June 2022

SASFORREACH Consortium
Information Letter 7
Synthetic Amorphous Silica:
Bulk silica (non-nano SAS)

The SASforREACH consortium would like to provide some clarifications about the current and future situation for the REACH registration of Synthetic Amorphous Silica.

1. The current registration covers only nano forms of Synthetic Amorphous Silica with its 2 set of nano forms (hydrophilic and hydrophobic SAS)
2. After the dossier updated the registration will also include non-nanoforms of SAS

Silicon dioxide has a long history as nanostructured material. The data which were available and generated for the REACH purpose by the members of the SASforREACH consortium and which are referred to in the REACH dossier and covered by the Letter of Access (LoA) are related to nanomaterials. Prior to the 01.01.2020 when the Commission Regulation (EU)2018/1881 entered into force, the identification as nanomaterial was not relevant for a REACH registration. After 01.01.2020 the data requirements for nanomaterials needs to be fulfilled and the lead dossier was updated accordingly to bring the registration dossier in line with the new data requirements for nano forms. However, the data set was the same as before. The study data were now marked as nanomaterial related and the dossier was update with requested studies (ECHA decisions) or new study to fulfill additional data requirements for nanoforms. From this time point onwards it was clearly that the registration does not contain any data on non-nanoforms of SAS.

This explicitly means that the REACH registration from the very beginning in 2010 and onwards already only included SAS data on nanomaterial.

Consequently, the SASforREACH consortium explicitly points out in the FAQs that only nanostructured material is covered by the REACH dossier and non-nanomaterial (aka bulk form) needs to be individually covered via an opt out dossier by each co-registrant individually.

Most of the relevant SAS manufacturing processes results in the generation of nanomaterials: precipitated silica, silica gel, colloidal silica and pyrogenic silica. Depending on the process, nanosized particles either stay in an unbound state or form agglomerates and aggregates which end up in the µm or mm scale. These agglomerates and aggregates must not be misinterpreted as manufactured SAS with a particle size > 100 nm in an unbound state.