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# CLP for mixtures in 2015

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**Abstract** From 1 June 2015, mixtures should be classified and labelled in accordance with the CLP Regulation. Companies completing the re-classification should be aware that the change in classification systems may result in a more hazardous classification under CLP than originally under the DPD system. To minimise the impact of these changes and to provide a more meaningful classification, companies can rely on more expert judgement and bridging principles than using the default calculation methods.

## INTRODUCTION

The Regulation (EU) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) (1) entered into application in January 2009. This legislation aligns the classification and labelling of chemical substances and mixtures within the EU with the UN's Globally Harmonised System (GHS) (2).

The CLP Regulation entered into operation with a transition period from 2010 to 2017. During this time, CLP repeals the existing legislation on classification, packaging and labelling for supply; that is the Dangerous Substances Directive (DSD) (3) and the Dangerous Preparations Directive (DPD) (4).

The transition period sets different deadlines for substances and mixtures (i.e. formulations or preparations composed of two or more substances). The deadline of the 01 December 2010 was set for substances being placed on the EU market to be classified and labelled according to CLP rather than DSD. For substances already on the market with DSD labelling there was a sell through period of two years for the substance to reach the final user without the need to re-classify and re-label in accordance with CLP. Therefore, from 1 December 2012, all substances on the EU market had to be labelled according to CLP.

The transition deadline for mixtures is 01 June 2015 for these products to be classified and labelled in accordance with CLP. As with substances, there will be a two-year sell through period for mixtures labelled according to DPD that are already in the supply chain.

Users of single substances will be aware of the visible CLP changes moving from the orange and black square hazard symbols to the new red-framed diamond shape hazard pictograms and they will have first-hand experience of using

the CLP classification system. However, for mixtures where data on the actual formulation are not available, changes to threshold concentrations may well result in a different classification under CLP, to that originally given under the DPD system.

This article aims to summarise the potential changes in classification of mixtures from DPD to CLP.

## Transition from DPD to CLP

Under DPD classification of mixtures, then referred to as preparations, under DPD was completed mainly by using the calculation method of ingredients, as data were not always available on the mixture itself for the specific classification endpoints. The CLP system provides more choice for classification of a mixture, such as classifying from test data on the mixture; using 'bridging' principles to read across from similar formulations; using a calculation method for ingredients or using the translation tables in CLP Annex VII. Further guidance on the application of CLP criteria for both substances and products is available from the ECHA website (5).

Classifying from test data obtained on the mixture is the most accurate, but often not viable for many formulators. The use of bridging principles requires data on mixtures of similar composition, which may be useful for mixtures that are diluted. As not all bridging principles apply to each hazard class, the rules regarding bridging principles must be reviewed before classification can be determined. The use of the CLP translation tables is possible for endpoints where there is reasonable coherence between the criteria of DPD and CLP. The use of this approach is limited to where there are no further data available for the considered hazard class; Annex VII specifically states that the translation table can be used to assist in a classification of CLP when the substance

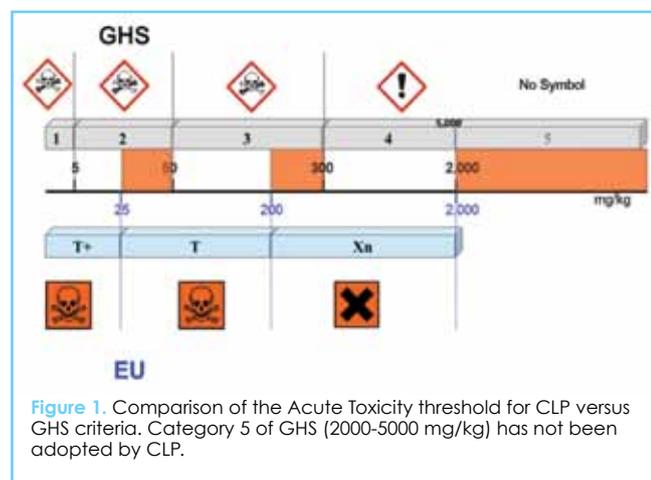
or mixture is classified under DSD or DPD. When data exists on the substance or mixture, the data should be used for evaluation and criteria in accordance with the CLP rules and not rely on the translation table(1). Classification using the additivity calculation will be the most common, as under DPD. However, CLP has different criteria to meet classification in certain categories.

### Classification by the calculation method

The difference in threshold concentrations for certain hazard categories will mean that some products will change classification under CLP, often with a more precautionary outcome. Some examples of changes to thresholds are:

#### Acute Toxicity hazards

A product with an oral LD<sub>50</sub> of 250 mg/kg would be classified as harmful under DPD. However, this same product would be classified as "Toxic" and require the "skull and cross bones" pictogram under CLP (Figure 1).



#### Eye Irritation hazards

A product containing a component causing a risk of serious damage to eyes at a concentration of 4 percent, would be classified as "irritant" under DPD. However, due to threshold concentration changes, this same product would be classified with the "corrosive" pictogram under CLP (Table 1).

