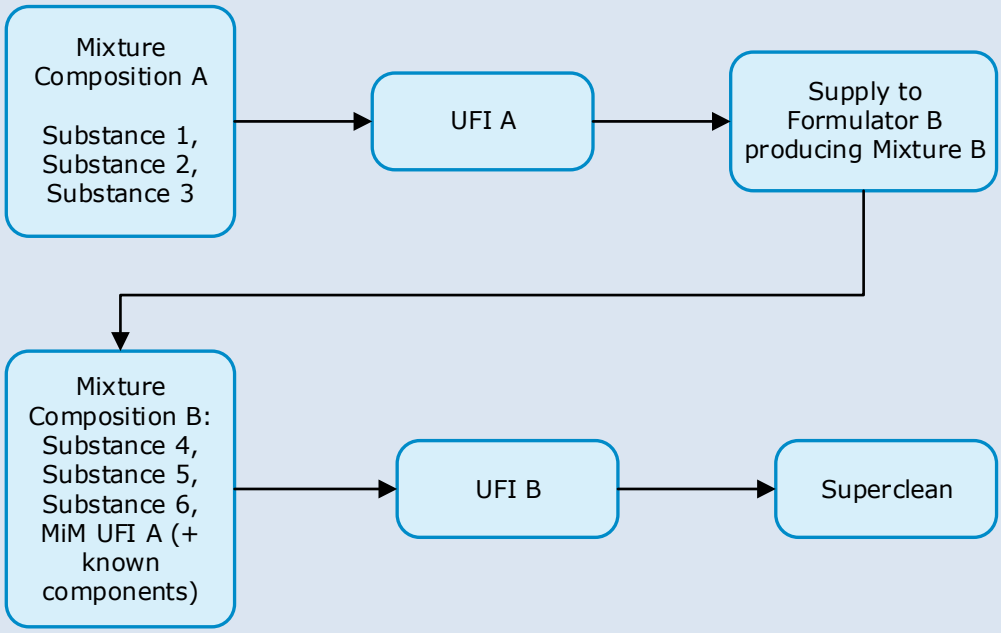
4.2.3.1 UFI and mixtures in a mixture

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). Provided that the submission for the MiM has been previously made 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.

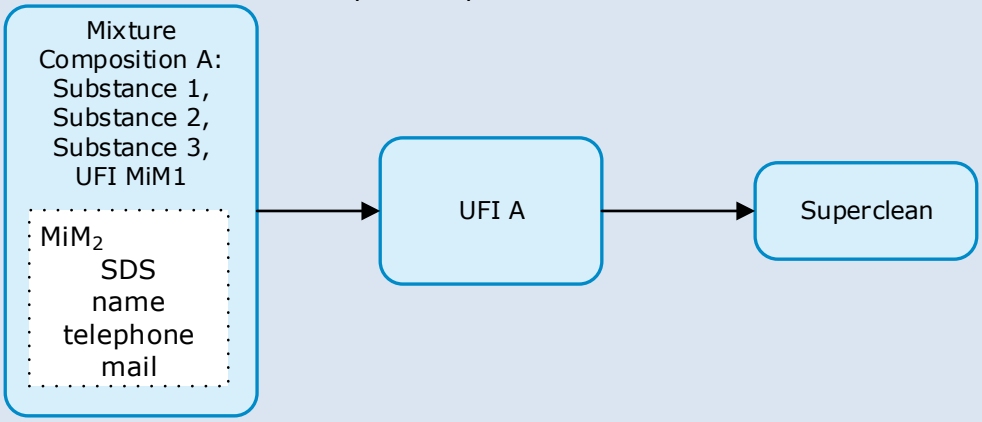
More details about information requirements for mixtures and their components is provided in section 5.

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; section 5.3.3 addresses also the case of absence of an SDS).

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 does not necessarily have to) be used by other downstream users/formulators in the supply chain (in case of a formulator, this would become the 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.

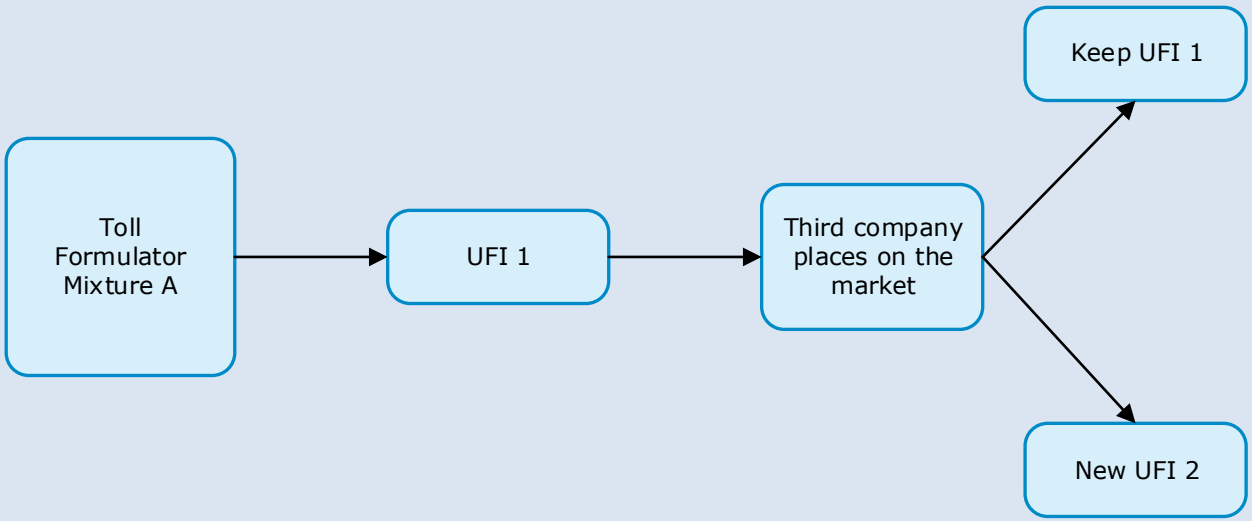
There may be cases (during the transitional period) where suppliers may decide to include the UFI on the labels already before making the submission (i.e. there is no obligation to submit yet, and the UFI is printed on the label voluntarily). In these cases it is strongly recommended to clearly communicate to the downstream user (that may use that mixture as MiM) that the information on the MiM has not been submitted yet. The inclusion of the UFI on the label should ideally be followed by the submission within a short period of time.

