



EFE0/IFRA
GUIDELINES ON
SUBSTANCE IDENTIFICATION AND
SAMENESS OF
NATURAL COMPLEX SUBSTANCES (NCS)
UNDER REACH AND CLP

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GUIDELINES ON SUBSTANCE IDENTIFICATION AND SAMENESS OF NATURAL COMPLEX SUBSTANCES (NCS) UNDER REACH AND CLP

1. INTRODUCTION

The purpose of this document is to guide potential registrants of Natural Complex Substances (NCS) in determining the chemical identity of their substances for registration, classification and labelling and safety data sheet purposes under the EU REACH¹ and CLP² Regulations. It has been drafted for professionals who are familiar with the REACH and CLP Regulations and who are also familiar with NCS.

This document has been prepared by EFEO/IFRA³, in close cooperation with the European Chemicals Agency (ECHA). Its purpose is to provide a simplified set of guidelines to identify Natural Complex Substances (NCS) for REACH and CLP purposes.

These guidelines do not contain all details included in the legal text of the REACH and CLP Regulations, nor in the full ECHA Guidance Documents, available at www.echa.europa.eu. These documents should therefore also be consulted. The information in these guidelines does not constitute legal advice and does not engage the responsibility of its authors. It is the responsibility of the users of this document to ensure compliance with REACH when registering and placing NCS on the market.

2. BACKGROUND

2.1. Substance Identification (SID) under REACH and CLP

A "substance" is defined in REACH (Article 3.1) and in CLP (Article 2.7) as: *"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"*.

The identification of a substance in a registration dossier must address the requirements specified in section 2 of Annex VI of REACH, which specifies that "For each substance, the information given (...) shall be sufficient to enable each substance to be identified".

Also, a series of rules apply to the identification and naming of substances in a safety data sheet under REACH and on the labelling of substances and mixtures containing them under the CLP, as described in Section 2.7 of these guidelines.

¹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

² Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)

³ The European Federation of Essential Oils (EFEO) and The International Fragrance Association (IFRA)

2.2. ECHA Guidance Document on SID

Additional guidance on SID can be found in the ECHA "Guidance for identification and naming of substances under REACH and CLP"⁴ (available on the ECHA Website (hereafter "the ECHA SID Guidance")).

This being said, conventions on SID have been established in the EU over the past 30 years and most of the concepts used in the ECHA SID Guidance originate from this long established practice⁵.

Also, the ECHA SID Guidance as any other ECHA Guidance document is not legally binding. As per the legal notice included in the ECHA SID Guidance, "the text of the REACH and CLP Regulations is the only authentic legal reference" and it is for the European Court to interpret the REACH and CLP Regulations.

In addition, a deviation from the basic rules set out in the ECHA SID Guidance is possible in individual cases if properly justified. As laid down in chapter 4.1 of the ECHA SID Guidance: *"if the registrant deviates from the substance identification rules and criteria of this guidance document, justification should be given. The substance identification should be transparent, accountable and ensure consistency"*.

2.3. Categories of SID for substances

The ECHA SID Guidance essentially distinguishes between:

- "Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters listed in REACH Annex VI section 2 which requires to provide information that is "sufficient to enable each substance to be identified". Among the information to be submitted is:
 1. The name or other identifier of the substance
 2. Name(s) in the IUPAC nomenclature or other international chemical name(s)
 3. Other names (usual name, trade name, abbreviations)
 4. EINECS or ELINCS number (if available and appropriate)
 5. CAS name and CAS number (if available)
 6. Other identity code (if available)

Well defined substances are in turn divided between:

- Mono-constituent substances: Substances in which one constituent is present at a concentration of at least 80% (w/w)
- Multi-constituent substances: Substances consisting of several main constituents present at concentrations generally above or equal to 10% and below 80% (w/w)
- "UVCB substances": Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified by the above parameters⁶.

⁴ The content of these guidelines has been developed according to Version 1.3 (February 2014) of the ECHA SID Guidance.

⁵ Additional guidance on the history of the SID concepts used in the EU can be found in the "Manual of Decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC", as well as in the "Criteria for Reporting substances on EINECS" also included in the Manual of Decisions. See ECHA SID Guidance.

The ECHA SID Guidance recognises that there will be borderline cases between the above categories of substances and that it is the responsibility of the registrant to identify a substance in the most appropriate way.

2.4. Natural Complex Substances (NCS)

Natural Complex Substances (NCS) of botanical origin are a very diverse family of substances that are notably used as ingredients in fragrance formulations and [directly or indirectly] added to cosmetic and other consumer products⁷.

NCS are well described in ISO standard 9235:2013⁸ (Aromatic natural raw materials - Vocabulary).

The most common NCS are:

- Essential oils
- Concretes and absolutes
- Oleoresins and Resinoids
- CO₂ extracts
- Infusions and alcoholic extracts

Being botanical products, there are natural variations in the chemical composition of NCS obtained from one unique genus and species. This is a consequence of:

- the region of growth
- the annual variations in climate within the region
- the part of the plant as source material

The methodologies for processing will also affect variations in chemical composition: drying, cutting, expression, extraction, distillation, fractionation, concentration, precipitation, etc.

Compositions of NCS vary widely in complexity ranging from simple (with only a few constituents) to very complex (in excess of 100 constituents). Their chemical characterisation varies with that complexity. Their composition is consequently not as predictable as for mono- and multi-constituent substances.

The combination of major and minor constituents as derived from the biological source is inherent to the NCS and is essential for its sensory properties. Therefore minor constituents are not regarded as "*impurities*".

⁶ The ECHA SID Guidance distinguishes between:
UVCB sub-type 1, where the source is biological and the process is a synthesis
UVCB sub-type 2, where the source is chemical or mineral and the process is a synthesis
UVCB sub-type 3, where the source is biological and the process is refinement
UVCB sub-type 4, where the source is chemical or mineral and the process is a refinement
NCS qualifying as UVCB fall under sub-type 3.

