

## **Eurocolour Position on the classification of Silica as STOT RE 1**

*On 10 June 2024 ECHA published a proposal for a harmonized classification and labelling in the hazard class specific target organ toxicity-repeated exposure 1 (STOT RE 1) for Silica. We do not see that this classification would be justified, as it is not based on intrinsic properties of the substances. We are concerned about disproportionate impacts.*

### **Specific Target Organ Toxicity Repeated Exposure Category 1 (STOT RE 1)**

The STOT RE classification is not suitable for low-toxicity particles such as Silica. Even though studies show an effect, it is not clear if this effect is provoked by the intrinsic toxic properties of the chemical. A similar debate was part of the judgement regarding TiO<sub>2</sub>, as there were serious doubts that the effects observed were actually caused by the inherent toxic properties and not an unspecific response due to particle exposure. Classifying a substance based on its particle effects deviates from the legal scope of the CLP Regulation. Inflammation as such does not justify the classification as STOT RE 1 as it represents an adaptive response of the immune system to particles. Furthermore, the concentration limits which are required for testing if a substance is STOT RE are not suitable for silica or other particulate substances.

### **Cut-off values for STOT RE classification by CLP are not workable**

The cut-off values for STOT RE classification are too high to be suitable for the assessment of silica. High concentrations lead to suffocation of the rat due to obstruction of the airways. Lower concentrations, which are used for STOT RE 2 classification, do not lead to this blockade but have a physical effect. Since the physical structure of a rat is not comparable those of a human, especially when talking about the diameter of the airways, the effects seen are not considered being relevant for humans.

The test methods used for studies are often not suitable for these kinds of materials. Silica tends to agglomerate. Testing methods, however, require often a specific particle size which is achieved by introducing high sheer forces. These sheer forces are much greater than those when using silica e.g. workplaces or in daily life. As a result, Silica is not tested as it is placed on the market, therefore this data shall not be used to classify according to the CLP-Regulation, Article 5, "The information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used".

As the ECJ judgement on TiO<sub>2</sub> stated, non-specific particle effects are not intrinsic substance properties and therefore do not belong in CLP. Therefore, the CLH classification procedure for SAS should be suspended until a final decision on TiO<sub>2</sub> has been made.

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### **Impact of the classification of Silica as STOT RE 1**

The impact of a classification on Silica needs to be determined, especially with regard to the plans of the European Commission to integrate the STOT RE classification into the general risk assessment (GRA), which is being introduced with the REACH Revision. Silica is used in several important areas, such as pharmaceutical and cosmetics production. The proposed classification could lead to restrictions in these areas without alternatives on hand. Therefore, the use of silica in the different downstream user processes should be considered as well as the next steps the Commission wants to take.

**In our view, the classification of Silica as STOT RE 1 is not justified as it does not refer to intrinsic properties of the substance. Therefore, the CLH classification procedure for SAS should definitely be suspended until a final decision on the TiO<sub>2</sub> case has been made. Due to high impact, which is to be expected, the use in downstream user processes as well as further regulatory intentions should be considered. Therefore, we advocate against the classification as STOT RE 1.**

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### *About Eurocolour:*

*Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.*

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