

Classification of mixtures in liquid form containing crystalline silica

The CLP Regulation

The CLP Regulation¹ implements in Europe the Globally Harmonised System on Classification and Labelling of Chemicals (GHS) developed by the United Nations.

Article 5 of the CLP Regulation requires each Manufacturer/Importer on the EU market to classify the substances (and mixtures) they manufacture/import in the EU.

Possibility to distinguish the form

The CLP Article 5.1 (Substances) and Article 6.1 (Mixtures) specify: “The information shall relate to the forms or physical states in which the substance (mixture) is placed on the market and (when relevant) in which it can reasonably be expected to be used.”

Article 8.6 specifies that “Tests that are carried out for the purposes of this Regulation shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.” In addition, the ECHA Guidance to the CLP Regulation published on 13 July 2009 mentions that “for human health, different forms (e.g. particle sizes, coating) or physical states may result in different hazardous properties of a substance or mixture in use” and therefore they may be classified differently.

It is therefore justifiable to consider only the fine fraction² of crystalline silica (quartz and cristobalite) for the purpose of classification.

Classification Decision

Since 2010, in accordance with the CLP Regulation, industrial minerals producers have jointly assessed that the warranted GHS classification for quartz (fine fraction) and cristobalite (fine fraction) is STOT RE Category 1 for the silicosis hazard.

As a consequence of this classification, substances and mixtures containing Crystalline Silica (fine fraction), whether in the form of an identified impurity, additive or individual constituent, will be classified as:

- STOT RE 1, if the quartz (fine fraction) or cristobalite (fine fraction) concentration is equal to, or greater than 10% (w/w);
- STOT RE 2, if the quartz (fine fraction) or cristobalite (fine fraction) concentration is between 1,0 and 10% (w/w);
- If the quartz (fine fraction) or cristobalite (fine fraction) in mixtures and substances is below 1,0% (w/w), no classification is legally required.

¹ Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures.

² The fine fraction of crystalline silica is the relevant fraction which, if made airborne, can potentially reach the deep lung, as defined by EN 481.



Decision on classification of products containing Crystalline Silica (fine fraction) takes into account the availability of those fine particles. If a product exists in a form which prevents particles within the fine fraction size range from becoming airborne (e.g. in liquid form), this will be taken into account in the classification decision.

Therefore, industrial minerals producers consider that when a mineral classified as STOT RE1 or STOT RE2 because of its Crystalline Silica fine fraction content is incorporated in a mixture in liquid form, the fine fraction is no longer available and classification would not be warranted.

Classification however applies to spray applications as hazardous respirable droplets may be formed when sprayed.

A comprehensive package regarding Crystalline Silica (fine fraction) classification and Respirable Crystalline Silica exposure prevention is available at the following website:
<https://safesilica.eu/>

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