⁷ NCS possess properties, which make them suitable for a variety of applications. NCS used in cosmetic applications remain subject to REACH but the safety assessment for human use falls within the scope of EU Cosmetics Regulation 1223/2009 (See art. 14.5 (b) of REACH). NCS are also used as flavourings in food, animal feed and pharmaceuticals. The volumes for such applications are exempt from REACH registration (See art. 2 of REACH for the comprehensive listing of the uses which are exempt from registration). Some NCS may also be applied as active substance in plant protection or biocidal products. Volumes of NCS if authorised for such applications are regarded as being registered (See art. 15 of REACH).

⁸ The International Standards Organisation (ISO) develops standards for the characterisation and identification of essential oils. See for standards and projects under the direct responsibility of ISO/TC 54 Secretariat http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=48956.

2.5. Substance Identification of NCS

NCS have historically been listed on EINECS under a generic heading and considered as UVCB.

More specifically, at the time of listing on EINECS, NCS were reported under a generic heading as follows: *"Plant extracts and their physically modified derivatives are listed in EINECS under generic heading, covering all products extracted from the same plant irrespective of the part of the plant or physical process used. Each plant extract identified with genus and species has its own EINECS entry. They are named with common names on the genus and species"*⁹.

This naming convention agreed at the time of the listing on EINECS is important as it has been used to name NCS in product labels and SDS for over 30 years.

Also, the concept of UVCB was already known at the time of the compilation of EINECS¹⁰.

Today, the ECHA SID Guidance generally considers that NCS fit the sub-category of "UVCB sub-type 3", which are named and identified by their botanical source and process. However, some NCS can also be characterised as "well defined substances" and may be registered as mono-constituent or multi-constituent substances depending upon their composition.

In principle, the key parameters to characterise NCS are:

- the botanical source
- the manufacturing process
- the chemical composition

Of these parameters, the chemical composition is key to determine whether a given NCS can qualify as a UVCB and / or as a mono- or multi-constituent substance, as per the definition of these terms in Section 2.3. above. Composition can also affect the hazard classification of the substance under CLP.

2.6. Registration of NCS

The characterisation of NCS (as UVCB, mono- or multi-constituent substance) will influence the registration of NCS under REACH, and more specifically (i) the "qualities" of NCS that can be registered in a single registration dossier, and (ii) the data that shall be relevant for such registration.

Additional information as to when and in which conditions NCS can be registered together in one registration dossier can be found in the Question & Answer section of this document (see Section 3 below).

Industry Guidance on the data requirements and methods of data collection for registration of NCS used as fragrance ingredients can be found in the "Protocol for REACH Registration of Natural Complex Substances" (revision 2, January 7, 2009)¹¹.

⁹ See Manual of Decisions, op. cit. footnote 2, page 30.

¹⁰ In particular, the article entitled 'Compilation of EINECS' by Rasmussen, Pettauer, Vollmer and Davis of 1998 specifies with respect to natural substances that *"UVCB substances derived from botanical (plant products) sources are identified by specifying the genus and species or unambiguous common names of the source. Therefore, e.g. plant oils which derive from the same genus and species are covered by the same entry in EINECS, even if their relative content of the components differs widely. On the other hand, plant oils having largely the same relative content of all components but deriving from different genus and/or species each have, where appropriate, a separate entry in EINECS"*.

¹¹ This Protocol has been prepared by EFEO in cooperation with IFRA and other downstream user organisations. The Protocol serves as guidance for NCS consortia and is available on request from the EFEO secretariat.

Finally, exemptions from the registration requirements as per Annex V may apply to NCS. In particular, the exemption under Annex V.8. may apply to NCS provided that they meet the three conditions outlined therein, i.e. that (i) the NCS meet the definition of a "substance which occurs in nature" as defined in Article 3.39 of REACH¹², (ii) that they do not meet the criteria for classification as dangerous or the criteria for PBT and vPvB substances and (iii) that they are not chemically modified.

2.7. Naming of NCS

The characterisation of NCS (as UVCB, mono- or multi-constituent substance) determines the naming of NCS for registration purposes. It also needs to be taken into account in safety data sheets and product labels.

As described in Section 2.5. above, at the time of listing on EINECS, NCS were reported under a generic heading named by reference to their common genus and species, irrespective of their composition.

a. For Registration Purposes

As noted above in section 2.3., for registration purposes, section 2 of Annex VI of REACH requires providing information that is "sufficient to enable each substance to be identified". Among the information to be submitted is:

- The name or other identifier of the substance
- Name(s) in the IUPAC nomenclature or other international chemical name(s)
- Other names (usual name, trade name, abbreviations)
- EINECS or ELINCS number (if available and appropriate)
- CAS name and CAS number (if available)
- Other identity code (if available)

According to the ECHA SID Guidance, the following names should be used for registration purposes:

- Mono-constituent substance: The name of the main constituent, present at or above 80%
- Multi-constituent substance: The words "*Reaction mass of ...*" followed by the chemical names of the constituents present at or above 10%
- UVCB: The name should use a combination of the source and the process, starting with the source

Further considerations on naming for registration are addressed in questions 12 and 14.

b. For Labelling and Safety Data Sheet Purposes

The rules for identifying substances on the label are provided in Article 18 (2) of the CLP Regulation.

The rules for the identification of substances in safety data sheets are provided in Annex II of the REACH Regulation.

These rules are summarised in **Appendix 1** to these guidelines. They also apply to NCS.

¹² Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means

c. Use of EINECS Names

As specified above, there may be cases where the NCS requires to be named in the registration dossier with a name that is different from its original EINECS name (see question 11). This does not mean, however, that the historical EINECS name cannot be used on labels and safety data sheets.

Labelling: The EINECS name and number can be used as the product identifier on the label if they are one of the identifiers appearing in Annex VI of the CLP Regulation (for substances with harmonised classifications) or in the C&L inventory (for other substances). In other cases, the EINECS number and name can still be applied on the label in addition to the CAS number (if available) provided that it is mentioned in the safety data sheet.

Safety Data Sheet: The EINECS number and name can also be included under section 1.1. of the SDS as the product identifier for the substance if it is used on the label and it is consistent with that provided in the registration (for substances subject to registration). The registration number shall also be given. Otherwise, the EINECS name and/or number can still be added as an alternative name and/or number in addition to the product identifier of the substance since Annex II of the REACH regulation permits the use of "*other names or synonyms by which the substance or mixture is labelled or commonly known such as alternative names, numbers, company product codes, or other unique identifiers*".

