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

Version 4.0
March 2021

ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki
19 February 2021

Note to the reader

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

Dear user of this Guidance,

When reading this ECHA Guidance document, please be aware that the consulted national authorities of EU/EEA Member States were unable to reach a consensus on the interpretation of duty holders under Article 45. The authorities of the following Member States disagree with the current Guidance where this considers certain operators, namely rebranders and relabellers, as distributors and not downstream users (section 3.1.2):

Belgium
Germany
Greece
France

The authorities of Sweden and Greece do not consider that Article 4(10) poses legal obligations on distributors in relation to Annex VIII as described in this ECHA Guidance document.

The authorities of Denmark are not in a position to express an opinion on the matter.

This is reflected in the CA/30/2019 (rev2) document which is available on the CIRCABC website.

Consequently, for information on the implementation of the aspects of Article 45 of the CLP Regulation covered by this note and CA/30/2019 in these Member States, the reader is invited to contact the competent authorities of those Member States.

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Executive Director

LEGAL NOTICE

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

Reference: ECHA-21-G-03-EN
Cat. Number: ED-03-21-081-EN-N
ISBN: 978-92-9481-822-5
DOI: 10.2823/375906
Publ.date: March 2021
Language: EN

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/contact

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DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	February 2019
Version 2.0	Update via fast track procedure to complete section 3 on duty holders. Details about obligations related to distribution steps have been added. In particular: - Modified introductory section 3.1 to clarify the activities leading to submission obligations for downstream users and importers under Article 45 and certain distributors under Article 4(10). - Modified example 4 (section 3.1.1) to include the scenario where the distributor makes the submission. - Restructured sections 3.1.1 and 3.1.2 to present separately activities leading to obligations under Art.45 and Art.4(10). - Moved example 6 to section 3.1.2 and new figure added. - Updated table 1 to include obligations for distributors. Removed column on "Obligations along the supply chain". In addition: - Revised section 6.3 to reflect the updated terminology referring to the submission tool provided by ECHA. - Revised section 6.4 to reflect the updated list of features provided by the ECHA submission tool. - Replacement of "deadline" by "date of applicability" with reference to the timeline to meet the obligations. - Updated the additional support section. - Editorial changes and typos corrected.	July 2019
Version 3.0	Update to implement the amendment of the legal text due to Commission Delegated Regulation 2019/11 of 29 October 2019. In particular: - Removed reference to Generic Product Identifier "Fragrances" throughout the document. - Added in section 3.1.1 new subsection on import/manufacturing of combination of mixture and article. - Added example 11 in section 4.2.3. In	May 2020

Version	Comment	Date
	addition, clarified labelling and SDS requirements in case of multiple UFIs in the notes to the examples. - Amended section 4.2.8 on labelling requirements and UFI placement and aligned with Guidance on Labelling and Packaging. - Clarified in section 4.2.8.2 that exemption to labelling requirements applies to mixture used at industrial site. - Added contact point in section 5.1.2, in addition to submitter details. - Clarified and further developed pH requirements in section 5.2.3. - Amended section 5.3.3 with regard to requirements for identification of MiMs when composition is not fully known. Clarified that for MiM not requiring an SDS, the compositional information is not mandatory. - Editorial changes and typos corrected. In addition, removal of Portugal from the list of countries mentioned in the Note to the reader.	
Version 4.0	Update to implement the amendment of the legal text due to Commission Delegated Regulation 2020/1677 and Commission Delegated Regulation 2020/1676 of 31 August 2020 (the "workability amendments"). In particular: - Added in section 3.1.1.4 reference to articles with integral substance or mixture intended to be released. - Added in section 3.3 clarification about the borderline between mixture and substance. - Added new section 3.3.1.3.1 to address the exemption for bespoke paints. - Added in section 3.4 a clarification about mixture with end use not subject to notification requirements. - Added in section 4.1 an introduction on the new workability solutions. - Added in section 4.2.1 a clarification of the UFI concept applied to Interchangeable Component Groups, Standard Formulas and Fuels. - Added in section 4.2.7 clarification about the need to update the UFI in case of notifications concerning Standard Formulas, fuels or containing Interchangeable Component Groups.	March 2021

Version	Comment	Date
	- Added new section 4.2.8.3 to provide details on the labelling requirements for bespoke paints. - Added in section 5.3.1 clarification about the extended exemption to the obligation not to notify components which are not present. - Added in section 5.3.2 a recommendation to report the presence of microorganisms in the mixture when relevant. - Clarified in section 5.3.3 the identification requirements for mixtures in mixture. - Added new section 5.5 on the Interchangeable Component Group solution. - Added new section 5.6 on the special provisions for ready-mixed concrete, gypsum and cement products (Standard Formulas solution). - Added new section 5.7 on the special provisions for certain fuels. - Added in section 7.3.1 clarification about security of submitted information. - Added new section 7.4.2.3 clarification about update rules applying to submissions made referring to Standard Formulas. - Added new section 7.4.2.4 clarification about update rules applying to submissions for fuels made referring to the safety data sheet. - Other editorial changes and typos corrected.	

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 State's 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, version 1.0 of the text was consolidated and edited by ECHA and underwent the formal consultation with ECHA Partners during 2018 and beginning of 2019. The document has been subsequently updated and consulted again with the same ECHA Partners to implement the changes in the legal text in 2020 and 2021.

[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

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[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, adding Annex VIII to CLP. The new Annex VIII entered into force on 12 April 2017. The same Annex was amended twice: by Commission Delegated Regulation (EU) 2020/11[6] and subsequently by Commission Delegated Regulation (EU) 2020/1677 and Commission Delegated Regulation 2020/1676 of 31 August 2020[7]. The provisions of the Annex apply to mixtures for consumer use and 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[8], 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 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 date for compliance with the new submission requirements are staggered and depend on the use type of the mixture (see section 3.4 for the definition of the different use types).

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[6] Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response.

[7] Commission Delegated Regulation (EU) 2020/1677 of 31 August 2020 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the workability of information requirements relating to emergency health response. Commission Delegated Regulation 2020/1676 of 31 August 2020 amending Article 25 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards bespoke paints.

[8] 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."*

Detailed information about timelines and compliance dates are 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.

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[9].

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

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

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 or are exempted from the requirements laid down in the same Annex.

- 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 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. Special provisions applying to certain products are explained in the same section.

- 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*).

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[10].

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[11].

1.6.2 Other legislation

The EU legislation for biocides, plant protection products, cosmetics[12] 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

[10] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
[11] 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 or on its components.
[12] Note that CLP does not apply to cosmetic products that are in the finished state intended for the final user (Article 1(5)(c)).

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[13] (BPR) and the Plant Protection Products Regulation[14] (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[15], 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[16] 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 broader or 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[17]. For more information it is

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[13] 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).
[14] 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.
[15] 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.
[16] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
[17] As an example, Norway, Denmark, Sweden and Finland will maintain the obligation to notify chemicals (substances and mixtures) to the national Product Registry in addition to the obligations under Article 45

recommended to contact the responsible authority in the specific Member State.

Note the following:

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

- all ECHA Guidance documents referred to in this document, are available in the Support section of the ECHA website at: https://echa.europa.eu/guidance-documents/guidance-on-reach.

and Annex VIII. Scope and information requirements may be partially overlapping, but the information submitted under the two different legal frameworks is used for different purposes by possibly different bodies.

2. Abbreviations/definitions

Standard term / Abbreviation	Explanation
Annex VIII	Annex VIII to CLP, as added by Regulation (EU) 2017/542 amending CLP by adding an Annex on harmonised information relating to emergency health response and Regulation (EU) 2020/11 amending CLP as regards information relating to emergency health response. Subsequently amended by Regulation (EU) 2020/11, Commission Delegated Regulation (EU) 2020/1677 and Commission Delegated Regulation 2020/1676 of 31 August 2020.
Article 45 Bespoke paints (in the context of submission of information under Annex VIII)	Article 45 of CLP A paint that is formulated in limited amounts on a tailor-made basis for an individual consumer or professional user at the point of sale by tinting or colour mixing.
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 EN	European Economic Area European Standards (or European Norms)
EU	European Union
EuPCS	European Product Categorisation System

Formulator	Company that produces a mixture. A formulator established in the EU is a downstream user.
GCI	Generic component identifier
ICG	Interchangeable Component Group
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.
SF	Standard Formulas (Part D of Annex VIII)
SiA Guidance	ECHA *Guidance on requirements for substances in articles*
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 performing certain activities and not directly bound by Article 45, but following other provisions in the CLP (in particular Art. 4(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 particular in the event of an emergency health response. The same information can also be used by appointed bodies to perform activities of toxicovigilance as foreseen by Article 45 (see section 7 for more information on the use of the submitted information).

'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 the submission of the information to appointed bodies. The importers and downstream users 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. Distributors, who only store and place mixtures on the market, without undertaking any other activity on the mixture, do not need, in principle, to submit the information to the appointed body following Article 45 and Annex VIII. This is also the case when a distributor transports the mixture between different sites that they own without placing the mixture on the market[18].

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 is 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[19] 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

[18] Please, note that in this case obligations coming from the transport legislation may apply.
[19] Art. 4(10): "*Substances and mixtures shall not be placed on the market unless they comply with this Regulation*".

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 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[20] on the market) from their obligations and responsibilities.

In the sections below it is clarified which activities carried out by the different operators may confer on 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[21], i.e. by outsourcing the preparation and submission of the information[22]. This could apply in various scenarios, for example:

- mother company/head-quarter submitting on behalf of a subsidiary (and vice versa),
- consultant on behalf of the duty holder.

3.1.1 Activities leading to submission obligations 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:

3.1.1.1 Import activities

An economic operator that imports a hazardous mixture into the European Economic Area (EEA), which includes EU Member States and Iceland, Liechtenstein and Norway, is an importer. Therefore, they place the mixture on the market according to Article 2 of CLP and have the obligation to submit information required by Annex VIII.

Companies importing mixtures from outside the EU/EEA must ensure that the information is submitted in the official language, or any other allowed language, of the Member State where the mixture is placed on the market.

The definition of importer is provided in Article 2(17) of CLP. Details are provided in section 2.1 of the *Guidance on Registration*[23].

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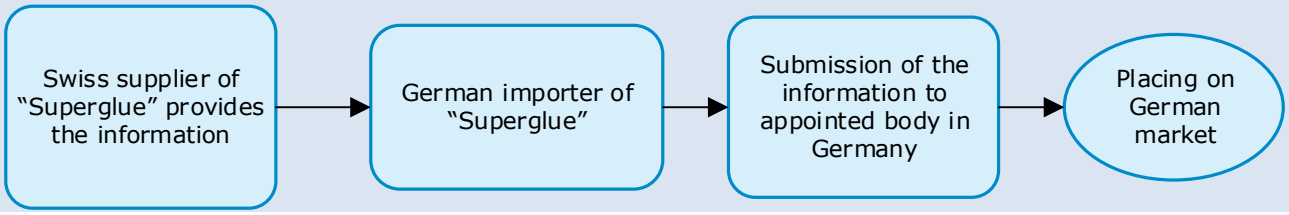
[20] When referring to hazardous mixtures in the context of Article 45, it is meant as classified for physical or human health hazards. This is explained in section 3.3.
[21] The availability of this option in case of national submission systems is to be checked with the relevant authorities.
[22] More information on ECHA accounts management is available in the ECHA accounts Manual available at https://idp-industry.echa.europa.eu/idp/. The possibility to assign a "foreign user" is included. Relevant information on Legal Entity management is provided also in the PCN: a practical Guide available at https://poisoncentres.echa.europa.eu/echa-submission-portal.
[23] 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.

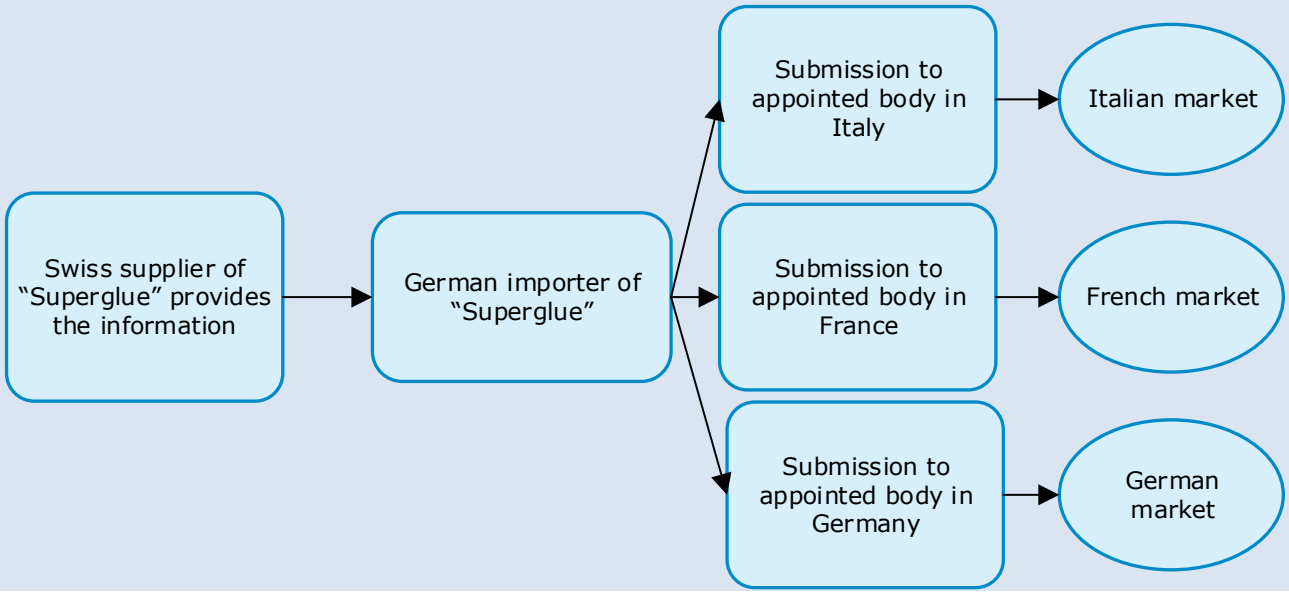
Example 1: EU operator importing from outside the EU, placing on the market in one EU country

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. 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 obligations apply to the importer.

The imported mixture could be used by the same importer to formulate another mixture. If this second mixture is hazardous and placed on the market, the same company has to fulfil the obligations for the imported as well as for the formulated mixture (they would be both importer and downstream user).

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 is advised 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 (see information on identification of mixtures in mixture in section 5.3).

A mixture can be imported also in combination with articles and in this case submission obligations may apply. See the section on "Import/production of articles" below.

3.1.1.2 Formulation activities

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

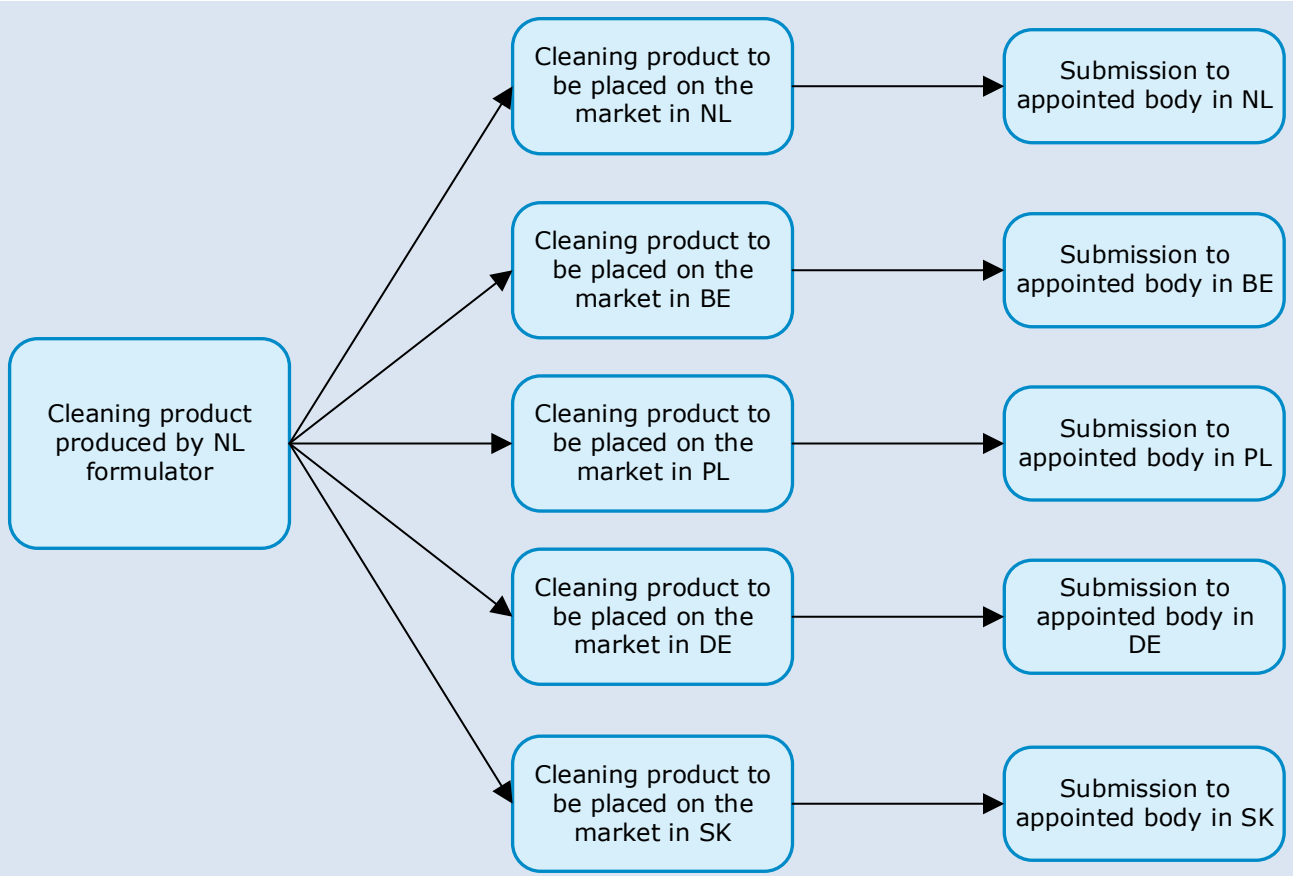
Therefore, any economic operator that formulates and places on the market a hazardous mixture meeting certain criteria (see section 3.3) has the obligation to submit the information in accordance with Annex VIII. The submission has to be made in all the Member States where the mixture is placed on the 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 (the company owning the mixture) is also a formulator (i.e. 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. However, if the same 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 (e.g. shape and size) in the different Member States by the same 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[24]. 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[25]. As long as there is no placing on the market (i.e. making the mixture available to a third party), this also applies if the warehouse that belongs to the downstream user is located in a different place from where the formulation takes place (possibly in the same or in a different Member State)[26].

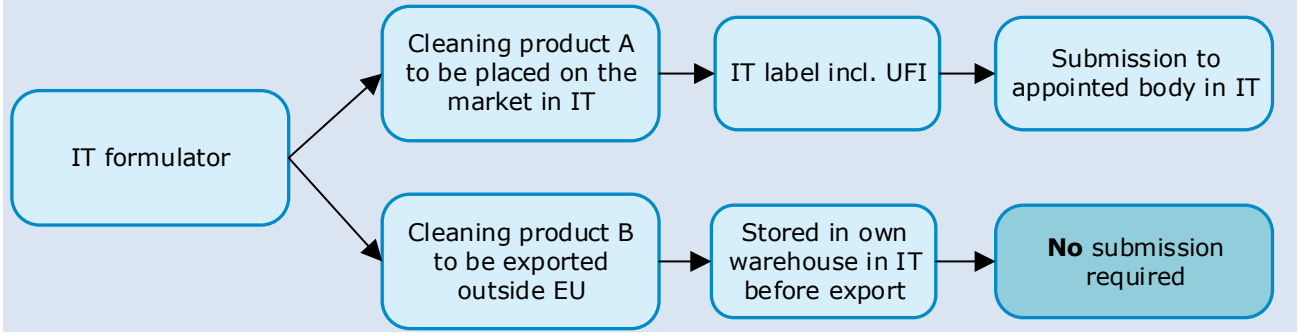
Example 4: Formulation, mixture to be placed on the market outside EU

A formulator in Italy formulates two cleaning products (product A and product B) which are classified for aspiration toxicity. Product B is stored in a warehouse owned 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 apply in the EU Member States (and in countries under the EEA agreement) there are no obligations to submit data for product B.

Product A is placed on the Italian market, therefore a submission according to Annex VIII has

[24] Please, note that other obligations under CLP may also apply.
[25] 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).
[26] Please, note that in this case obligations coming from the transport legislation may apply.

to be made to the Italian appointed body.



3.1.1.3 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 activity according to CLP. This re-packaging company is therefore a duty holder for the purposes of Annex VIII and 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 repackaging company, but it will also resolve the issue where the repackaging company often does not have access to the full composition.

However, where their supplier does not include the information from the repackaging company in their notification, the repackaging company must make a separate submission themselves.

The repackaging company can use the same UFI as the supplier, or alternatively, they can generate their own UFI. In both cases, the product can be specified as consisting of 100% of the mixture purchased from the supplier (final repackaged mixture = 100% supplier's UFI as Mixture in Mixture or "MiM"[27]).