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 i.e. a 'third company' and often also provides the label with the contact details and brand name of the customer (more details are in section 3.1). 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 their customer. If the customer does not change the formulation, they 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) which needs to be included in the toll formulator's submission to the Member States where it is placed on the market (and include it on the label) – bearing in mind that the toll formulator remains the duty holder.

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



4.2.5 UFI and non-EU suppliers

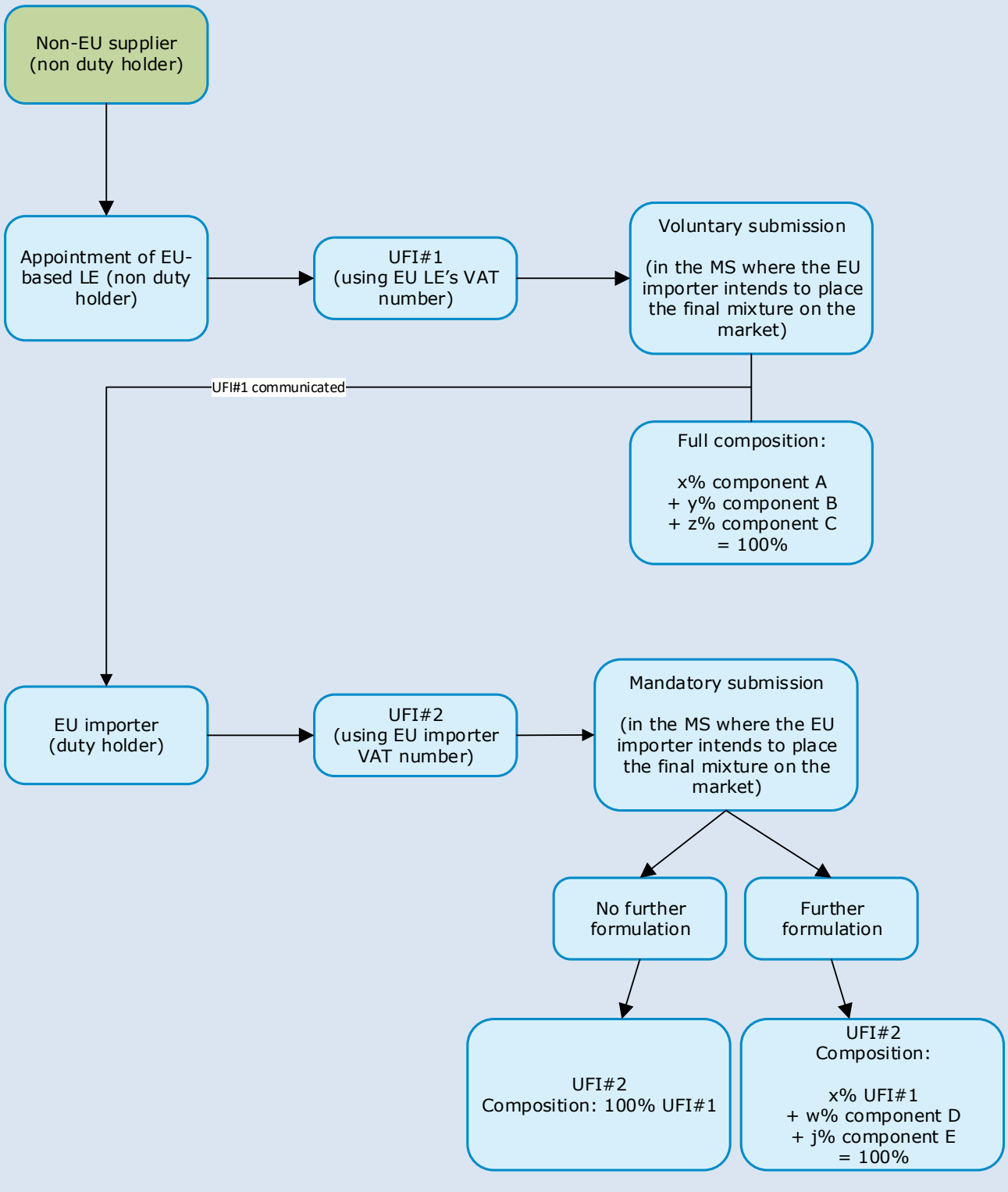
In case of import, UFI can be used in the communication with a non-EU supplier. The following way can be considered to work around possible communication problems.

The non–EU supplier has a legal entity based in the EU (or a contractual agreement with an EU-based legal entity), which creates a UFI and makes a voluntary[31] submission to the Member States where the EU importer intends to place the mixture on the market. The non-EU supplier informs their customer (the EU-importer) about this UFI and confirms that the submission is done. Subsequently, the EU importer, who is the actual duty holder, makes their own submission with a reference to this UFI in relation to the compositional information. The importer could therefore make a submission for a mixture containing 100% of the MiM supplied by the non-EU supplier. This option could be useful also when the EU importer uses the mixture to formulate another mixture, and the non-EU supplier wants to protect the confidentiality of the information on the mixture they supply to the EU importer. The obligation to place UFI on the label lies with the importer. It is possible for the non-EU supplier to already label their product with the correct UFI before supplying it to the importer.