This means that the EINECS name and number:

1. Can ALWAYS appear on the labels and SDS, in addition to other product identifiers if required by Article 18(2) of the CLP.
2. Can be applied both on the labels and SDS as the ONLY identifiers when listed in Annex VI of the CLP Regulation or, if not, in the C&L inventory, provided that the use of such name is considered consistent with that provided in the registration.

This should be interpreted to mean that, when the registration dossier contains the EINECS name as an "other name" as required by section 2.1.2. of Annex VI of REACH (usual name, trade name, abbreviation) and/or the EINECS number, the use of such name and number in the safety data sheet, and consequently on the label, should be considered as "consistent with" the registration of such substance.

IUCLID 6 will provide a possibility to refer to the previously used EINECS number, while providing a more specific description of the substance in the registration dossier. The EINECS number will also be visible in the ECHA dissemination website.

Illustrative examples of product identifiers for substances used in NCS registrations, safety data sheets and labels are provided in **Appendix 2** of these guidelines.

3. QUESTIONS AND ANSWERS (Q&A)

3.1. IDENTIFICATION OF NCS AS UVCB sub-type 3

Question 1. What are the general rules for the identification of NCS as UVCBs?

The basic rules for substance identification are laid down in the ECHA SID Guidance.

According to the rules for UVCB sub-type 3, NCS should be described by the plant source and the manufacturing process.

The first main identifier is thus the family, genus and species of the organism from which the substance originates. The part of the plant used for the extraction of the substance should be given, e.g., seeds, leaves or roots if appropriate.

If the UVCB substance is derived from a different species, it will be in principle regarded as a different substance, even if the chemical composition is similar. However, deviation of the basic rules is possible for individual cases if properly justified (see question 5).

The second main identifier is the processing of the substance, e.g. the extraction process, the fractionation, purification or concentration process or other processes that influence the composition.

For extracts, the extraction process shall be described to the level of detail relevant for the identity of the substance. At least the solvent used shall be specified.

When further process steps are used for manufacturing the substance, such as fractionation or concentration, the combination of relevant process steps shall be described, e.g. the combination of extraction and fractionation.

Question 2. Can different "qualities" of one NCS be covered in one UVCB registration dossier?

Different qualities of a NCS from the same botanical source may arise from variations in the (generic) manufacturing process such as differences in distillation temperature, distillation fraction(s) chosen, manufacturing site, level of rectification, etc.

Provided that the NCS is characterised by the key parameters specified in section 2.5. of these guidelines, coverage of several qualities of one NCS in one registration dossier is in principle possible if the qualities:

1. come from the same botanical source (family, genus, species) and
2. are obtained from the same generic process (e.g. cold pressing, extraction and/or distillation, or a specific combination of them) and
3. have a similar composition (see question 3).

In some cases, however (see question 5), a single registration may be possible even if the source or the process differ. Finally, the composition may vary and influence the classification and labelling, which also needs to be considered (see question 9).

Question 3. How can one determine that the qualities of one NCS are similar in composition?

The term "similar composition" is not defined under REACH nor in the ECHA SID Guidance. However, various tools exist that may be used by the NCS registrant as a support to determine whether different qualities of a NCS are "similar in composition".

- The International Standards Organisation (ISO) develops standards for the characterisation and identification of essential oils¹³. If an essential oil is described in an ISO standard (or other standards, e.g. AFNOR), those composition ranges may be used for purposes of substance identification. In general, NCS complying with those composition ranges in the said standard could be regarded as similar for registration under REACH.

¹³ See for standards and projects under the direct responsibility of ISO/TC 54 Secretariat: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=48956

- If there is no standard or if the existing standard does not fit with the qualities that are currently placed on the market, other tools addressing the concept of "composition similarity", though not designed for substances, may be used by analogy for NCS. This could be the JRC Guidance on Assessment of Mixtures¹⁴ which incorporates the definition of "similar mixture" of the US Agency for Toxic Substances and Disease Registry (ATSDR)¹⁵, as follows: "similar mixtures are mixtures having the same chemicals but in slightly different proportions or having most but not all chemicals in common and in highly similar proportions."

It will be up to the registrant to decide the appropriate methodology to demonstrate similarity in composition.

Question 4. How can one determine that two NCS have the same botanical source?

The botanical source is the family, genus and species of the organism from which the substance originates. The part of the plant used for the extraction of the substance may be considered if relevant for the purpose of identification because of a difference in composition.

Due to different botanical systems of classification (ex: Citrus genus), it might be useful to check the right name ("Accepted Latin name") and look for synonyms by which the species has been identified¹⁶.

Question 5. Can a single UVCB registration be made for two or more NCS with a similar composition, but obtained from different botanical sources?

This would be a deviation from the basic rule, as explained in the ECHA SID Guidance. The Guidance defines that the source of one substance needs to be defined on the species level, however it is logical not to artificially separate two substances from different sources (different species) when it can be shown that these are (for the purpose of REACH) the same, i.e. they share the same constituents (see question 3) and they can be shown to have the same hazard profile despite their unavoidable differences in concentrations and their variation.

If this can be shown, based on knowledge of the composition, it is reasonable and in line with the objectives of REACH to group two NCS of different botanical species but with similar composition which by default would be identified as different substances.

The reasoning for reporting both NCS in one dossier should be well documented, supported by data and provided explicitly in the dossier. Be aware however that the grouping into one dossier may be questioned if differences in hazard or substantial differences in composition are revealed by further investigation.

Some UVCB substances may be on the border to a well-defined substance (mono or multi-constituent substance). For those cases it may be possible to argue that the main constituents present are sufficient to identify the substance (eventually including also other major constituents present below 10% w/w if relevant) and to define this substance as a well-defined substance. It should be ensured that the description of the substance should cover at least about 80% w/w of the substance. This is especially relevant to consider in cases with high concentration variations and may have to be stated explicitly if it is not obvious from the reported composition.

