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Impurities and (degree of) purity in CLP and in the CLH process

Due to recurring discussions and questions raised by submitters of dossiers proposing harmonised classification and labelling (from here onwards referred to as CLH dossiers) concerning the requirements on substance identity for CLH purposes there is a need clarify these requirements. This paper is informing the dossier submitters on the necessary information on impurities and degree of purity to be reported in CLH dossiers.

A substance placed on the market is defined as such (CLP, Article 2(7)): *'substance' means 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...".* Thus, what is defined by one chemical identifier may in reality correspond to several different compositions of one substance, potentially requiring different classification. Certain ECHA processes, such as dossier evaluation, deal with substances having specific composition(s) that include specific impurities and additives, *i.e.* the substances as they are actually placed on the market by a certain company. In the context of other processes, the composition of a substance in terms of impurities and additives may not be relevant, *e.g.* CLH, restrictions and SVHC. The assessment/management of substances in these processes does not necessarily refer to a specific composition. Therefore the name and numerical identifiers used to describe a substance are not associated to a specific composition. Any composition matching with the identifiers used for CLH, restriction or SVHC is regarded as falling within the scope of that entry unless otherwise stated in the entry.
This paper is based on the understanding that Annex VI to CLP lists the classification warranted by the substance as such (unless otherwise stated in the entry). An M/I/DU of a substance with a certain set of impurities/additives cannot possibly know if their particular composition has been assessed. As a consequence, when classifying substances or mixtures placed on the market, M/I/DUs need to take their particular impurities/additives into account.

1. Cases where the information on impurities/degree of purity impact Annex VI entries

The CLP Regulation refers to a number of cases where impurities are important for Annex VI entries. In case a submitted CLH dossier falls within any of these categories below, data on impurities and/or additives are considered relevant information to be included in the CLH dossier:

1. The vast majority of entries in Annex VI to CLP refer to a substance (which can be a mono-constituent, a multi-constituent or a UVCB[1]) without specifically mentioning impurities. In CLP, Annex I, section 1.1.1.4 it is stated that "*Impurities, additives and minor components are **normally** not mentioned unless they **contribute significantly** to the classification of the substance.*"

[1] Substances of Unknown or Variable composition, Complex reaction products or Biological materials

2. It is additionally mentioned that: "*Some substances are described with a specific percentage of purity. Substances containing a higher content of active material (e.g. organic peroxide) than this percentage are not included in the entry in Part 3 and may have other hazardous properties (e.g. explosive) and should be classified and labelled accordingly.* "
3. Furthermore, Part 1 of Annex VI to CLP, section 1.1.1.4 specifies that "*Certain entries contain a reference to impurities; in these cases the name of the substance is followed by the text: '(containing ≥ xx % impurity)'. The reference in brackets is then to be considered as a part of the name, and must be included on the label.*"
4. In some cases, entries in Annex VI to CLP mention a Note for the presence of another substance already regulated and hazardous (which can be an impurity or a constituent like benzene, benzo(a)pyrene, 1,3-butadiene) so that it clearly influences the classification at a certain concentration.

2. Need for information on impurity/degree of purity in the CLH process

2.1. In the CLH process, data on impurities and additives are normally not needed except where relevant, as follows:

a. In case impurities/additives in a test material influence a (eco)toxicological test that is the basis for classification: The basis may be test data (with or without the substance) showing that impurities/additives are hazardous and may influence the outcome of tests on the substance when present leading to different C&L. It may also be if the impurities/additives have a harmonised classification and are present in the test substance above G/SCL. Test data on a test substance with a hazardous constituent may not be relevant for the classification of the substance itself. If impurities of the test substance fulfil the criteria above, they should be reported under the CLH process and, if relevant, assessed by RAC. In reality we seldom see these data.

b. In case the proposal is for an entry indicating the presence of impurities/additives (see examples above): If needed for the proposed entry, impurities/additives need to be included. An impurity/additive pivotal for the classification cannot for obvious reasons be claimed confidential. The DS may always propose an entry for the substance as such even if (some of) the substance(s) placed on the market presently includes impurities/additives warranting classification. If impurities fulfil the criteria above, they could be reported under the CLH process. However, the responsibility is on the manufacturer to correctly classify its product.

2.2. In the CLH process, information on the degree of purity is needed in cases where the results of tests clearly show that:

c. Purity (or % w/w of substance(s)) leads to different intrinsic hazardous properties e.g. due to physico-chemical properties (e.g. the azeotrope of nitric acid).

The degree of purity and concentration levels of the constituents other than impurities are also

needed in order to establish the name of a substance and, eventually, the International Chemical Identifier. As a general rule, for mono-constituent substances at least the lower concentration level is needed to be able to confirm the identity of the substance intended to be covered by the proposal. For multi-constituent substances, also the upper concentration levels are needed. For well-defined substances, impurities present in the composition at concentration levels above 10% may be relevant for determining the identity of the substance.

For UVCB substances the degree of purity, however, has no meaning. Information on the composition of the UVCB substance should be reported as detailed as possible. For this type of substances, a description of the manufacturing process is also part of the identification of the substance. Information on the composition and manufacturing process of a UVCB substance should be reported in a confidential annex to the CLH report.

As mentioned in the beginning of this document, its aim is to clarify when information on impurities and degree of purity is relevant for the CLH process and/or for the Annex VI entry and, as a consequence, has to be included in the CLH dossier. ECHA will not anymore request that information on impurities and additives of the substance(s) proposed for classification to be included on a regular basis in all CLH dossiers, but only where relevant. As a result of the above-mentioned situations, the following **conclusions** on the need to report information on impurities/purity are drawn:

- **Impurities** are not needed unless they contribute significantly to the classification of the substance.
- Degree of **purity** should be included in the dossier if required to establish the name of a substance (mono- or multi constituent) and in cases where the degree of purity is important for the intrinsic properties of the substance, not considering the consequence of mere dilution.

3. Information to be included in a CLH dossier (CLH report):

Information on the composition of the substance for which harmonised classification and labelling is proposed has to be provided in the relevant section(s) of the CLH report.

- CLH report, Section 1 (Identity of the substance): The new CLH report template published on ECHA's website clearly indicates which information is needed to correctly and unambiguously identify a substance. Dossier submitters are advised to use the new format when preparing a CLH dossier. In this regard, please note that ECHA will no longer accept CLH dossiers using old versions of the CLH report template as from the 1st January 2018.
- Confidential information on impurities relevant for the classification should be provided in a confidential annex.

  Note on confidential information: Any other confidential information should also be provided as a separate attachment to the CLH report, clearly marked as confidential.