The EU importer and non-EU supplier are strongly recommended to enter into a contractual agreement to cover the details of the submission approach chosen. It should be kept in mind that that the EU company remains in any case the duty holder and therefore responsible in front of the enforcement authorities. Furthermore the EU importer remains responsible for the fulfilment of other obligations under CLP (e.g. classification of the mixture).

[31] The non-EU entity is not legally required to do so under CLP (they do not place the mixture on the EU market). More about voluntary submissions in section 3.3.1.3.

Example 16: Import into the EU – Non EU supplier acting via EU-based legal entity to protect CBI



4.2.6 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" [32] 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 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, it could be necessary to generate new different internal codes for each mixture to be used in the UFI generation. This may be necessary in order to ensure different UFIs are assigned to mixtures with differences in composition (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, physico-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.

4.2.7 New UFI as a result of composition changes

Since the main purpose of the UFI is to unambiguously link a product on the market and the corresponding information relevant for an emergency health response, the UFI is always linked to a specific composition[33]. 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[34]. 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

[32] Available at https://poisoncentres.echa.europa.eu/ufi-generator.
[33] Note, in case of group submission the same UFI could be used to refer to several similar mixture compositions.
[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.

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. To be noted that if a fragrance or perfume component is removed from all the mixtures of the group an update of the submission is required (see section 7.4.6; according to B.3.1 perfume or fragrance components have to be present in at least one mixture of the group).

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 and no requirement to update the 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 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 exceed the 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 7.4. Please note that these changes will not necessarily change the classification of the mixture and therefore an update of the label in this regard would usually not be triggered.

The UFI should be updated also when the indicated range of one or more components are changed, even if the actual concentration remains the same. For example a concentration of 30% of a particular component is originally indicated with the range 28-33% and the submitter changes the indicated range to 30-35% (without changing the actual concentration). Since poison centres normally use the upper range limit in their assessment (calculation of exposure), the same UFI for two different submitted compositions may generate confusion.

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.

4.2.7.1 Changes in MiM's UFI

When a mixture is used by an operator downstream as component of another mixture, a change in the UFI of this MiM may trigger the need to update the UFI of the final mixture.

It may be in some cases that a MiM supplier changes the UFI either for commercial reasons (i.e. they can guarantee that the mixture composition remains the same), or the mixture composition has changed. In both cases the submission for the MiM needs to be updated to add the new UFI.

Where the MiM composition has changed, the new MiM UFI will also need to be reflected in the

submission of information for the final mixture (see the examples in section 7.4.4) and this requires also the UFI of the final mixture to be changed.

If the UFI of the MiM changes for commercial reason only (i.e. no changes in the composition) there is no impact on the final UFI and therefore it does not need to be changed. The submission will need to be updated by adding the new MiM's UFI (more information on update rules are provided in section 7.4).

4.2.8 Display, position and placement of UFI

The UFI must be printed on or affixed to the label of the hazardous mixture for which submission obligations apply (see derogations mentioned in section 4.2.8.2).

In case of a hazardous mixture for industrial use (see section 4.4 on limited submission) the UFI may alternatively be indicated in Section 1.1 of the SDS. In case of mixtures which are unpackaged, the UFI shall be indicated in Section 1.1 of the SDS[35].

The UFI code itself must be preceded by the acronym "UFI" in capital letters and must be clearly visible, legible and indelibly marked. The acronym "UFI" must always be used using the Latin alphabet, independent of the country, language and national alphabet(s).

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.
- Affixing the UFI to the label is possible instead of printing directly on the label. The sticker is to be 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).
- To help distinguish the acronym from the beginning of the UFI, 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).

For practical reasons, the UFI could be also printed on the packaging, as long as it remains in the proximity of the other labelling information and clearly visible.

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.

[35] Section 1.1 of Annex II to REACH. See also ECHA *Guidance on the compilation* of SDSs. CARACAL has endorsed the interpretation that no default requirement to place the UFI in the SDS (except for unpackaged mixtures) is needed. Please note that the amendment proposals for Annex VIII to CLP and Annex II to REACH are currently under discussion in CARACAL.

This leads to strings such as

UFI:VDU1-414F-1003-1862
(23 characters)

UFI: VDU1-414F-1003-1862
(24 characters)

UFI: VDU1-414F
1003-1862
(23 characters on two lines)

Font colour also needs to be considered. For example, black on a light background is a good option; conversely, a light coloured font should be used on a dark background. In principle, any colour can be used, notably in order to consider the printing equipment capabilities, provided it meets the requirements of being clearly and indelibly marked.

Monospaced style fonts have proven to be suitable - 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 font style to ensure that the UFI is legible for a person with average eyesight (e.g. legibility could be improved by using a slightly larger font size for a bolder font; more details can be found in section 5.2 of the *Guidance on Labelling and Packaging in accordance with CLP*[36]).

There are no explicit rules concerning the positioning of the UFI on the product. Article 25(7)[37] of CLP defines the UFI as supplemental information. While this type of information should be located in the section for 'supplemental information' on the label' for example near the hazard pictograms (see section 4.8 of *Guidance on Labelling and Packaging in accordance with CLP*) the UFI could be alternatively outside the label as long as it is located 'with' the other label elements[38]. This allows some flexibility for the cases where frequent formulation changes occur requiring a new UFI to be put on the product. In any case, where exactly the UFI is positioned is left to the discretion of the person responsible for compiling the label or designing the packaging, though as a general rule, the UFI is easy to locate and read.

