



EU Classification and Labeling Rules for Mixtures Effective June 2015

On June 1, 2015, new rules take effect for the classification and labeling (“C&L”) of hazardous mixtures distributed in the European Union (“EU”).

The new standards were established in the EU’s Classification, Labeling, and Packaging Regulation 1272/2008 (“CLP”), and they are binding upon all manufacturers, importers, or downstream users (“operators”) bringing hazardous mixtures to market.

Also on June 1, 2015, a transitional period, during which operators could choose between applying either the CLP or the previous Dangerous Preparations Directive 1999/45 (“DPD”), will come to the end. In addition and on the same date, a sell-off “grandfathering period” for mixtures with the DPD C&L already in the supply chain will commence and then run until June 2017.

Among other changes, the CLP:

- Introduces different classification thresholds in certain hazard categories, such as acute toxicity and eye/skin irritation, which may result in classification to a more severe hazard category than under the DPD.

- Implements new classes for physical hazards, which are in line with the United Nations’s Globally Harmonized System of Classification and Labeling (“GHS”), as well as multiplying “M-factors” for mixtures containing substances classified as hazardous to the aquatic environment.
- Sets more stringent thresholds for the use of precautionary statements for mixtures containing sensitizing substances.
- Introduces new hazard pictograms, which are in line with the GHS and which should replace DPD pictograms.

New Tools for Classifying Mixtures

Notably, the CLP introduces, in line with the GHS, two new tools for the classification of mixtures—the “bridging principles” and “weight of evidence.”

These tools either replace or are to be used in conjunction with calculation methods using default-concentration thresholds of the ingredient substances. In essence, these tools may prevent the application of more severe classifications to the chemicals or mixtures in question.

The new tools are designed to use available data on similar mixtures (bridging principles), and/or read-across and other alternative data sources, using expert judgment (weight of evidence).

Similar to the DPD, Article 6(1) CLP provides that for the classification of a mixture, operators should primarily take into consideration the relevant available data on the mixture itself. Going beyond the DPD, however, Article 9(3) CLP explicitly allows the use of expert judgment and the weight of evidence approach where classification criteria cannot be applied directly to the available data.

In another new feature, Article 6(5) CLP (in connection with Article 9(4) CLP) provides that where data are not available on the mixture itself, other available information on similar-tested mixtures should be used, using so-called bridging principles (Section 1.1.3. to Annex I CLP).

Only in cases where data on the mixture itself—or on similar mixtures—are not available, taking into consideration the weight of evidence assessment, should the operators use calculation methods on the basis of hazardous substances contained in the mixture, using respective default concentration thresholds (see Article 6(5) in connection to Article 9(4) second paragraph).

Thus, the decision tree is as follows:

1. Use testing data available on the mixture as a whole (using the weight of evidence, if appropriate). If such data is not available or only partially available, then:
2. Use testing data on similar mixtures, applying bridging principles. If still impossible to classify, then:
3. Use calculation methods based on the hazard of known ingredients and the use of default concentration thresholds.

(See similar sequence in Section 1.6.3. and under Figure 1.6.1–a of the [European Chemicals Agency \(“ECHA”\) Guidance on the Application of the CLP Criteria](#).)

Note: The precedence of bridging principles over calculation methods, however, is not applicable to carcinogenic, mutagenic, and reproductive toxicity endpoints. For those endpoints, data on the mixture itself or on similar mixtures can be

used only upon demonstration that the calculation methods based on the hazard of known ingredients are not conclusive.

Scope of the Bridging Principles

Application of the bridging principles is set out in Section 1.1.3. of Annex I to CLP, which provides, “where the mixture itself has not been tested to determine its hazardous properties, but there are sufficient data on similar tested mixtures and individual hazardous ingredient substances to adequately characterize the hazards of the mixture, these data shall be used (...).”

As follows from detailed rules in Section 1.1.3., the bridging principles are in fact applicable only if the target mixture and the original tested mixture are substantially similar with respect to their hazardous ingredient substances, i.e., if they contain ingredient substances in the same hazard category and within the same concentrations, or within permitted concentration variations as set out in Table 1.2. For example, Section 1.1.3.1. sets out that even if the target mixture is diluted with a nonhazardous diluting agent, it should still have the same classification as the (nondiluted) original mixture. It is clear that in this case, operators would rather use the calculation methods, in order to take into consideration lower concentrations in the target mixture.

These considerations limit the usability of the bridging principles. The ECHA confirms, “the bridging principles mainly apply to either very simple mixtures or very straightforward compositional changes in an already classified mixture.”

The CLP encourages networks of operators to facilitate the exchange of data and application of the bridging principles. Thus, operators seeking to explore opportunities to apply the bridging principles should contact relevant industry associations, e.g., Registration, Evaluation, Authorization, and Restriction of Chemicals (“REACH”) consortia, etc.

Conditions for the Use of Weight of Evidence

The CLP provides that weight of evidence principles should be used where classification criteria cannot be directly applied to available identified information, “in order to ensure that existing information can be used for as many mixtures as possible.”

The weight of evidence includes grouping and read-across techniques, whereby endpoint information from one chemical is used to predict the same endpoint for another chemical considered to be similar. These techniques are similar to the bridging principles, but they can also be used where information is insufficient for the applicability of the bridging principles.

Similar to the classification of substances, the weight of evidence for mixtures also includes other elements, such as results of suitable in vitro tests, relevant animal data, (Quantitative) Structure-Activity Relationships (“(Q)SAR”) results, human experience such as occupational data and accident databases, epidemiological and clinical studies, and well-documented case reports and observations. All available information bearing on the determination of a hazard should be considered together. Expert judgment is needed in a total weight of evidence approach.

Further information on the weight of evidence determination is provided in the [ECHA Guidance on information requirements and chemical safety assessment](#).

Conclusion

The CLP’s C&L rules for mixtures, which will become binding as of June 1, 2015, notably introduce greater flexibility for operators via the “bridging principles” and the “weight of evidence” approaches. Such methodology can be used instead of calculation methods using default-concentration thresholds of the ingredient substances.

The bridging principles use the testing data on similar mixtures for the classification of the target mixture. However, the actual applicability of such principles is rather limited. In fact, the bridging principles are applicable only if the target mixture and the original tested mixture are substantially similar with respect to their hazardous ingredient substances, i.e., if they contain ingredient substances in the same hazard category and within the same concentrations (or within permitted concentration variations).

The applicability of the weight of evidence approach may be broader, as it allows the use of additional alternative data. If such data, when considered together with expert judgment, suggest a classification of the mixture, the applicability of calculation methods might be avoided.

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