Status: 21 April 2026

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. This proposal has since been confirmed in a RAC Opinion and is in discussion in the CARACAL for adoption into ATP. We do not see that this classification as justified, as it is not based on intrinsic properties of the substances. We are concerned about disproportionate impacts which were not taken into account in the RAC Opinion.

RAC Opinion misses scientific depth

The RAC Opinion adopted on 7 March 2025, supports the proposed classification of STOT RE 1 which bases though primarily on assumptions lacking evidence. Several parts are copied from the CLH proposal. However, some of the original justifications have been omitted. The RAC also addresses key arguments against the classification raised during the consultation. Here, it is denied that particle effects are the trigger of the observed effects, arguing instead that the silanol groups are responsible for the reaction in the lung. However, this cannot be verified as the study referred to in the document is not cited, neither in the RAC opinion nor in the CLH-Dossier. It is therefore unclear what the exact experimental conditions were and how the RAC come to this conclusion. This needs to be addressed before classifying a substance. Furthermore, the role of silanol groups in the formation of reactive oxygen species is controversially discussed, a point which is not fully addressed by the RAC.

It is RAC's responsibility to review carefully all data provided during the public consultation and to give a comment on it. This happened only to some extent as comments often were dismissed without plausible reasons. Additionally, several studies showing that no classification is required were disregarded by RAC. For the sake of transparency and comprehensibility all data need to be considered and reviewed including epidemiological studies. Conclusions must be based on clear supportive evidence and not on assumptions.

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_2, 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. In the TiO_2 Case the effect was dismissed by the court as it has not been proven to be from titanium dioxide but rather particles in general. 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.

Eurocolour e. V.

Mainzer Landstraße 55
60329 Frankfurt/Germany

phone: +49 (0)69 - 2556 - 1351
e-mail: contact@eurocolour.org

www.eurocolour.org

Guidance values for STOT RE classification by CLP are not workable

The guidance 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 to those of a human, especially when talking about the diameter of the airways, the effects seen are not considered relevant for humans.

The test methods used for studies are often not suitable for these kinds of materials. Silica, like other particles, 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_2 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 it is clear how particles should be handled under CLP.

Impact of the classification of Silica as STOT RE 1

The impact of a classification on Silica needs to be determined, especially with regards to the plans of the European Commission to integrate the STOT RE classification into the general risk assessment (GRA), which could be 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. It is not timely to only consider the hazard while looking at classification. The effect of the classification needs to be considered as well, especially if a substance has such a broad use like Silica.

PSLT needs to be understood and alternatives to classification are required

Eurocolour supports the efforts by the Commission and Member States for more safety for human health and the environment. But mindless classification of substances based on questionable science is not what the CLP regulation is intended to be. Classification needs to be based on intrinsic properties. Not every effect seen can be linked to an intrinsic property. This has been shown in the titanium dioxide trial, and the Commission and Member States aim to repeat this mistake with Silica and Talcum. There are different options besides classification to increase health protection. However, before these options can be applied for particulate substances the particle effect needs to be understood by the authorities and a definition for poorly soluble low toxicity (PSLT) particles is needed. To achieve this goal Eurocolour supports the work of the Cefic Particle Platform as well as the proposed formation of an expert group regarding this topic in CARACAL 56. ECHA and RAC have already started with the scooping study for an OEL for PSLT. Finding a definition is in our opinion a key part of this work and can be used as starting point toward alternative solutions. The proposal for an OEL can be used

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Mainzer Landstraße 55
60329 Frankfurt/Germany

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as alternative for classification if it is implemented with a workable concentration and in collaboration of Authorities as well as the industry.

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 stopped as it is scientifically not justified and will not hold up in court as the titanium dioxide case has shown. 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.

Your contact partner at Eurocolour:

Dr. Heike Liewald, Managing Director
+49 69 2556 1351
liewald@vdmi.vci.de

Marco Silbach
+49 69 2556 1362
silbach@vdmi.vci.de

Registration No. EU Transparency Register: 90219 263 4607-21

About Eurocolour:

Eurocolour represents European manufacturers of pigments, dyes, fillers, and ceramic colours and glazes. It brings together around 100 companies – approximately 75% of which are SMEs – with a combined annual turnover of €5.7 billion. The sector accounts for one-third of global production and directly employs over 18,000 people across Europe.