In general the placement of the UFI on the label or on the pacakging, will follow the general rules in accordance with Article 33 of CLP. The UFI is considered to be part of the supplemental labelling information and the corresponding labelling requirements need to be followed. The

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

[37] Regulation (EU) 2017/542 amended CLP by adding the new Annex VIII and the additional paragraph 7 to Article 25 (Additional labelling information).

[38] Please note while it is the Commission's and a majority of the Member States' view that legal interpretation of the CLP allows placement of the UFI on the packaging and this approach was endorsed by CARACAL, based on a limited number of Member States' comments on the legal interpretation, discussions are to be finalised whether the current legal text already allows such a combined reading of Art. 32(4) and Art. 31(5) or whether an amendment of Annex VIII, Part A, section 5.2 and Article 25(7) of the CLP Regulation is required.

Guidance on Labelling and Packaging in accordance with CLP, provides, in particular but is not limited to, information on:

- Exemptions for labelling requirements in specific cases in section 5.3 (e.g. small packaging, use of fold-out labels and outer packaging).
- Specific rules for transport labels and labelling outer, inner and single packaging in section 5.4.
- Example labels e.g. for multi-component products in section 6.

4.2.8.1 Multi-component products

Mixtures can be placed on the market not only as products containing a single mixture, but also as part of a set of multiple mixtures (e.g. reagent or testing kits). In these cases, each single mixture bears the label relevant to that mixture, where required[39]. Each mixture that is part of a set 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 cases, 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 adhesives). The company placing multi-component products on the market must provide a UFI for each component-mixture in separate submissions[40]. Nevertheless information concerning the final mixture is also potentially important for the emergency response, and should be provided (if available and relevant) in the submission of the component mixtures (e.g. in the toxicological section). The proportion in which the component mixtures are foreseen to be mixed in the final mixture is an example of such final mixture related information which could be provided. Section 6.2 of the Guidance *on Labelling and Packaging in accordance with CLP* provides relevant additional information and examples on the labelling of these specific products.

4.2.8.2 Exemption from labelling requirements [A.5.3]

For mixtures which are intended for industrial use it is not mandatory to include the UFI on the label provided it is indicated in the SDS. This does not include industrial mixtures that are further formulated into 'final mixtures' for consumer or professional use i.e. the derogation applies if the condition for a limited submission are met. The same derogation applies for mixtures irrespective of the end user type which are placed on the market but not packaged (e.g. cement, according to Part 5 of Annex II to CLP).

4.3 EuPCS

A harmonised European product categorisation system (EuPCS) maintained by ECHA[41] is used

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

[40] The rationale is that the obligation to submit information concerns mixtures 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.

[41] 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/.

to describe the intended use of a mixture for which information according to Annex VIII has to be submitted (section 3.4 of part A of Annex VIII). Examples of product categories from version 1 of the EuPCS include "Hand dishwashing detergents", "Adhesives and sealants for construction", "Decorative paints and coatings"[42]. 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 be used 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 making a submission for a hazardous mixture, duty holders must assign a product category which best defines the intended use of the product(s). The same principle is followed in the case of mixtures that may fit multiple product categories, for example, a 2-in-1 laundry detergent also containing a stain removal agent: it is the responsibility of the notifier to select the main intended use, which in this case, the main intended use would likely 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. An EuPCS practical guide has been published[43] to support categorising products according to their main intended use.

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 3.4. The 'use type' is based on the final end user of the mixture (and 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' for example raw material fragrance mixture, which is eventually incorporated into a 'final mixture' for example 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 made fulfilling the information requirements for mixtures for consumer use (i.e. deadline for submission 2020) and its intended use must be categorised as code 'F' - 'Mixtures for further formulation'.

ECHA is responsible for the maintenance and any changes to the EuPCS. Requests for updates or adaptations can be made 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 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

[42] The latest version of the EuPCS is available from the ECHA Poison Centre website.
[43] The EuPCS Practical Guide is available at https://poisoncentres.echa.europa.eu/eu-product-categorisation-system.

rationale for this specific regime is provided in Recital 11 of Regulation (EU) 2017/542,[44] 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 make a limited submission are invited to consult *ECHA's Guidance on the compilation of safety data sheets*,[45] 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 5.3.4 for more information.

It needs to be noted that if a submission was made for a mixture originally intended for industrial use only (limited submission) and this mixture starts being used in consumer or professional products, the full set of information required for a standard submission needs to be submitted before placing on the market the products with the new use type.

In the case when there is a difference in the definitions of industrial, professional or consumer use under national and the harmonised systems, no obligations apply for this reason only until the end of the transitional period (1 January 2025).

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 Part B 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;
- a telephone number accessible 24 hours per day and 7 days per week, where 'additional detailed product information', which is not included in the SDS but would be requested by Annex VIII in a standard submission, can be obtained by the appointed body in case of an emergency;
- an email address for follow-up exchange of information between the submitter and the responsible authority or medical personnel.

Please note that the contact details could belong to the submitter or to a third party appointed under the responsibility of the submitter in charge to deliver the required information.
The person who is requested to provide the additional information may want to verify that the request comes from an appointed body. As an example, a reference to a submission identifier could serve this purpose as it should be available to the submitter and authorities only.

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

[44] 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.
[45] *Guidance on the compilation of safety data sheets*, in particular section 3.3 'Composition/ information on ingredients'.

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.

Note that rapid access must be provided in a language(s) of a Member State where the mixture 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 to meet a medical demand by formulating preventative and curative measures in the event of an emergency. Annex VIII (section B.1.3) indicates that rapid access to detailed information, in case of limited submission, has to be available for appointed bodies. It is to be underlined that it is normally poison centres (or bodies other than the appointed bodies) who are dealing with poisoning accidents and will need rapid access to the information.

