Classification and labelling of Silica Monolithics
in accordance with the CLP Regulation


The producers of Silica Monolithics, members of PRE, produce a wide range of refractory mixtures used in the lining of melting and holding vessels/furnaces used in the melting processes of various materials, both metals and non-metals.

A series of meetings on Respirable Crystalline Silica (RCS) and internal and external measurements of the level of RCS in the range of products have been organised in 2010-2011 by a number of PRE member companies. The concentration of RCS is an important contributing factor that may lead to the classification and labelling of Silica Monolithics. To quantify the content of respirable particles within the mixture, the scientific SWeRF (Size Weighted Respirable Fraction) methodology has been strictly followed. It is clear from the results of these measurements that the RCS concentration in the Silica Monolithics is always below 10%. Considering the IMA Position Paper on classification and labelling of RCS, these companies have agreed to classify and label their newly produced mixtures containing 1-10% RCS as STOT RE 2 (Specific Target Organ Toxicity - Repeated Exposure, Category 2). These labelling changes need to be introduced no later than 1 June 2015. Some companies may voluntarily choose to introduce these changes earlier if they wish.

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1 Companies involved in this exercise include: Caldeyers, Dörentrup Feuerfestprodukte GmbH & Co. KG, EKW GmbH, EKW - KREMEN d.o.o., Insertec, SAS Fours et Refractaires and Sibelco Nordic Oy Ab.
**Background information**

**The classification of Respirable Crystalline Silica**

The industrial minerals producers, members of IMA-Europe, the European Industrial Minerals Association, have conducted a Review and Hazard Assessment of the health effects of respirable crystalline silica. On this basis, industrial minerals producers have jointly determined it best and appropriate to classify respirable quartz and respirable cristobalite as STOT RE 1 for the silicosis hazard. STOT refers to Specific Target Organ Toxicity. RE refers to ‘Repeated Exposure’. Based on scientific evidence, it is generally necessary to inhale significant quantities of respirable quartz and respirable cristobalite in an occupational setting for prolonged and repeated periods of time before any possible health effect may occur.

As a consequence of this classification, mixtures containing RCS, whether in the form of an identified impurity, additive or individual constituent, will be classified as:

- **STOT RE 1**, if the respirable quartz fraction or respirable cristobalite fraction concentration is equal to, or greater than 10%  
- **STOT RE 2**, if the respirable quartz fraction or respirable cristobalite fraction concentration is between 1 and 10%

If the respirable quartz fraction or respirable cristobalite fraction in mixtures and substances is below 1%, no classification is legally required.

The deadlines to which the C&L requirements belong are presented schematically in the diagram below:
The SWeRF method

To quantify the content of respirable particles within a bulk product, the IMA-Europe Metrology Working Group has developed a scientific method entitled the Size Weighted Respirable Fraction (SWeRF) methodology. The SWeRF CS quantifies the respirable crystalline silica content in a bulk product. The procedure to standardize this methodology in an official CEN standard is on-going. The first draft standard is available on the following link: http://www.crystallinesilica.eu/fileadmin/crystallinesilica/documents/PQdraft_SWeRF_to_CEN.pdf

Further information

A comprehensive package regarding RCS classification and prevention, including the IMA-Europe position paper, is available at the following dedicated website: www.crystallinesilica.eu

For further questions, you can contact your supplier or the PRE secretariat:

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