

SASFORREACH Consortium
Information Letter 8
Synthetic Amorphous Silica EC 231-545-4:
Dossier update 2022

Dear co-registrants,

The SASFORREACH consortium would like to inform you about the recent dossier update which was submitted and accepted by ECHA.

Impacts from lead dossier update to member registrants' dossiers

On October 18, 2022, the lead registrant Evonik submitted on behalf of the joint submission an update of the joint registration dossier. The update introduced the **NEW** boundary composition for a bulk (a non-nano) form of synthetic amorphous silica (SAS) including new study data and read-across justification.

The dossier now contains the boundary compositions for the following SAS forms:

- Nano structured SAS Set 1 (untreated) – since 12/2019
- Nano structured SAS Set 2 (treated) – since 12/2019
- Non-nano structured SAS (bulk) – since 10/2022
 - Stöber process
 - Wet route process

Two forms of SAS (bulk and nano) are currently part of the joint submission dossier. We would like to stress that basic data used to establish nano set 1 (untreated) and nano set 2 (treated) SAS are part of the registration dossier since entering into force of REACH. Since 2009 new data on nano SAS was generated to fill and address data gaps for the nano SAS forms only.

Therefore, all registrants must check whether their member registration is referring to correct boundary composition for nano, bulk or both SAS forms. We would like to remind the co-registrants that according to the Implementing Regulation (EU/2020/1435) the update of the lead dossier triggers a legally binding deadline to update member registrants' registration dossier within a certain deadline. We would like to stress that without a dossier update the member registration would be incompliant and actions by ECHA may be triggered.

In case of **nano-form**, the member registrants need to update the individual legal entity composition in their dossier with a reference to the respective boundary composition

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

of the nano-form(s). Furthermore, the individual nano-forms of the registrants need to be described with the respective REACH Annex VI data.

In case of **bulk-form**, the reference to the new established BULK boundary composition must be included in the legal entity composition of the member dossier by submitting a member dossier update. Furthermore, the data according to REACH Annex VI must be conclusive to demonstrate the non-nano structure of the registered substance. In both cases action from all member registrants is needed unless the registrants had already updated the member dossier and established a link to a nano boundary composition. **Please be aware that any member registration without individual opt-out, could not cover bulk SAS-form before.**

No additional costs would be incurred for the time being, if member registrants chose either the bulk- or the nano-form, but also no reimbursement will be granted, if registrants chose the bulk-form. Member registrants of the bulk-form may need to contribute to the costs of the dossier generation and additional studies which are done on bulk SAS to fulfill their registration obligations. This information will be available once the process is completed and registrants have communicated their intention to register one or more specific set(s) of the nano-form, the bulk-form, or both to the Consortium.

Impacts from ECHA's draft decision to member registrants' dossiers

The SASFORREACH consortium would like to inform you about ECHA's draft decision on the SAS Dossier. In the draft decisions (CCH-D-2114599940-33-01/D; CCH-D-2114599908-21-01/D). ECHA has requested to update the nano boundary composition as well as to provide an additional information on the nature of the surface modification:

- Report d10, d50 and d90 values based on the number-based particle size distributions as well as the values of the number fraction of constituent particles.
- Provide a list of all the agents (incl. CAS and EC numbers) used for surface treatment of all the nano-forms or at least a description of the chemical nature of the modified surface.

The SASFORREACH consortium is currently working on an action plan how to compile the requested data from the member registrants in order to be considered in the next joint registration dossier update. Without this input the consortium cannot assess whether the SAS forms of the member registrants will be covered by the joint registration dossier. In case of very specific SAS forms more actions from you may be required, i.e. an own nano-form or set of similar nano-forms.

Actions from the member registrants

In order to fulfil the REACH obligations, the member registrants are called up to review their company specific data and **provide feedback which SAS forms are relevant for their registration.**

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Those companies which have registered or need to register nano SAS forms will be asked to answer a questionnaire to address ECHA's draft decision.

The Consortium must urgently stress again that your feedback is crucial to define the boundary composition of the nano-forms in the most convenient way for all registrants to ensure that most if not all forms are sufficiently covered. Otherwise, it might be the case, that your SAS forms may not be covered by the updated boundary composition. This could result in no registration status and could lead to enforcement actions of national authorities.

Obligation of each registrant

Each registrant is responsible for registering the nanofoms that they themselves manufacture or import. Therefore, each registrant has the obligation to characterise the nanofoms (either individually or through sets of nanofoms) they manufacture/import and to ensure that a specific hazard data set is provided for each nanofom or set of nanofoms.

The information required by REACH Annex VI, including the characterisation of nanofoms, must always be submitted separately by each registrant in their IUCLID dossier. However, co-registrants can submit jointly or via the opt-out mechanism (if any of the conditions listed in Article 11(3) and 19(2) is met) the classification and labelling and the hazard data (i.e., information requirements of Annexes VII to X) on the nanofoms of the substance. See also ECHA's Q&A 1689 at [Questions and answers - ECHA \(europa.eu\)](#).