If, following receipt of the 'additional detailed product information', the appointed body makes a 'reasoned request' according to Section 3.2 of Part A of Annex VIII to the submitter that further additional information or clarification is necessary, the submitter must provide the necessary information or clarification requested without undue delay (see section 7.2 for more details).

It should be noted that the 'limited submission' is optional. Operators dealing with hazardous mixtures for industrial use and who are required to make 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 Annex VIII allows to submit, under certain conditions, information for several mixtures with a single submission, which is called 'group submission'.

A group submission is possible if:

- 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 a hazardous mixture on the market for which they have made a submission under Article 45 (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 4.2).

In addition to this, there are other elements from the label which are important to poison centre operators such as the *"complete trade name or names of the mixture […], including, where relevant, brand name, name of the product and variant names as they appear on the label"* [B.1.1]. 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[46]. 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 different products exist with the same main name (e.g. brand name or trade name) and different other names. The latter would therefore facilitate a correct identification.

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

[46] Note that a limited variability in composition may still exist if generic product identifiers are used to cover different components. See following subsections for more details.

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 the Member State(s) 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 (including supplemental hazard information) (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 SDS of the mixture as specified in Annex II to REACH apart from the classification regarding the environment hazards. Note that even in situations where Annex I to CLP allows for reduced label elements, the full set of label elements indicated in Section B.2.2 of Annex VIII (and reported above) have to be included in the submission.

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 required for 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 test, 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, for example contain information on toxicokinetics, metabolism and distribution as well as more elaborate information on the toxicological effects and test methods.

The submitter 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 should 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, pH, intended use and user 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). Some of the information may need to be adequately linked to the specific trade name/product 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, for example 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 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). In case the submission covers a mixture where the colouring agent(s) relevant to a specific trade name varies [47], 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

[47] For both standard and group 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.

provided taking into account its purpose, i.e. for an 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. The PCN provided by the Agency supports the identification of colours by providing the list of colours identified as appropriate in this context (including the possibility of indicating multiple colours as well as colourless mixtures).

- *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 use type(s) of the mixture as supplied by the submitter has to be indicated in the submission. As use type is based on end-use, the end-user group must also be reflected since the final end-use of the mixtures determines the deadline for submission and information requirements. For example in case the mixture is supplied for professional use but is also available for consumer use, then consumer use has also to be reflected in the submission. Similarly, the submission concerning a mixture for industrial use needs to additionally reflect the consumer end-user if it finally ends up in a mixture (as a MiM) for consumer use. The use types are defined in section 3.4 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, for example 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 on human health 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 made (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 is normally required, except when certain conditions apply (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.

To be noted that a "generic product identifier" can be used to indicate certain components (either a substance or a MiM). This is explained later in this section.

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, for example because he has added it intentionally or it has been communicated to him by a supplier in, for example a safety data sheet. Submitters are not legally required to analyse their mixtures to determine the presence of components. Nevertheless, it is recommended to make an effort in actively seeking missing information from their suppliers, 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. the substance is classified for inhalation only but its 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 (SCL)[48] exists 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% and the substance con/centration is between SCL and 0.1 %). There is no obligation to include the justification in the submission. This can be the object of a "reasoned request" by the appointed body if it decides so (see section 7.2).

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, for example 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, for example 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. Substance 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. Where MiM components or substances are the same (i.e. have the same chemical identity) but are classified differently by different suppliers, it is recommended that the submitter contacts the suppliers to investigate the reasons for such difference with the aim to agree on a common classification.
- 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 (exact value or range) and UFI, when available (see point C below for information about concentration and classification). Also all known MiM components

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

must be provided (e.g. based on the SDS) in separated form, i.e. not aggregated[49]. It should be noted that, if the full composition is not known, a mixture purchased from different suppliers who assign different classifications cannot be considered to be chemically the same mixture[50]. Enforcement authorities may enquire how the duty holders have complied with this legal condition for lower information requirements.

- As a last resort, in the 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 the two above scenarios. In the meantime, 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. Such information may be, for example, "accessible" upon request; the duty holders would then have met the legal condition if they demonstrates that they contacted the suppliers by email which replied that the requested information cannot be provided because it is confidential. Enforcement authorities may enquire about how the duty holders have complied with this legal condition for lower information requirements (no access to information).

In the absence of UFI and in the absence of SDS (for mixtures not classified for any hazards, where no obligations to create UFI and provision of SDS exist), the submitter should retrieve information available from other sources (e.g. CAS number, name of main component(s) used when purchasing, etc.).

Example 17: Aggregation of components from different sources

A company purchases 2 mixtures (MiMs) and 2 substances from different suppliers to formulate their product SuperClean which they intend to place on the EU market.

The company has knowledge of the full composition of these ingredients (see table below). Same substances are included in the final mixture as components of the MiMs X and Y as substances as such (1 and 2).

Ingredients purchased by Company A	Concentration in final mixture	Composition
Mixture X (MiM X)	20%	Substance 1 - 30% Substance 3 – 40% Substance 4 – 30%
Mixture Y (MiM Y)	30%	Substance 2 – 15% Substance 3 – 25% Substance 5 – 60%

[49] In case the composition of the MiM is not fully known, information should be provided for each known component separately, in order to reduce the risk of confusing information for emergency responders.
[50] To be noted that the Commission's workability study currently ongoing (and planned to be finalised by the end of 2019) will potentially address this issue.

