

(Respirable) Crystalline Silica in REACH and GHS

1. No registration duty for crystalline silica under REACH


Amongst other obligations, REACH requires the registration of chemical substances, followed by an evaluation process. In this process the substances on their own, in preparations or in articles are evaluated in respect to health, safety and environmental aspects when manufactured, stored and used. The registration process will stretch over the next 11 years and will be preceded, for the so-called phase-in substances (i.e. currently on the market or formerly existing substances), by a pre-registration phase (1 June 2008 – 1 December 2008).

REACH plans that "minerals which occur in nature, if they are not chemically modified" are explicitly exempted from registration and evaluation (Article 2 § 7(b) and Annex V point 7) because such a registration is deemed inappropriate or unnecessary for these substances and their exemption from these requirements does not prejudice the objectives of this Regulation. Consequently, crystalline silica – quartz or cristobalite and related products which do not result from a chemical modification – placed on the market fall under this exemption and therefore will not be registered.

2. Crystalline silica classification under GHS


There is no regulatory classification in the EU of (respirable) crystalline silica and thus it is not listed in Annex I of Directive 67/548/EEC on dangerous substances. However, because of the potential for generation of airborne respirable crystalline silica, and the main effect of inhalation of respirable crystalline silica being local alveolar inflammation followed by fibrosis after prolonged exposure, European industrial silica producers, who are members of EUROSIL, self-classify and label Silica Flours² as harmful (Xn) with the risk phrase R48/20 (Harmful: danger of serious damage to health by prolonged exposure through inhalation).

Anticipating the consequences of GHS implementation, the European industrial silica producers hereby inform you of the likely modifications for the classification and labelling of silica flours.

According to the table 1.1 of the Annex VII of the European Commission proposal¹, this classification should be translated into Specific Target Organ Toxicity – Repeated exposure, Hazard Category 2 i.e. STOT Rep. 2, under the GHS classification and labelling scheme (see the enclosed appendix 1 for more details).

Consequently, Silica Flours will be self-classified and labelled accordingly as soon as this proposed Regulation will enter into force, i.e. on 1 December 2010 according to the European Commission proposal¹.

EUROSIL, 14 September 2007

¹ COM(2007)355 final
² Silica flour is a flour manufactured by producers of high grade silica products by the milling of silica sand or any grade of silica, with the exception of uncalcined amorphous silica.
Appendix 1: extract from Annex VII of the COM(2007)355 final

Table 1.1
Translation between classification in accordance with Directive 67/548/EEC and this Regulation

<table>
<thead>
<tr>
<th>Classification under Directive 67/548/EEC</th>
<th>Physical state of the substance when relevant</th>
<th>Classification and hazard statements assigned under this Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xn; R48/20</td>
<td>STOT Rep. 2</td>
<td>H373 (3)</td>
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</tbody>
</table>

(3) The route of exposure could be added to the hazard statement in the future as indicated in the current classification; if it is conclusively proven that no other routes of exposure cause the hazard.

**STOT Rep.2**: Specific target organ toxicity – Repeated exposure, Hazard Category 2

**H373**: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.