It is important to note that even in cases where this information is submitted by their supplier (under contract), the repackaging company, as the duty holder under Article 45, remains responsible for the information submitted.

3.1.1.4 Import/manufacture of combination of mixture and article

A company incorporating a mixture in an article in the context of its activity is a downstream user. An object fulfilling the definition of "article" is outside the scope of Annex VIII, therefore notification requirements and inclusion of UFI on the label do not apply, except where mixtures are placed on the market (including import) in combination with articles.

An "article" is defined in Article 2(9) of the CLP Regulation and that definition should be interpreted as explained in the *Guidance on requirements for substances in articles* (SiA

[27] This can be done only in case the UFI has been previously notified by the supplier as part of a submission in the same Member State. Otherwise the MiM cannot be identified via the UFI only, see section 5.3 for the available options. The ECHA Submission system includes automatic checks which support the submitter in the preparation of the submission; more information is provided in section 6 and on the Poison Centres website at https://poisoncentres.echa.europa.eu/tools.

Guidance) and it should be considered by companies importing or producing such objects.

An object can be a combination of one or more articles and one or more mixtures. In these cases, obligations under Annex VIII may apply to the mixture(s), if the mixtures are classified for health or/and physical hazards.

The SiA Guidance, in chapter 2, explains that objects can be "classified" as:

1. **Substance/mixture** (as such), e.g. wax crayon, blasting grit;
2. **Combination of an article** (functioning as a container or a carrier material) **and a substance/mixture**, e.g. an inkjet printer cartridge, candles, wet cleaning wipes, desiccant bags;
3. **Articles** (as such), e.g. one-piece plastic spoon;
4. **Article with an integral substance/mixture** (i.e. the substance/mixture forms an integral part of the article), e.g. thermometer with liquid.

A mixture belonging to group 1 (usually in solid state) is subject to all REACH and CLP requirements applicable to mixtures (including obligations under Article 45 and Annex VIII relating to mixtures placed on the market that are classified as hazardous based on their physical and health effects).

Where an object, belonging to group 2, is considered to be a combination of an article (functioning as a container/carrier material) and a mixture (according to the criteria defined in the SiA Guidance), is placed on the market and the mixture is classified as hazardous based on its physical or health effects, then this mixture is subject to the submission obligations under Article 45 and Annex VIII.

Objects belonging to groups 3 and 4 are considered as articles under REACH and CLP. In these cases, CLP Article 45 and Annex VIII will not apply even when the object contains a liquid mixture (e.g. electrolytes in a battery, liquid in a thermometer, adhesive in a tape for fixing carpets). This is also the case with articles with an integral substance or mixture that is intended to be released from them (e.g. scented articles, such as scented children toys), as they fulfil the REACH and CLP definition of article (see section 4 of the SiA Guidance). Article 45 and Annex VIII do not apply to such mixtures in articles[28].

More details and guidance to assess each individual case is provided in the *Guidance on requirements for substances in articles*.

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 hazardous mixtures supplied in its Member State. A distributor placing on the market a hazardous 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

[28] Note, that other REACH or CLP obligations may apply. For instance, substances intended to be released from these articles may be required to be registered under REACH Article 7(1) when certain conditions are met.

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 the option to include this information in their submission to all the relevant Appointed Bodies (even if the downstream user is not obliged to notify in Member States where the distributor places the mixture on the market). Note that the distributor is ultimately responsible for compliance with its notification obligations.

- Alternatively, if the distributor does not want to disclose the information upstream, or the original submitter refuses to include the distributor's information in their submission, the distributor 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 (the distributor will possibly indicate that the mixture composition is made 100% by the mixture purchased from the supplier; if this mixture is identified using a UFI, then this UFI and the information on the mixture should be available to the relevant appointed body; see section 5.3 for more details on information on components)[29].

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).

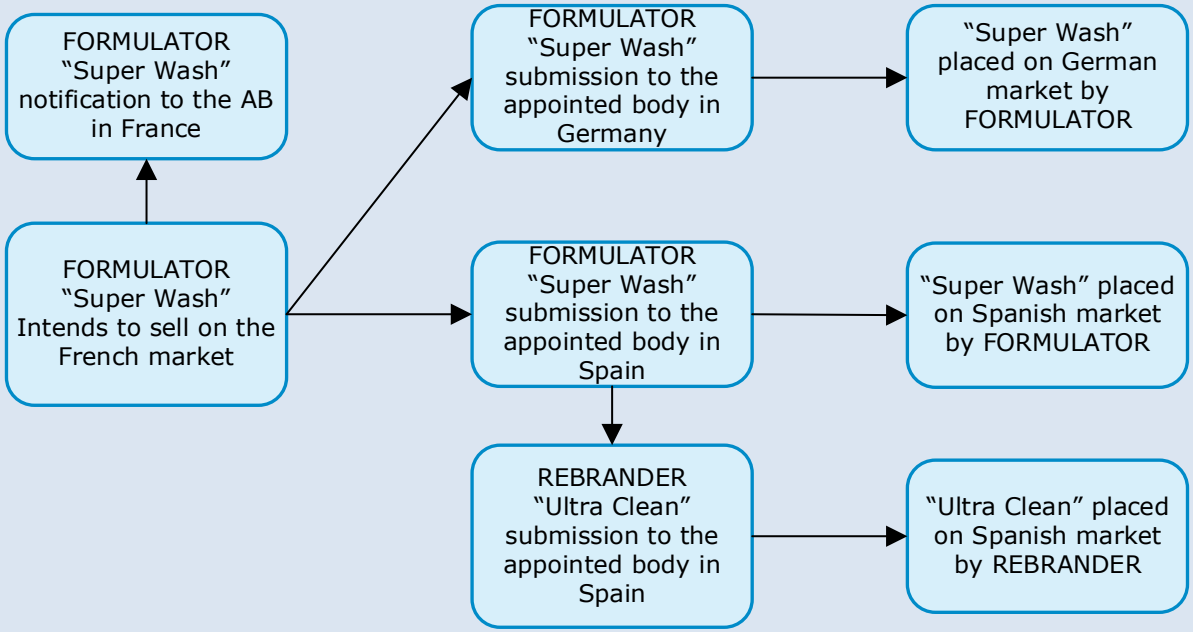
[29] Note, that currently the ECHA Submission portal does not provide the possibility for the distributor to indicate in their submission who is the actual duty holder under Article 45 (i.e. the supplier). Communication should happen outside the submission system.

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 as 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 themselves.



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 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; this scenario is depicted in the figure below) or, e.g. for confidentiality reasons, to make a submission to the appointed bodies of Denmark and Norway themselves instead. The label for the laundry detergent includes (in this example) all three languages.

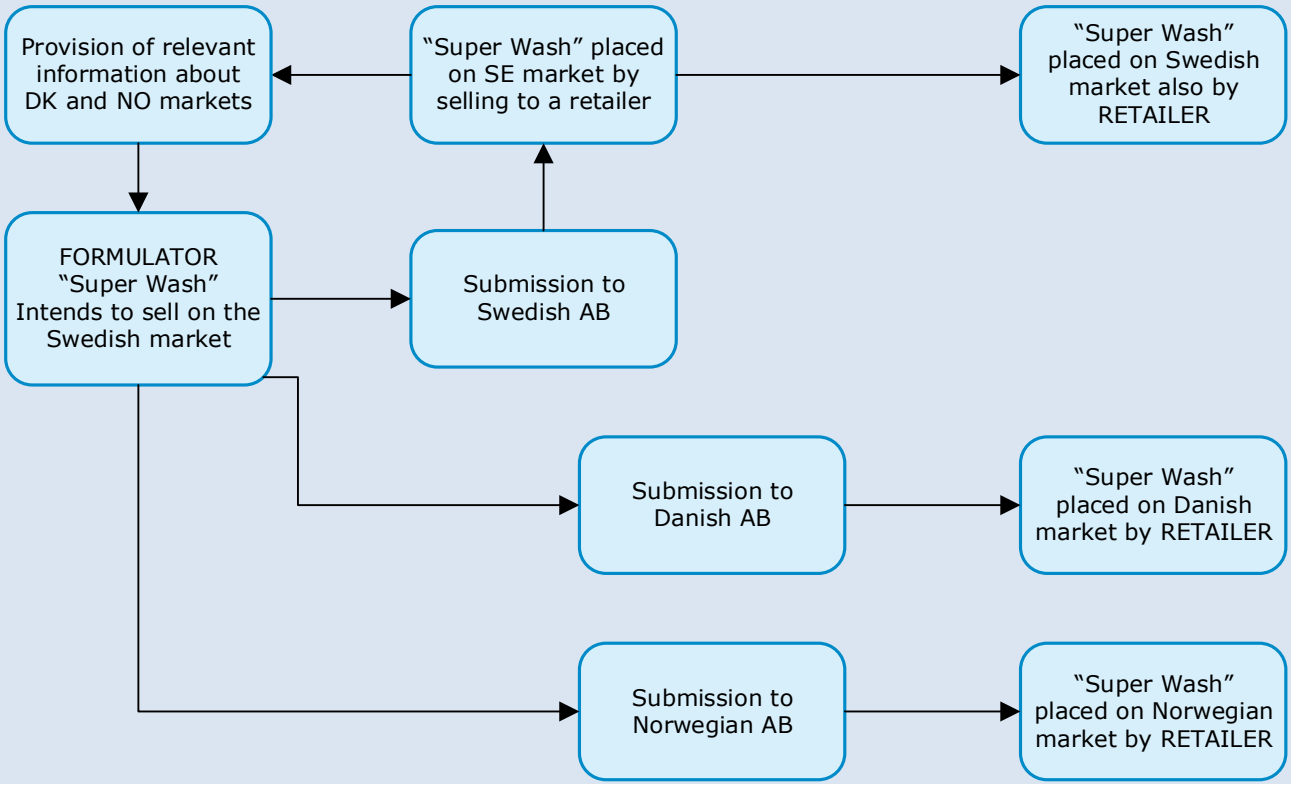


Table 1: Overview of operators and activities triggering (or not triggering) obligations to comply with Annex VIII

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 or other company (e.g. mother 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)	

Activity	Operator	Legal obligation to submit information? (duty holder)?	Why?	Options
Toll formulation	DU	Yes	Toll formulators are downstream users. See ECHA *Guidance for downstream users*. (Art.45)	
Production of combinations of mixture with article Import of combinations of mixture with article	DU Importer	Yes, if the object is to be considered a mixture itself (therefore not an article) or the combination of an article and one or more mixtures	Article producers are potentially downstream users. Importer of articles are potentially also importer of mixtures. See ECHA *Guidance for downstream users* and *Guidance on requirements for substances in articles*. (Art.45)	
Distribution	Distributors	Possibly 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 do not 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
Retail	Distributor (retailer)	Possibly 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). They store/place on the market mixtures to consumers without performing any activity qualifying as DU activity. See also ECHA *Guidance for downstream users.*	

Activity	Operator	Legal obligation to submit information? (duty holder)?	Why?	Options
Re-branding	Distributor	Yes, if the trade/brand name is not included in the original submission or if distributing in Member States other than the ones included in the original submission.	Actor who applies his own brand to a mixture that somebody else has formulated and places the product on the market. Even if the activity is not considered as a DU activity (see also ECHA *Guidance for downstream users*), they have the obligations to provide information through Art.4(10)).	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).
Re-labelling	Distributor	Yes, if the relevant information (e.g. UFI) is not included in the original submission or if distributing in Member States other than the ones included in the original submission.	Actor that adapts corporate colours or identifiers on the label to a mixture or adapts the label in another manner. Even if the activity is not considered as a DU activity (see also ECHA *Guidance for downstream users*), they have obligations to provide information through Art. 4(10).	

Activity	Operator	Legal obligation to submit information? (duty holder)?	Why?	Options
Consultancy	Commercial representative (=consultant)	No	Legal text. The commercial representative is not an actor for CLP purposes, so not subject to Art.45 or Art. 4(10).	The commercial representative may be assigned the task to submit in the name and on behalf of the duty holder via the "foreign user" functionality.
Supply	Non-EU Formulator/supplier	No	CLP does not apply to operators not established in the EU/EEA.	The non-EU supplier may be assigned the task to prepare and submit on behalf of the duty holder via the "foreign user" functionality.

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 the mixture is sold via their distributors (unless the distributor chooses to notify themselves, see section 3.1).

The information will be made available by the appointed body of each Member State to their poison centres and the personnel dealing with emergency responses in that Member State where the mixture is placed on the market. How the data is transferred will depend on the situation in each Member State. In particular, where the appointed body and the poison centres are different institutions the latter may obtain direct access to the database from the appointed body. Alternatively, they may regularly receive copies of data submitted to the appointed body to be fed into a local database. In any case specific security requirements will have to be guaranteed, as per provision of Article 45(2) of CLP.

3.2.1 Member States' appointed bodies

Article 45(1) of CLP establishes that each Member State must appoint a body (or bodies)[30] 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 will typically 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[31] 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.

Mixtures can be as simple as a single substance diluted in a solvent. Nevertheless, case by case assessment may be needed in certain situations to conclude whether the product is indeed a mixture or should rather be considered a substance. In case of a substance there would be no obligation to submit a notification and include a UFI on the label. More details and

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

guidelines are provided in the *Guidance for identification and naming of substances under REACH and 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 the criteria defined in Part 2 and Part 3 of Annex I to CLP fall under the scope of Article 45 and Annex VIII. Nevertheless, some exemptions apply; these are explained below.

3.3.1.1 General exemption from CLP Regulation

Pursuant to Article 1(2) (3) and (5) 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*";
- *"non-isolated intermediates"*
- 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.

It is to be noted that if the same mixture has also uses that are not listed above, the exemption does not apply with reference to these uses.

Additionally, pursuant to Article 1(4) *"Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence."*

3.3.1.2 Exemptions from Article 45 of CLP

Among the mixtures which fall under the scope of the CLP Regulation, for the following the obligations under Annex VIII do not apply because they are excluded by Article 45 (other obligations under CLP may apply):

- mixtures classified for environmental hazards *only*;
- 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.

3.3.1.3 Exemptions from the obligation to submit information under Annex VIII

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

- mixtures for scientific research and development (as defined in Article 2(30) of the CLP Regulation),
- mixtures for product and process oriented research and development (as defined in Article 3(22) of the REACH Regulation),
- 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).

3.3.1.3.1 Exemption for bespoke paints

Bespoke paints are mixtures formulated on customer demand in a potentially unlimited number of colour variations. In the context of CLP Article 25(8), Article 45 and Annex VIII, the definition of bespoke paints also includes the pre-requisite that the final paint is formulated at the point of sale.

Compliance with the standard obligations under Annex VIII would require including the UFI of the mixture on the label and the submission of information before placing on the market each imaginable colour variation before placing them on the market, or else to postpone each supply at the point of sale until the information had been submitted and the UFI created. This would place an unnecessary burden on the point of sale and there would be limited benefit for emergency response, especially where a particular final paint is never actually placed on the market.

To avoid disproportionate administrative burden, Annex VIII, part A, section 2.2a., provides for a possibility to opt not to submit information regarding bespoke paints when they are formulated for an individual and professional consumer[32] at the point of sale. In addition, the special provisions allow duty holders to not generate a UFI for the final paint. This includes also the case where consumers or professional users pre-order (e.g. online) but they only conclude the sales contract by paying at the place where the paint is formulated, then the place of formulation and point of sale normally coincide and the exemption under Article 25(8) of CLP applies.

Bespoke paints that are not formulated at the point of sale are not covered by the exemption. This means that pre-orders where the sales contract is concluded from a place other than where the paint is formulated (e.g. it can be the case of on-line sales where payment takes place online), require the generation of a UFI and the submission of information on the final paint as supplied, in accordance with the standard Annex VIII requirements. Indeed, the formulator typically has more time to submit a notification and attach a UFI before handing over or delivering the paint to the consumer or professional user.

Bespoke paints in the context of the exemption are paints formulated in limited amounts where the final tailor-made colouring takes place on demand by an individual customer – consumer or

[32] Paints intended for industrial users are not covered by the definition of bespoke paints in Article 25(8) and are subject to submission of information under Annex VIII.

professional user - at the point of sale. The requested colour can be achieved by the below means:

- Systems where relatively small quantities of "tinters" are added to a tintable paint base. The tinters are highly concentrated pigment dispersions and cannot be used as such to paint an object, as they do not have the properties of a paint. The paint base has all the desired properties of the final paint, except the right colour. The addition of the tinters to the paint base is an automated process using tinting machines that can perform very accurate dosing.

- Systems where the right colour is produced by mixing together several toners. The system uses a series of toners, where each toner has all the properties of the final paint but contains only one pigment. The ratio of the toners used depends on the colour desired. The process of colour mixing is typically done manually, supported by IT systems to provide the composition and to calculate any required corrections in case the mixed paint does not show an exact colour match.

It should be noted that information on the component mixtures of the bespoke paint (the paint base, the tinter mixtures and toners), when they are subject to notification under Article 45, must be submitted by the formulator(s) or importer(s) of those mixtures before they place the mixtures on the market. Hence, each of the component mixtures will have its own UFI. When a duty holder decides not to submit the information on a final bespoke paint falling under the scope of Article 45, they will need to include on the label of the final bespoke paint the UFIs of all the component mixtures, present in the paint above 0,1% and subject themselves to Article 45. The classification of the actual final bespoke paint has to be reflected on the label. The specific labelling provisions that apply are described in section 4.2.8.3 of this Guidance and further details are provided in section 5.3.2.5 of the *Guidance on Labelling and Packaging*.

3.3.1.4 Submission of information made voluntarily

For mixtures which are not subject to submission obligations or are exempted from Annex VIII (see sections 3.3.1), a submission in accordance with Annex VIII may be done on a voluntary basis. This could be the case for example for mixtures classified for environmental hazards only, or mixtures classified as gases under pressure only (or a combination of the two), or non-classified mixtures (possibly those subject to supplemental labelling information in accordance to Part 2 of Annex II to CLP). Additionally, also mixtures falling under the definition of "bespoke paints" can be notified 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 of 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 Safety Data Sheet (SDS) of that mixture (if available), which does not provide all the relevant information. The supplier could, following a submission made voluntarily, communicate the compositional information to the customer via

the UFI[33] 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 submission made voluntarily for a mixture to be used in another mixture can allow the emergency responder to retrieve all the necessary information.

Submissions can be voluntarily made also on hazardous mixtures by an operator who does not have the obligation to do so. This can be the case for an EU-based legal entity appointed by a non-EU supplier (for more information about this scenario, see section 4.2.5).

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 compliance date (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. '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)[34]. In applying this approach to mixtures, this means that the use of a mixture continues when it is incorporated in another mixture until it reaches its end-of-life stage.

Therefore, if a mixture formulated to be used in an industrial setting ("original mixture") is subsequently also integrated by a downstream user into a mixture for 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 compliance date 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) has 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

[33] For mixtures not subject to Annex VIII it is not mandatory to generate and submit a UFI, even when a submission is made voluntarily. Nevertheless, it is recommended to include the UFI to facilitate it identification when used in the formulation of another mixture downstream.

[34] 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.

submission, the information submitted under Annex VIII needs to be updated accordingly if needed.

Note that the submission should reflect not only the use type of the original mixture as placed on the market by the submitter, but should also consider the use type of the final mixtures in which it may end up (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 use types of these final mixtures do not need to be considered for submission purposes with regard to the original mixture. Annex VIII defines a 'mixture with an end use not subject to notification' as a mixture, incorporated in another mixture, where the latter is intended to be used by consumers or professional users, but which is not subject to the information requirements in Article 45. In this case, the use type of the final mixture, which falls outside the scope of Article 45 and Annex VIII, does not need to be taken into consideration when defining the use type of the mixture to be notified. For example, if a mixture supplied for use in an industrial setting ends up in a final mixture for professional or consumer use, which is classified for environmental hazards only, a submission for mixtures for industrial use will suffice (relevant compliance date and option for limited submission). The same applies if the mixture supplied for use in an industrial setting has its final use in a mixture fulfilling the definition of a cosmetic product (provided that the mixture does not end up in any other mixtures subject to Article 45).

3.5 Timelines

3.5.1 Compliance dates

The compliance date for the submission of the information following the new requirements set by the amended CLP Regulation[35] 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 and 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 date and information requirements on the basis of the use type.

Where a mixture has several types of use, the earlier corresponding compliance date 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 professional use and industrial use, the earlier date of 1 January 2021 will apply.

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

Before these dates, mixtures continue to be subject to existing national requirements. Companies placing on the market mixtures falling under the scope of Article 45 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/

[35] It is amended by Commission Regulation (EU) 2017/542 by adding Annex VIII and further amended by Commission Delegated Regulation (EU) 2020/11, Commission Delegated Regulation 2020/1677 and Commission Delegated Regulation 2020/1676 of 31 August 2020.

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 also for industrial mixture and whether this releases from the duty to make a parallel submission according to national provisions being in force until the compliance date of Annex VIII.

Relevant information on how each Member State plans to implement Annex VIII (e.g. fees and submission systems), has been reported in the *"Overview of Member states decisions on implementing Annex VIII to the CLP"* available from ECHA's poison centre website at https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009.