Substance 1	5%	Na
Substance 2	10%	Na
Water	35%	Na

The company will indicate in the submission the components of their final mixture in an aggregated form. The concentration of each substance will refer to the final mixture SuperClean:

Component	Concentration in final mixture
Substance 1	6 (20% x 30%)+ 5 = 11%
Substance 2	4.5 (30% x 15%)+ 10 = 14.5%
Substance 3	8 (20%x40%) + 7.5 (30%x25%) = 15.5%
Substance 4	6% (20% x 30%)
Substance 5	18% (30% x 60%)
Water	35%

A **generic product identifier –** "perfumes", "fragrances" 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.

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[51].

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

In case a range is used, its width should be chosen in a way that for each possible value within that range, Table 1 (table 2 above) is complied with. This means that if, e.g., the exact concentration is 26% and a width of 5% units is used, its lower limit should be not less than 25. Any concentration value below 25% would require a maximum width of 3%.

[51] This should not be done in case the composition of the MiM is only partially known as it may lead to misleading information for poison centres and emergency responders.

Example 18: 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: 23-26% (since the exact value can possibly be < 25, a maximum range of 3% units has to be used), 24-27%, 25-28%, 25-29%, 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.

This applies also to components identified by means of generic product identifiers.

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.

All components classified as hazardous on the basis of their health or physical effects may need to be included in the submission even if present in concentrations below 0.1% if 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

Also with regards of components of minor concern, in case a range is used, its width should be chosen in a way that for each possible value within that range Table 2 (table 2 above) is complied with.

Example 19: 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[52].

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 a submission needs to be made contains one or more MiM(s) (for which full composition is 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.

Example 20: Use of Generic Product Identifiers

In option A, all components are included in the submission with the 'chemical name', health/physical hazard 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 fragrance/perfume components are grouped. Note: the indicated concentrations, classifications and number of components are chosen with the sole purpose of explaining the requirements.

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

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.3.2.3]. '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 (GPI)	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 concentration 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% (or alternatively of "Fragrance chemical name 7"as long as the limit of 5% is not exceeded).

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*[53].

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 not classified components, and sets for the hazardous components to be indicated concentration thresholds and ranges 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%).

Additionally, in this case information on the packaging is not required and can be provided on voluntary basis.

5.4 Group submission [A.4]

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 (see section 4.3 for details on the EuPCS);

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

- have very similar composition (see section 5.4.2 for details);
- 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, MiM, 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 A.4.3 of Annex VIII. The latter 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, for example '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 (and their distributors). A group submission can only include the details of one 'legal submitter' (i.e. duty holder). It is not possible to group mixtures that are placed on the market by different duty holders.

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 provided to facilitate the fulfilment of the obligations: 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 3.4 of this Guidance.

Trade names, colour, packaging, use types and UFIs should be indicated for every individual product in the group. This information may be useful 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 of the colour field can be accepted for paints and other similar categories for example inks, where high numbers of products with great colour variability can be included in the same group submission (provided they are not classified).

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

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).

The same product category has to be assigned to the mixtures of the group.

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 all 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 of the group, or are those differing between the mixtures). In practice this means that if the mixtures contain common fragrances/perfumes indicated by chemical name or GPI, the 5% threshold will have to include those common fragrances/perfumes, leaving less than 5% for the varying fragrances/perfumes.

The perfumes and fragrances contained in each mixture of the group must be given by providing a list to identify the perfumes or fragrances they contain, including their classification.

The information required on the mixture composition in a group submission is illustrated by examples 21 and 22. 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 21: 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: - N200-U0CW-5009-QWHJ - G500-C029-F00T-D83M - P800-U0RP-S009-1KPP 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)	<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 % (in MiM) 8-12 % (in MiM)	Other *[Optional]* *[Optional]*

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 as required in section B.3.1 of Annex VIII:

Name	Fragrance or perfume	Classification*
Trade name 1 UFIs: N200-U0CW-5009-QWHJ G500-C029-F00T-D83M	Fragrance chemical name 1	Other
	Fragrance chemical name 3	Major concern
	'Perfume MiM' A67T-VHG2-DMM4-NH2A	Other
Trade name 2 UFI: P800-U0RP-S009-1KPP	Fragrance chemical name 2	Major concern
	Fragrance chemical name 4	Other (skin sens. cat. 1)
	Perfumes (GPI)	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 all perfumes and fragrances contained in each mixture does not exceed 5%' [A.4.3]. This concerns the sum of 'actual concentrations' (which are known to the submitter, see below) 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 [B.3.2.2]. Classification of MiM's components can be provided on voluntary basis.
- Since the MiM composition is not fully known, information on the concentration of known MiM components refers to the MiM itself.
- The specific concentration of the components included under GPI "Perfumes" does not have to be indicated provided that the total concentration of those perfumes or fragrances does not exceed 5%'.
- While classification of the mixture is a mandatory information requirement, the classification of the known components of a MiM is not (but it useful information which can be provided on voluntary basis).

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 3.8%.

Example 22: Grouping of mixtures with difference in perfume/fragrance components

GROUP SUBMISSION
UFI: C4P7-GHVS-ED8M-42DH
Product category: All-purpose (or multi-purpose) non-abrasive cleaners
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	Serious eye irritation cat. 2	7-10%
	Processing aid xxx	Not classified	1-2%
	Water	Not classified	66-76.4%
	Perfumes components	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: # *(optional)* Known component 2: # *(optional)*	UFI A67T-VHG2-DMM4-NH2A + known component 1+known component 2 + …etc	-	*Not needed [B.3.4.2]*
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	-	0.6-1.6%

Product- trade name CDE				
Components	**Classification**	**UFI**	**SDS**	**Concentration**
Perfume mixture b	Skin sens. Cat 1B + asp. tox	Not available	Provided	0.5-0.9%
Perfume (GPI)	Not classified	Not applicable	-	0.1- 1.1%

Notes to the tables of example 22:

- 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 Group submission		
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 1B + asp. tox.	Products- trade names ABC+CDE
Perfume (GPI)	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 [A.3.1]. 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. The tools support the preparation of 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 [A.6].