¹⁴ JRC Science and Policy reports : Assessment of Mixtures - Review of Regulatory Requirements and Guidance (2014)

¹⁵ US Agency for Toxic Substances and Disease Registry (ATSDR) Guidance document for the assessment of joint toxic action of chemical mixtures (2004).

¹⁶ See for example The Plant List at: <http://www.theplantlist.org/>

Example: Spearmint essential oil

Spearmint essential oil is produced by distillation treatment of two mentha species: *Mentha spicata/gracilis* (EC # 283-656-2) and *Mentha cardiaca/gracilis* (EC # 294-809-8). The source concerns the same areal parts of the plants, which are processed in the same way (cutting and field drying followed by steam distillation) to obtain Spearmint oil. All qualities of the oils share the same classification and are very similar in composition as shown in the below table:

COMPOSITION OF SPEARMINT OILS	CAS no	Spearmint oil (Mentha spicata/ gracialis)		Spearmint oil (Mentha cardiaca/gracilis)	
		Typical % w/w	Range % w/w	Typical % w/w	Range % w/w
L-Carvone	6485-40-1	68	62-80	68	49-85
Limonene (1L)	5989-54-8	11	5-16	17	2-20
Other 8 identified constituents $\leq 2,5$ and $\geq 1.0\%$ present in both NCS*		11		6	
Other 23 identified constituents $< 1.0\%$		7		7	
Not identified		3		2	
Total		100		100	
*myrcene-beta, terpinen-4-ol, Cineol 1, 8, beta-bourbonene, trans-dihydrocarvone germacrene D, sabinene hydrate, 3-octanol					

Spearmint oils from *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* as obtained by the above described process consist of the same constituents in typically the same concentrations with minor variations in the concentration ranges.

A single UVCB registration for spearmint oil would thus be possible in this case. The substance would be identified in the registration dossier according to the rules for UVCBs sub-type 3, i.e.: "Essential oil of Spearmint obtained from the aerial part of *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* by distillation".

The multi-constituent approach may also be considered in this case because of the typical concentration and ranges of the main constituents (see chapter 3.2.).

Question 6. Can a single UVCB registration be made for NCS from the same botanical source, but with different composition due to the use of different parts of the same plant (e.g. the peel and the leaves and twigs of the same botanical species)?

As indicated above, similarity in composition is key to determine whether a single registration is possible. In addition, the ECHA SID Guidance provides that the part of the plant used for the extraction of the substance should be given in the substance identifier, if appropriate.

Therefore, if NCS extracted from different parts of a same botanical species differ in their composition (difference in constituents or in their proportions, see question 3), they should be registered separately and the part of the plant should be provided in the name.

Example: Essential oils of *Citrus aurantium* (Rutaceae)

(Orange bitter and Petitgrain oil)

Orange bitter (or orange, sour, ext;. EINECS 277-143-2) is obtained from the peel of *Citrus aurantium* (Rutaceae) by cold pressed extraction and/or followed by distillation.

Another essential oil, known as Petitgrain oil, is also produced from the same botanical species *Citrus aurantium* (Rutaceae) but by steam distillation of the leaves and twigs of the plant. Petitgrain oil possesses olfactive characteristics that are very different from Orange Bitter oil, due to a different composition of constituents as shown in the table below:

NCSs of <i>Citrus aurantium</i> (Rutaceae)		
	Petitgrain oil Typical composition %(w/w)	Orange Bitter oil Typical composition %(w/w)
Limonene (d and l)	1	87
Linalool	25	< 1
Linalyl acetate	49	< 1
Terpineol alpha	5	< 1
Other identified constituents < 4 and \geq 1.0% present in both NCS*	15 (7 constituents)	4 (4 constituents)
Other 23 identified constituents < 1.0%	3 (7 constituents)	4 (16 constituents)
Not identified	2	5
TOTAL % IDENTIFIED	100	100

The composition of Orange Bitter oil is dominated by one constituent (D-limonene), whereas the Petitgrain oil consists predominantly of linalool and linalyl acetate.

Therefore Petitgrain oil should be subject to a separate registration and it should be assigned an additional identification number (see question 11 below).

Question 7. Can a single UVCB registration be made for NCS with similar composition, but obtained from different steps in the same generic process (e.g. different levels of rectification)?

Yes. As indicated above, similarity in composition is key to determine whether a single registration is possible. Therefore, NCS obtained from different steps in the same generic process can be registered in one dossier if they have a similar composition.

Question 8. What about specifications and concentration ranges of constituents?

Concentration ranges as identified in each individual registration dossier (Section 1.3) should reflect the reality of products as manufactured or imported.

However, one registration dossier (lead dossier) as a UVCB can cover NCS with similar composition (see question 2), but with a variety in typical percentages of the main constituents.

Given the variable nature and large variation of NCS in use, it is left to the registrants of a single NCS to establish appropriate ranges per constituent. When these ranges are larger than those typically seen in registration dossiers (e.g. 20 percentage points difference between min and max concentration) registrants are advised to justify these (e.g. larger ranges may be acceptable for constituents resulting from natural variations or variations inherent to a given process).

Question 9. Can one UVCB registration be made for several NCS with differences in hazard classification?

Yes. Substances can be the same and justify one registration dossier even if they do not have the same hazardous properties, for example due to the presence of specific constituents in certain concentrations which will trigger the classification above certain thresholds. In other words, substances administratively "the same" (for registration purposes) do not necessarily have the same hazardous properties.

Example: Rosemary

Rosemary oil is a NCS example of which the composition for some of the constituents varies per quality justifying different classifications for the eye irritation endpoint, if the hazard classification is derived by read-across from the classification of the constituents:

The content of constituents classified for eye irritation (H 319) in Rosemary oil can typically vary from 9 to 19 %.

Camphene is the main contributor for this hazard with levels between 2 and 13 %.

Four other constituents contribute to the eye irritation hazard with varying levels of 1 to 6 %.

The CLP method for classification applies a threshold of 10 % for read-across of the eye irritation hazard.

Depending on actual measured levels of the eye irritant constituents in the marketed qualities, a classification for eye irritation applies as of 10 % in total for the concerned constituents.

