

# Classification of mixtures under CLP

#### Introduction

Since 1 June 2015, substances and mixtures alike must be classified and, where required, labelled in accordance with CLP before they are placed on the market. There was a two-year derogation for mixtures already labelled under the Dangerous Preparations Directive (DPD) and placed on the market by that date, which allowed them until 1 June 2017 to reach the end user without the need to be re-labelled. Beyond 1 June 2017 mixtures labelled under the DPD needed to be relabelled in accordance with CLP. But for any new batches of existing formulations, as well as newly designed mixtures, CLP applies in its entirety. The key tasks which importers and formulators of such mixtures should focus on are:

- <u>Classifying</u> mixtures according to CLP before placing them on the market;
- For imported hazardous mixtures, <u>notifying</u> the component ingredients that are responsible for the hazard classification to the Classification and Labelling Inventory;
- <u>Labelling</u> all mixtures classified as hazardous, or which require labelling in accordance with Annex II;
- Updating all relevant documentation, including safety data sheets, websites, catalogues, advertisements etc with the new CLP classifications.
- Notifying any hazardous mixtures placed on the market and classified as hazardous on the basis of their health and physical effects to poison centres.

This document introduces the methods available to classify mixtures under CLP and discusses how it differs from classifications under the DPD.

# How should you go about classifying your mixtures?

CLP allows for several different methods of classification:

#### · Classification based on test data

Basing your classification on relevant and good quality test data will provide the most accurate assessment of the hazards presented by the mixture.

For physical hazards, testing is normally required for all mixtures, unless a particular hazard can be excluded using the screening principles set out in Article 14 (2) and Annex I, Part 2 to the CLP regulation.

For health and environmental hazards, testing of mixtures is not often carried out, although the increased availability of in vitro tests may lead to more mixtures being tested using this approach.

### Classification based on similar tested mixtures (bridging principles)

The bridging principles set out in CLP allow for common sense comparisons between a tested mixture and another similar mixture. Details of the bridging principles, and which principles can be used for which endpoints, are set out in Annex I, Part 1.1.3 and in each section of Parts 3 and 4 of Annex to the CLP regulation.

Classification based on consideration of the component ingredients



The use of simple calculations and concentration limits to assess the impact of component ingredients on the overall hazards of a mixture was common practice under the DPD, and is also provided for in CLP. There are a number of differences, though, in the calculations and concentration limits to be used, and these need to be identified and understood so that the impacts of CLP can be fully appreciated.

### Read across from the old DPD classification to the new CLP classification using the Annex VII translation table

You may also re-classify your mixtures using the Annex VII translation table, where this is possible. Note that the Annex VII translation table is only intended to be used where classification by other routes is not possible, and cannot be used where data exist. There are also a number of limitations to its use, particularly for mixtures containing component ingredients that are classified as corrosive, irritant and toxic for reproduction.

More information on these limitations can be found in the ECHA <u>Guidance on the Application of the CLP</u> <u>Criteria.</u>

## Expert judgement

CLP also allows for greater flexibility in the use of expert judgement when classifying mixtures to deviate from standard classifications. There is no definition of what constitutes expert judgement, but if you can provide a sound scientific explanation of why you think your mixture should be classified differently to the standard approach, you can modify your classification accordingly. If you are taking this approach, you may want to consult with an expert to make sure your reasoning is valid.

# Has your classification changed?

Once you have carried out your classifications, you may find that the classification of your mixture has changed and has become more or less severe or is classified for different endpoints. Such changes may occur for several reasons:

## New test data or changes to classifications of component ingredients

If you have carried out some new testing on your mixture the results may give you a more accurate picture of the hazards presented, and you should take this into consideration when you carry out your classification.

Changes to the classifications of component ingredients may also have an impact on the classification of your mixture. If the classification of a component ingredient has changed, you may want to find out why this is the case. Has the classification changed because the CLP classification criteria for the substance are different? Has the supplier found new data about the substance, perhaps as part of the REACH registration process? Has a new or updated entry in Annex VI to CLP resulted in a change of classification? You should check your supplier's safety data sheet for more information, and contact them if the reason for the change is not clear, particularly if you disagree with the change. If the change has come from a new or updated entry in Annex VI, then you must use the new Annex VI classification.

### Changes to the classification criteria



CLP introduced many changes to the classification criteria, some very minor and some with a more significant impact.

For physical hazards, the classification criteria split up substances and mixtures into a greater number of categories and sub-divisions. Broadly, however, the scope of the classification criteria are the same, with the exception of some new hazard categories that have been introduced as a result of the alignment of the GHS, on which CLP is based, with the UN Model Recommendations of the Transport of Dangerous Goods (the Orange Book).

For health and environmental hazards key differences include:

- Changes to the classification criteria for substances with toxic effects on repeated exposure, and substances which present an aspiration hazard;
- Changes to the way that the acute toxicity of mixtures is calculated;
- Changes to the generic concentration limits for mixtures containing components that are corrosive, irritant or toxic for reproduction.

You can find a detailed discussion of these changes in chapter 1.7. of the ECHA *Guidance on the Application of the CLP Criteria*.

## Managing the effects of a classification change

Impacts of classification of mixtures under CLP compared to the old classifications under DPD included:

- Changes to packaging;
- Changes to transport requirements;
- Changes to storage and warehousing requirements;
- Changes to SEVESO (COMAH in the UK) tier;
- Updating of COSHH (or equivalent workplace chemical legislation for non-UK companies) assessments and changes to working practices;
- Substitution of less hazardous ingredients in the mixture to meet customer requirements or downstream legislation.

### Further information

If you need help meeting your CLP obligations, we can help! Why not come along to one of our forthcoming workshops to learn more about the CLP Regulation, how it affects your business and what you can do to comply? These practical workshops can also be delivered in house, tailored to your particular needs or products.

Alternatively, if you are looking to outsource this work, through our Matchmaker programme we can put you in touch with Approved Service Providers who have the necessary skills and expertise to help you comply. Matchmaker is a free service available to all our subscribers, with priority access for our Gold subscribers.

And as a Gold subscriber you can send in your queries to the helpdesk by phone (+44 (0)207 901 1444) or email (enquiries@reachready.co.uk).