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 Tools for preparing IUCLID XML files

ECHA will provide companies with an online and an off-line tool for dossier preparation that allows manual entry of data and creation of XML files. Those tools are the ECHA Submission portal (online) which features the guided dossier preparation and the IUCLID software (off line).

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(1) CLP. Submissions must be made to the appointed bodies by electronic means endorsed by them for that purpose. It is at the discretion of each Member State to define the technical means of submission, including the possibility to 'outsource' this task and allow the submission of information centrally via the ECHA Submission portal. Submitters are invited to carefully verify the conditions and instruction for the submission of the information with the countries where the mixture is placed on the market.

The ECHA Submission portal provides for industry the following main features:

- Online preparation of dossiers in the IUCLID Cloud using the guided dossier preparation tool

and on line submission via the ECHA Submission portal;

- offline preparation of dossiers using the IUCLID software and on line submission via the ECHA Submission portal;

- off line preparation of dossiers using the company's own internal IT system adapted to the XML format and submission to the ECHA Submission portal via system-to-system integration.

For Member States the following main features are provided:

- submissions can be downloaded manually together with a submission report;

- submissions are received automatically via system-to-system integration (i.e. eDelivery solution).

- access to submissions in a central data base (view and search) hosted by ECHA.

Whether the submissions are made by industry and received by Member States centrally through the ECHA Submission portal, or locally through 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.

Information on the tools provided by ECHA and how to prepare and submit the required information is provided on the Poison Centres website, in particular "Tools" and "Support" sections: https://poisoncentres.echa.europa.eu/.

6.5 Fees

The usage of XML formats, UFI generator, EuPCS and ECHA Submission Portal 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 before 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.

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 7.3). No additional information can be requested under national legislation to that specified in Annex VIII for the purposes provided for under Article 45. 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 (expected within a short timeframe after the submission). Should the appointed bodies identify areas that are deficient, unclear or maybe considered conflicting, they could contact the company who made the submission and request clarification or justification for any open or conflicting areas (e.g. regarding the quality of toxicological information provided or its consistence with other information). These checks are related to the overall compliance of the submitted information with the requirements of the Annex VIII.

Additionally, 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. In the case of an emergency, unforeseeable situations or in general on an *ad hoc* basis, appointed bodies may request under point A.3.2 other information (potentially exceeding the boundaries of Annex VIII) which is necessary to perform the activities under Article 45 (see section 7.3 below). These requests, should be justified, limited to particular cases, cannot be made on a systematic basis and can occur at any point in time.

Examples of a reason for requesting additional information could be the following:

- A need for access to more detailed data, based on which the toxicological information was prepared by the submitter.
- To evaluate the correctness of assigned product category according to EuPCS.
- To enquire about possible presence of non-classified components which are not required to be included in the submission (low concentration thresholds) but could be relevant to assess the hazard (e.g. synergistic effects) or the potential exposure (e.g. bittering agents).
- To enquire about packaging information not included in the submission following incidents involving children (e.g. child-resistant fastening).

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. These data can help to identify particular trends in incidents or to adjust the focus of preventative actions.

7.3.1 Security and confidentiality of the submitted information

Information submitted to appointed bodies may contain sensitive and confidential elements. Systems which handle this information should be designed to follow strict security standards. The information can be used by personnel authorised by the appointed bodies.

Appointed bodies and poison centres have to 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, unless it is necessary to inform health care professionals about a specific substance to ensure the patient receives the correct treatment.

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. It 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. Duty holders are required to provide the relevant information in compliance with Annex VIII before placing a product 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.

It should be noted that existing submissions made in accordance with national rules are valid until 1 January 2025 (see section 3.5). However, if a change described in Section 4, Part B takes places before that date (and after the relevant deadline according to the use type described in section 3.4), a submission update has to be made in accordance with Annex VIII.

7.4.2 Update rules according to Annex VIII

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 3.5.1 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 mixture 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, or
- the composition of the mixture is changed following:
  a) Addition, substitution or deletion of one or more of the components that needs to be indicated[54], or
  b) Change in the concentration range provided in the original submission; i.e. the concentration of a component of the mixture, is changed beyond the concentration range provided in Table 1 and 2 Annex VIII, or
  c) Change in the exact concentration provided in the original mixture; i.e. 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.

Note that whenever changes listed above occur, an update of the submitted information is required before the mixture, as changed, is placed on the market.

7.4.2.1 When declaring concentration ranges

Changes in the mixture component concentration ranges, for instance for a hazardous component of major concern (see Table 1 in Part B of Annex VIII), can be illustrated in example 22. The component 'B' present at a concentration of 20.5%, can be reported using a range of 3% (for instance 19.9-22.9%). If the new concentration falls out of this range (e.g. the new concentration is 23.5%), an update of the submission is required and a new UFI has to be created. However, if the change in the concentration stays within the mentioned range (e.g. the new concentration is 22.1%), there is no obligation to update the submission.

Example 23: 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

7.4.2.2 When declaring exact concentrations

When declaring the exact concentration of mixture components, only limited changes to the exact value are allowed within a certain variation without the need to update. Allowed

[54] To be noted that the substitution of one component (substance or MiM) by 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.

variations are listed in Table 3 of Annex VIII (see Table 4 below). If the new concentration exceeds the allowed variation, an update is required and a new UFI has to be created. Example 24 illustrates that if a component is present in a mixture in a concentration of 72% when the original submission is made, an allowed variation of ±5% (or more) of the initial concentration triggers the need to update the submission. Therefore an update is needed if the new concentration is <68.4% or >75.6%.