In that case, however, it is required that both classifications be addressed in the Chemical Safety Report (CSR) and/or guidance on safe use. Another option would be to submit two separate registration dossiers.

Question 10. Can one UVCB registration dossier be made for NCS having different compositions but having the same classification?

Yes, provided it is from the same botanical origin. This is allowed as per "recital 45" of REACH, which specifies that UVCBs "may be registered as a single substance, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification".

It is important to note that "the same classification" should result from the same "qualitative composition" despite quantitative differences.

Note: The use of recital 45 will trigger some close scrutiny from ECHA, as ECHA will verify that all compositions included in a registration dossier warrant the same classification.

Question 11. When can a NCS be registered as a UVCB with the historical EINECS number?

The use of the historical EINECS number is important for NCS because it has been traditionally used in the identification of NCS in the supply chain, and as a common reference in quality control, production and product documentation systems in the EU and across the world.

However, there are situations where a generic EINECS entry covers different NCS since EINECS identifies NCS by naming the biological species and a generic process description which may cover different NCS in the sense of REACH.

For the purpose of REACH substance identification, it is therefore necessary to distinguish different NCS covered by the same EINECS number. However, there is also a need for the industry to maintain the use of the historical EINECS number as an identifier.

The following convention is considered suitable for the continued use of EINECS numbers as an identifier under REACH:

1. If a NCS is of the same botanical species as the one defined in the EINECS entry, and the manufacturing process is listed in the EINECS description, then the historical EINECS number should be maintained as the sole EU reference number.
2. If a NCS is of the same botanical species as the one defined in the EINECS entry but more than one NCS are identified for the purpose of registration, then,
 - a) one of these NCS can be selected by (pre-)registrants for registration under the historical EINECS number
 - b) the other NCS of the species will be identified in the registration by a new List number

In this way, the adjustment for the communication in the supply chain and IT systems is kept to a minimum. The ID-numbers per NCS will lead to the identification parameters and the specifications as recorded in the dossiers and REACH IT.

The registration dossiers should however include a plausible justification for the choice of the ID-number(s) referencing this convention.

See also decision tree in Appendix 3

Question 12 How should a NCS regarded as a UVCB substance be named for registration purposes?

As per the ECHA SID Guidance (Section 4.3.1.2), the name of a UVCB substance is a combination of source and process with the general format: first the source and then the process(es).

As indicated in question 1, the first main identifier is thus the family, genus and species of the organism from which the substance originates. The part of the plant used for the extraction of the substance should be given, e.g. seeds, leaves or roots if appropriate. The second main identifier is the processing of the substance, e.g. the extraction process, the fractionation, purification or concentration process or other processes that influence the composition.

This principle should be followed for NCS identified under REACH with the EINECS number and/or a List Number (see question 11).

Example:

1. EINECS Description: Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Vetiveria zizanioides*, Gramineae. IUPAC Name in the registration dossier: Essential oil of *Vetiveria zizanioides* (Poaceae) obtained by steam distillation.
2. EINECS Description: Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Rosmarinus officinalis*, Labiatae. IUPAC Name in the registration dossier: Essential oil of *Rosmarinus officinalis* L. (Lamiaceae) obtained from leaves, flowers and twigs by steam distillation.

3.2. Identification of NCS as Multi-Constituent Substance

Question 13. What are the general rules for the identification of NCS as multi-constituent substances?

Unlike for UVCBs, for multi-constituent substances only composition matters, as they are well defined substances for which the composition is known.

According to the ECHA SID Guidance, the identification as a multi-constituent substance is in general possible, if the sum of the constituents present at or above 10 % (and below 80%) adds to at least 80 % of the total composition. For the summation, the typical percentage of the concentration range per constituent should be taken.

Please note that the "80% rule" is a rule of thumb and that deviations from that rule may be acceptable if justified. Alternatively, or if the justification cannot be made, the substance might be registered as a UVCB.

Question 14. How should multi-constituent substances be named for registration purposes?

As per the ECHA SID Guidance (Section 4.2.2.1), multi-constituent substances are in principle to be named as "Reaction mass of..." followed by the constituents present at concentration levels between 10 and 80% (also called main constituents). The main constituents should exceed the 10% level in all the registered qualities. This approach ensures that all substances with very similar chemical compositions are recognised as the same under REACH and will be registered together to ensure optimal working of the Registration process, including data-sharing obligations.

As it is expected to be unlikely that other industries will manufacture substances with similar chemical compositions to NCS, whenever appropriate, the prefix "Reaction mass of..." can be replaced by the prefix "Complex substance of..." reflecting that these substances are in the vast majority of cases not the outcome of a synthesis involving chemical transformations. The prefix must always be followed by the list of the main constituents.

This naming convention is acceptable as long as it does not compromise the basic principle laid down in the ECHA SID Guidance that well-defined substances presenting the same main constituents refer to the same substance. These substances should be registered as part of the same joint submission regardless of the process used to obtain them. Companies therefore need to ensure that the prefix used for naming the NCS is appropriate for all the registrants having the same multi-constituent substance.

It is important to note that any eventual regulatory obligation for a multi-constituent substance will apply irrespective of the prefix used by the registrants for naming the NCS.

Question 15. How to report constituents of NCS below 10% in a multi-constituent substance registration?

According to the ECHA SID Guidance, constituents of a multi-constituent substance should be present at a concentration between 10-80%. Components present at lower concentrations would typically be reported as impurities. NCS often contain components below 10%; however the nature and function of these components do not match with the definition of an impurity. Hence, for NCS also components below 10% should be reported under the 'Constituents' heading. An explanation for the deviation from the multi-constituent rule should be added in the field 'Remarks' of each such constituent.

Please note that although all constituents (even below 10%) are listed in IUCLID, the name of the substance does not change and remains "complex substance of [x and y]", indicating only constituents above 10%.

Question 16. What about specification and concentration ranges in a multi-constituent registration?

Concentration ranges as identified in each individual registration dossier (Section 1.2 of the IUCLID file/dossier) should reflect the reality of products as manufactured or imported.

