

Important Changes to the Labelling of Hazardous Substances & Mixtures

The CLP Regulations

On 1 June 2015, new regulations come into force across the EU which affect how chemicals must be classified and labelled. These changes will have significant changes for the lubricants industry and all users.

The regulation is intended to identify hazardous chemicals and inform users about their specific hazards, by using standard symbols and phrases on the packaging labels and through Safety Data Sheets (SDSs). The aim of the regulation is to improve the level of protection to human health and the environment, and to make Classification & Labelling more consistent, transparent and comparable worldwide.

The purpose of this brief is to provide a summary of the changes, including the background and the effects of the new regulations.

Background

The <u>CLP Regulation (Regulation (EC) No. 1272 /2008</u> on Classification, Labelling and Packaging of Substances and Mixtures), which adopted the so-called GHS¹, entered into force on 20 January 2009.

Since December 2010 suppliers of substances in the EU have followed the new CLP rules to classify and label their products. For mixture suppliers, it has only been voluntary to follow the new CLP rules up until now, and many have continued to classify and label their products according to the earlier <u>Dangerous Preparations Directive</u> (1999/45/EC or DPD). However, CLP becomes mandatory for suppliers of mixtures from 1 June 2015.

As a result of adopting the new CLP rules, many mixtures such as lubricants are now labelled as "Hazardous" (i.e. dangerous) even though their composition has remained unchanged. This affects physical, environmental and health hazards, with the latter ones being arguably the most critical. Moreover, in some cases the new label wording looks more severe than before. There is general concern that this may create un-necessary alarm among users even though the *inherent hazard* of the lubricant that workers and customers are using has not changed in practical terms. As such, a revised hazard assessment has to be carried out to clarify if any

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¹ United Nations Globally Harmonised System of Classification and Labelling of Chemicals



additional workplace risk measures are needed once an updated SDS or revised label has been received from a supplier. In the longer term, unlabelled lubricants will become rare.

Changes

In brief, the major changes regarding health hazards are as follows.

The most notable visible changes are in **hazard symbols** or "**pictograms**" as they are known under CLP. These pictograms are red-bordered squares-on-a-point containing a black symbol. As well as having a different shape and colour to the more familiar black on orange hazard symbols, there are also two new symbols to become familiar with; these are an exclamation mark (!) which replaces the 'X' for certain hazards and the 'exploding body'. There are also new statements to describe the hazards and to give advice on how to handle a substance safely. These Hazard "H" statements and Precautionary "P" statements replace the old familiar Risk "R" and Safety "S" phrases.

Besides these obvious visible changes in the labelling of hazardous (dangerous) mixtures, there are a number of other changes under the new CLP rules compared with the old EU labelling system that have significant implications for the labelling of mixtures.

The **criteria** by which a substance or mixture will be labelled under the new scheme as "Hazardous" (dangerous) have changed considerably for some end points. As a result many substances and mixtures that were previously thought to be more or less harmless will become classified as Hazardous (dangerous) according to the new CLP criteria².

It is also therefore very likely that a lubricant which was once classified as "dangerous" is now given an even higher hazard symbol or classification.

The main changes related to the lubricant industry are as follows:

- Low viscosity oils (Aspiration hazard): this is considered by many to be far the most serious change, and it is not well understood. Hydrocarbon mixtures (including most lubricants) with a viscosity of less or equal than 20.5 mm² / s take on the new hazard labelling under CLP as follows:
 - H304: "May be fatal if swallowed and enters into airways."
 - Signal word "Danger"
 - Hazard Symbol GHS08 "health hazard", the so-called "Exploding Body" pictogram.

² For example, the threshold value for labelling an untested mixture as a "skin irritant" was 20% if it contained one or more ingredients irritating to the skin but now it is 10%.