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%

Example 24: Mixture submitted with exact concentrations of 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 UFI (%)**
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

Note: 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) and 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.

7.4.3 Other (voluntary) updates relevant for an emergency health response

It needs to be underlined that other changes not listed in Section 4.1 Part B of Annex VIII may take place and these 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 are particularly relevant when affecting mixture identifiers) or update a submission with new information (e.g. change in packaging type).

The submitter is recommended to voluntarily update the submission as soon as one or more pieces of the information not listed in Section 4.1 Part B of Annex VIII changes. It is important

that a submission always reflects the most recent information about a product.

In general, it is an obligation for the duty holder to make sure that a submission containing all the relevant information on a product placed on the market and required by Annex VIII, is made to the relevant appointed body(s).

7.4.4 How updates are technically handled

While all the changes described above require or should trigger an update of the information submitted (depending on the legal or voluntary reason), they may be handled differently by the system at the technical level in order to respond to the need of the ultimate user, i.e. the poison centres.

From the submitter's perspective it will always be an update of the submitted information, but from a technical point of view, different 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). These are:

(i) addition of information (e.g. new additional trade name, new additional packaging, new additional UFI for MiM component); the information originally submitted remains relevant for the poison centre (e.g. mixture keep being placed on the market with the original name in addition to the new one).

(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; new contact information for rapid access to additional product information); the information originally submitted is not relevant anymore for the emergency responders even for products already on the market only the new information should be considered.

(iii) creation of a technically new 'submission 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).

Examples and clarifications

Table 5 below presents some examples of changes and the associated scenarios. In most cases they apply to both single and group submissions. Information specific for updates of group submissions, when different from single submissions, can be found in the next section (7.4.5).

Table 5: Examples of possible changes requiring an update and their related scenarios.

Changes	Legal requirement or voluntary update	Scenario triggered
Addition of a new trade name only[(a)].	Legal requirement	Scenario (i) – addition of information.
Addition of a new UFI only[(a)].	Legal requirement	Scenario (i) – addition of information.

Changes	Legal requirement or voluntary update	Scenario triggered
Modification of the classification for health or physical hazard[(b)] following change in classification criteria.	Legal requirement	Scenario (ii) – replacement of old with new information.
Addition of new toxicological information (e.g. results from new tests on the mixture become available). The existing information remains valid.	Legal requirement	Scenario (i) – addition of information.
New packaging *Note, the mixture in original packaging may remain on the market for long time.*	Voluntary	Scenario (i) – addition of information.
Supplier changes MiM UFI but the composition remains the same (change due to commercial reasons)	Legal requirement	Scenario (i) – addition of information *Note that a new UFI is not required.*
Change in telephone number for rapid access to additional product information	Voluntary	Scenario (ii) – replacement of old with new information.
Addition, substitution[(c)] , deletion of component(s). Supplier changes MiM UFI due to compositional changes of MiM, which impact composition of final mixture (for group submissions with perfumes, fragrances or generic product identifiers, see below 7.4.5).	Legal requirement	Scenario (iii) – creation of a technically new 'notification record'. *Note that a new UFI must be provided.*

Changes	Legal requirement or voluntary update	Scenario triggered
Modification of reported concentration ranges, **beyond** the indicated range.	Legal requirement	Scenario (iii) – creation of a new 'notification record'. *Note that a new UFI must be provided.*
Modification of reported exact concentration **beyond** the indicated range	Legal requirement	Scenario (iii) – creation of a new 'notification record'. *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) The classification of a mixture may change when a new harmonised classification of a component in the mixture is agreed or when new information becomes available. In that case, an update is required no later than when the new classification becomes applicable.

(c) 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.

7.4.5 Updates – special cases with 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 "perfume" or "fragrance" 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.

When changes are made to components declared as generic product identifiers in a group submission, refer to section 7.4.6 below.

7.4.6 Updates – special cases with group submissions

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.

Nevertheless, if a perfume/fragrance covered by the generic product identifier is added, but the total concentration of the generic product identifiers remains <5 %, no update is 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 25: 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 Classification: # Product Category: #	Product names: - Trade name 1 - 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)	<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) 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 total concentration of components indicated with GPI *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.

• *Addition of not classified perfume/fragrance to a mixture in a group submission*

- If a perfume/fragrance not classified for any health hazards is added (i.e. which can be identified via the GPI), but the total concentration of the components identified via the same generic product identifier remains <5 %, no update is required.
- If a perfume/fragrance not classified for any health hazards is added and it is indicated with the chemical name, an update of the component is needed. If the total concentration of this perfume/fragrance together with the components identified via the generic product identifiers remains <5 %, the concentration does not need to be indicated [B.3.4.2].

• *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: the total concentration of all 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.

7.5 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 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 ECHA Submission Portal 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 or statistical analysis for improved risk management measures in the context of 3.2. of Part A of Annex VIII. It is at the discretion of each Member State to decide whether to apply a cut-off date to 'clean' information from their databases for practical reasons, for example 20-25 years after the submitter indicated cease of the activity (diminishing the likelihood of an incident), or after, for example, 10 years if there has been no incident involving the mixture during that period.

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 Annex VIII related topics
- UFI generator and the user guide in all EU languages
- PCN format and support documentation (including data model)
- Tools for the preparation and submission of information
- European product categorisation system and manual
- Targeted support pages e.g. for industry ("Step for industry" which supports in fulfilling the obligations step by step).
- Publications e.g. 'In brief' material
- Animations

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

- Webinars
- Helpdesk support

National Helpdesks

National Helpdesks have been established as the first point of contact for questions on 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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