However, one registration dossier (lead dossier) as a multi-constituent substance can cover NCS with similar compositions (see question 2), but with a variety in typical percentages of the main constituents.

Given the variable nature and large variation of NCS in use, it is left to the registrants of a single NCS to establish appropriate ranges per constituent. When these ranges are larger than those typically seen in registration dossiers (e.g. 20 percentage points difference between min and max concentration) registrants are advised to justify these (e.g. larger ranges may be acceptable for constituents depending on the hazard profile).

Question 17. Can one multi-constituent registration be made for several NCS with differences in hazard classification?

A difference in hazard classification for the specified qualities of a multi-constituent substance in the same dossier is acceptable.

3.3. Identification of NCS as Mono-Constituent Substance

Question 18. What are the general rules for identification of NCS as mono-constituent substances?

If the NCS consists of a constituent X typically present at 80% or more, then the 80 % rule for mono-constituent substances is in principle leading and as a consequence the registration should be merged with the dossier of the substance X, unless it is plausible and can be justified to submit a specific dossier for the NCS as an exceptional case.

If the spread in composition for a constituent X can be above and below the 80 % threshold, then in principle the qualities should be divided over two registrations:

- one for the qualities typically > 80 % and
- one for the qualities with constituent X typically < 80%, unless it is plausible and can be justified to submit a specific dossier for the NCS as an exceptional case.

Appendix 1 - Summary of the Provisions on Substance Identity for EU Labels and Safety Data Sheet and of the Use of EINECS Name & Number

SUBSTANCES	Label	SDS
<p>Main provisions</p>	<p>CLP Art 18(2)</p> <p>The "product identifier" shall consists of at least:</p> <ol style="list-style-type: none"> 1. If substance has harmonised classification, "a" name and "an" identification number as in Annex VI; OR 2. If no harmonised classification, but substance appears on C&L Inventory, "a" name and "an" identification number as given in the C&L Inventory; OR 3. if the above conditions are not met, the CAS # (if available) and the IUPAC or another international name 4. If the CAS is not available, the IUPAC or another international name. 	<p>Annex I and II of SDS Regulation (EU) 2015/830:</p> <p>Section 1.1 of SDS to include:</p> <ol style="list-style-type: none"> 1. A "Product identifier" as per Article 18.2 CLP (See column 1) AND 2. the registration number of the substance <p>Section 1.1 <u>can</u> also include other alternative names and numbers ("other names or synonyms by which the substance is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers").</p>
<p>Notes</p>	<p>No requirement for the "product identifier" to be that used in the registration dossier, but the identification term used on label shall be the same as on SDS.</p>	<p>The product identifier should be "consistent with" registration and should be as provided on the label</p> <p>Other means of identification can also be placed in section 3.</p>
<p>EINECS Name & Number</p>	<ol style="list-style-type: none"> 1. The substance <u>is</u> listed on Annex VI: <ul style="list-style-type: none"> - The EINECS number/name can be used as "the" product identifier if they are one of the identifiers on Annex VI. - The EINECS number and name can still be labelled in addition to the "product identifier" in other cases. 2. The substance is <u>not</u> listed in Annex VI but is listed on the C&L inventory: <ul style="list-style-type: none"> - The EINECS number/name can be used as "the" product identifier if they are one of the identifiers on Annex VI or C&L Inventory. The EINECS number and name can also be labelled in addition to the "product identifier" in other cases 3. The substance is <u>not</u> listed in Annex VI or on the C&L inventory: <ul style="list-style-type: none"> - The EINECS name and number can be used as the "product identifier" (international name) in addition to the CAS number, if available 	<p>The EINECS number and name can be included under section 1.1 of the SDS either:</p> <ol style="list-style-type: none"> 1. as "the" product identifier provided that this name also appears on the label and is "consistent" with the registration, or 2. in addition to the product identifier as an "alternative name and number" (EINECS name is "commonly known")

Appendix 2 – Identification of NCS for REACH registration, SDS and Labels: Examples

This annex provides fictitious examples of three different NCS (identified as UVCB, multi- and mono-constituent substances) to illustrate the identifiers used in a fictitious registration dossier and the corresponding identifiers that can be used in the safety data sheet and on a label.


For each type of substance, a summary card is presented based on the following scheme:

Example of substance registered as [UVCB, multi- or mono-constituent] – Example name	
Identifiers in the IUCLID dossier	<p>1.1 <u>Substance Identification</u></p> <ul style="list-style-type: none"> a) Chemical name b) Public name c) EC no d) CAS no
Identifiers in the safety data sheet	<p>1.1 <u>Product identifier</u></p> <ul style="list-style-type: none"> a) Trade name b) REACH Registration number c) Substance registration name (EC no) d) Other identifiers and EC no and CAS no <p>(Other means of identification can also be placed in section 3)</p>
Identifiers in the label	<p><u>Identification by</u></p> <ul style="list-style-type: none"> a) Trade name b) International name c) CAS no.

Example of substance registered as UVCB – Vetiver oil




IUCLID dossier

1.1 Substance Identification


- a) Chemical name
 - b) Public name
 - c) EC no
 - d) CAS no
 - e) other names
- 
- a) Vetiver ext.
 - b) Vetiver essential oil
 - c) 282-490-8
 - d) 84238-29-9
 - e) **trade name** : Vetiver oil

Substance: Vetiver ext. / Vetiver ext. /


Substance identification


Chemical name: Vetiver ext.
 Public name: Vetiver essential oil
 Legal entity flags: 
 Legal entity: 
 Third party flags: 
 Third party:

Role in the supply chain

Role flags: 
 Role: Manufacturer Importer Only representative Downstream user

Reference substance

Reference substance flags: 

 Vetiver ext. / Essential oil of *Vetiveria zizanioides* (Poaceae) obtained from roots by distillation / *Vetiveria zizanioides*, extract / 84238-29-9

EC number	EC name
282-490-8	<i>Vetiveria zizanioides</i> , ext.
CAS number	CAS name
84238-29-9	<i>Vetiveria zizanioides</i> , extract
IUPAC name	
Essential oil of <i>Vetiveria zizanioides</i> (Poaceae) obtained from roots by distillation	

