



Downstream Users of Chemicals Co-ordination group

DUCC comments on ECHA's paper on the "use of Bridging Principles - based on individual views in the HelpNet" (13 June 2016)

On 13 June 2016, ECHA issued the document "*Use of Bridging Principles- based on individual views in the HelpNet*" which summarizes the thoughts from HelpNet CLP correspondents regarding the implementation of the Bridging Principles under CLP. In that document, ECHA raises a series of open questions that may need additional clarifications (e.g. via interpretation provided by the Commission or by UN SCE GHS or via ECHA Guidance).

DUCC supports any effort aimed to improve a harmonized application of CLP criteria across Europe. DUCC is grateful to ECHA for listing the open questions collected from HelpNet CLP correspondents and would like to contribute to this process sharing its views on the questions under consideration.

DUCC is ready to further engage with ECHA, the European Commission, the HelpNet CLP correspondents and any other interested party in order to find a practical way to harmonise the application of Bridging Principles across EU. In this sense, DUCC would favour additional exchanges e.g. via a dedicated working group regarding the various points highlighted in this ECHA document.

1) Question n°1:

It was underlined that in accordance with the legal text, there must be sufficient data on the similar tested reference mixture and individual hazardous ingredient substances to adequately characterise the hazards of the mixture under evaluation (1.1.3, Annex I, CLP). It was considered not clear whether in the context of interpolation within one toxicity category (1.1.3.4), substantially similar mixtures (1.1.3.5) and aerosols (1.1.3.7) the concept of 'in the same hazard category' and "the mixture is classified" can also include 'not classified'. On one hand, it could be said that 'not classified' is not a category, but on the other hand, it is the result of a classification process. ***Can the Commission clarify if a mixture not fulfilling the classification criteria can be used as a reference mixture, according to each specific bridging principle?***

DUCC answer:

DUCC of the opinion that "Not classified as hazardous" is a classification result (i.e. it is the outcome of toxicological studies when CLP classification criteria are not met) and it should therefore also be possible to apply the Bridging Principles (BP) in the absence of hazard (whatever the BP is). Indeed, "not classified as hazardous" is part of available information that should be used for classification purposes. The idea is to make most and best use of existing data- taking into account the results as "not classified"- and therefore to prevent from carrying out new testing.



Downstream Users of Chemicals Co-ordination group

According to the decision logics 3.2.3.4 and 3.3.3.4. for the classification of mixtures in ECHA guidance on the application of CLP criteria¹, it is suggested that “no classification” is also considered as being a hazard category:

- Decision logic 3.2.3.4- Step 7b asks “Can bridging principles be applied?” and if YES, “Classify in appropriate category (Skin Corr. 1A or Skin Corr. 1B or Skin Corr. 1C or Skin Irrit, 2 or no classification)”.
- Decision logic 3.3.3.4– Step 6b asks “Can bridging principles be applied?” and if YES, “Classify in appropriate category (Eye Dam. 1 or Eye Irrit, 2 or no classification)”.

This would suggest that BP can be applied using similar tested mixtures which are ‘Not classified as hazardous’.

The worked example from the UN GHS guidance webpage (also included in the UNITAR training package) on substantially similar mixtures in the context of skin sensitization² is based on a tested mixture not classified for skin sensitization.

2) Question n°2:

Bridging can only be applied when the reference mixture has been tested. To most, it seems clear that the results of a test must conclusively lead to a classification before the bridging principles can be applied, as “tested mixture” is used in the legal text for the reference mixture(s) (1.1.3, and repeated for each Bridging principle in Annex I, CLP). However, it has been brought to discussion whether a classification conclusion not based on test data but on a weight-of-evidence evaluation of the reference mixture(s) when applying the criteria, could be used when applying the bridging principles. There seems to be agreement that “test” data means *in vivo*/*in vitro* tests, which must be available for the reference mixture(s). In addition, the test data on the reference mixture(s) must be reliable and adequate for the hazard of concern, and generated with a test method that has been validated and is considered suitable for mixtures. Also based on a comment provided with reference to Paul Brigandi (consultant, US), it would seem that the latter approach would not be in line with the original intention of the bridging principles. ***Could the Commission clarify this?***

☑ DUCC answer:

DUCC fully supports the view that Bridging Principles can only be applied when referring to reference mixtures which have been tested according to suitable test methods (in vivo and/or in vitro).

“DetNet”³, an A.I.S.E. collective voluntary initiative in the framework of the CLP Regulation, is an example of a secured web-based IT system containing more than 200 detergent and cleaning tested

¹ https://echa.europa.eu/documents/10162/13562/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5

² Ref.Doc: ST/SG/AC.10/C.4/2010/15 as amended by INF.40 (20th session), annex 2:
https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/guidance_docs/3-4a_2010-15e.pdf



Downstream Users of Chemicals Co-ordination group

mixtures for which ingredients information as well as suitable toxicological studies (skin and/or eye in vivo and in vitro studies) are available. By applying CLP “bridging principles” and/or “weight of evidence”, an expert can derive the hazard classification of an untested mixture by using existing data on similar tested mixtures made available by “DetNet”.

3) Question n°3:

The term ‘ingredient’ needs to be defined in the legal text (or in the guidance). However, it was noted that according to 1.1.3, Annex I to CLP, the bridging principles cannot be used if there are not “sufficient data on similar tested mixtures and individual hazardous ingredient substances to adequately characterise the hazards of the mixture...” and therefore it would not seem that a mixture in a mixture should be regarded as a single ingredient. In the context of bridging principles, **can an ‘ingredient’ be composed of several substances or can it be a mixture?**

☒ DUCC answer:

The Bridging Principles definitions use the terminology “ingredient” which is neither defined in the CLP⁴ regulation nor in GHS⁵. However, **the worked example from the UN GHS guidance webpage (also included in the UNITAR training package) on substantially similar mixtures in the context of skin sensitization⁶ refers to Ingredients A and C being mixtures in a mixture. Therefore, in line with this UN GHS example, DUCC supports that the terminology “ingredient” can refer to a substance or a mixture. Indeed, ingredients can comprise of more than one substance.**

4) Question n°4:

It was expressed (in the only answer received) that in order to apply any of the bridging rules, there must be enough information on the individual substances (identity and concentration) to allow comparison for a certain hazard, meaning that information on component substances is needed to apply “substantially similar mixtures”. If an ingredient can be a mixture, **would data be needed on that mixture (instead of or in addition to data on the individual substances) when applying the bridging principle of “substantially similar mixtures”?**

☒ DUCC answer:

Considering that the “substantially similar mixture” Bridging Principle could apply to mixtures containing more than 2 ingredients, DUCC agrees that information on the classification should be available for each ingredient (being a substance or a mixture).

DUCC believes that a prerequisite for bridging data from a tested mixture to a new mixture under assessment is the availability of sufficient compositional and physico-chemical information on the

³ <http://www.det-net.eu/>

⁴ CLP Regulation (EC) No 1272/2008

⁵ Globally Harmonised System of Classification & Labelling of Chemicals

⁶ Ref.Doc: ST/SG/AC.10/C.4/2010/15 as amended by INF.40 (20th session), annex 2



Downstream Users of Chemicals Co-ordination group

new mixture as well as the tested mixture. This includes the identification of the relevant individual ingredients contained in the mixture (with their respective CAS numbers when applicable), their levels in the mixture, their toxicological profile as well as their classification according to CLP.

5) Question n°5:

Can the bridging principle ‘substantially similar mixtures’ apply to mixtures that have more than two ingredients? If yes, how can it be justified according to current legal text, which refers to two ingredients? Or can the text in CLP be considered as an example showing that only one ingredient can be changed?

This is again related to the term ‘ingredient’, (see above): can an ‘ingredient’ comprise several substances?

☑ DUCC answer:

Neither the CLP regulation nor the GHS define what an “ingredient” is. However, they do not specify that the application of BP should be limited to simple binary systems, i.e. mixtures containing only 2 ingredients. Such mixtures do not reflect the reality of chemical formulations, especially in the detergents sector.

This is illustrated in the worked example from the UN GHS guidance webpage (also included in the UNITAR training package) on substantially similar mixtures in the context of skin sensitization (Ref.Doc: ST/SG/AC.10/C.4/2010/15 as amended by INF.40 (20th session), annex 2) in which the test mixture (i) and untested mixture (ii) both contain 5 ingredients each.

6) Question n°6:

It would be helpful if ***criteria for what is a ‘substantially similar mixture’*** could be developed.

☑ DUCC answer:

The CLP regulation (Annex I, section 1.1.3.5.) defines the criteria for the application of the “Substantially similar mixture” Bridging Principle. In particular, the hazard data on the ingredient in the tested mixture which is being replaced and the new ingredient in the untested mixture should be “substantially equivalent”. By this, ***DUCC considers that these ingredients must have the same hazard classification, potency and mode of action and they should not be expected to affect the hazard classification of other remaining ingredients. A less severe hazard classification of the ingredients in the untested mixture is not being expected to affect the hazard classification of other remaining ingredients and should be acceptable also.***

7) Question n°7:

It has been discussed whether the bridging principles take precedence when classifying a mixture with an extreme pH. However, it was agreed in the discussions that if the mixtures have different pH



Downstream Users of Chemicals Co-ordination group

(one not extreme), they cannot be considered as substantially similar and classification in accordance with the pH will then take precedence. ***Can this view be confirmed?***

☑ DUCC answer:

DUCC agrees that if, between the tested mixture and the untested mixture, the untested one has an extreme pH and the tested mixture does not, then the “Substantially similar mixture” Bridging Principle cannot be applied. In this case, the classification of the untested mixture should be derived by another means, taking into account the pH.

DUCC also notes that the UN GHS example on the BP “Interpolation within one hazard category”⁷ does include an untested mixture with extreme pH to be classified.

⁷ https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/guidance_docs/3-2b_2012-25e.pdf