Independent 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 compliance date according to the use type

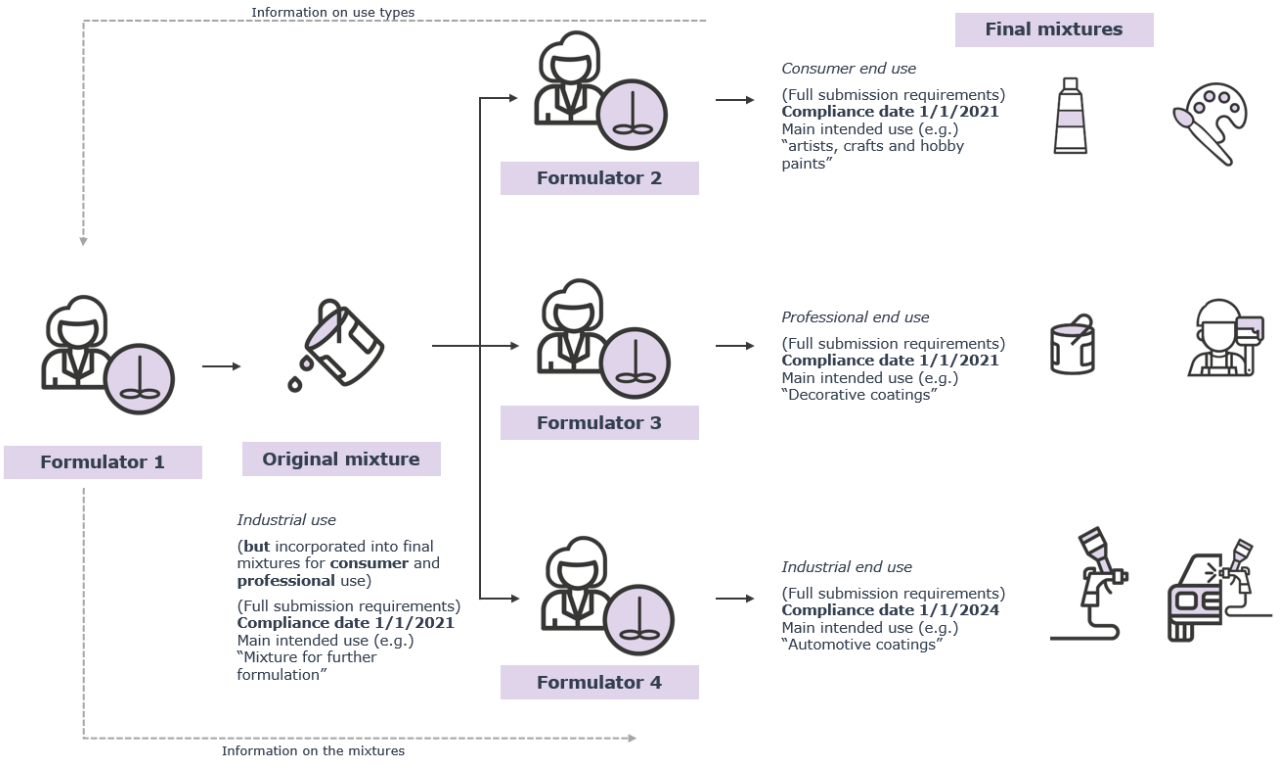
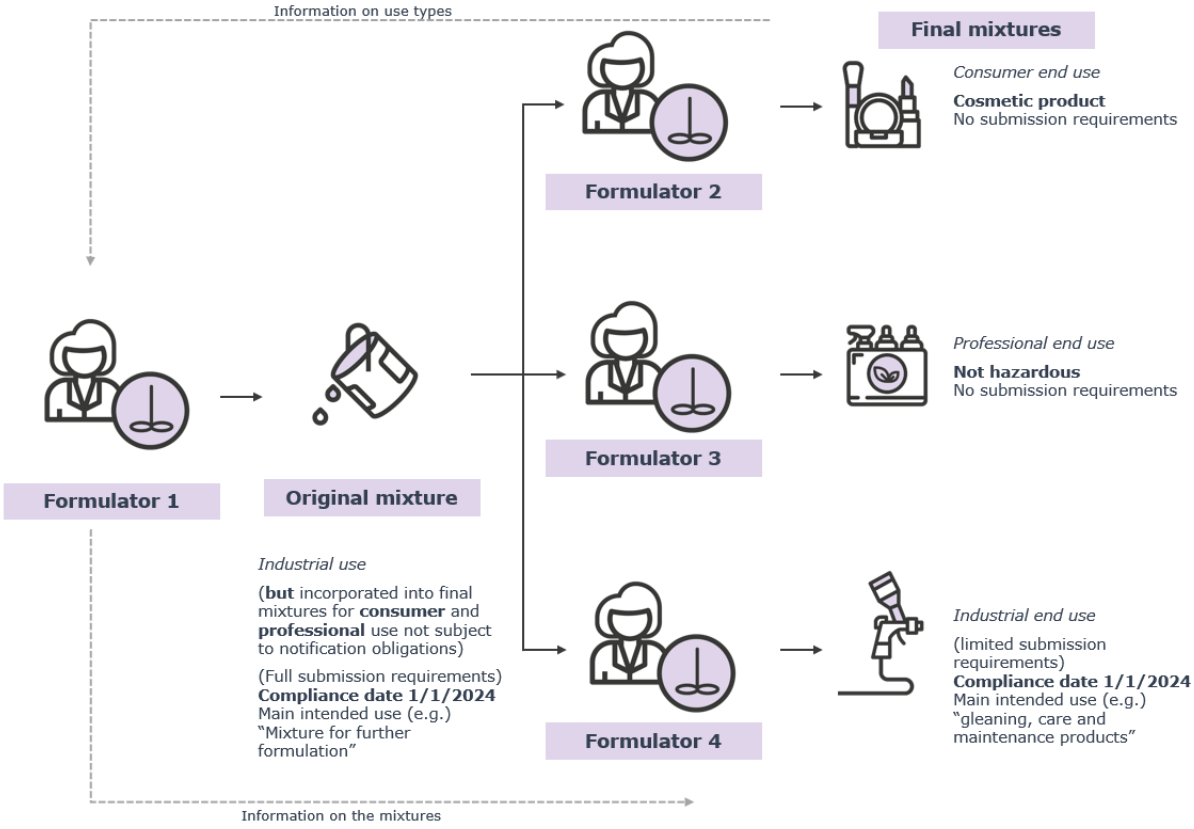


Figure 2: Identification of information requirements and compliance date for a mixture with end not subject to article 45



3.5.2 Transitional period for already notified mixtures

National requirements apply for notifications before the relevant compliance date (i.e. before 1 January 2021 or 1 January 2024 on the basis of the use type). Until those dates, there is also no obligation to include the UFI on the label. For new mixtures placed on the market after those dates, information needs to be submitted according to Annex VIII. If a company has already submitted information relating to hazardous mixtures to an appointed body in accordance with Article 45(1) before the relevant compliance date (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 accordance with Annex VIII and include the UFI on the label by that date. As of 1 January 2025 'old' submissions (according to national legislation) will be considered as 'archived' and not relevant with regard to Annex VIII. Thus, operators must ensure that a new, Annex VIII compliant submission is made in due time to allow them to continue placing the mixture on the market after the end of the transition period.

However, if there is a change in the mixture composition, product identifier or toxicological properties (as indicated in Part B, Section 4.1 of Annex VIII) during the transitional period (i.e. after the relevant compliance date mentioned in Part A, Section 1.5. 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). In this scenario,

the duty holder must comply with Annex VIII; meaning that the UFI labelling requirement must also be fulfilled. If changes occur which are not listed in Part B, Section 4.1 of Annex VIII, there is no obligation to comply with Annex VIII until the end of the transitional period (therefore there is no need to generate a UFI and include it on the label). National update obligations may still apply.

3.5.2.1 When national definitions of end use vary

It may be that definitions of end use types have been implemented differently in different Member States before the entry into force of Annex VIII. For example, a mixture for industrial end use in one Member State may now be the equivalent of a professional end use under Annex VIII. In these cases, any submissions made according to the existing definition of end use in a specific Member State will remain valid and the duty holder does not need to comply with Annex VIII before the end of the transitional period. In other words, the duty holder will benefit from a transitional period even if the use of the mixture qualifies for a different end use type based on Annex VIII.

3.5.2.2 Annex VIII submissions before the relevant compliance date

Member States may decide, any time before the first compliance date, to accept submissions of information, required under Article 45, using the new ECHA Submission portal to fulfil their current national requirements (i.e. the Annex VIII format is simply the vehicle to transmit information which is required by national law).

Where submissions are made through the ECHA Submission portal before a relevant compliance date, the information must comply with the Annex VIII requirements in order to pass the validation checks (see section 6.4). In this scenario, the use of the ECHA Submission portal does however not automatically trigger the obligation to include the UFI on the label before the compliance date. For mixtures for industrial use, a notification can be made in the same format as Annex VIII (via the ECHA Submission portal or a national system) any time without the need to apply a UFI on the product before 1 January 2024. A UFI will have to be affixed by 1 January 2024 (therefore, the transitional period does not apply; the notifications are in accordance with Annex VIII).

Useful information in this regard is provided in the *Overview of Member states decisions on implementing Annex VIII to the CLP* available on the Poison Centres website at https://poisoncentres.echa.europa.eu/.

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 the 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 subject to obligations under Article 45 on the market, 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. In some instances, this may be done by a company submitting on behalf of the actual duty holder. This can be, for example, a legal representative or a distributor having entered into a contractual agreement with the duty

holder to carry-out the submission on their behalf[36]. In other cases, distributors (including re-branders and re-labellers) might have the obligation to submit the information by virtue of Article 4(10) (see section 3.1.2). The submission must be made either directly to the national appointed body via a national submission system 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)[37]. 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 under Article 45 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 available also for mixtures which end up in final mixtures intended for professional or consumer uses but which are outside the scope of Article 45 and Annex VIII. 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.

Additionally, specific provisions are foreseen for certain mixtures whose composition is highly variable or cannot be precisely defined at each point in time. Annex VIII provides for specific provisions which allow for the deviation from the standard information required on the mixture composition and a greater degree of variability. This is the case in the following situations:

- when certain components can be grouped under a so-called Interchangeable Component Group (ICG) without the need to indicate the concentration of each of them (see section 5.5 for the details and the criteria on when components can be grouped);

[36] Note that the responsibility for the submission remains on the duty holder.
[37] Part A, Section 5.2 of Annex VIII includes derogations for mixtures with multi-layer packaging and mixtures not packaged. Part A, Section 5.3 includes derogations for mixtures used at industrial sites (see section 4.2 for more details). In addition, Part A, Section 2 includes a derogation for bespoke paints from submission and labelling requirements, provided the obligations under Article 25(8) are fulfilled. This is explained in section 3.3.1.3.1.

- when certain mixtures conform with specific Standard Formulas listed in the legal text itself (in Part D of Annex VIII) and for certain fuels listed in Part B, Section 3.7; for such mixtures information on components identified and concentration can be provided according to the relevant Standard Formula or the SDS (see section 5.6 and 5.7 of this Guidance for detailed information).

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 an SDS under REACH usually does not contain all the information required by Annex VIII. Duty holders under Article 45 will thus normally need to complement information from other sources or consult their supplier for more specific information, especially regarding composition where practical, unless the special provisions allowed by Annex VIII apply. The specific information requirements for the different submission types (standard and limited, individual and by group) and for the cases where derogations from standard information on the composition apply, 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). Information on the language(s) accepted in each Member State for the submission is available on ECHA's Poison Centre website in the *Overview of Member states decisions on implementing Annex VIII to the CLP*. 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 supports multi-market submissions with the distribution of the dossier to the relevant appointed bodies. The portal allows to provide part of the information in the specific 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(s), 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 a submission is made with the same UFI need to share the same composition[38]. This applies to mixtures whose composition can be precisely defined and also to mixtures with a composition which can vary within certain limits:

[38] 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. In case of a single mixture submission where the so-called Generic component identifier "colouring agents" or "perfumes" is used (addressed in section 5.3.3), the same UFI could be used to refer to several mixture compositions differing for the colour or perfume only.

- within the boundaries of a Standard Formula (when applicable, see section 5.6); or
- within the boundaries of the composition from the SDS (when applicable, see sections 5.6 and 5.7); or
- according to the specific interchangeable component(s) included in an ICG and present at some point in time (see section 5.5).

However, different UFIs can be used for the same mixture, as long as those UFIs have been submitted to the appointed bodies. The same mixtures may be placed on the market under different trade names and by the same or different operators. In those cases, operators can decide to use the same UFI, as long as the mixture composition does not change or the variation is limited and does not have an impact on the toxicological information (see section 5 for details). For marketing and/or confidentiality reasons, operators may also decide to generate and affix on the label of each product a different UFI although the mixture composition of those products remains the same. In such case, all UFIs assigned to the mixture must be provided as part of the submission for that mixture.

The UFI is meant to complement the other means used by poison centres to identify the 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 for details section 5.3 where the Generic component identifier is mentioned, section 5.4 on Group Submission and sections 5.5, 5.6 and 5.7 on products for which special provisions may apply). 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. A submission made voluntarily for mixtures not subject to Annex VIII, should preferably include the UFI as well. This will allow the link with the submitted information in case the mixture is used as MiM identified with the UFI.

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. Alternatively, a UFI generating algorithm is also available for users who wish to incorporate the UFI Generator into their own systems. The tools and support 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 not supposed to be a 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 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 it is possible for companies to generate UFIs if they do not have a VAT number or

prefer not to use it for the generation of their UFIs, for example, due to confidentiality concerns. This possibility is available in both the UFI Generator tool itself and in the UFI generating algorithm (through a 'company key'). More information and support is available on the UFI dedicated section of the ECHA Poison Centres website (https://poisoncentres.echa.europa.eu/ufi-generator).

It is not necessary for each duty holder to generate UFIs individually. The same UFI can be used by different companies (including distributors), regardless the way how the code has been generated (i.e. by using a VAT number or a company key), as long as the composition of the mixture covered by that UFI remains the same. The use of the same UFI should be agreed among the interested operators. Section 3.1 provides examples of when this can happen, as well as section 4.2.3 below.

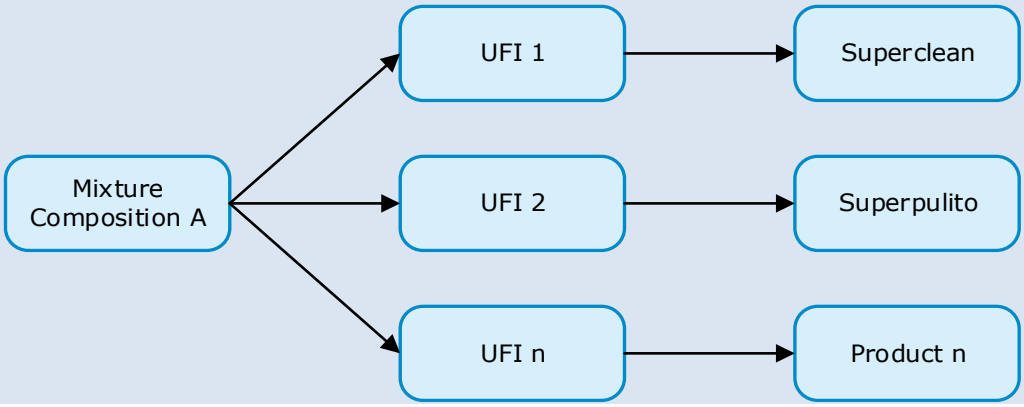
4.2.3 How to use the UFI

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 (and by different companies) only if those products share the same composition according to concentration ranges defined in Annex VIII (See section 4.5).

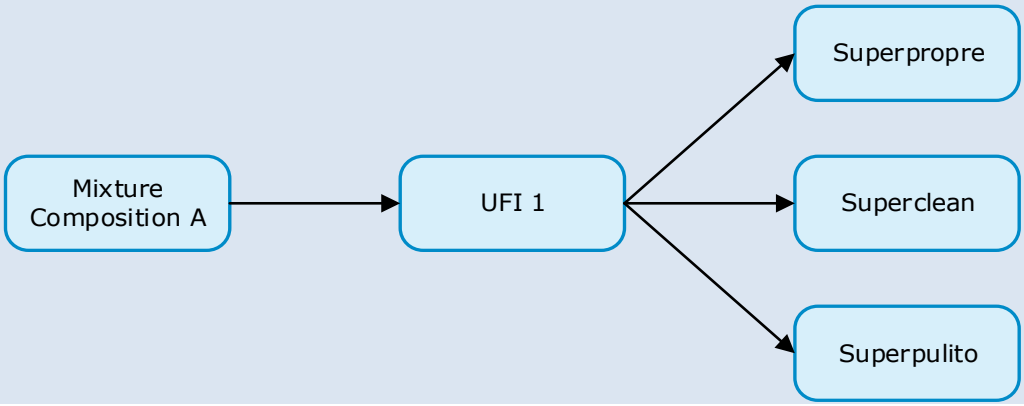
Note that the same UFIs can be used across the EU market for the same mixtures, providing that for those mixtures submission including the UFIs has previously been done to the relevant Member States.

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

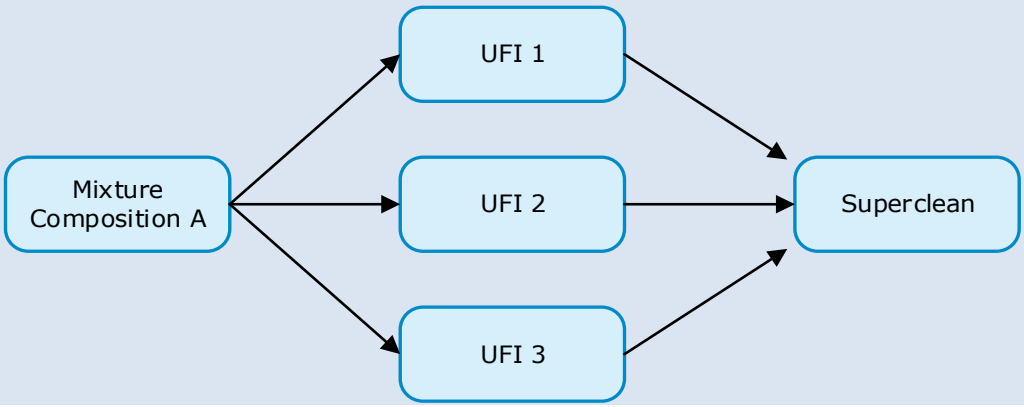
Example 8: 1 Mixture composition– 2 or more UFIs – 2 or more products placed on the market with same composition



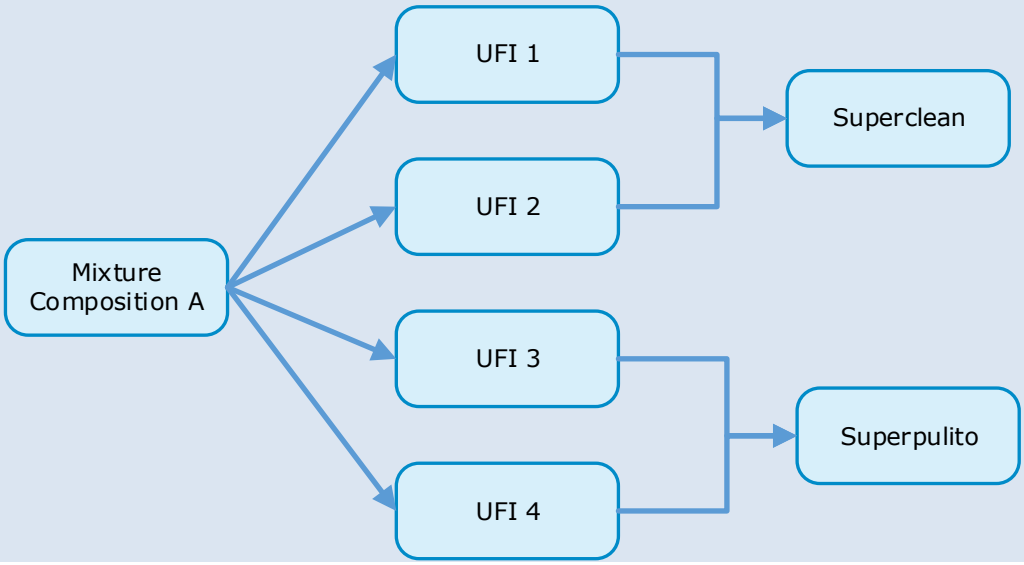
Example 9: 1 Mixture composition – 1 UFI – 3 products placed on the market



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



Example 11: 1 Mixture composition – 2 or more UFIs – 2 products placed on the market

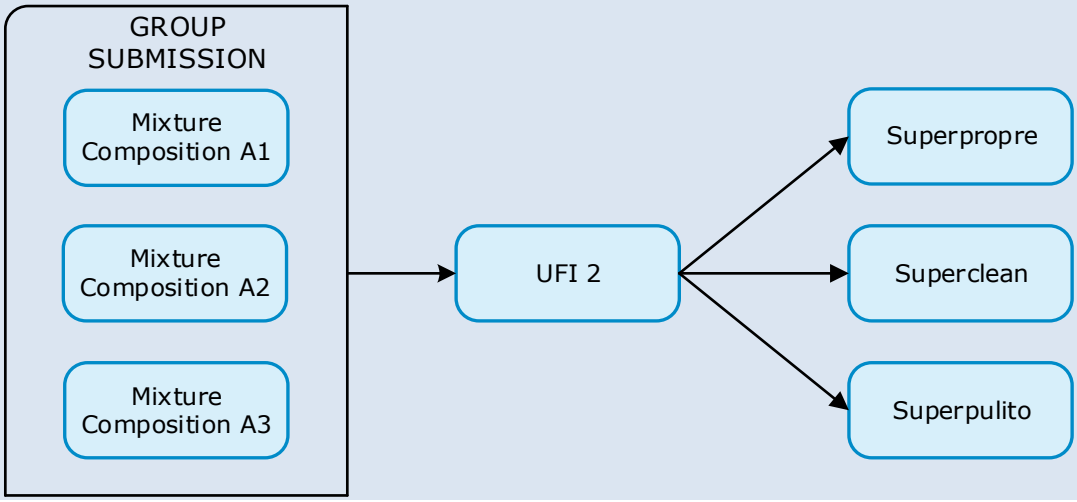


Note to examples 7 to 11 When several UFIs have been generated and assigned to one mixture, all those UFIs need to be included in the submission to the relevant Member State and can be submitted individually or in the same submission. When more than one UFI is assigned to the same product (containing the same mixture), it is sufficient and recommended to include only one UFI (among those notified to the relevant appointed body) on the label of the product (examples 10 and 11). Note that it is not mandatory to include the UFI in the SDS unless the mixture is unpackaged (Annex VIII, Section 5.3

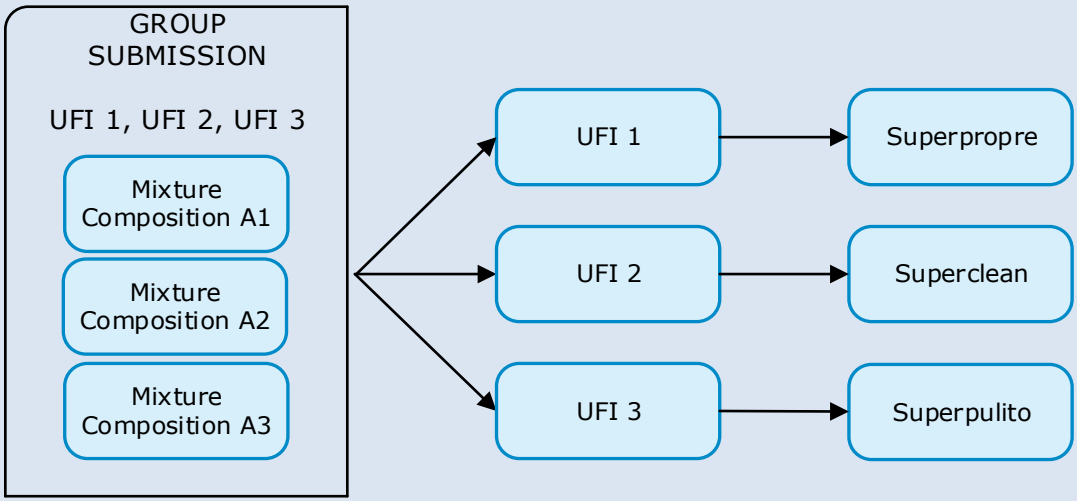
of Part A), but it can be included voluntarily. The inclusion of multiple UFIs on the SDS is not recommended, and the UFI(s) used on an SDS should be notified to the relevant appointed body.