Type of substance

Composition: UVCB
 Origin: other: Extracts of biological materials

Other names

Flags	Name Type	Name	Country	Remarks
	Trade name	Vetiver oil		

Safety data sheet

1.1 Product identifier

- a) Trade name
- b) REACH Registration N°
- c) Registration name (EC no)
- d) Other identifiers and EC no and CAS no


1. Identification of the substance and of the company

1.1 Product identifier

- a) Vetiver oil
- b) xxxxxx
- c) Essential oil of *Vetiveria zizanioides* (Poaceae) obtained from roots by distillation (282-490-8)
- d) *Vetiveria zizanioides*, ext. (CAS 84238-29-9)

Label example

Identification by

- a) Trade name
 - b) International name
 - c) CAS no.
 - d) EINECS N°
- 
- a) Vetiver oil
 - b) *Vetiveria zizanioides*, ext.
 - c) 84238-29-9
 - d) 282-490-8

Vetiveröl

Vetiveria zizanioides, Extrakt
 EINECS 282-490-8

Achtung

Kann allergische Hautreaktionen verursachen.

Warning

May cause an allergic skin reaction.

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. Bei Berührung mit der Haut: Behutsam mit viel Wasser und Seife waschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Vetiver Oil

Vetiveria zizanioides, ext.
 CAS 84238-29-9



Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

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Example of substance registered as multi-constituent substance – Lavandin oil

IUCLID dossier

1.1 Substance Identification

- a) Chemical name
- b) Public name
- c) EC no
- d) CAS no
- e) other names



- a) Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl acetate and 3,7-Dimethyl octa-1,6-diene-3-ol
- b) Lavandin essential oil
- c) /
- d) /
- e) **Trade name :** lavandin oil (related EINECS N° 297-385-2)

Alternative name:
Lavender, *Lavendula hybrid grosso*, ext. (related EINECS N° 297-385-2)

Substance: Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl acetate and 3,7-Dimethyl octa-1,6-diene-3-ol / Complex substance of linalyl acetate and linalol / Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl and 3,7-Dimethyl octa-1,6-diene-3-ol

Substance identification

Chemical name: Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl acetate and 3,7-Dimethyl octa-1,6-diene-3-ol

Public name: Lavandin essential oil

Legal entity flags:

Legal entity:

Third party flags:

Third party:

Role in the supply chain

Role flags:

Role: Manufacturer Importer Only representative Downstream user

Reference substance

Reference substance flags:

Complex substance of linalyl acetate and linalol / Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl and 3,7-Dimethyl octa-1,6-diene-3-ol / Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl and 3,7-Dimethyl octa-1,6-diene-3-ol

EC number: EC name:

CAS number: CAS name:

IUPAC name:

Complex substance of 3,7-Dimethyl octa-1,6-dien-3-yl and 3,7-Dimethyl octa-1,6-diene-3-ol

Type of substance

Composition: multi constituent substance

Origin: other: Extracts of biological Materials

Other names

Flags	Name Type	Name	Country	Remarks
	Trade name	Lavandin oil		related EINECS information: EC# 297-385-2
	Alternative name	Lavender; <i>Lavandula hybrida grosso</i> , ext		related EINECS information: EC# 297-385-2

Safety data sheet

1.1 Product identifier

- a) Trade name
- b) REACH Registration N°
- c) Registration name (EC no)
- d) Other identifiers and EC no and CAS no

1. Identification of the substance and of the company

1.1 Product identifier

- a) Lavandin oil
- b) xxxxxx
- c) Complex substance of *linalool and linalyl acetate*
- d) Lavendel, *Lavendula hybrida grosso*, ext. (CAS 93455-97-1, EINECS 297-385-2)
proposed naming for NCS if registered as a multi-constituent substance.

Label example

Identification by

- a) Trade name
- b) International name
- c) CAS no.
- d) EINECS N°



- a) Lavandin oil
- b) Lavendel, *Lavendula hybrida grosso*, ext.
- c) 93455-97-1
- d) 297-385-2

Lavandinöl

Lavendel, *Lavandula hybrida grosso*, Extrakt
EINECS 297-385-2

Achtung

Verursacht Hautreizungen.
Kann allergische Hautreaktionen verursachen.
Schädlich für Wasserorganismen, mit langfristiger Wirkung.

Warning

Causes skin irritation.
May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. Behutsam mit viel Wasser und Seife waschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Lavandin Oil

Lavender, *Lavandula hybrida grosso*, ext.
CAS 93455-97-1



Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Example of substance registered as mono-constituent substance – Star Anise seed oil

IUCLID dossier

1.1 Substance Identification

- a) Chemical name
- b) Public name
- c) EC no
- d) CAS no
- e) other names



- a) (E)-anethole
- b) Star anise essential oil
- c) 224-052-0
- d) 4180-23-8
- e) **Alternative name :**
Trans-anethole

Trade name : Star anise oil (related EINECS N° 283-518-1)

Alternative name: Star anise, *Illicium verum*, ext. (related EINECS N° 283-518-1)

Substance: (E)-anethole / 1-methoxy-4-(1E)-1-propen-1-yl-benzene / trans-1,4-Cyclohexanediol / Benzene, 1-methoxy-4-(1E)-1-propen-1-yl-

Substance identification

Chemical name: (E)-anethole
 Public name: Star anise essential oil
 Legal entity flags:
 Legal entity:
 Third party flags:
 Third party:

Role in the supply chain

Role flags:
 Role: Manufacturer Importer Only representative Downstream user

Reference substance

Reference substance flags:

1-methoxy-4-(1E)-1-propen-1-yl-benzene / trans-1,4-Cyclohexanediol / Benzene, 1-methoxy-4-(1E)-1-propen-1-yl- / 4180-23-8

EC number	EC name
224-052-0	(E)-anethole
CAS number	CAS name
4180-23-8	Benzene, 1-methoxy-4-(1E)-1-propen-1-yl-
IUPAC name	
trans-1,4-Cyclohexanediol	

Type of substance

Composition: mono constituent substance
 Origin: other: Extracts of biological materials

