

SASforREACH GbR, the industry consortium for the REACH registration of Synthetic Amorphous Silica and Silicates, would like to provide its comments to the targeted public consultation for *Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl), hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide (CAS # 68909-20-6) (HMDZ-treated SAS)*, which is a nanoform under the REACH submission for Silicon Dioxide.

SASforREACH concurs with the comments submitted by ASASP (The Association of Synthetic Amorphous Silica Producers, a sector group of CEFIC):

The classification of the aforementioned HMDZ-treated SAS as

- Acute Tox 2, inhalation and
- STOT RE 2, inhalation

is **not warranted**. The conducted mechanistic OECD TG 436 study clearly shows that lethality of the rats is not based on intrinsic properties of *Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl), hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide*, but on physical properties of the particles, which could also be expected to be established for any material of similar density, hydrophobicity and particle size.

With regards to the results of the mechanistic study, SASforREACH comments as follows:

The animal part of the mechanistic study was conducted according to OECD TG 436 in order to comply with an internationally accepted standard. The goal of the OECD TG 436 test was not to determine the lethal concentration of particles in air, but to explain unambiguously the pathological reason for the lethality upon exposure. The mechanistic study contains two sections:

**Section 1:** describes the dispersion and (re)–agglomeration behaviour of powders, including HMDZ–treated SAS. (Wessely et al. 2022)<sup>1</sup>

**Section 2:** investigates the actual mechanism for the lethal outcome in test according to OECD TG 436. (Krueger et al. 2022)<sup>2</sup>

The mechanistic study (including pathological results) clearly concludes on the reason of death to be suffocation due to agglomerated hydrophobic particles in the nasal cavities. An intrinsic chemical toxicity can thus be ruled out. It additionally justifies the Klimisch 3 rating applied to the existing studies on *Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl), hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide* in the REACH dossier. Thus, these studies should be disregarded for any assessment.

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<sup>1</sup> Wessely et al. “Experimental Study on the Transport and Alteration Behaviour of Aerosols From Low Density Powders for Acute Inhalation Toxicology Studies” in Front. Public Health, 17 June 2022; Sec. Occupational Health and Safety; Volume 10; 2022. <https://doi.org/10.3389/fpubh.2022.907202>

<sup>2</sup> Krueger et al. „Physical Obstruction of Nasal Cavities With Subsequent Asphyxia, Causes Lethality of Rats in an Acute Inhalation Study With Hydrophobic HMDZ Surface–Treated Synthetic Amorphous Silica (SAS)“ in in Front. Public Health, 17 June 2022; Sec. Occupational Health and Safety; Volume 10; 2022. <https://doi.org/10.3389/fpubh.2022.907078>