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 12 and 13 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 12: Three similar mixtures (1 Group submission) - one UFI, one or more products placed on the market



Example 13: Three similar mixtures (1 Group submission) – several UFIs, one or more products placed on the market.



A single and the same UFI can be used to identify a mixture notified by referring to a Standard Formula, including when the mixture is placed on the market in different Member States and/or by different operators. The same UFI can be used by different companies to identify each of the fuels listed in Part B, Section 3.7 of Annex VIII. This is possible notwithstanding the fact that the variability in the composition is potentially higher than when the standard Annex VIII limits are applied.

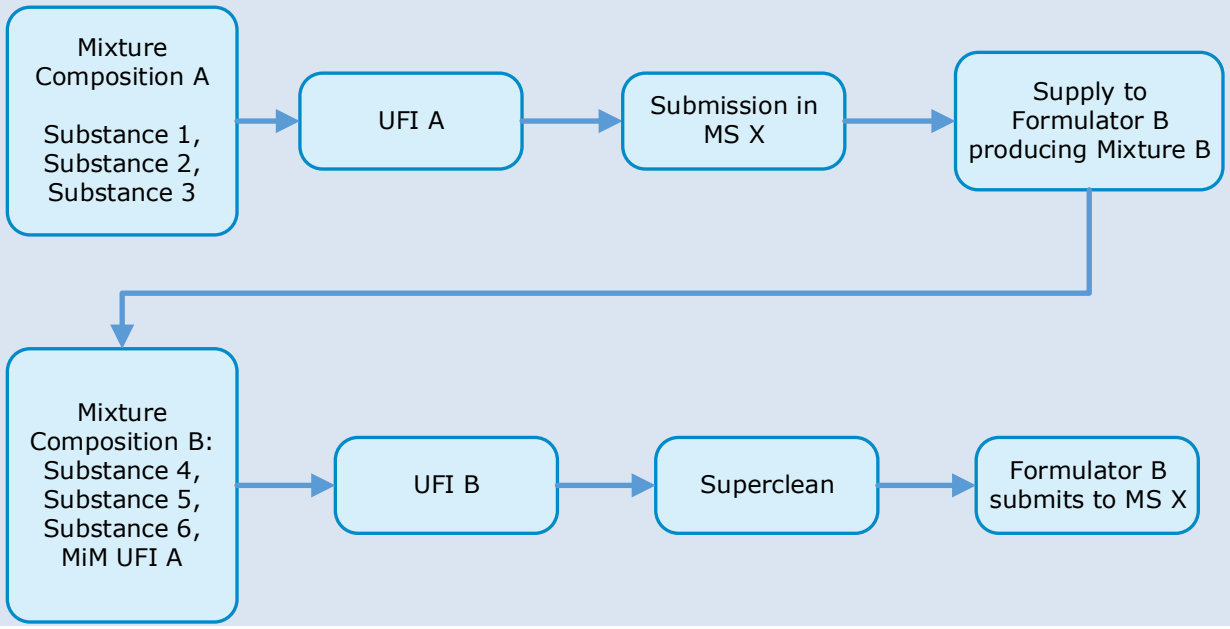
Similarly, one single UFI can be used in case of a mixture including one or more Interchangeable Component Groups, even if it is not known which interchangeable component(s) is(are) present at each point in time.

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 under Article 45 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 its product identifier. The UFI can be used to identify the MiM without the need to indicate any of its components, only when the submission for the MiM has been previously made to the appointed bodies in the Member States where the final mixture(s) (containing that MiM) is(are) placed on market. In this case 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.

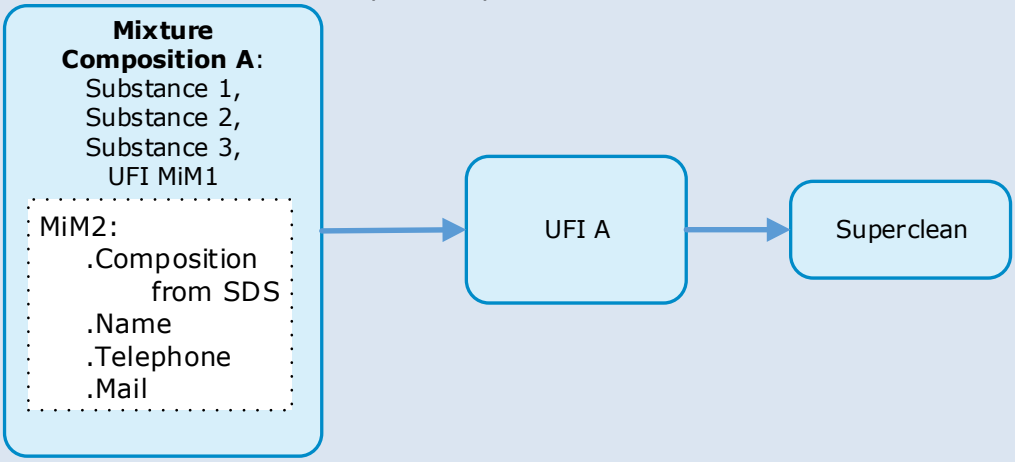
More details about information requirements for mixtures and their components is provided in section 5.

Example 14: 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 (or the MiM's UFI has not been previously notified in the Member State where the final mixture is placed on the market) and the composition is not fully known, as a last resort the compositional information from the safety data sheet of the MiM must be provided as well as the name, email address and telephone number of the MiM supplier. The UFI, when available, has to be in any case additionally provided even if not previously notified in the same Member State. This will facilitate the identification of the MiM once a notification including this UFI is made by the supplier (see section 5 for more details on information requirements; section 5.3.3 addresses also the case of absence of an SDS).

Example 15: 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.

In practice, the downstream user will have the following options:

- Include in their submission the full mixture composition if provided by the supplier; the downstream user can assign to the mixture (and include in the submission) a new UFI or the same UFI as the supplier.
- Indicate in the submission that the composition is constituted of 100% of one MiM, which is the mixture provided by the supplier; this MiM can be identified with the supplier's UFI if this was previously notified in the same Member State (or, as a last resort, by the compositional information from the SDS, see section 5.3); the downstream user can assign to the final mixture a new UFI or still use the same UFI as the supplier.

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).

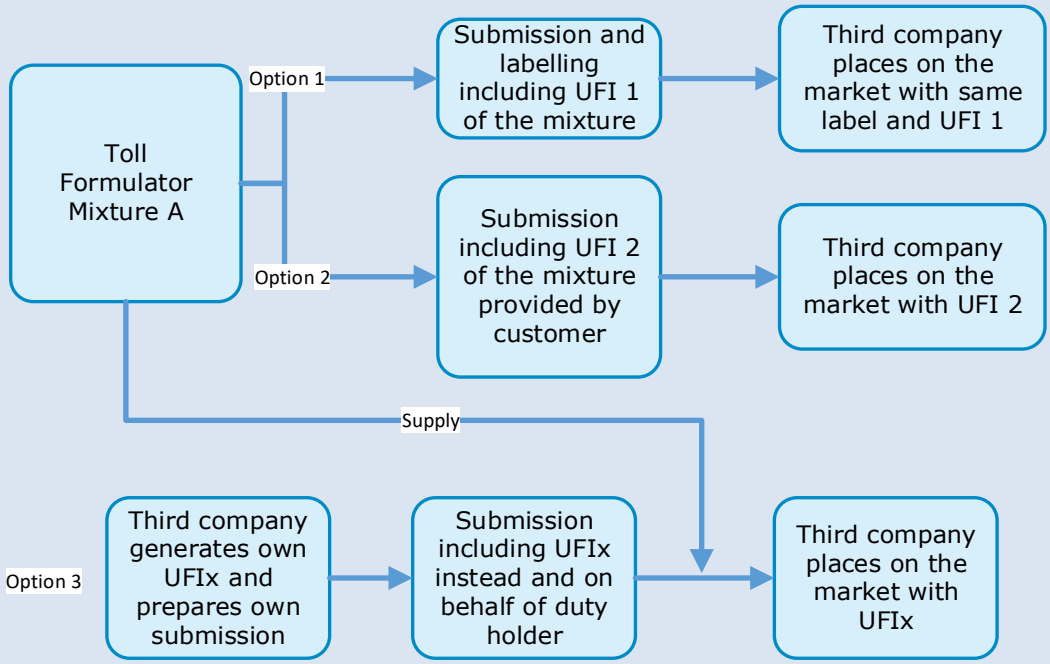
4.2.4 Toll formulator and UFIs

A toll formulator is a service providing company that formulates a mixture on behalf of another company, i.e. a 'third company (or the customer)' 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 is generally expected to generate a UFI for

the mixture being placed on the market, include it in their submission and provide it to their customer (option 1). If the customer does not change the formulation, they can use the original UFI provided by the toll formulator. Alternatively (option 2), the toll formulator's customer can create their own UFI (instead of or in addition to the supplier's UFI) if desired 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). It is also possible that the toll formulator's customer may want to make the submission themselves (option 3) relieving the toll formulator of the task. This should be agreed between both parties bearing in mind that the toll formulator remains the duty holder under Article 45.

Example 16: 1 Mixture by a toll formulator - 1 or more UFIs 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 non-EU supplier does not have obligations under the CLP Regulation and it is not allowed to prepare and submit a notification itself, using their own account[39] in the ECHA Submission portal. The following way can be considered to work around possible communication problems (e.g. if the non-EU supplier intends to protect the confidentiality of the mixture information).

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 submission voluntarily[40] 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, directly or via the EU-based legal entity)

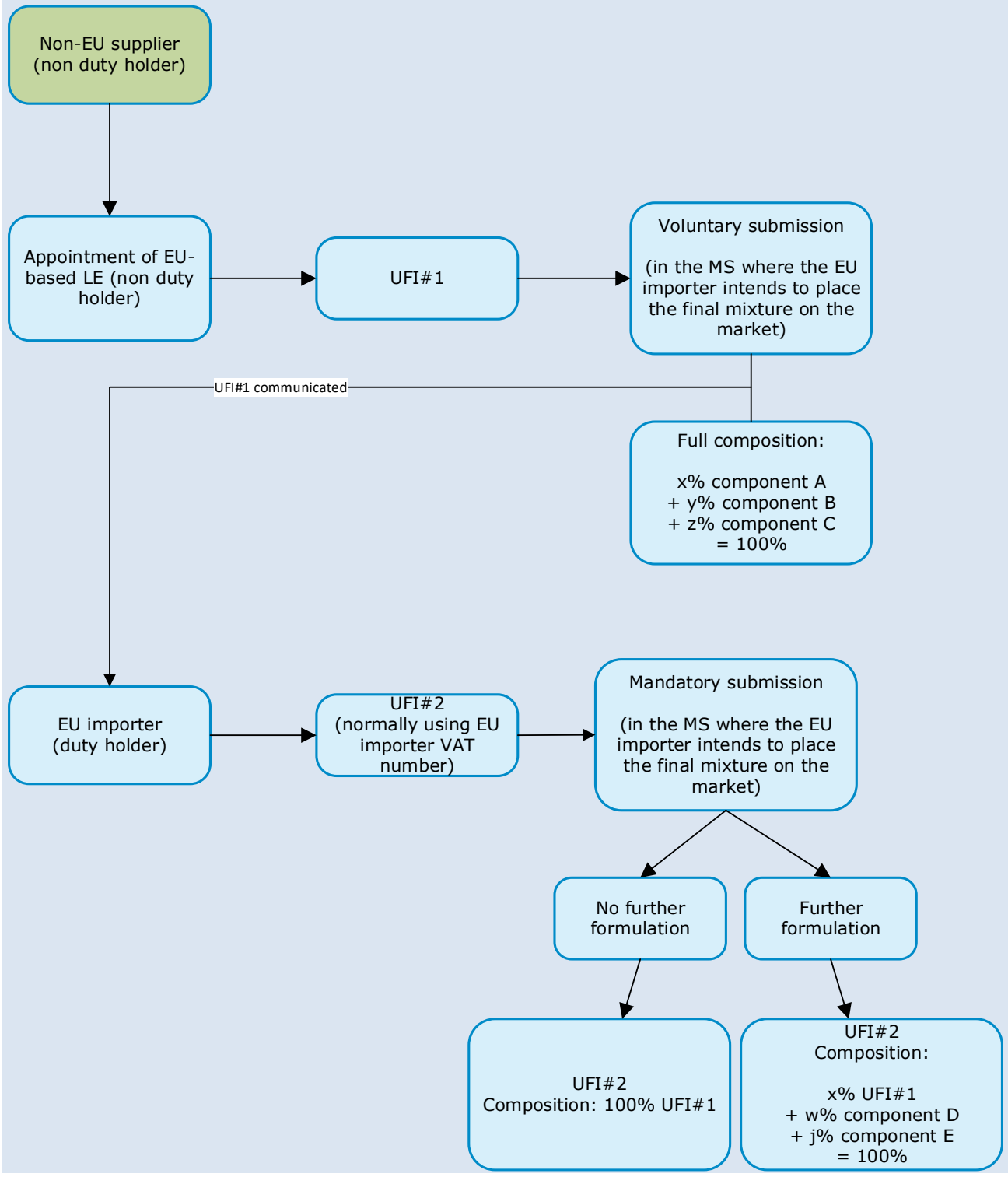
[39] The non-EU supplier has the possibility to prepare and submit a notification acting the same way as a consultant, but in this way the information is to be shared with the EU duty holder, which remains the one responsible for the notification. More information is available on the *ECHA Accounts Manual* at https://idp-industry.echa.europa.eu/idp/.

[40] 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 submissions made voluntarily in section 3.3.1.3.

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 EU importer. It is possible for the non-EU supplier to already label their product with the correct UFI before supplying it to the EU 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 the EU importer 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).

Example 17: 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" [41] the UFI is normally generated on the basis of a company VAT number and on an internal formulation number. The latter needs to be a number between 0 and 268435455 (maximum 9 digits) 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.

As an alternative to the use of the VAT number, the online tool can also automatically assign a "company key" which is used by the same algorithm for the generation of the UFI (example of Company key is "1828639338661").

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, physic-chemical properties, classification) and its UFI. This will be useful for the efficient management of the current products (e.g. different batches of the same mixture for which labels have to be created) and to keep track in case of updates.

4.2.7 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[42]. 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

[41] Available at https://poisoncentres.echa.europa.eu/ufi-generator.
[42] Note, in case of group submission the same UFI could be used to refer to several similar mixture compositions. In case of submissions referring to Standard Formulas or including Interchangeable Component Groups, the same UFI can be used to refer to a limited variable composition.

considered a major change requiring the creation of a new UFI[43]. Note that this applies to the components which are required to be indicated in the submission (e.g. the change in a component which is not classified for health or physical effects and present in concentration < 1% would not require a new UFI). Two derogations to this principle are provided:

a. No change of UFI is required for mixtures in a group submission containing perfumes if the change in the composition only relates to those components. To be noted that if a 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 components have to be present in at least one mixture of the group).

b. No change of UFI is required for mixtures containing an ICG if the change only concerns one or more components included in an ICG already present in the original submission. To be noted that if a component is added, replaced or removed from an existing ICG an update of the submission is required (see section 7.4).

Note that new UFI is required also in case a new ICG is added or an existing individual component is replaced by an ICG. This is because the new composition may include components not originally present.

2. ***A change in concentration beyond the concentration range provided in the original submission*** – For the declaration of the concentration of mixture components (including an ICG) it is possible to use concentration ranges (see section 5.3.3 b 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 of the actual concentration is within the original 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 (including an ICG) it is possible to use the exact concentration, in which case concentration changes are allowed within certain limits (see section 5.3.3 b on information on mixture components). 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.

4. ***A change in the composition of a mixture that conforms with a Standard Formula (as a whole or partly) listed in Part D, in a way that it does not conform to that Standard Formula anymore*** – if a new component, not included in the Standard Formula, is added or the new concentration of an existing component is outside the range specified in the Standard Formula, or a component listed in the Standard Formula is removed (unless the original concentration range includes "0"[44]), a new UFI is required. This is the case also when a Standard Formula is used to identify

[43] 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.
[44] The reason for this is that the component could have been already absent from the original mixture.

part (i.e. one or more components) instead of the full composition of the final mixture and the changes concern this part of the composition. To be noted that these changes require an update of the submission with the provision of the full standard requirements (i.e. the mixture or the part of it does not conform with the Standard Formula anymore and cannot benefit from the special provisions; see section 7.4).

5. ***A change in the composition of a mixture which originally conformed with a Standard Formula listed in Part D, but was notified by providing composition information from the SDS, in a way that Section 3 of the SDS requires update and the mixture does not conform with the Standard Formula anymore*** – If for any reason Section 3 of the SDS of the mixture needs update with regard to the composition, a submission update has to be submitted. This will have to include a new UFI when the changes lead to the mixture not being conform with the original Standard Formula anymore. In this case the changes require an update of the submission in line with the normal notification provisions (i.e. the mixture does not conform with the Standard Formula anymore and cannot benefit from the special provisions; see section 7.4). This can be the case when a component to be indicated in Section 3 of the SDS in accordance with Annex II of REACH and not present in the original Standard Formula is added[45].

6. ***A change in the composition of a fuel listed in Part B, Section 3.7 of Annex VIII which was notified by providing composition information from the SDS, in a way that Section 3 of the SDS requires update*** – If for any reason Section 3 of the SDS of the mixtures needs to be updated with regard to the composition, a submission update including a new UFI has to be submitted (see section 7.4 for more information).

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 (it may nevertheless need to be updated because of the new UFI, when this is printed on it; see next section for more details on the labelling options).

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

[45] Please, refer to the ECHA *Guidance on the compilation of safety data sheets* for details about the relevant provisions.

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 mixture and therefore in principle its UFI does not need to be changed. This is possible if the downstream user has information from the supplier that the MiM composition is actually the same.

4.2.8 Display, position and placement of UFI

Article 25(7)[46] of CLP defines the UFI as supplemental information that should be located with the other labelling elements, for example near the hazard pictograms. Therefore, the inclusion of the UFI will follow the normal labelling rules, including the options foreseen by Article 29(1) for particular shapes or sizes of the packaging. 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).