There is a concern that this classification might apply to a large number of lubricants compared with the situation today where this classification as an Aspiration hazard is only applied to lubricants with a viscosity of up to 7.5 mm²/s. (these are assigned the 'X' symbol and the risk phrase R65 " Harmful: may cause lung damage if swallowed"). Since the viscosity threshold value is now changed, many lubricants will need to be reclassified as "Hazardous" and be assigned H304 and the 'exploding body' pictogram without any change in the formulation. In addition, the wording of the hazard statement H304 sounds more serious when compared to the old risk phrase R65 because it includes the words "May be fatal") rather than ""Harmful". This may well be confusing for users since the same hazard pictogram and signal word (Danger) are also used for far more dangerous chemicals (e.g. carcinogenic substances) and will need careful explanation.

2) Other rules according to which the hazard of a mixture, e.g. a lubricant, is calculated have also changed. This means that some mixtures may now become classified as "Hazardous" (dangerous), which were not before under the old EU DPD scheme. Examples include skin and eye irritation:

a) Skin irritation

Under CLP, skin irritants are subdivided into two categories – Skin Corrosive Category 1 (A, B or C) and Skin Irritant Category 2. The labelling threshold for mixtures containing one or more Category 2 skin irritants (equivalent to R38 under the 'old' EU rules) has been reduced from 20% to 10%, meaning that more untested mixtures might be classified as "Hazardous" under the new CLP rules.

b) Eye irritation

Under CLP, eye irritants are subdivided into two categories – Irreversible Eye Effects Category 1 and Reversible Eye Effects Category 2. The labelling threshold for mixtures containing one or more Category 2 eye irritants (equivalent to R36 under the 'old' EU rules) has been reduced from 20% to 10%, meaning that more untested mixtures might be classified as Hazardous under the new CLP rules. Additionally, the labelling threshold for Category 1 eye irritants (equivalent to R41 under the 'old' EU rules) have been reduced from 10% to 3%. Category 1 substances also cause a mixture to be classified as Hazardous when present at 1% or greater (it was 5% under the 'old' DPD rules). Since the labelling threshold for mixtures will be significantly lower under CLP compared with DPD, mixtures classified as Category 1 eye irritants are assigned the GHS08 "Corrosive" pictogram. In those situations where the product is not considered to be dangerous goods for transport then this has the potential to be highly confusing to users and may need careful explanation.

3) Some **hazard identification wordings** have been changed. Thus, for example, the "harmful" classification is now called "Toxic, Category 4", etc. To a non-technical person the new CLP wording makes the product hazard sound more serious compared



to the old wording even though the *inherent hazard* of the product and therefore its *risk* to workers and customers remains the same.

4) **Flammability**: the limit for the classification of a product as flammable changes. In the CLP legislation the lower limit for considering a liquid as flammable increases from 55°C to 60°C. Thus, some lubricants will now become labelled as "flammable".

Additionally, new hazard information is continuously being generated for many of the chemical materials present in lubricants as a result of other legislation such as the REACH Regulation³. As a result, new hazardous properties for substances commonly used by lubricant suppliers may be found which have not previously been assessed by the lubricant supply chain, or the substances have previously been considered safe by lubricant suppliers because of limited exposure to their workers and/or customers (at least in a relevant dosage). A new hazard assigned to a substance following testing for other regulatory purposes may result in the need for a new hazard assessment by the lubricant supplier. This new information must be examined for their risk to human health and to the environment, regardless of whether there is any exposure to people or the environment.

Example of a Generic Metal Working Product

Without any changes on the composition, product labelling has changed from "no label" to "H318 eye damage, category 1" with the following pictogram GHS05 "corrosive" assigned.



The reason for this labelling change is that the hazard threshold for labelling mixtures as "Category 1 eye hazard" has been reduced under new CLP rules from 10% down to 3%. It is also worthwhile highlighting that although the "corrosive" pictogram is needed for labelling under CLP for Irreversible Eye Effects, this does not mean that the lubricant is considered to be "Corrosive" for transport. It has been a common experience that this apparent discrepancy has caused significant confusion along the lubricant supply chain, especially among hauliers.

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³ <u>Regulation (EC) No 1907/2006</u> concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals