SASFORREACH Consortium Information Letter 10 Synthetic Amorphous Silica EC 231-545-4: Dossier update 2024

Dear Co-Registrant of SAS,

on March 31, 2024, the lead registrant (EVONIK) submitted an update of the SAS joint registration dossier which is designed to comply in due time with the following two information requests issued by ECHA:

- (a) to respond to the two targeted CCHs on the two nano sets already in the dossier (with a <u>deadline of 2/4/24</u>) (Nano Set 1 (i.e., 'synthetic amorphous silica, nanostructured material_Set 1') and Nano Set 2 (i.e., 'synthetic amorphous silicon dioxide, nanostructured material, silanized Set 2') and
- (b) to respond to the TCC failure (with a <u>deadline of 19/4/24</u>) of our update with the harmonized classification of the surface treated nanoform (HMDZ-SAS) (classification came into force 1 December 2023).

Please contact the SASFORREACH Consortium to receive the boundary compositions as a IUCLID file (i6z) of the following sets of nanoforms including the justifications of reporting of similar nanoforms (each a "Set") as well as bulk (i.e., non-nano) silica:

- 1. **Set 1** contains the nanoform of precipitated silica, pyrogenic silica and silica gel, without surface treatment, without classification
- 2. **Set 2** contains surface-treated SAS nanoforms of precipitated silica, pyrogenic silica, silica gel and colloidal silica(*), non-classified. The treatment is limited to typical organic/silane-based treatments and does <u>not</u> include inorganic substances as treating agents
- Set 2A contains HMDZ-treated pyrogenic silica only (at present) which is classified officially through the 18th ATP
- 4. **Set 3** contains plains colloidal silica, which is only stabilized using different ions such as, e.g., Aluminum, Sodium or Ammonium. The stabilizers are regarded as a part of the substance relying on Article 3 of REACH.
- 5. **Bulk Silica** (non-nano SAS)
- (*) Surface modified colloidal silica will form a new set of nanoform and will be separated from the Set 2 in an up-coming dossier update.



Member Companies

Albemarle Europe, BASF SE, Cabot Corp., Evonik Operations GmbH, Grace GmbH, IQE S.A., PPG Ind. Inc., PQ Corporation, Rhodia Operations S.A.S., Clariant Produkte Deutschland GmbH, Wacker Chemie AG, Zeochem AG

Please note the new names of the Sets defined in the joint registration dossier. Each coregistrant has the obligation to assign its registration to one or more of the abovementioned Set(s) and/or to Bulk Silica. Each Set as well as the Bulk form represents a separate sub-registration with the full data requirements laid down in Annex VII to X of REACH. Each assignment has to be accompanied with the corresponding substance ID and the prove of being included in the range of the boundary composition of the corresponding SET or Bulk Silica.

As SAS is typically a nano structured substance, we explicitly draw your attention to REACH Annex VI no. 2.4.

Furthermore, please note that the aforementioned IUCLID file will only be made available to co-registrants who have complied with their statutory obligations to provide information needed by the SASFORREACH Consortium to ensure compliance with the applicable EU sanctions regime (cf. https://reach-as.org/ News item 2023-06-21 "Request for information regarding EU Sanctions").

SASFORREACH Consortium