By derogation from Article 25(7), Article 29(4a) [47] provides some flexibility by stating that the UFI can be printed on or affixed to the inner packaging, as long as it is with the other label elements and clearly visible (i.e. not necessarily within the label, refer to Section 5, Part A of Annex VIII). This is meant to ensure that the UFI is easily identifiable by checking the label or next to the label. In case of multiple-layer packaging, it is not necessary to include the UFI on each layer, as long as it is included on the inner packaging. This may reduce the burden, for example, in cases where frequent formulation changes occur requiring a new UFI to be indicated. In any case, the exact positioning of the UFI is left to the discretion of the person responsible for compiling the label or designing the packaging, though as a rule, the UFI must be easy to locate and read. In cases where the shape or size of the inner packaging does not allow the inclusion of the UFI, this can be affixed on a fold-out label, a tie-on tag or an outer packaging, always with the other label elements. Section 4.8 of *Guidance on Labelling and Packaging in accordance with CLP* provides more details with regard to labelling requirements and options.

In general, the inclusion of the UFI in the safety data sheet is not a standard requirement. In cases where a hazardous mixture is used at an industrial site, the UFI may be indicated in Section 1.1 of the SDS (in this case the inclusion on the label or packaging is not mandatory; see section 4.2.8.2 for further details).

In case of hazardous mixtures which are sold not packaged, the UFI must be indicated in Section 1.1 of the SDS[48]. In the specific case of hazardous mixtures listed in Part 5 of Annex II to CLP that are supplied to the general public the UFI has to be included in the copy of the label elements provided for in Article 29(3), e.g. attached to the delivery note.

The UFI code itself (wherever it is used) 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) and must be followed by a colon.

In addition to the requirements described above, 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.

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[46] Regulation (EU) 2017/542 amended CLP by adding the new Annex VIII and the additional paragraph 7 to Article 25 (Additional labelling information).
[47] Regulation (EU) 2020/11 amended CLP by adding the new paragraph 4a to Article 29 (Exemption from labelling and packaging requirements).
[48] Section 1.1 of Annex II to REACH. Please, note that an amendment of Annex II to REACH is currently in the final step of the approval process. It includes reference to UFI.

- No additional marker than "UFI:" should appear before the actual UFI code[49].
- 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, an optional space may be placed after the colon (e.g. if it can improve the legibility using the selected font).

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

This leads to the most preferred strings such as

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

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

Alternatively, the following strings are also allowed.

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

UFI:
VDU1-414F
1003-1862

(22 characters and 3 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

[49] In exceptional circumstances when the same label is used in different countries where different UFIs are used, a country code should be used in proximity of the UFI code (see section 5.3.1.1 of the Guidance on labelling and packaging in accordance with CLP).

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*[50]).

The *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. reagents, samplers or testing kits). In these cases, each single mixture bears the label relevant to that mixture, where required[51]. Each mixture that is part of a set and is classified as hazardous regarding human health or physical effects, 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. A new mixture may be created upon the use of the product (e.g. certain adhesives, resin with an hardener, paint with an activator) following active mixing by the user or automatic mixing by means of the provided device part of the packaging. Certain multi-component products may consist of mixtures not intended to be mixed but rather acting separately (e.g. dish washing tablets, laundry tabs). The company placing multi-component products on the market must provide a UFI for each component-mixture in separate submissions[52]. 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 intended way how the mixtures are expected to act (e.g. expected to mix or not) and the proportion in which the component mixtures are foreseen to be mixed in the final mixture (if relevant) is an example of such final mixture related information which could be provided. Additionally, it may be useful to indicate whether the mixing ratio can be influenced by the user or not. 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 to be used at industrial sites it is not mandatory to include the UFI on the label (or packaging) provided it is indicated in the SDS. It is to be noted that this

[50] See *Guidance on Labelling and Packaging in accordance with Regulation (EC) 1272/2008* at https://echa.europa.eu/guidance-documents/guidance-on-clp
[51] See *Guidance on Labelling and Packaging in accordance with Regulation (EC) 1272/2008* at https://echa.europa.eu/guidance-documents/guidance-on-clp
[52] 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 or the set of mixture constituting a kit. Furthermore, the label of the product bears the information on the component mixtures (and hence their UFIs) and not of the final mixture.

option is not limited to mixtures eligible for a limited submission (i.e. mixtures intended to be used at industrial sites only, as described later in section 4.4). It applies also to mixtures which are supplied to industrial sites but are included in consumer or professional products by downstream operators (i.e. do not benefit from the limited submission which will be described later, in section 4.4).

4.2.8.3 Special labelling requirements for bespoke paints [Article 25(8)]

The duty holder may decide to generate a UFI and submit information for the bespoke paint itself. In this case, the standard provisions apply and only the bespoke paint's UFI will be included on the label. Alternatively, if the duty holder decides to benefit from the exemption for bespoke paints (see section 3.3.1.3.1), specific provisions apply.

When information has not been submitted on the final bespoke paint, the UFIs of each of the component mixtures present in the final paint above a concentration of 0.1%, and subject themselves to notification obligations, must be added to the supplemental labelling information of the final paint. These have to be located together and listed in descending order of the mixtures' concentration in the bespoke paint, in accordance with the provisions of section 5 of Part A of Annex VIII. Examples on how this can be done are given in *the Guidance on labelling and packaging*.

This means that the UFIs of the paint base and of the relevant individual tinter mixtures, or of all the toners used in a final paint (where they are subject to the obligation to submit information under Article 45 CLP and present above 0.1%) need to be displayed on the bespoke paint's label in order to allow the emergency operator to identify the hazardous components and hence to retrieve the information required for appropriate medical response related to exposure to the final paint. More details on the display of the UFIs are provided in section 4.2.8.

It should be noted that when the concentration of any mixture with a UFI in the bespoke paint exceeds 5%, the concentration of that mixture must be included next to its UFI in the supplemental information on the label of the bespoke paint, in accordance with section 3.4. of Part B of Annex VIII. The indication "≤5%" could be voluntarily added next to the UFI of other components that have to be indicated.

4.3 EuPCS

A harmonised European product categorisation system (EuPCS) maintained by ECHA[53] is used 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 the EuPCS include "Hand dishwashing detergents", "Adhesives and sealants for construction", "Decorative paints and coatings"[54]. 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

[53] 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/.
[54] The latest version of the EuPCS is available from the ECHA Poison Centre website at https://poisoncentres.echa.europa.eu/eu-product-categorisation-system.

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[55] 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 use, professional use or industrial use, 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. compliance date for submission from 1 January 2021) 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]. This option applies also to mixture included in final mixture intended for professional or consumer uses, when the latter are outside the scope of Article 45 and Annex VIII ("mixtures with an end use not subject to notification").

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]. The rationale for this specific regime is provided in Recital 11 of Regulation (EU) 2017/542,[56] 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*

[55] The EuPCS Practical Guide is available at https://poisoncentres.echa.europa.eu/eu-product-categorisation-system.
[56] 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.

on the compilation of safety data sheets,[57] 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:

- a telephone number accessible 24 hours per day and 7 days per week, where 'detailed additional product information', which is not included in the SDS but can be relevant for emergency response purpose, can be obtained by the personnel who is providing the emergency response in the language accepted by the specific Member State. The requester normally belongs to bodies or institutions recognised by the appointed body or to the appointed body itself; this additional information refers normally to the complete compositional information;
- an email address for follow-up exchange of information between the submitter (or a knowledgeable person designated by 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 or an emergency response personnel. 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 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

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

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, but does not specify who can make the request. 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. In any case the appointed bodies remain responsible for receiving and making the information submitted under Article 45 and Annex VIII available to the emergency responders. Therefore, the person requesting the additional information should be authorised by the relevant authority.

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 under specific conditions, and for each of the components, the reported concentration or concentration range is the same; and
- all mixtures in the group have the same classification for health and physical hazards.

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

5. Information contained in the submission

The company that intends to place a hazardous mixture on the market for which they have to make 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. Furthermore, information required when specific derogations apply are also detailed. The reference to the relevant section of the legal text is indicated in square brackets next to 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. In addition, the Unique Formula Identifier (UFI) code is one of the main information elements 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(s) of the mixture […], including, where relevant, brand name(s), 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 does not change, all these trade names can be included in the same submission[58]. 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 and contact point [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 relevant 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.

A distinction must be made between the submitter, who bears the legal obligation to provide the necessary information in a submission, 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).

In addition and where relevant, it is possible to indicate also the details of an additional point of contact for authorities to obtain information which may be necessary for providing an emergency response if the information is not included in the submission (appointed bodies

[58] Note that a limited variability in composition may still exist if, for example, generic component identifiers are used to cover different components or an ICG is used to cover different interchangeable components. See following subsections for more details.

may consider that additional information may be needed in case of emergency). This contact can be used also for queries concerning clarifications regarding the content of the submission, to correct potential errors or to discuss details relevant for follow up and toxicovigilance activities. This additional contact point could be used in case the submitter cannot provide such information themselves or decides not to be the qualified person to be contacted to discuss emergency health related issues in the context of the specific submission. In this case the name, full address, telephone number and email address also of this contact point have to be included in the submission. To be noted that this contact does not need to be available 24/7.

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 a mandatory additional specific contact 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) or another language accepted by 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, but can be voluntarily provided for completeness.

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. (oral) 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. Classification for environmental hazards does not need to be provided. It should be noted that all applicable P-statements, covering all use(s) of the mixture, have to be included even if all may not be required to be included in the SDS (e.g. statements relevant only for consumers). 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) has 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 bodyweight (rat)
- Skin corrosion/irritation: Corrosive (rabbit, OECD 404, 4h)
- Skin sensitisation: Not sensitising (guinea pig, OECD 406)

Toxicological information specific for the mixture which should be included in the submission, includes, for example the acute toxicity estimate (ATEmix) where a mixture as a whole has been classified for acute toxicity using it.

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 [59], it is not necessary to indicate the specific colour of each trade name but basic generic colour names can be used. It is important that colour information is provided taking into account its purpose, i.e. for an 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 dossier preparation tools provided by the Agency support 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 and, additionally, the intensity).

- *The pH*. The pH value referring to the mixture as placed on the market (i.e. 100% solution concentration) has to be provided.

  In case of mixtures supplied in solid form, the pH should refer to a solution of the same solid mixture. Where the pH has been measured by diluting the mixture in water, the concentration of the solution must also be provided.

  If for any reason the pH cannot be provided, a justification must be indicated. The provision of a pH value does not apply to mixtures in a gaseous state. In some other cases it may not be meaningful to provide a pH value due to, e.g., the mixture being insoluble in water (the justification should be always provided).

  In general, the information has to be consistent with the SDS (Section 9 of the SDS) but always in compliance with the aforementioned criteria.

- *Product category.* 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 compliance date 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 supplied for industrial use needs to additionally reflect the consumer end-user if it finally ends up in a mixture (as a MiM) for consumer

[59] 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.

use subject to Article 45. 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. In addition, special provisions are available with regard to the composition information for certain specific products. This and the following sections provide 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 section 5.3.3 below), and
- Its concentration (exact concentration or range – see section 5.3.3)

Furthermore, the classification of the component is normally required, except when certain conditions apply (see section 5.3.3).

It is normally 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. Specific derogations exist in the following situations:

- Perfume components in a Group Submission may present only in certain mixtures of the group but not all (see section 5.4).
- Interchangeable components notified as part of an ICG may not be present at each point in time or in each batch of the mixture; nevertheless, these components have to be present at some point (i.e. they have to be among the components effectively used in the formulation of the mixture). (See section 5.5)
- Components notified in accordance with one of the Standard Formulas listed in Part D or Section 3.7, Part B of Annex VIII, when the lower limit of their concentration range is zero (see sections 5.6 and 5.7). Due to natural variation of the raw material and the specific production process, certain minor components may not be present in each batch of the same mixture.

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 component 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. 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)[60] 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 concentration 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).

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

Note: Hazardous mixtures that are subject to the obligation to submit a poison centre notification may, in addition to substances and mixtures, contain micro-organisms which are out of the scope of CLP. An example of such mixtures are certain plant protection and biocidal products. The presence of a micro-organism can be relevant for emergency response, in particular because of their potential to produce toxins and to cause allergic reactions. Specific labelling information is required for products containing micro-organisms under the Biocidal Products and Plant Protection Products legislations. This information is part of the obligatory supplemental information section of the CLP label, and shall be included in the submission. In the submission, it is thus recommended to also indicate (when adding the relevant supplemental labelling element) the micro-organisms present, providing sufficient information for their identification, including the scientific name and taxonomic group.

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, 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 added 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 but is provided with the MiM's UFI, this MiM 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 the UFI (see point C below for information about concentration and classification). When the information on the MiM, including the UFI, is available to the appointed body as part of a prior submission there is no need to indicate any of the MiM's components.

Nevertheless, the known MiM components could be still provided (e.g. based on the SDS), and this should be done in separated form, i.e. not aggregated[61]. 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. Enforcement authorities may enquire how the duty holders have complied with this legal requirement so as to account for the provision of partial/incomplete information.

- As a last resort, in the absence of a UFI or if this UFI and the information on the MiM has not been previously submitted to the relevant appointed body, the MiM must be identified by means of its product identifier (according to Article 18(3)(a) of CLP) and by indicating the components available from the SDS. In addition, the name, email address and telephone number of the MiM supplier must be indicated[62]. If known, the UFI of the MiM has to be provided. Appointed bodies and Poison centres will hence be able to use it once and if a submission is made by the supplier, without the need for an update. 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 (at least when the final mixture is notified in the same Member State as the MiM). 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 demonstrate that they contacted the suppliers by email and they received the reply 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 relevant information available from the supplier and other sources (e.g. CAS number, name of main component(s) used when purchasing, chemical nature, etc.). Eventually the MiM (for which an SDS is not required) could be identified by means of its product identifier and the contact details of the supplier only.

[61] 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.
[62] Please note that the EU importer is responsible for the mixtures imported into the EU. A non-EU supplier has no obligations to provide additional information in case the appointed body sees the need, and should not be used for the identification of the MiM.

Example 18: 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%
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 component identifier (GCI) –** "*perfumes*" or "*colouring agents*" - can be used to identify one or several components of the mixture, if they are used exclusively to add perfume or colour, respectively, to the mixture. The generic component 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 component identifier does not exceed:

- 5% for the sum of perfumes;
- 25% for the sum of colouring agents

Mixtures whose composition differs only in components which can be identified by the same generic component 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 component 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 come from different sources (e.g. as component of a MiM and as single substance), the information should be provided in aggregated form[63].

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.

[63] 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.

Table 2: Concentration ranges applicable to hazardous components of major concern for emergency health response - 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 in Part B of Annex VIII (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%.

Example 19: 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 component 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 – 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 regard to 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 in Part B of Annex VIII (Table 3 above) is complied with.

It is to be clarified that the distinction between "components of major concern" and "other hazardous components" in this case is based on the perspective of emergency health response where acute and short-term effects are more relevant. Furthermore, the severity resulting from the exposure to components classified for those hazards is also taken into consideration. This is why components classified for some serious hazards such as carcinogenic, mutagenic and toxic to reproduction are included in the second category.

Example 20: 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%.

C) Classification of mixture components [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 Section 3.2.1 of Annex II to the REACH Regulation (requirements for the compilation of SDSs). Section 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[64].

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. The classification of the components of the MiM(s) which are available and

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

indicated has to be provided as well. This applies regardless of the identifiers provided for the MiM (i.e. both when the MiM's UFI is available or not). The components of the MiM are effectively components of the final mixture.

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 component identifier may present physical hazards which would need to be indicated.

Example 21: Use of generic component 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 perfume components (1-8) and three other components (A,B,C).

The use of generic component identifiers is illustrated in the option B below where perfume components are grouped. Note: the indicated concentrations, classifications and number of components are chosen with the sole purpose of explaining the requirements.

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

This composition can alternatively also be submitted as presented in option B (below).
Perfume components 1 to 3 are indicated with the generic component identifier "*Perfumes*". 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 component identifier does not exceed 5% [B.3.2.3].
'Perfume chemical name 4 to 7' cannot be indicated with a generic component identifier because these components are classified for a health hazard.

OPTION B – SOME COMPONENTS INDICATED WITH A GENERIC COMPONENT 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%
Perfumes (GCI)	not classified	3%, 2-5%
Perfume chemical name 4	acute toxicity, cat 1	0.3-0.6%
Perfume chemical name 5	skin corrosion, cat 1C	2-3%
Perfume chemical name 6	skin sens. cat. 1	2%
Perfume chemical name 7	aspiration toxicity, cat 1	3-6%
Perfume chemical name 8	not classified	4%

Additional notes to the example:

- 'Perfume 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 perfumes can be grouped within the same generic component identifier because if 'Perfume chemical name 8' is included, the total concentration is 7%. Other non-classified perfume components must be indicated individually with their chemical name.
- It would also have been possible to, for example, indicate 'Perfume chemical name 2' and 'perfume chemical name 8' with a generic component identifier "*Perfumes*" since the total concentration does not exceed 5%. In that case the other non-classified perfume components (1 and 3) must be indicated individually with their chemical name.
- On the indicated concentration:
  The generic component 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 of Annex VIII, for example 2-5% (3% units bandwidth allowed; with a maximum of 5%).

5.3.4 Limited submission [B.3.1.1]

When a company decides to opt for a limited submission (possible for mixtures intended for industrial use only and for mixtures with an end use not subject to submission) the list of components to be provided may be limited to that included in Section 3.2 of the SDS. The information to be provided on the concentrations of such components may be also 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*[65].

In practice, the information provided in this case will be less detailed than a standard

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

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);
- have very similar composition; the only differences can concern certain perfumes (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 MiM, and components which are allowed to be indicated with 'generic component identifiers' (see section 5.3.3).

All mixtures in the group must contain the same components, except for perfume components, as referred to in Section 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, a group submission is basically possible for mixtures with compositions that differ, under certain conditions, in perfumes. These would be 'product variants' (possibly marketed under different trade names), for example detergents with a difference in perfumes.

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 under Article 45.

Ultimately, the difference between a standard and a group submission concerns the possibility to group mixtures with variation in perfumes which cannot be indicated with a generic component 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 mixture without grouping it with

other mixtures.

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 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[66]).

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).

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 components. Those components may only differ between the mixtures of the group under the conditions described below (Section A.4.3 and B.3.1 of Annex VIII). The total concentration of the perfumes which differ in each mixture of the group cannot exceed 5%. In case the concentration of the differing perfumes in a mixture is above this threshold, the mixture cannot be included in the same

[66] In this case the use of the generic component identifier "*colouring agent*" can possibly cover different colorants.

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 content.

It is to be underlined that the calculation of the 5% threshold should take into account only the perfumes in each mixture which vary from the others (i.e. which are not present in all the mixtures of the group, but in one or some of them). In practice this means that if the mixtures contain common perfumes indicated by chemical name or GCI, the 5% threshold does not refer to those common perfumes.

The perfumes contained in each mixture of the group must be listed to identify the perfumes they contain, including their classification.

The information required on the mixture composition in a group submission is illustrated by examples 22 and 23. 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.

Special case: perfume components
In the case of perfume components in a Group Submission 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. This applies to both types of perfumes, those which vary across the mixtures of the group and those which are common to all the mixtures.
For colouring agents with a generic component identifier, Table above (section 3 5.3.3) applies.

Example 22: Grouping of mixtures with difference in perfume components

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

GROUPING OF MIXTURES WITH DIFFERENCE IN PERFUME 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[a]**
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

Since some of the perfumes vary between the mixtures contained in the group, a list must be provided of the mixtures and the perfumes they contain, including their classification.

Name	Perfume	Classification[a]	Conc. range	Actual conc.[b]
Trade name 1 UFIs: N200-U0CW-5009-QWHJ G500-C029-F00T-D83M	Perfume chemical name 1	Other	1 - 2 %	1.2 %
	Perfume chemical name 3	Major concern	0.4 - 0.7 %	0.6 %
	'Perfume MiM' A67T-VHG2-DMM4-NH2A *(UFI and relevant MiM's information known to the relevant appointed body)*	Other	0.5 – 1.5 %	1 %
	Perfume chemical name 5	Other	1 – 4 %	
Trade name 2 UFI: P800-U0RP-S009-1KPP	Perfume chemical name 2	Major concern	0.3 – 0.6 %	0.4 %
	Perfume chemical name 4	Other	1 – 3 %	1.4 %
	Perfumes (GCI)	Not classified	n.a.	1.4 %
	Perfume chemical name 5	Other	1 – 4 %	

Note to the tables:

(a) 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'.

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

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 'Perfume chemical name 1 - 4', 'Perfume MiM' and the perfumes indicated with the generic component identifier "perfumes" that are at least present in one of the mixtures [A4.3]. The component 'Perfume chemical name 5' is a common component of all the mixtures in the group. Therefore, its concentration is not considered in the allowed limit of perfumes in mixtures part of a group submission.
- The difference between the mixtures concerns only perfumes and 'the total concentration of the perfumes which differ 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 not fully known, the UFI has to be provided as long as the relevant appointed body has received it as part of a valid submission for the MiM [B.3.2.2].
- The specific concentration of the components included under GCI "Perfumes" does not have to be indicated as the perfume is not classified [B.3.4.2]. .
- The concentration of the perfumes components has to be provided as exact value or as ranges of percentages following the same rules as for any other component.

Trade name 1:
Perfume chemical name 1 - indicated 1-2% - actual concentration 1.2%.
Perfume chemical name 3 - indicated 0.4-0.7% - actual concentration 0.6%.
Perfume MiM - indicated 0.5-1.5% - actual concentration 1%.
The actual concentration of differing perfume components in the mixture is 2.8%.

