(Respirable) Crystalline Silica in REACH and GHS

1. No registration duty for crystalline silica under REACH

The European Parliament and the Council adopted, on 18 December 2006, a new regulatory framework for chemicals known as REACH (Registration, Evaluation, Authorisation and restriction of CHemicals). The REACH Regulation (EC)1907/2006 was published in the Official Journal of the European Union on 30 December 2006 and entered into force on 1 June 2007.

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

On 27 June 2007, the European Commission issued a proposal[1] for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006). This proposal which aims at implementing the Global Harmonised System (GHS) is now subject to the approval of the European Parliament and of the Council, and its final adoption is expected by the end of 2008, with entry into force on 1 December 2010.

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 Flours[2] 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 proposal[1], 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 proposal[1].

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[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

Classification under Directive 67/548/EEC	**Physical state of the substance when relevant**	**Classification and hazard statements assigned under this Regulation**		
		Classification	**Hazard statement**	**Note**
Xn; R48/20		STOT Rep. 2	H373	(3)

(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*>.