Other names

Flags	Name Type	Name	Country	Remarks a
	Alternative name	Trans-anethole		
	Trade name	Star anise oil		Related EINECS information : EC # 283-518-1
	Alternative name	Star anise, <i>Illicium verum</i> , ext.		Related EINECS information : EC # 283-518-1

Safety data sheet

1.1 Product identifier

- a) Trade name
- b) REACH Registration N°
- c) Registration name (EC no)
- d) Other identifiers, EC and CAS Numbers

Identification of the substance and of the company

1.1 Product identifier

- a) Star Anise seed oil
- b) xxxxxx
- c) (E)-1-Methoxy-4-(1-propenyl)benzene (224-052-0)
- d) Star anise, *Illicium verum*, ext. (CAS 84650-59-9, EINECS 283-518-1)

Label example

Identification by

- a) Trade name
- b) International name
- c) CAS no.
- d) EINECS N°



- a) Star Aniseed Oil
- b) Star anise, *Illicium verum*, ext.
- c) 84650-59-9
- d) 283-518-1

Sternanisöl

Sternanis, *Illicium verum*, Extrakt
 EINECS 283-518-1

Gefahr

Kann allergische Hautreaktionen verursachen.
 Kann vermutlich genetische Defekte verursachen.
 Kann vermutlich Krebs erzeugen.
 Schädlich für Wasserorganismen, mit langfristiger Wirkung.

Danger

May cause an allergic skin reaction.
 Suspected of causing genetic defects.
 Suspected of causing cancer.
 Harmful to aquatic life with long lasting effects.

Vor Gebrauch besondere Anweisungen einholen. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. Vorgeschriebene persönliche Schutzausrüstung verwenden. Bei Berührung mit der Haut: Behutsam mit viel Wasser und Seife waschen. Bei Exposition oder Verdacht: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

Star Aniseed Oil

Star anise, *Illicium verum*, ext.
 CAS 84650-59-9

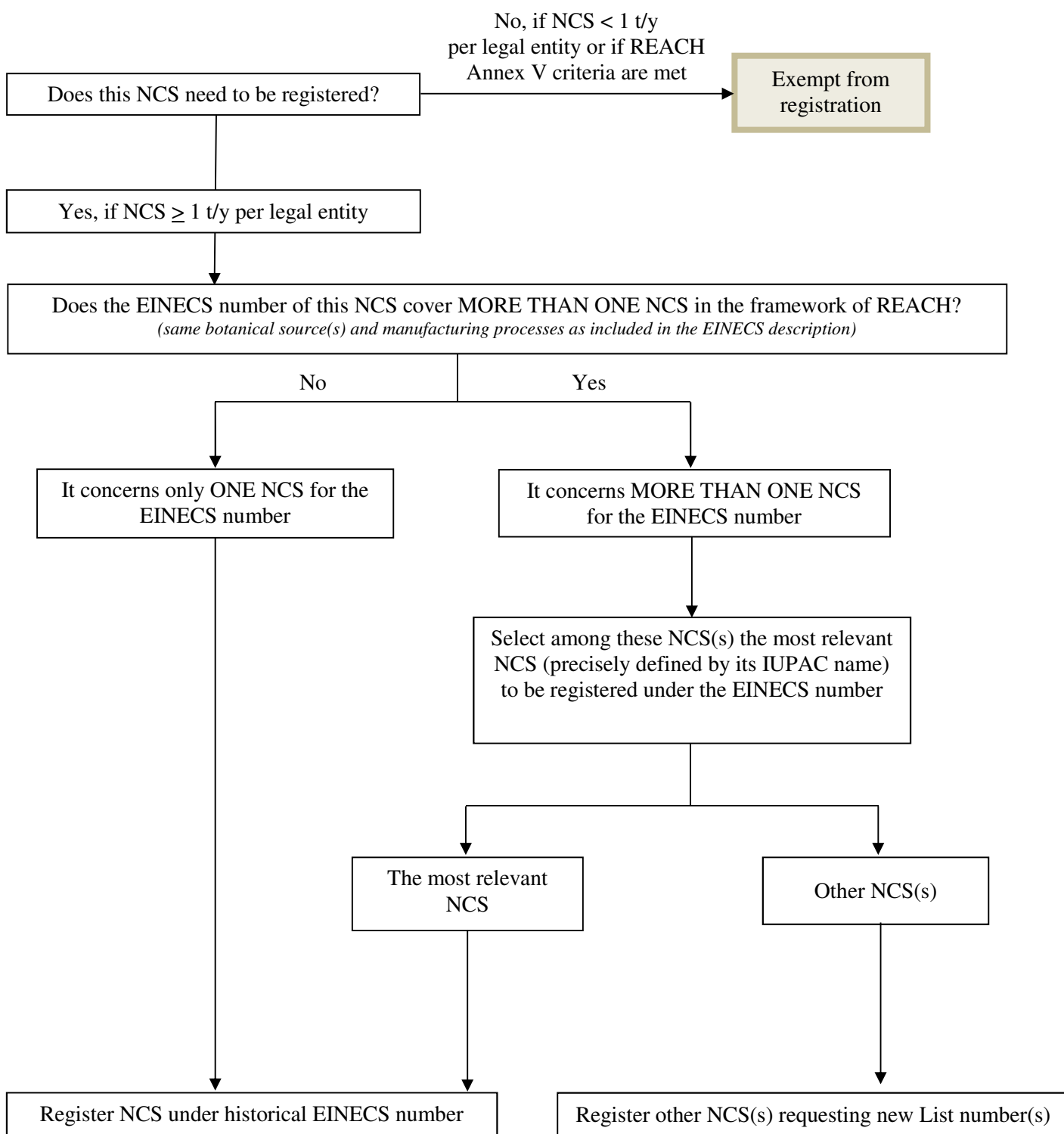


Obtain special instructions before use. Wear protective gloves/protective clothing/eye protection/face protection. Use personal protective equipment as required. If on skin: Gently wash with plenty of soap and water. If exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention.

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Appendix 3 - Convention for the REACH registration of NCS and EINECS numbers

Decision tree for registration of NCS and EINECS numbers.





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