Trade name 2:
Perfume chemical name 2 - indicated 0.3-0.6% - actual concentration 0.4%.
Perfume chemical name 4 - indicated 1-3% - actual concentration 1.4%.
Perfumes – not indicated – actual concentration 1.4%
The actual concentration of differing perfume components in the mixture is 3.2%.

Example 23: Grouping of mixtures with difference in perfume 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	5-7 %

Perfume components:

Product- trade name ABC			
Components	**Classification**	**UFI or SDS components**	**Concentration**
Perfume mixture a	MIM: Skin sens. Cat. 1	UFI A67T-VHG2-DMM4-NH2A	*Not needed [B.3.4.2]*
Perfume mixture b	Skin sens. Cat 1B + Asp. tox. Cat. 1	*(UFI not available)* Substance A Substacne B Substance C	MiM: 0.5-1.5% SubA: 10-15% SubB: 20-30% SubC: 15-25%

Product- trade name BCD			
Components	**Classification**	**UFI or SDS components**	**Concentration**
« Perfume » (Generic component identifier)	Not classified	Not applicable	0.6-1.6%

Product- trade name CDE			
Components	**Classification**	**UFI or SDS components**	**Concentration**
Perfume mixture b	Skin sens. Cat 1B + Asp. tox. Cat.1	*(UFI not available)* Substance A Substance B Substance C	MiM: 0.5-0.9% SubA: 10-15% SubB: 20-30% SubC: 15-25%
Perfume (GCI)	Not classified	Not applicable	0.1- 1.1%

Notes to the tables of example 23:

- Total "perfume a" + "perfume b" in product- trade name ABC should not exceed 5% because both are perfumes components which varies (i.e. are not common to all the mixtures of the group) [A.4.3].
- Total "perfume b" + "perfume" (GCI) in product-trade name CDE should not exceed 5% for the same reason as above [A.4.3].
- Components of "perfume a" are included in the submission of this perfume a by a supplier upstream (link with UFI).
- "Perfume" (GCI) does not contain any hazardous component [B.3.2.3].
- The concentration of the MiM "Perfume mixture b" 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 (GCI)	NC	Products- trade names BCD+CDE

5.5 Interchangeable component group (ICG) [B.3.5]

5.5.1 Grouping of components

Providing the standard information on components as required in Annex VIII to CLP (and described in the previous sections), can be challenging in specific situations where very similar components, possibly purchased from different suppliers, are used together in the same production line. It may be difficult to know which exact components are present in the composition at each point in time (e.g. in each batch), and at which concentration.

Different components may be grouped in a so-called 'Interchangeable component group' (ICG), when they are not chemically identical, but are sufficiently similar to be considered equivalent regarding their hazard and, but not necessarily, regarding their technical function in the final mixture. The final mixture might contain only one of the interchangeable components at a time or a blend of several interchangeable components where the individual concentrations of the components in the blend cannot be precisely identified (e.g. when the interchangeable components are stored in the same storage container or as a result of mixing different batches of the final mixture afterwards). In other words, the components in an ICG do not have to be mutually exclusive (i.e. one does not necessarily exclude the presence of others), but more than one can be present at the same time. When specific conditions for an ICG are met, the submitter is allowed to indicate information on the concentration at ICG level, instead of indicating the concentration of each individual component within the group (as these individual concentrations may simply be unknown).

The application of this approach implies that not all the components grouped in an ICG are necessarily always present in each batch of the mixture placed on the market. This is a specific derogation in Annex VIII from the prohibition to notify components which are not present in the mixture. Each component included in an ICG must nevertheless be currently used in the production of the final mixture. The ICG solution is not intended for notifying components which might possibly be used only in the future, and therefore should not be used in order to avoid the need to update the submission. Components in an ICG can be added or removed when needed via an update (see section 7).

Section 5.5.2 below provides details on when the ICG approach can be applied. Section 5.5.3 clarifies the information requirements when an ICG is used.

It is to be emphasised that even when the criteria for ICG are met, using the ICG approach is optional. The information normally required by Annex VIII is recommended to be provided whenever this is possible. Submitters are encouraged to limit the use of the ICG approach to the specific situations for which this workable solution was envisaged.

5.5.2 Conditions for grouping components in an ICG

Components can be grouped in an ICG when they meet one of the two sets of conditions described in Section 3.5, Part B of Annex VIII. These two sets allow certain flexibility in the application of the ICG approach, for example by not limiting it only to components with the same technical function in the final mixture.

An ICG can include substances or MiMs. Where multiple components fulfil the criteria to be grouped in an ICG, it is not mandatory to necessarily group all of them in an ICG. Their concentration, if known, should be reported according to the standard rules.

The two sets of criteria are described in sections 5.5.2.1 and 5.5.2.2 below.

5.5.2.1 General rules for grouping components

Components in a mixture may have the same technical function even if they are not chemically exactly the same. For example, when they are purchased from different suppliers to ensure continuity of the supply. It is possible to group the components in an ICG when three conditions are met by each individual component in the specific ICG.

All components in the same ICG must have:

- Identical technical function(s) in the final mixture placed on the market.
- Identical classification for health and physical hazard(s). This means that both the hazard class and the hazard category are identical.
- Same toxicological properties, at least both target organ(s) and the type of toxicological effects must be the same for all the components in the ICG. Conclusions could be based on the mechanisms of toxicity of the components.

Information on the toxicological properties of the components is not part of the submission. The submitter should nevertheless be able to provide this information to the appointed body on their request.

In addition to the conditions above, the variation of interchangeable components in the final mixture must not influence the classification and labelling information of the final mixture. The following information has to be always the same, regardless of the interchangeable component(s) present and their individual concentration:

- the classification and the labelling elements of the final mixture, referred to in Sections 2.1 and 2.2, Part B; and
- the toxicological information of the final mixture referred to in Section 2.3, Part B; and
- the additional information on the final mixture referred to in Section 2.4, Part B:
    - the types and sizes of the packaging used to place the mixture on the market for consumer or professional use;

- the colour(s) and the physical state(s) of the mixture, as supplied;
- the pH, if available, of the mixture as supplied;
- product category (EuPCS);
- use: consumer, professional, industrial, or a combination of any of the three.

5.5.2.2 Alternative rules for grouping components with specific hazard classifications

An alternative set of criteria applies to components which are classified only for one or more of the following hazards:

- skin corrosion or irritation,
- eye damage or irritation,
- aspiration toxicity,
- respiratory or skin sensitization.

Using the ICG solution under this alternative set of criteria is only possible if the ICG does not contain more than five components.

The criteria which have to be met by components in order to be grouped in an ICG are the following:

- all the components must have the same classification for health and physical hazard(s) (classifications listed above).
  This means that both the hazard class and the hazard category are identical.

- the pH for all components, where applicable, is the same, i.e., either acidic, neutral or alkaline. This applies to components classified for skin corrosion, skin irritation, eye damage and eye irritation. A certain flexibility is allowed for the grouping of components. Components with a pH between 6 and 8 can be considered 'neutral'; components with a pH below 7 are considered as acidic, components with a pH above 7 are considered as alkaline for the purposes of the ICG. The variability in the pH cannot nevertheless affect the hazardous properties of the components and the emergency response. The possibility to measure the pH depends on the physic-chemical characteristics of the compound. Similar considerations in order to determine the circumstances when the pH cannot be measured as those made about the final mixture (see section 5.2.3) apply here. However, the pH of the components does not need to be included in the submission and a justification why the pH is not available does not need to be provided. The submitter may nevertheless be asked by the appointed body for information on the pH of the individual components in the ICG.

The toxicological properties of components are not an information required to be included in the submission. Nevertheless, in order to facilitate a proper emergency response, it is recommended to only group components with very similar toxicological properties. If it is known that the toxicological properties are different (despite identical classification), the submitter should consider refraining from using an ICG.

As for the first set of criteria explained in section 5.5.2.1 above, the components can be grouped in an ICG only if the information on the final mixture remains the same, regardless of the possible combinations (this means identical hazard identification and identical additional information required by Section 2 of Part B).

It is to be underlined that, unlike the criteria explained in section 5.5.2.1, this alternative set of criteria does not require the interchangeable components to have an identical technical function.

5.5.3 Information requirements

5.5.3.1 Identification

When components are notified as part of an ICG, a meaningful name has to be provided for the group itself. The legal text requires the name to reflect the technical function(s) of the grouped components. This name should normally allow the emergency operator to promptly identify at least the nature and kind of components covered by the group, without the need to look at the full list.

When an ICG groups components with different technical functions, all these have to be reflected in the name.

Preferably the name should also be toxicologically relevant, such as a chemical group name. 'Anionic surfactant' is an example of a combination of 'function' and 'chemical group' which is toxicologically relevant. Another example is 'Air-entraining agent with main components surfactants'.

Additional information on the identification of the ICG may have to be provided to the appointed body upon their request, if this is considered necessary.

Each component (substances or MiMs) in an ICG must be identified following the standard rules for any other component, as described in section 5.3.3 of this Guidance (i.e. in accordance with Section 3.2.1. or 3.2.2 of Annex VIII, Part B, as applicable).

5.5.3.2 Concentration

For components which are reported as part of the same ICG, there is no need to provide the concentration of the individual components. Instead, the concentration is to be provided for the ICG as a whole. This reflects a reality where the submitter does not know which interchangeable components are present at each point in time and in which concentration.

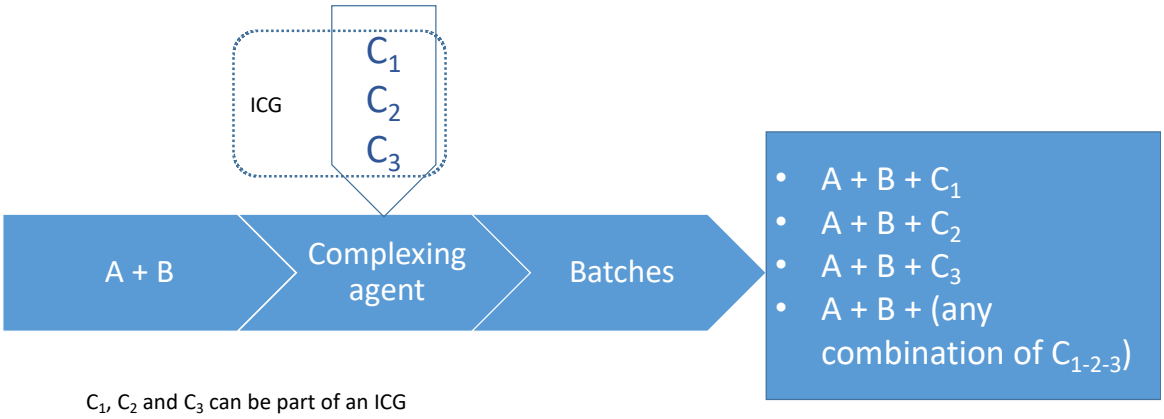
The concentration for the ICG can be provided as an exact value or as a range of percentages, following the rules described in section 5.3.3 of this Guidance.

5.5.3.3 Classification

The classification for health and physical hazards can in practice be reported either for each component of the group or for the ICG as a whole. This includes hazard classes, categories and statements as for any other component of the mixture.

5.5.4 Examples

Example 24: Grouping interchangeable components having the same technical function



In this example, a formulator mixes components A and B plus the complexing agent C in a continuous production process to formulate a final product. Component C is purchased from three different suppliers to ensure the continuity of supply. The formulator does not know whether the components are chemically identical, irrespective of the supplier. Nevertheless, the components have the same technical function in the final mixture and can be used interchangeably. Without the ICG approach, the formulator would need to submit several notifications, one for each combination of components. Yet in a continuous production process, it is not possible to know exactly which component, C_1, C_2 or C_3, is present in the final mixture that is placed on the market. In such cases, the ICG approach can provide a workable solution, provided that the components C_1, C_2 and C_3 fulfil the required conditions set in Section 3.5 of Part B.

Components C_1, C_2 and C_3 have the following characteristics:

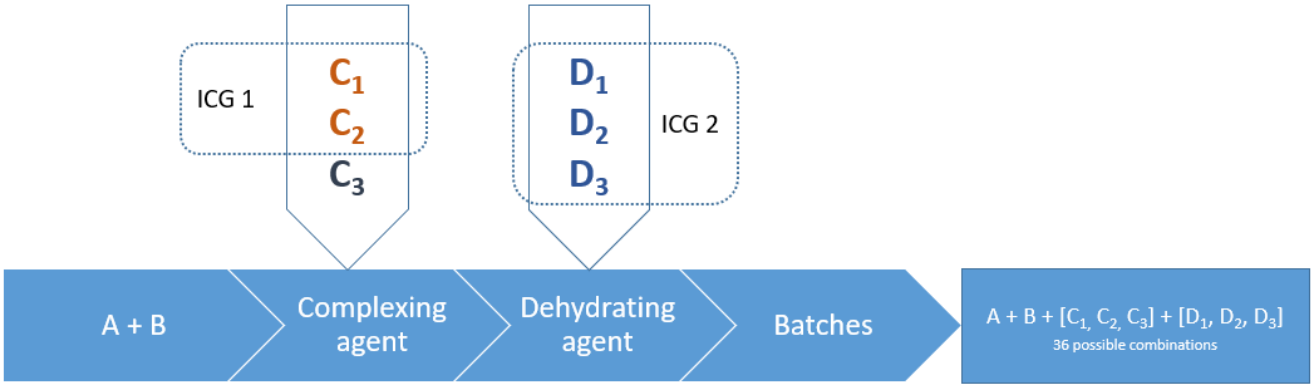
Components supplied by multiple suppliers			
Component	**Technical function**	**Hazard classification**	**Toxicological properties**
C_1	Complexing agent	Acute toxic oral, cat. 3	Set of properties S_1
C_2	Complexing agent	Acute toxic oral, cat. 3	Set of properties S_1
C_3	Complexing agent	Acute toxic oral, cat. 3	Set of properties S_1

Components C_1, C_2 and C_3 all have the same technical function, same classification for health and physical hazards and same toxicological properties (as a minimum the same target organs and toxicological effects). The total concentration of the complexing agent C is known to be 4-5% following the formulation process, and regardless of the combinations or blends of components C_1, C_2 and C_3, at this concentration the hazard identification of the final mixture is always the same. The additional information required by Annex VIII (Section 2 of Part B) on the product does not change either. Therefore, these components can be grouped in one ICG. The ICG is named 'Complexing agent'.

Components A and B are reported with their identifiers and concentrations as required by Annex VIII.

Each of the components C grouped in the ICG are identified in accordance to the standard rules for substances or MiMs (explained in section 5.3 of this Guidance). The concentration is provided for the ICG as a whole as exact value (5%) or with a range, in accordance with Table 1 of Annex VIII (due to the classification of the mixture; maximum 1% unit in this case).

Example 25: Grouping components in different ICGs according to the technical function



C_1 and C_2 can be part of one ICG 1
D_1, D_2 and D_3 can be part of a second ICG 2

C_3 cannot be part of the same ICG 1 and has to be reported individually (possibly in a separate submission)

Submission UFI 1:
A + B + [C_1, C_2] + [D_1, D_2, D_3]

Submission UFI 2:
A + B + C_3 + [D_1, D_2, D_3]

In this example, the formulator relies on different sources for two of the components used in the formulation of the final mixture: a complexing agent C and a dehydrating agent D.
Three alternative components (C_1, C_2 and C_3) are used as complexing agents and three alternative components (D_1, D_2 and D_3) used as dehydrating agent.
These have the following characteristics:

Components supplied by multiple suppliers			
Component	**Function**	**Hazard classification**	**Toxicological properties**
C_1	Complexing agent	Acute toxic oral, cat. 3	Set of properties S_1
C_2	Complexing agent	Acute toxic oral, cat. 3	Set of properties S_1
C_3	Complexing agent	Acute toxic oral, cat. 1	Set of properties S_2
D_1	Dehydrating agent	Flammable liquid, cat. 3	Set of properties S_3
D_2	Dehydrating agent	Flammable liquid, cat. 3	Set of properties S_3
D_3	Dehydrating agent	Flammable liquid, cat. 3	Set of properties S_3

Components A and B are reported with their identifiers and concentration as required by Annex VIII.

Regarding the complexing agent C, even if all three alternatives have the same technical function in the final mixture, C_3 does not have the same classification as C_1 and C_2. Therefore, they cannot all belong to the same ICG, even if the hazard identification of the final mixture remains the same.

Components C_1 and C_2 have the same classification and toxicological profile and their combination leads to identical hazard identification of the final mixture as well as identical additional information. Therefore, they can be grouped in one ICG.

Regarding the dehydrating agents D, all the alternative components have the same classification and toxicological properties. The hazard identification of the final mixture remains the same as well as the additional information on the product. Consequently, they can be grouped in another ICG.

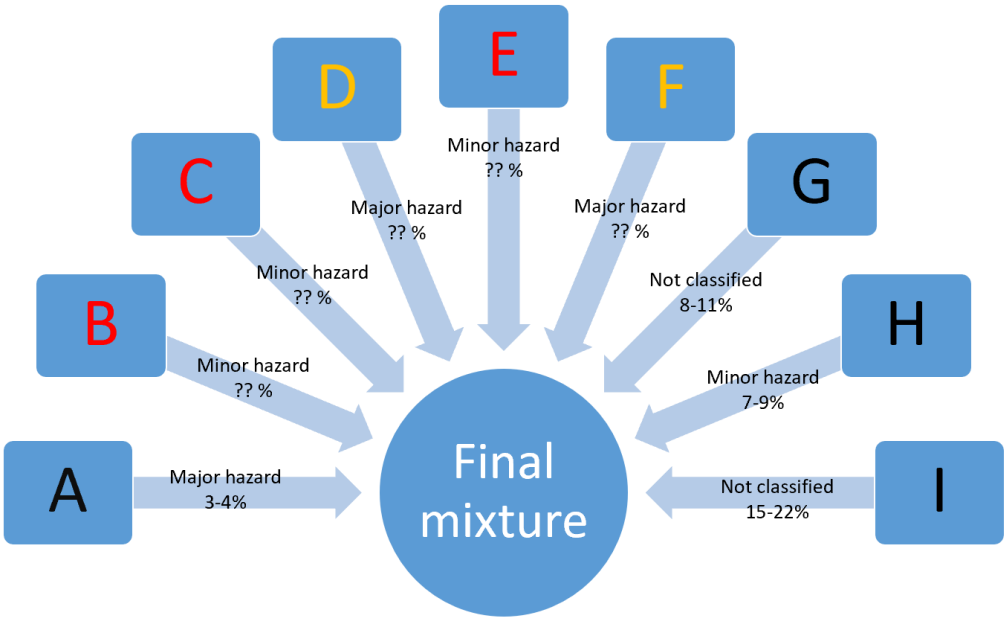
C_3 has to be reported individually with its own concentration. For the case when C_3 is present while C_1 and C_2 are absent, a separate submission with a different UFI is needed.

Several submissions and UFIs may be needed also if the variability of C_3, D or the ICG (grouping C_1 and C_2) exceeds the limits of the ranges allowed by Table 1 or 2 as applicable.

Example 26: Grouping components having different technical functions

In this example, the formulator mixes nine components in the mixture. The submitter is not in a position to know the exact concentration of five components (B, C, D, E, F) or whether they are all always present in the final mixture. This is due to the components being used depending on their availability, and they are fed into a continuous production process. These components are purchased from different suppliers and cannot be regarded as the same from a chemical point of view. The properties of the nine components are the following:

Components in the mixture			
Component	**Hazard classification**	**pH**	**Toxicological properties**
A	Acute toxic oral, cat. 3	12	Set of properties S_1
B	Aspiration hazard, cat. 1	7	Set of properties S_2
C	Aspiration hazard, cat. 1	6.5	Set of properties S_2
D	Eye damage, cat. 1	10	Set of properties S_3
E	Aspiration hazard, cat. 1	7.5	Set of properties S_2
F	Eye damage, cat. 1	9	Set of properties S_3
G	Not classified	6.5	Not applicable
H	Aspiration hazard, cat. 1 Eye irritation, cat. 2	9	Set of properties S_4
I	Not classified	7	Not applicable



- B, C and E can be part of one ICG
- D and F can be part of a second ICG
- A, G, H and I have to be reported individually

Components A, G, H and I are reported individually with their identifiers and concentration as required by Annex VIII (either exact concentrations or ranges in accordance with Table 1 or 2, as applicable).

Components B, C and E could be grouped in one ICG following the alternative set of criteria (section 5.5.2.2 of this Guidance): all three have the same classification and are classified for aspiration hazard only. The pH, even if not exactly the same, is within a range which can be considered as being neutral for the grouping purpose (i.e. between 6 and 8). Additionally, the submitter is able to provide the concentration range according to Table 2 of Annex VIII for the ICG. Furthermore, this ICG groups fewer components than the permitted maximum of five. This is possible even when the technical function is not the same for each component in the final mixture.

Toxicological sameness is not considered in the grouping of components B, C and E. Nevertheless, their toxicological properties can be expected to be similar based on the fact that they have the same classification and limited differences in pH (see 5.6.2.2).