DPD Classification	CLP Classification
Substance = R41  "Irritant" Risk of serious damage to eyes	Substance = Eye Cat. 1 H318  "Danger" Causes serious eye damage
Preparation: C <sub>2</sub> 10 percent = R41 	Mixture: C <sub>2</sub> 3 percent = H318 
5 percent ≤ C < 10 percent = R36: Irritating to eyes 	1 percent ≤ C < 3 percent = Eye Cat. 2 Warning, H319: Causes serious eye irritation 
0 percent ≤ C < 5 percent = No Labelling	0 percent ≤ C < 1 percent = No Labelling

Table 1. Eye irritation hazard thresholds.

DPD Classification	CLP Classification
Substance = R34  "Corrosive" Causes burns	Substance = Skin Corr. Cat. 1B H314  "Danger" Causes severe skin burns and eye damage
Preparation: C <sub>2</sub> 10 percent = R34 	Mixture: C <sub>2</sub> 5 percent = H314 
5 percent ≤ C < 10 percent = R38: Irritating to skin 	1 percent ≤ C < 5 percent = Skin Corr. Cat. 2 Warning, H315: Causes skin irritation 
0 percent ≤ C < 5 percent = No Labelling	0 percent ≤ C < 1 percent = No Labelling

Table 2. Skin irritation hazard thresholds.

#### Skin Irritation hazards

A product containing a corrosive to skin component at a concentration of 6 percent, would be classified as irritant under DPD. However, this same product would be classified as causing severe skin burns with the corrosive pictogram under CLP (Table 2).

#### Skin Sensitisation hazards

A product containing a component that is sensitising to skin at a concentration less than 1 percent, would not require labelling under DPD. However, CLP introduces subcategories such that a component with a sensitising component at a concentration of 0.1 percent could trigger the requirement for the product to be classified and labelled under CLP. Furthermore, a mixture containing a sensitising substance at a concentration as low as 0.01 percent triggers a special labelling requirement in section 2.8 of Annex II, for EUH208: 'Contains (name of sensitising substance). May produce an allergic reaction'. This lower concentration limit for elicitation is a requirement to protect already sensitised individuals (Table 3).

#### Environmental hazards

The introduction of multiplying factors (M-Factor) for highly toxic components of mixtures (Acute category 1 and Chronic category 1) may lead to a more severe hazard classification for the aquatic environment. M-Factors are applied for each component depending upon the individual substance environmental toxicity, the more toxic to the environment an individual substance is, the higher the multiplying factor, thereby giving the particular substance component an increased weighting in the mixture calculations.

#### The way forward

The above tables show that a mixture classified under DPD may need to be labelled differently under the CLP system. The main issues are with potential re-classification of mixtures as corrosive, sensitizers and aquatic hazard, especially in consumer products where this can be seen as a more severe classification and the resultant labelling more extreme.

If you are in the situation where a product is classified more severely under CLP there are essentially three options:

- 1) Accept the default classification by calculation
- 2) Fund your own *in vitro* tests or use existing data for your product

The CLP Regulation is very clear that for purposes of classification, data shall not be generated by means of testing on humans. Similarly, the

DPD Classification	CLP Classification
Substance = R43  "Irritant" May cause sensitisation by skin contact	Substance = Skin Sens. Cat. 1 & subcategories 1A, 1B H317  "Warning" May cause an allergic skin reaction
Preparation: C <sub>z</sub> 1 percent = R43  0 percent ≤ C < 1 percent = No Labelling	Mixture: Category 1 C <sub>z</sub> 1.0 percent = H317  C <sub>z</sub> 0.1 percent = EUH208* 0 percent ≤ C < 0.1 percent = No Labelling  Subcategory 1A C <sub>z</sub> 0.1 percent = H317  C <sub>z</sub> 0.01 percent = EUH208* 0 percent ≤ C < 0.01 percent = No Labelling  Subcategory 1B C <sub>z</sub> 1.0 percent = H317  C <sub>z</sub> 0.1 percent = EUH208* 0 percent ≤ C < 0.1 percent = No Labelling
<small>*For sensitising substances with specific concentration limit below 0.1 percent, the concentration limit for elicitation should be set one tenth of the specific concentration limit.</small>	

Table 3. Skin sensitisation hazard thresholds.

assessment of hazards and the obligation to generate information on the intrinsic properties should be completed by means other than testing on animals. However, if data are already available and carried out using human or animal studies, these can be used as evidence for classification.

3) Share information with companies that have completed testing of a similar product, so that bridging principles can be applied for similar materials.

This scenario would involve companies being in a network with similar formulators. The International Association for Soaps, Detergents and Maintenance Products (AISE) has developed and piloted such a scheme to help the detergents industry network and share existing data that can be used in bridging principles for CLP (6).

The change in hazard classification of products may also impact upon other pieces of legislation, for example the requirement for packaging to be fitted with child-resistant fastenings and tactile warnings when the mixture is classified in skin corrosion category 1 and sold to the general public. The classification change may also impact transport legislation and cosmetic legislation and may trigger higher tier Seveso III Directive requirements, possibly triggering these requirements for the first time.

## CONCLUSION

The change in threshold concentrations in the CLP Regulation may result in products being classified as a more severe hazard when companies change over to the CLP classification and labelling system. Companies may, therefore, wish to use existing data, bridging principles and expert judgement rather than the default calculation method when evaluating their products. The use of the different

options for classification does require more training, expertise and perhaps input from experts in this field.

## REFERENCES AND NOTES

1. The European Parliament and The Council, Regulation (EC) No 1272/2008
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