Position Paper Classification and labelling of crystalline silica (fine fraction)

The CLP Regulation

The CLP Regulation[1] 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. Also, Title V of the CLP Regulation requires that by 1 December 2010 substances which meet the criteria for classification as hazardous according to the CLP Regulation or substances subject to registration under REACH must be notified to the classification and labelling inventory of the European Chemicals Agency (ECHA).
In the case of crystalline silica[2], although there is no harmonised EU classification for this group of substances under the European Dangerous Substances Directive, it has been a practice in the minerals sector for many years before 2010 to self classify and label crystalline silica flours as harmful with the label Xn and the risk phrases R48/20 (danger of serious damage to health by prolonged exposure through inhalation).

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 fraction[3] of **quartz and cristobalite** for the purpose of classification.

Classification Decision

In accordance with the CLP Regulation, industrial minerals producers have conducted a Review and Hazard Assessment of the health effects of crystalline silica (fine fraction).
The classification decision relies upon the following main arguments:

- Health effects are limited to the fine fraction of crystalline silica.

[1] Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures.
[2] The term 'crystalline silica' covers quartz, cristobalite and tridymite. Tridymite as such is not put on the market by IMA Members.
[3] 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.

- Despite the ubiquitous presence of crystalline silica in the environment, specific health effects of Crystalline Silica (fine fraction) only appear at the workplace not in the general environment.

- The route of exposure is by inhalation and the target organ is the lung.

- Silicosis is the main health effect of Crystalline Silica (fine fraction) exposure and it occurs, in the vast majority of instances, only after long-term exposure to high concentrations.

- Any lung cancer excess risk is demonstrated only under high occupational exposures to Crystalline Silica (fine fraction) and varies between different industries. No other cancer risk is observed.

- Any cancer effect is indirect via inflammation, i.e. through silicosis. Therefore preventing silicosis prevents lung cancer.

On this basis, industrial minerals producers have jointly determined it best and appropriate to classify **quartz (fine fraction)** and **cristobalite** (**fine fraction)** as **STOT RE Category 1** for the silicosis hazard (see sample label below for hazard elements).
STOT refers to Specific Target Organ Toxicity. RE refers to "Repeated Exposure". Based upon scientific evidence, it is generally necessary to inhale significant quantities of quartz (fine fraction) and cristobalite (fine fraction) in an occupational settings for prolonged and repeated periods of time before any possible health effect may occur.

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

The industrial minerals producers and other producers of substances and mixtures susceptible to containing Crystalline Silica (fine fraction) have to assess the content of Crystalline Silica (fine fraction) in the various grades of their products and have to assess the hazard of their substances and mixtures accordingly. As specified in Article 11 of the CLP Regulation, if a substance contains a hazardous substance as an identified impurity, additive or constituent, the classification will be based on the available information for the individual ingredients of the substance using concentration limits for the ingredients classified as hazardous **(= mixture rule**).

On a case by case basis, conclusive scientific information for the substances (including their impurities, additives or constituents) may be used for classification, when demonstrating that effects have not been established from the evaluation based on the individual ingredients (Article 12 of CLP).

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 wet slurry form), this will be taken into account in the classification decision.

To quantify the content of Crystalline Silica (fine fraction) within a bulk product, the IMA-Europe Metrology Working Group has developed a scientific method entitled the Size Weighted Relevant Fine Fraction of Crystalline Silica (SWeRF $_{CS}$). A procedure to standardise the method through CEN has been launched. See https://safesilica.eu/ for more information.

Hazard elements[4] of the STOT RE[5] 1 label for quartz (fine fraction > 10%) or cristobalite (fine fraction > 10%)

(The legal provisions related to the labels of hazardous substances are provided in Title III chapter 1 of the CLP Regulation.)

Danger

H 372: Causes damage to lungs through prolonged or repeated exposure via inhalation

P260: Do not breathe dust

P285: In case of inadequate ventilation wear respiratory protection

P501: Dispose of contents/containers in accordance with local regulation

Hazard elements of the STOT RE 2 label for products containing quartz (fine fraction 1-10%) or cristobalite (fine fraction 1-10%)

Warning

H 373: May cause damage to lungs through prolonged or repeated exposure via inhalation

P260: Do not breathe dust

P285: In case of inadequate ventilation wear respiratory protection

P501: Dispose of contents/containers in accordance with local regulation

[4] According to Article 17 (d to g) of the CLP Regulation.

[5] Specific Target Organ Toxicity Repeated Exposure

The classification of Crystalline Silica (fine fraction) as STOT RE 1 is accompanied by a series of key measures to bring about actual improvements in the current workplace situation, among them the reinforcement of the existing Social Dialogue Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it (see www.nepsi.eu). 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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