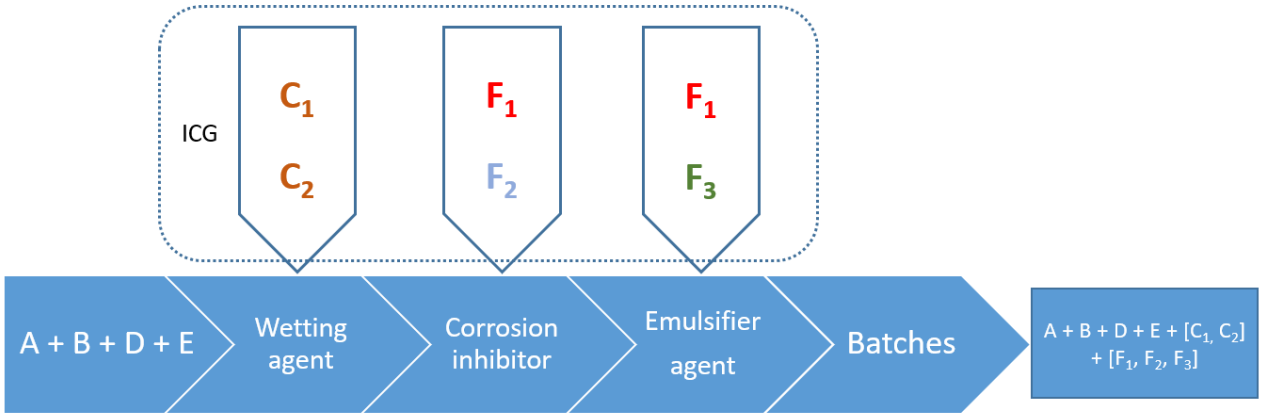
Components D and F can also be grouped in a separate ICG, following the second set of criteria: they have the same classification (Eye damage cat. 1 only), are all alkaline (pH > 7, not necessarily exactly the same but similar enough not to affect hazard properties and emergency response), and there are fewer than five components. Also, in this case, the technical function in the final mixture does not have to be the same and the toxicological properties can be expected to be very similar. The submitter also in this case is able to provide the concentration range according to Table 2 of Annex VIII for the ICG.

Several submissions and UFIs may still be needed depending on the concentration of both ICGs in the final mixture, in particular if the variability of the ICGs exceeds the limits of the ranges allowed by Tables 1 or 2, as applicable.

The hazard identification of the mixture placed on the market is the same for all possible combinations, regardless the individual concentration of components A, H, I and ICGs in the

resulting final mixture. The information referred to in Section 2 of Part B is also identical.

Example 27: Grouping components having different technical function in different ICGs



C_1, C_2, F_1, F_2 and F_3 can all be part of one ICG
A, B, D, and E have to be individually reported with their concentration

A formulator regularly manufactures batches of a hard surface cleaner concentrate. They source wetting agents (identified as C1 and C2) from two different suppliers and these are used interchangeably. The product also includes an ingredient (F1) which functions as a corrosion inhibitor and emulsifying agent. This can be substituted with two separate ingredients (corrosion inhibitor F2) and emulsifying agent (F3). Therefore, there are four potential recipes 1, 2, 3 and 4 which could be used depending on the availability of ingredients.

Components common to all recipes				
Component	**Technical function**	**Hazard class and category**	**pH**	**Concentration (%)**
A	Solvent	Not classified	*not relevant*	82.3 – 82.6
B	Detergent base	Acute toxic oral, cat. 4; Acute Toxic dermal cat. 4; Acute toxic inhalation, cat. 4; Skin corrosion, cat 1B; Eye damage, cat. 1; Specific target organ toxicity, single exposure, Cat. 3 (respiratory irritation)	*not relevant*	11
D	Solubiliser	Not classified	*not relevant*	0.3
E	Surfactant	Acute toxic oral, cat. 4; Eye damage, cat. 1	*not relevant*	1.9
Specific components recipe 1				
C1	Wetting agent	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	2.6
F1	Emulsifier/corrosion inhibitor	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	1.6
Specific components recipe 2				

C2	Wetting agent	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	2.6
F1	Emulsifier/corrosion inhibitor	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	1.6
Specific components recipe 3				
C1	Wetting agent	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	2.6
F2	Corrosion inhibitor	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	1.2
F3	Emulsifier	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	0.7
Specific components recipe 4				
C2	Wetting agent	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	2.6
F2	Corrosion inhibitor	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	1.2
F3	Emulsifier	Skin corrosion, cat 1B; Eye damage, cat. 1	Acidic (<7)	0.7

After manufacture and quality control approval, each batch is pumped to a bulk storage tank to release the blending vessel for another product. As orders are received, product from the bulk storage tank will be packaged into containers. The bulk storage tank will normally contain some product before transfer of a batch takes place, and hence different batches of product get mixed in the storage tank. Therefore, it would be practically very difficult for the formulator to make a submission according to the requirements of Annex VIII, as the precise composition of the product at the point of packaging is unknown.

Components A, B, D and E are reported individually with their identifiers and concentration as required by Annex VIII (either exact concentrations or ranges in accordance with Tables 1 or 2, as applicable).

Components C and F could be all grouped in one ICG, following the alternative set of criteria (section 5.5.2.2 of this Guidance): all components used as wetting agent, emulsifier and/or corrosion inhibitor have the same classification and are classified for the skin corrosion hazard only. The pH, even if not exactly the same, is acidic (<7) within a limited range which does not affect hazardous properties and emergency response. Furthermore, this ICG groups fewer components than the permitted maximum of five. This is possible even when the technical function is not the same for each component in the final mixture.

Toxicological sameness is not considered in the grouping of components B, C and E. Nevertheless, their toxicological properties can be expected to be similar based the fact that they have the same classification and the pH is below 6 for all possible components (see 5.6.2.2).

5.6 Special provisions for ready-mixed concrete, gypsum and cement products: Standard Formulas [B.3.6]

Providing the required information can be very difficult where raw materials with a highly variable or unknown composition are used in the formulation of the mixture. In these situations, it may not be possible to know the exact composition of the mixtures, which could vary from batch to batch, and to provide the concentration of each component within the limits set in Annex VIII.

In order to address potential difficulties encountered by the gypsum, ready-mixed concrete and cement sectors in complying with the standard requirements of Annex VIII, the legal text includes in Part D a list of Standard Formulas which can be used for the submission of the information relevant for emergency health response. Suppliers of mixtures within the three sectors mentioned above, subject to the obligations under Article 45 and conforming with one of those Standard Formulas, are allowed to deviate from the information requirements regarding the composition of the mixture.

The intention of the provisons related to Standard Formulas is to allow duty holders to comply with the emergency health response requirements without reducing the level of safety. The information provided on these specific mixtures by using the Standard Formulas is considered as detailed enough for the poison centres to be able to provide effective emergency response in the case of accidents with these specific products.

5.6.1 Standard Formulas

Part D of Annex VIII includes a list of 23 Standard Formulas:

- 20 Standard Formulas related to cement,
- one Standard Formula related to gypsum binder,
- two Standard Formulas related to ready-mixed concrete .

The list is exhaustive. Only mixtures belonging to these three product types and conforming with one of the Standard Formulas included in Part D can benefit from the special provisions described in this section.

For each of these Standard Formulas, the information in Part D includes the list of components with their identifiers and concentration ranges. The latter can be broader than what is allowed by applying Tables 1 and 2 of Part B of Annex VIII. This is based on the assumption that the hazard of the mixture and the emergency measures to be adopted in case of exposure, do not change within the concentration ranges specified for the mixture's composition in the Standard Formula and included in the notification.

Standard Formulas can be used in a submission to describe the final mixture (i.e. the final mixtures's composition conforms to the Standard Formula) or part of the final mixture (substances or MiMs). (this is explained in section 5.5.2 below). In the latter case, the final mixture compositon may contain additional components besides those included in the Standard Formula.

The assumption behind the use of a Standard Formula is that the classification of the final mixture does not change within the components' concentration ranges specified in the same Standard Formula (regardless the fact that the Standard Formula describes the whole or part of the mixture).

"*Conforming*" with a Standard Formula means that the mixture or part of a mixture contains only and all the components specified in the relevant Standard Formula and within the ranges

indicated in it. There is the possibility though that some of the components may not always be present, for example, in each batch of the product (when the concentration range as provided in the Standard Formula includes 'zero' as lower limit). This is due to the nature of the components (e.g. natural origin) or of the production process.
For mixtures or part of the mixture conforming with one of the Standard Formulas, the information on identification of components and their concentration ranges can be reported as in the Standard Formula itself[67].

It is important to underline that the derogation from information requirements concerns the composition only. This means that the duty holder is allowed to deviate from the standard requirements concerning which components have to be indicated (Part B, section 3.3 of Annex VIII), how the components should be identified (Part B, Section 3.2 of Annex VIII) and how the concentration should be reported (Part B, Section 3.4 of Annex VIII). All the remaining information about the mixture and the product as required by Part B of Annex VIII has to be provided as per a normal submission. This means that the product has to be identified as required in Section 1 of Part B (explained in section 5.1 of this Guidance) and the hazard identification and product information has to be provided as required in Section 2 of Part B (section 5.2 of this Guidance).

The classification of the components has to be provided as set out in Section 3.8, Part B of Annex VIII, and explained in section 5.3.3 of this Guidance.

The name and product description of the Standard Formula as indicated in Part D of Annex VIII should be included in the submission.

5.6.2 Using Standard Formulas: whole mixture composition vs part of the mixture composition (substances or MiMs)

Annex VIII foresees the possibility to use a Standard Formula either to report the whole composition of the mixture which is intended to be notified or only a part of it.

In the first case, all the components of the final mixture are those (and all) listed in the Standard Formula, i.e. the final mixture's composition conforms to the Standard Formula. The information on identity and concentration ranges of all the components can be provided as in the Standard Formula (as an alternative to the standard requirements of Sections 3.2, 3.3 and 3.4 of Part B of Annex VIII).

In the second case, the final mixture itself does not conform to a Standard Formula, but part of it (i.e. one or more of its components) does. In this case, there are two possibilities:

- A MiM component can be identified by using a Standard Formula, providing its product identifier (e.g. name of Standard Formula and, if available, the UFI) and composition accordingly (i.e. the compositon of the MiM corresponds to the Standard Formula).
- Individual components which together correspond to the Standard Formula in its entirety can be identified as in the Standard Formula itself at the level of the final mixture; this means that identification and concentration of the substance components can be provided as in the Standard Formula included in Part D of Annex VIII.

In both cases all other components (not conforming to a Standard Formula) of the final mixture have to be notified in accordance with Sections 3.2 or 3.4 of Annex VIII, Part B, as

[67] Note that the information available in the SDS may have to be provided instead, see section 5.6.3 below.

explained in section 5.3 of this Guidance. See examples below.

When components are reported by using a Standard Formula, their identification and concentration ranges have to be reported exactly as in that Standard Formula (unless more detailed information is available, see next section 5.6.3).

5.6.3 Standard Formulas vs SDS information

Even when a mixture or part of it qualifies for the derogation described in this section, the duty holder is required to provide the most detailed information available to them. Therefore, when the SDS of the mixture contains more detailed information than what would be provided by using a Standard Formula, the information on the identity and concentration of all the mixture's components as specified in the Safety Data Sheet has to be provided instead of using the Standard Formula.

The above is applicable not only when the full mixture composition of the final mixture conforms with a Standard Formula, but it may also be applicable where a Standard Formula is used to identify some of the components (e.g. a MiM), while other components are reported in accordance with the Annex VIII requirements. If this information as a whole is less detailed than that given in the SDS for the final mixture, the information on the identity and concentration of all the mixture's components conforming with the Standard Formula has to be provided as given in the SDS.

This can be the case when, e.g., the concentration ranges shown in the SDS are narrower than those in the Standard Formulas for the same components. The comparison between Standard Formula and SDS shoud take into account the completeness of the composition and the width of the concentration ranges.

The duty holder is therefore still allowed to deviate from the Annex VIII standard information requirements with regard to the composition (points 3.2, 3.3 and 3.4 of Part B) for the components conforming to the Standard Formula, but the more detailed available information from the SDS has to be provided.

5.6.4 Examples

In this section, the use of the Standard Formulas included in Part D of Annex VIII is explained by means of examples intended to address different possible submission scenarios. In all the examples, the duty holder is expected to submit a notification for a generic 'mixture A' which they intend to place on the EU market. Except where clearly indicated otherwise, the reference is to a generic Standard Formula "SF1".

Note. The following is applicable to all the example scenarios:

- Classification and labelling information and other additional information as requested in Annex VIII, Part B, has to be provided for the final mixture A. This includes:
    - Product identifier of the mixture and submitter details (see section 5.1)
    - Toxicological information (section 5.2.2)
    - Additional information on the product (section 5.2.3)
- Classification information on single components has to be provided as for any standard notification.

Generally speaking, there are two main ways how Standard Formulas can be of use:

1. Final mixture A conforms to Standard Formula.
2. Final mixture A does not conform with any Standard Formula but part of it does (i.e.

contains at least one mixture component that conforms with a Standard Formula).

Example 28: Final mixture conforms with a Standard Formula

The final mixture A (i.e. the mixture to be notified) conforms with SF1 included in Part D of Annex VIII. All its components are reported as in SF1 (all the components which are part of the Standard Formula are also part of the mixture composition):

Composition of final mixture A		Identification	Concentration	Classification
Component A	The **whole final** composition conforms with SF1	As in SF1	As in SF1	To be provided
Component B		As in SF1	As in SF1	To be provided
Component C		As in SF1	As in SF1	To be provided
Component D		As in SF1	As in SF1	To be provided

Example 29: Only part of the final mixture conforms with a Standard Formula (not the final mixture as a whole)

The following scenario aims to exemplify a case where a Standard Formula is used to describe a *part* of the final composition. The full composition of the final Mixture A does **not** conform with any specific Standard Formula. One or more components of the final mixture are reported as in a Standard Formula.

Scenario 1

The final mixture A itself (i.e. mixture to be notified) does **not** conform with any Standard Formula included in Part D, but includes one MiM which does conform with SF1 listed in Part D:

Composition of final mixture A		Identification	Concentration	Classification
Component A		As in B.3.2	As in B.3.4	To be provided
Component B		As in B.3.2	As in B.3.4	To be provided
Component C		As in B.3.2	As in B.3.4	To be provided
MiM D (SF1)	The MiM conforms with SF1	Name of Standard Formula "SF1" Composition information as in SF1 Concentration of components of MiM to be given according to SF1	Concentration of MiM in final mixture to be given according to B.3.4.	To be provided

Scenario 2

The final mixture A (i.e. mixture to be notified) does **not** conform with any of the Standard Formulas included in Part D but part of its composition does conform with Standard Formula listed in Part D. The Standard Formula "Gypsum binder" is taken as an example for simplicity as it contains two components only.

Composition of final mixture A		Identification	Concentration	Classification
Component A		As in B.3.2	As in B.3.4	To be provided
Component B		As in B.3.2	As in B.3.4	To be provided
Component C		As in B.3.2	As in B.3.4	To be provided
Component D: Gypsum sulphate	**This part** conforms with Standard Formula "Gypsum binder Standard Formula"	As in Gypsum Binder Standard Formula: 231-900-3	As in Gypsum Binder Standard Formula: ≥50% and ≤ 100% ***NB**: this value, taken from the* Standard Formula *in Part D, refers to the composition of the final mixture*	To be provided
Component E: Calcium dihydroxide		As in Gypsum Binder Standard Formula: 215-137-3	As in Standard Formula Gypsum Binder: (e.g. <5%) ***NB**: as above*	To be provided

5.7 Special provisions for fuels conforming with standards or technical specifications [B.3.7]

Annex VIII includes special provisions for specific fuels, listed in Section 3.7, Part B of the same Annex. These products are normally formulated from naturally occurring substances, which vary in composition. Fuel products are produced to meet EN standards and/or technical specifications. These standards define the required technical performance of the products rather than the detailed composition. This means that while the major mixture components are well understood, the specific composition (as per the Annex VIII requirements) may vary due to the natural variations in the natural base material (crude oil). Furthermore, petroleum products (i.e. mixtures) are produced as a continuous blending process, meaning that there can be frequent small incremental compositional changes. These changes could lead to a need for frequent notification updates.

Ultimately, fuels placed on the market normally conform to a technical standard and/or technical specifications rather than a specific chemical composition. Different batches of what industry considers to be the 'same' commercial product (under relevant standards such as e.g. EN590, which describes the characteristics that all automotive diesel fuels must meet if it is to

be sold in the EU and Switzerland) can have sufficiently different chemical compositions to necessitate, in principle, separate Annex VIII notifications. This would also result in multiple UFI numbers being generated for the 'same' commercial product, containing the same ingredients (albeit in different concentrations). EN standards and technical specifications provide requirements in terms of chemical compositions of petroleum products with wide ranges of concentrations and generic description of components, which can be hazardous or non-hazardous chemicals.

In order to address such issues, and considering the low number of poisoning incidents with fuels reported by Poison Centres, a derogation from the standard requirements for Annex VIII notifications is foreseen for the fuels listed in table 3 under Section 3.7, part B.

Instead of providing exact concentrations or ranges according to tables 1 and 2 in Annex VIII, it is allowed to submit compositional information as contained in the safety data sheet, complemented with the identity and concentration of any other known component (including for instance non-hazardous components), so as to reduce to the minimum the uncertainty regarding the composition. The submitter should normally aim at providing the full composition, in cases when the information is available to him.

5.7.1 Definition of fuels

A fuel is a material that is burned to produce heat or power for a plant, vehicle or machine.

The derogation from the normal notification regime applies to the fuels listed in Table 3, Section 3.7, Part B of Annex VIII.

Table 4: List of fuels - Table 3, Part B of Annex VIII

Fuel	Product description
Gasoline EN228	Automotive fuels - Unleaded petrol
Gasoline E85	Automotive fuels –Ethanol (E85) automotive fuel
Gasoline alkylate	Motor fuels – special petrol for powered implements
LPG	Liquefied Petroleum Gas used as fuel
LNG	Liquefied Natural Gas used as fuel
Diesel fuel	Automotive fuels - diesel engine fuels with/without biofuel
Paraffinic diesel fuels (e.g. GTL, BTL or HVO)	Automotive fuels - Paraffinic diesel fuel from synthesis or hydrotreatment
Heating oil	Liquid mineral fuels with the characteristics of domestic fuel oil
MK 1 diesel	Automotive fuels – Diesel fuel oil of environmental class 1 and 2 for high-speed diesel engines
Aviation fuels	Aviation turbine engine and piston engine fuels
Kerosene - Illuminating paraffin	Illuminating paraffin lampoil Type B and C
Heavy fuel oil	All grades of heavy fuel oil
Marine fuel	Marine fuels, containing or not biodiesel

Fatty acid methyl esters (FAME) – Diesel B100	Fatty acid methyl esters (FAME) for use in diesel engines and heating applications

All commercially available fuels conform to either an international or a national standard or another technical specification. Some examples include:

- ISO 8127 Petroleum products — Fuels (class F) — Specifications of marine fuels
- ASTM D1655 - Standard Specification for Aviation Turbine Fuels
- EN589 - Automotive fuels. LPG
- ÖNORM C 1109 – Liquid fuels - Domestic fuel oil - Gasoil for heating purposes (Austria)

Enforcement authorities may inquire about the documentation of the standard and/or technical specification met by a product placed on the market.

A typical composition of a fuel is a mix of

- one or more petroleum fuel substances and its stabilizers;
- one or more non-petroleum components and its stabilisers with concentration varying from zero to a certain level;
- specific well identified additives which can be e.g. colourants for tax purposes;
- performance additives, usually proprietary.

The compositions of such blends vary due to the complex supply chains and continuous blending process except for the performance additives. The concentration of the latter does not normally vary as they are often added at the step before delivery to customer.

5.7.2 Information requirements on composition

The submission for fuels can deviate from the standard information requirements with regard to:

- Section 3.2, Part B: Identification of mixture components;
- Section 3.3, Part B: Mixture components subject to submission requirements;
- Section 3.4, Part B: Concentration and concentration ranges of mixture components.

Section 3.7, Part B specifies that the identification and concentration of the components can be reported as in the SDS and do not need to follow the standard Annex VIII requirements. The identity and concentration of any other known component not listed in the SDS has to be reported as well. Non-hazardous known components present in concentrations equal or greater than 1% and known hazardous components present in concentrations equal or greater than 0.1% should at least be included. Known components not included in the SDS should be reported according to the standard rules (i.e. with regard to identity and concentration). Industry is researching and introducing more sustainable and often less hazardous substitutes of fuels' components. An example is the use of non-hazardous component Fatty Acid Methyl Esters (FAME) instead of certain hazardous components in diesel fuels EN 590, listed in Table 3 of Annex VIII, Part B as "Diesel fuel - Automotive fuels - diesel engine fuels with/without biofuel". Being non-hazardous, FAME does not need to be included in section 3 of the SDS even if it partially substitutes some of the hazardous components listed there. Therefore, when it is not listed in the SDS, it is not required to be included in the submission, unless its presence in the fuel is known.

The classification of the components has to be provided as required in Section 3.8, Part B of Annex VIII, as explained in section 5.3 of this Guidance.

All other information required by Annex VIII has to be provided according to standard rules:

- information on the identification of the mixture, submitter and, if relevant, contact point (section 5.1 of this Guidance);

- hazard identification of the mixture (section 5.2 of this Guidance);
- additional information on the product (section 5.2 of this Guidance).

