

CLP Briefing Note: Classification of substances

Classification: what's it all about?

Classification and labelling of substances has been part of EU law for more years than most of us have worked, and it has gone through many step changes. We are used to the hazard warning labels found on household bleach and some other household chemicals, but we know we don't find these labels on all domestic cleaning products. That's because household bleach has a measurable effect in terms of eye damage – in other words it's classified as hazardous. Common salt (sodium chloride) makes your eyes sting but does not have a strong enough effect to damage your eyes – it's not classified as hazardous.

This sorting of chemicals into those of concern (hazardous) and those we can be relatively relaxed about is known as classification and it can only be done with some information about the properties of a chemical. The REACH regulation has made it possible to have more information available for classification. For many chemicals the classification for health and environmental effects is done on the basis of the data which is available – and this includes consideration of similar chemicals or chemicals of the same group. This leads us into the stepwise procedure of classification; but first we need to remember that all this has been going on for a long time and maybe someone has done the job before!

The health warning

The CLP Regulation is one of the largest EU regulatory texts. It can easily overwhelm even the most dedicated health and safety professional. In addition, the official ECHA Guidance weighs in at some 600+ pages – not for the fainthearted! But you should have both of these documents (and make sure they are up to date) to hand if you embark on the task of classification – see:

http://echa.europa.eu/legislation/classification_legislation_en.asp and
<https://echa.europa.eu/guidance-documents/guidance-on-clp>

We can't claim to reduce the complexity of classification to just a few pages. Don't be tempted to try this yourself unless you are confident of your ability – and are ready to defend it in court if challenged. In this Briefing Note we hope to show you how to get started and to identify what you can do yourself and when you need to get expert help. But don't forget – for REACHReady's Gold subscribers the first port of call for help is our Helpdesk – only an e-mail (enquiries@reachready.co.uk) or phone call away (+44 (0)207 901 1444).

Useful shortcuts to classification

Annex VI

For many hundreds of substances EU Government experts have agreed the classification and these have been made legally binding. In the past these agreements were accumulated into Annex I of the Dangerous Substances Directive, now these have been transferred to Annex VI of CLP. In the process, the classifications have been converted to the new GHS based system. So if you have a

substance which is listed in the Annex your first task is to regard the classification there as mandatory for the end-points given. Is that all you need do? Sadly not!

Firstly, you must check for any notes or other qualifications to the classifications. These are indicated by asterisks or the word “note” followed by a letter or number. Check the meaning of these with the introduction to the Annex and follow any relevant instructions.

Secondly you need to check that there is no recent data on the substance which would lead to classification in one of the classes not listed in the entry. Such data could be obtained as part of the REACH registration process and you would be aware of this if you are involved in registration. But if your tonnage is below the 1 tonne/year threshold, you will need to check on the ECHA website when the registration details appear.

REACH Registration

Once a substance has been registered under REACH then ECHA will post the classification on its website. You cannot use this classification to override the Annex VI classification above, but you can use it to fill gaps or to help you classify substances not in Annex VI.

CLP Annex VII

If your substance is not in Annex VI or not already registered under REACH you have two choices, you can classify from scratch or you can use Annex VII to do part of the job. Annex VII is a simple read across table – from old DSD classifications to new CLP classifications. You need to read and understand the qualifications in the introduction to the Annex and you will need to fill in gaps (as for Annex VI). One vital point to remember is that some substances which were not classified under CHIP may be classified under CLP, for example the criteria for aspiration are wider under CLP than CHIP. So, this means that Annex VII needs to be used with care and with more expertise than you might need for substances in Annex VI.

The long route to classification – Annex I

If you are dealing with substances which are not yet registered, and not in Annex VI, or end points where Annex VII does not provide a short cut, you will have to use the criteria in Annex I of CLP. Here we need to be clear; whilst some of the criteria can be interpreted by a competent general scientist, others do need a good deal of specialised expertise. So, you must proceed with care and be prepared to seek advice on occasions. And you should have the ECHA Classification Guidance to hand throughout the process. You should take a stepwise approach.

The information used for classification must be **assembled** with care. The starting point is to collect together all available information on the substance, based on literature searches, databases, international or national programmes of testing, in-house information etc. The collection should not be confined to standard test data, your considerations should include any non-standard test results, epidemiological data, practical experience, clinical information, the behaviour of similar substances and assessments based on structure activity.

The next task is to **critically examine** the information to see what is suitable as evidence for classification. Ask whether the information is adequate, reliable and scientifically valid to be used in relation to the criteria in Annex I of CLP. And remember that classification is not a once and for all process, there is a stream of information emerging from various sources (e.g. REACH) which will mean you have to review and update from time to time.

It is possible that your information will fall short of what is needed to reach a confident view on the hazards of the substance. If this is the case CLP does not require you to carry out further testing if it involves animals, indeed you need to meet strict conditions if you want to do this voluntarily. However



CLP does require you to have physical test data unless there is adequate and reliable information already.

With the selected information you should now be in a position to use the criteria in Annex I to **classify for each endpoint in turn**. This may involve expert judgement and may require you to assess conflicting data. Once again, we must emphasise the need to be competent for this task – it should not be undertaken lightly. But if you are able to do it then **record the arguments and the conclusion** you reach. Finally consider whether you need to have these peer reviewed, it's not required but is often wise.

Need further help?

If you need more help understanding the CLP Regulation and how it may affect your business, why not register on one of our CLP training courses? For details about our workshops, including the next available dates, please see our events webpage at <http://www.reachready.co.uk/events>, or contact us on events@reachready.co.uk. Remember, all our training can be provided in house either as a standard or tailored package, or via our advice and mentoring service.

As one of our Gold subscribers one of our experts will answer your questions – simply call us on +44 (0)207 901 1444 or email enquiries@reachready.co.uk.