Example 30: Submission of information for a fuel product listed in Table 3 of Annex VIII

The submission to the relevant appointed bodies for a fuel product listed in Table 3 of Annex VIII needs to include information on the composition as shown in the generic table below:

Fuel type and name as mentioned in Table 3, Section 3.7, Part B of Annex VIII			
Composition of fuel product	**Identification**	**Concentration**	**Classification**
Component A	As in SDS	As in SDS (i.e. deviating from B.3.4)	Hazardous, classification to be provided
Component B	As in SDS	As in SDS (i.e. deviating from B.3.4)	Hazardous, classification to be provided
Component C	As in SDS	As in SDS (i.e. deviating from B.3.4)	Hazardous, classification to be provided
Component D	As in SDS	As in SDS (i.e. deviating from B.3.4)	Hazardous, classification to be provided
Component E	Not listed in SDS because concentration is below threshold for inclusion (REACH Annex II). If known, provide identification according to standard Annex VIII rules	Not listed in SDS because concentration is below threshold for inclusion (REACH Annex II). If known, provide concentration according to standard Annex VIII rules	Hazardous
Component F	Listed in the SDS even if not required according to Annex II to REACH). Identification to be provided according to standard Annex VIII rules	Provide as in the SDS	Not-hazardous
Component G	Not listed in the SDS. If known, identification to be provided according to standard Annex VIII rules	If listed in SDS, provide as in SDS. If not listed in SDS and presence is known, provide as per Annex VIII, Part B, section 3.4 rules.	Not-hazardous

Based on the generic table above, the compositional information to be included in a submission for (as an example) a diesel fuel meeting the standard EN590 and which is included in the list in Section 3.7, Part B as "Diesel fuel: Automotive fuels – Diesel engine fuels with/without

biofuel", would have to be notified as illustrated below.

The composition of the product varies seasonally and geographically according to the availability of components and operational requirements. A typical composition of a diesel fuel is shown in the table below:

Chemical Name	EC No.	Concentration w/w%	Classification
Fuels, diesel	269-822-7	0-100%	Flam. Liq. 3 (H226), Acute Tox. 4 (H332), Carc. 2 (H351), Asp. Tox. 1 (H304), Skin Irrit. 2 (H315), STOT RE 2 (H373), Aquatic Chronic 2 (H411)
C8-C26 – branched and linear hydrocarbons – Distillates	481-740-5	0-100%	Flam. Liq. 3 (H226), Asp. Tox. 1 (H304)
Renewable hydrocarbons (diesel type fraction)	618-882-6 700-571-2	0-100%	Asp. Tox 1 (H304)
Fatty acids, C16-18 and C18-unsatd. methyl esters	267-015-4	0-7%	Not classified
Fatty acids, vegetable oil, methyl esters	273-606-8	0-7%	Not classified
Fatty acids, C14-18 and C16-18-unsatd., Me esters	267-007-0	0-7%	Not classified
Performance additive A	UFI A	300 ppm	Asp. Tox 1 (H304), Skin Irrit 2. (H315), Eye Irrit. (H319), Skin Sens. 1 (H317), Carc. 2 (H351), STOT SE 3 (H336), Aquatic Chronic 2 (H411)
2-EHN cetane	248-363-6	1-8.5 ppm	Acute Tox 4 (H302), Aquatic Chronic 2 (H411)

The information in Section 3 of the SDS for the same product is given in table below.

Chemical Name	EC No.	Concentration	Classification
Fuels, diesel	269-822-7	0-100%	Flam. Liq. 3 (H226), Acute Tox. 4 (H332), Carc. 2 (H351), Asp. Tox. 1 (H304), Skin Irrit. 2 (H315), STOT RE 2 (H373), Aquatic Chronic 2 (H411)
C8-C26 – branched and linear hydrocarbons – Distillates	481-740-5	0-100%	Flam. Liq. 3 (H226), Asp. Tox. 1 (H304)
Renewable hydrocarbons (diesel type fraction)	618-882-6 700-571-2	0-100%	Asp. Tox 1 (H304)

The following components are not listed in section 3 of the SDS in accordance with the

requirements in section 3.2 of Annex II of REACH on SDS[68]:

- Fatty acids, C16-18 and C18-unsatd. Me esters: not hazardous
- Fatty acids, vegetable oil, methyl esters: not hazardous
- Fatty acids, C14-18 and C16-18-unsatd., Me esters: not hazardous
- Performance additive A: hazardous but concentration below 0.1%
- 2-EHN cetane: hazardous but concentration below 1%

In addition to the components listed in section 3 of the SDS, the submitter must provide the information on the components which are not listed in the SDS, but are known to him. According to the general rules of Annex VIII (Section 3.3, Part B), non-hazardous components which are identified have to be notified when are present in concentrations equal or above 1%, while classified components should be notified even when are in concentrations under 0.1%, if known and relevant.
Applying these rules to the example, the components not included in section 3 of the SDS will be handled as follows for the notification:

- The 3 non-hazardous fatty acid methyl esters and their know ranges will be included in the notification. Standard rules apply (unless these components are included in section 3 of the SDS), therefore the concentration should be given either as exact percentage or with a range in accordance with Table 2 of Annex VIII.
- The cetane improver, given the low concentration, low level of toxicity (Acute toxicity 4) and the fact that the component "Fuel, diesel" classified as acute tox 4 and present in higher concentration is notified, will not be mentioned in the notification. The submitter considers it irrelevant for emergency response and is able to demonstrate it in case of inquiry from the relevant authorities.
- The performance additive A will be included because, despite its concentration being below 0.1%, it is considered relevant for the emergency response due to the skin sens. 1.

The submitter cannot report the components which are not known to him and it is not required to investigate further. Examples are colourants or specific performance additives.

In the notification format, it should be mentioned which type of fuel product in table 3, section 3.7, part B of annex VIII the product conforms to.

Applying this to the example of diesel B7, the notification will contain composition the information as given in table below.

In this example the three FAME components are not listed in Section 3 of the SDS, therefore the concentration has to be provided in accordance to Table 1 of Annex VIII.

Diesel fuel: Automotive fuels – Diesel engine fuels with/without biofuel			
Component	***Identification***	***Concentration***	***Classification***
Fuels, diesel	269-822-7	0-100%	Flam. Liq. 3 (H226), Acute Tox. 4 (H332), Carc. 2 (H351), Asp. Tox. 1 (H304), Skin Irrit. 2 (H315), STOT RE 2 (H373), Aquatic Chronic 2 (H411)
C8-C26 – branched and linear hydrocarbons –	481-740-5	0-100%	Flam. Liq. 3 (H226), Asp. Tox. 1 (H304)

[68] These components can be voluntarily included in the Section 3 of the SDS. In this case the concentration can be provided as in the SDS.

Distillates			
Renewable hydrocarbons (diesel type fraction)	618-882-6 700-571-2	0-100%	Asp. Tox 1 (H304)
Fatty acids, C16-18 and C18-unsatd. methyl esters	267-015-4	0-1%	Not classified
Fatty acids, vegetable oil, methyl esters	273-606-8	0-1%	Not classified
Fatty acids, C14-18 and C16-18-unsatd., methyl esters	267-007-0	0-1%	Not classified
Performance additive A	UFI A	300 ppm	Asp. Tox 1 (H304), Skin Irrit 2. (H315), Eye Irrit. (H319), Skin Sens. 1 (H317), Carc. 2 (H351), STOT SE 3 (H336), Aquatic Chronic 2 (H411)

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 assist both the submitters and the Member States appointed bodies in fulfilling their obligations and performing 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's Poison Centres website (https://poisoncentres.echa.europa.eu/poison-centres-notification-format) 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

There are three ways to prepare dossiers (IUCLID XML files). The submitter can decide which one to use based on their specific business needs and IT systems.

- **Online in the ECHA Submission portal**: The portal features IUCLID Cloud, an online tool to guide the user through the preparation of a dossier, allowing to enter data manually and store the information in the ECHA Cloud.
- **Offline in IUCLID 6**: In IUCLID 6, data can be entered manually using a specific poison centres notification interface. This option is available for companies using local installations of IUCLID. The desktop and server versions of the software can be downloaded from the IUCLID 6 website.
- **Using the PCN format in the company's own system**: companies can prepare and create a dossier directly in their own systems, using the IUCLID-compatible PCN format.

6.4 Submission of information

The dossier, 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 instructions for the submission of the information with the countries where the mixture is placed on the market.

Dossiers can be submitted through the ECHA Submission portal in one of two different ways, either:

- **Directly online through the portal**: Regardless of whether or not a dossier has been created online or offline, the ECHA Submission portal will forward the dossier to all Member States indicated in the IUCLID XML file. This means that a single submission can reach several Member States.
- **Through a system-to-system (S_2S) transfer service:** An automatic S_2S transfer service allows companies that have created IUCLID XML files in their own systems to make their submission through the ECHA Submission portal. Dossiers are then forwarded from the portal to all the relevant Member States.

The ECHA Submission portal can be accessed from the ECHA Poison Centre website at https://poisoncentres.echa.europa.eu/echa-submission-portal.

Secure access to the information by designated authority users is available on the ECHA Poison Centre website at https://poisoncentres.echa.europa.eu/tools-for-authorities.

Whether the submissions are 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 the date for submission, content, quality and update of the submissions etc.

6.4.1 Validation of information

Dossiers submitted through the ECHA Submission portal are also subject to validation rules, developed in cooperation with appointed bodies, poison centres and industry. Incompliance with

some of these rules may lead to non-acceptance of the notifications. Other rules may trigger a warning, which do not prevent the submission but forward a validation report (containing the warnings) along with the dossier to the receiving Member State.

A validation assistant is made available by ECHA to industry in order to validate the information before submission. The list of validation rules is also published on ECHA's Poison Centres website at https://poisoncentres.echa.europa.eu/poison-centres-notification-format.

The validation rules concern the specific aspects of the dossier content, which can be expected to be checked by an automated tool without expert judgement:

- presence of information (preventing submission of dossiers not in compliance with the information required by Annex VIII);
- quality of certain pieces of information (ensuring that information provided is meaningful to operations of poison centres);
- internal dossier consistency (ensuring that information in various sections of the dossier is not contradictory);
- dossier accuracy with previously submitted information (updates).

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.

6.5 Fees

The usage of XML formats, UFI generator, EuPCS and the ECHA Submission Portal provided by the Agency is free of charge.

However, it needs to be noted that while most Member States have indicated that they will not solicit a fee, this may be levied in some 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. The document "Overview of Member State decision on implementing Annex VIII to the CLP" available on the Poison Centres website provides an overview of the available information.

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 poison centres have the relevant information on the products available on the market 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 a quality check of the submitted information, either on a regular basis or following specific criteria (for example on the basis of the warnings resulting from execution of validation rules by the ECHA Submission portal - see section 6.4 - or other "alerts", e.g. under indication of the poison centre). 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 consistency 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 Section 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 Section 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.

These requests should be addressed to the contact point indicated in addition to the submitter and mentioned in section 5.1 of this Guidance.

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

- A need for more detailed information as a result of the analysis of warnings delivered by the ECHA Submission portal.
- A need for access to more detailed data, based on which the toxicological information was prepared by the submitter.
- To evaluate the correctness of an 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 relevant toxicological information related to components grouped in an ICG (e.g. to verify the sameness of the toxicological information).
- To enquire about packaging information not included in the submission following incidents involving children (e.g. child-resistant fastening).
- To discuss and obtain information relevant for toxicovigilance activities.

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 only be used by personnel authorised by the appointed bodies.

ECHA guarantees the security of the information submitted and stored in its protected IT-infrastructure. Submission portal and data base are secured according to the same security practices as other ECHA databases which contain sensitive registration data. Access to the searchable database is strictly controlled, its security settings are hardened and security is continuously monitored as well as content of the database is regularly backed up.

Appointed bodies and poison centres, which have access to the searchable database through ECHA's standard secure remote access system, 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 place before that date (and after the relevant compliance date 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:

1. the name of the mixture (the product identifier, e.g. trade name/brand/identification of the mixture) or the UFI is changed, or
2. the mixture classification for health or physical hazards changes, or
3. 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
4. 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[69], 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.

With regard to submissions made by referring to Standard Formulas included in Part D (for ready-mixed concrete, cements and gypsum products as explained in section 5.6 of this Guidance) and for fuels listed in Part B, section 3.7 of Annex VIII, part B, specific provisions apply with regard to the update obligations under point 4 above. These are addressed in detail in the sections 7.4.2.2 and 7.4.2.3 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.

When a submission includes one or more Interchangeable Component Group, the submission has to be updated if a component is added, deleted or replaced within an existing ICG. However, there is no need to change the UFI.

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 31. 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 (and no need to update the UFI).

The same applies when components are grouped in an ICG and its concentration is reported with a range.

[69] 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.

Example 31: 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 variations are listed in Table 4 of Annex VIII (see Table 5 below). If the new concentration exceeds the allowed variation, an update is required and a new UFI has to be created. Example 32 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%.

The same applies when components are grouped in an ICG and its concentration is reported with an exact value.

Table 5: Variations of the concentration of components requiring a submission update (Table 4 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 32: 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.

7.4.2.3 When referring to a Standard Formula included in Part D

When the whole or a part of a mixture composition is provided by using a Standard Formula included in Part D of Annex VIII, a submission update is required when the composition of the full mixture or that part changes in a way that it does no longer conform with the Standard Formula. This can be the case when:

- A new component is added, which is not included in the Standard Formula;
- The concentration of an existing component changes and it exceeds the concentration ranges listed in the Standard Formula;
- A component listed in the Standard Formula is removed from the mixture (a component where the lower limit of the allowed concentration range is above zero).

When such changes occur, the mixture (or part of it) no longer conforms with the Standard Formula listed in Part D. Therefore, the special provisions can no longer be applied, and an update is required, with **new UFI** and the **full information** required by Annex VIII.

For mixtures conforming with one of the Standard Formulas listed in part D, for which the information from the SDS is provided because it is more detailed than the Standard Formula, an update of the submission is required when Section 3.2 of the SDS is updated (a new UFI is needed when the Section 3 of the SDS is updated with regard to the composition in a way that the mixture does not conform anymore with the original Standard Formula; this is addressed in section 4.2.7).

The requirements for compiling an SDS are laid down in Annex II to REACH. For mixtures, the substances to be included in Section 3.2 are specified in section 3.2.1 of Annex II to REACH. Further details are given in the *Guidance on the compilation of safety data sheets available at https://echa.europa.eu/guidance-documents/guidance-on-reach*.
To be noted that the need to update the SDS is, among others, triggered when new information affecting the risk management measures or new information on hazard becomes available[70]. An update of section 3.2 of the SDS due to the addition of a component classified for the environment only would trigger a need to update the submission.

In case the initial submission contains other substances in addition to those in the Standard Formula (i.e. only part of the mixture conforms to the Standard Formula), changes in these other components may trigger the need to update the submission (including the UFI). These are the cases described in section 7.4.2 of this Guidance.

In this case the part of the final composition conforming with the Standard Formula continues to benefit from the derogation from the standard Annex VIII requirements.

[70] See Article 31(9) of REACH.

7.4.2.4 When referring to a fuel included in Part B, Section 3.7 of Annex VIII

When a submission for a fuel listed in Section 3.7, Part B, is made by providing the information on component identity and concentrations from the SDS, an update is required when Section 3 of the SDS is updated. This means that an update of the submission is required even if there are no changes in the actual composition but the Section 3 of the SDS is nevertheless, for any reason, updated.

The requirements for compiling an SDS are laid down in Annex II to REACH. This defines specific concentration thresholds which trigger the need to indicate the component. As an example, when the following occur the submission needs to be updated:

- a substance which is required to be included in Section 3 of the SDS is added, and therefore the SDS is updated; or
- a substance which was required to be included in Section 3 of the SDS is removed, and therefore the SDS is updated; or
- the concentration of an existing substance included in Section 3 of the SDS exceeds the original range, and therefore the SDS is updated.

Changes in the composition requiring update of Section 3 of the SDS, trigger the need to update both submission and UFI.

Normal update rules apply to components not listed in the SDS but included in the submission because they are known. A change in their concentration will trigger the need for an update including a new UFI if the variation exceeds the limit in Table 4 of Annex VIII (in case of exact values) or the new concentration falls outside the original range.

7.4.3 Other updates relevant for an emergency health response

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).

Changes other than those listed in Section 4.1 Part B of Annex VIII may take place and these may be relevant for the purposes of the CLP 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 required to 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. Change of UFI is not required in these cases.

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 at the technical level by the system provided by ECHA in order to respond to the need of the ultimate users, 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). In the system this is referred to as an "update" where the mixture composition remains the same. Both versions remain potentially relevant for the poison centres and appointed bodies.

(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 original contact details are not valid anymore); 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. In the system this is referred to as an "update" where the mixture composition remains the same, as in the previous case.

(iii) creation of a technically new 'submission' as a change in composition leads *de facto* to two different mixtures 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 potentially a long time). It is still an update from a regulatory point of view but technically it becomes a "new notification after significant change of composition".

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

Changes	Scenario triggered	Technical option
Addition of a new trade name only[(a)].	Scenario (i) – addition of information.	Update
Addition of a new UFI only[(a)].	Scenario (i) – addition of information.	Update
Modification of the classification for health or physical hazard[(b)] following change in classification criteria.	Scenario (ii) – replacement of old with new information.	Update
Addition of new toxicological information (e.g. results from new tests on the mixture become available). The existing information remains valid.	Scenario (i) – addition of information.	Update
New packaging *Note, the mixture in original packaging may remain on the market for long time.*	Scenario (i) – addition of information.	Update
Addition of a component in an existing ICG (e.g. from a new supplier)	Scenario (i) – addition of information.	Update
Change in telephone number for rapid access to additional product information	Scenario (ii) – replacement of old with new information.	Update

Changes	Scenario triggered	Technical option
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 or generic product identifiers, see below 7.4.5).	Scenario (iii) – creation of a technically new 'notification'. *Note that a **new UFI** must be provided.*	New notification after significant change in composition
Modification of reported concentration ranges, **beyond** the indicated range.	Scenario (iii) – creation of a new 'notification record'. *Note that a **new UFI** must be provided.*	New notification after significant change in composition
Modification of reported exact concentration **beyond** the indicated range	Scenario (iii) – creation of a new 'notification record'. *Note that a **new UFI** must be provided.*	New notification after significant change in composition
Modification in reported concentration range of one or more components, beyond the range indicated in the Standard Formula	Scenario (iii) – creation of a new 'notification record'. *Note that a **new UFI** must be provided.*	New notification after significant change in composition

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 component identifiers

When ingredients covered by the generic component identifiers "perfumes" or "colouring agents" are included (see section 5.3), an update is not required if a perfume or colouring agent for which a generic component 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 component identifier remains below the allowed maximum level (5% for perfumes 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 components in a group submission which are 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. This specific provisions applies to perfume components not necessarily identified with a generic component identifier.

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

Notification for a mixture initially made as a standard submission, is updated to a group submission

When a mixture is initially notified with a standard submission (i.e. not a group submission), it is possible to update it to a group submission to include one or more mixtures differing for perfumes only (the total concentration of the differing perfumes is not more than 5%). A new UFI is not required.

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

When the perfumes 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 perfumes they contain as required in Annex VIII Section 3.1 must be updated. If the change of perfumes is the only change, a new UFI is not required.

Nevertheless, if a perfume covered by the generic component identifier is added, but the total concentration of the generic component identifiers remains <5 %, no update is required.

It is to be reminded that if the change leads to an increase in the content of differing perfumes 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 33: Changes in a group submission for two mixtures with a difference in perfume components, submitted to an appointed body.

GROUP SUBMISSION OF TWO MIXTURES WITH DIFFERENCE IN PERFUME 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
Perfumes (Generic component identifier)	<5%	2	Not classified
Chemical name perfume 1	1-4%	1.5	Other
Chemical name perfume 2	0.3-0.6%	0.4	Major concern
Chemical name perfume 3	1-2%	1.1	Major concern
Chemical name perfume 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 identified with a given generic component identifier in each mixture cannot exceed 5% [B.3.2.3].

Perfumes 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 perfumes) in each mixture does not exceed 5% [B.3.4.2].

LIST OF PERFUMES IN THE MIXTURES TRADE NAME 1 AND TRADE NAME 2		
Name	**Perfume**	**Classification[b]**
Trade name 1	Perfume chemical name 1	Other
	Perfume chemical name 3	Major concern
	'Perfume MiM' A67T-VHG2-DMM4-NH2A	Other
Trade name 2	Perfume chemical name 2	Major concern
	Perfume chemical name 4	Other (skin sens. cat. 1)
	Perfumes (Generic component 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 component identifiers*

If the total concentration of components indicated with GCI *perfumes* is changed, but still does not exceed 5 %, no update is required.

• *Change of concentration of classified perfume component*

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

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

- If *Chemical name perfume 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, 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 to a mixture in a group submission*

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

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

- If *Chemical name perfume 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 contained in each mixture of the group could exceed 5% when considering both perfumes which vary and common perfumes. If the perfumes which vary in a specific mixture exceed 5%, this mixture cannot be grouped and a separate submission is 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/)

- ECHA Submission portal and
    - *Guide to dossier preparation and submission*;
    - *PCN: a practical Guide*
- *Overview of Member States decisions in relation to implementation of Annex VIII to the CLP*;
- '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);
- 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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