As indicated in ECHA's Q&A 1690 at [Questions and answers - ECHA \(europa.eu\)](#), once the lead registrant has submitted their dossier, you must update your member registration to link your nanofoms with the relevant Annex VII-X information in the lead dossier. This is done by referring to the corresponding boundary composition name(s) of the lead dossier, in the section 1.2 Legal entity compositions of your own dossier by using the field 'Reference to related composition(s)'."

AS THE COMPLIANCE WITH THE REACH REGULATION IS THE SOLE RESPONSIBILITY OF REGISTRANT, THE CONSORTIUM WILL NOT TAKE ANY WARRANTY FOR REACH COMPLIANCE OF ANY JOINT REGISTRANT.

SASFORREACH Consortium

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Annex I different SAS forms

SAS is typically manufactured as a nanostructured material. Precipitated silica, silica gel, colloidal silica or pyrogenic silica are subject of the REACH nano definition by the internal structure (so called constituent particles) or by size.

According to Annex VI of the REACH Regulation, a “nano-form” is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm (Please see Appendix for nano-forms applicable to the Guidance on Registration and Substance Identification. Version 2.0 – January 2022).

The internal structures form agglomerates and aggregates in the μm or mm size (gel, precipitated or fumed SAS). Colloidal SAS in mono- or poly disperse form is present in most cases as particles below 100 nm, colloidal forms with a d_{50} particle size above 100 nm fall into the bulk-form of SAS, please see here the latest Q&A on the SASFORREACH webpage. In some rare cases non-colloidal SAS exists also as a non-nanoform (bulk SAS), which constituent particles are larger than 100 nm, please also the a.m. Q&A.

Electronic microscopy images, provided on the page 5-6, illustrate various forms of SAS to provide guidance and help for your determinations. The images do not replace your obligation to generate own electron microscopy investigations to determine the status for your SAS forms placed on the EU market.

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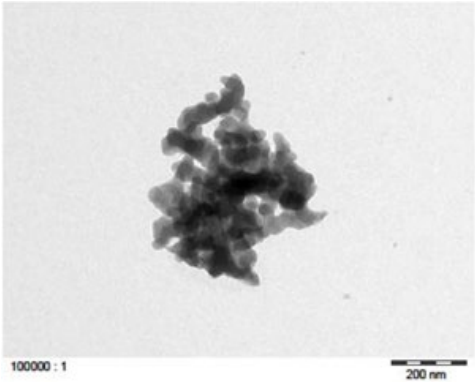


Figure 1: TEM image of a precipitated nano SAS

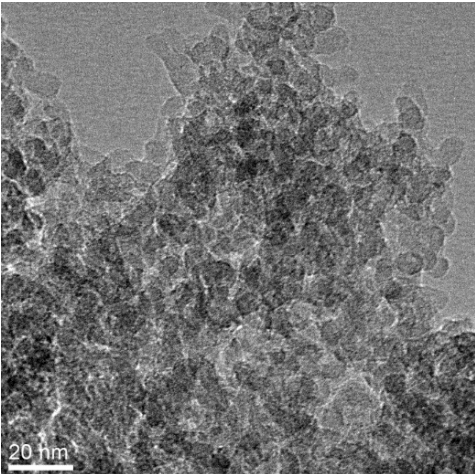


Figure 2: A TEM image of a nano silica gel

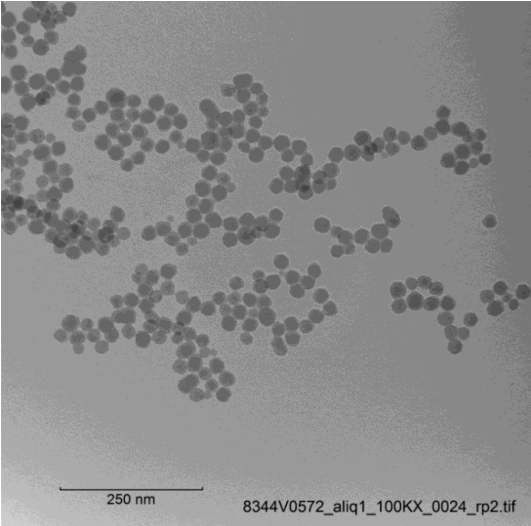


Figure 3: A TEM image of a colloidal nano SAS

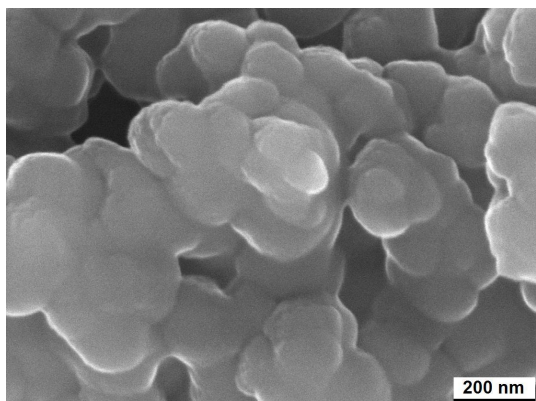


Figure 4: A SEM image of a precipitated bulk SAS

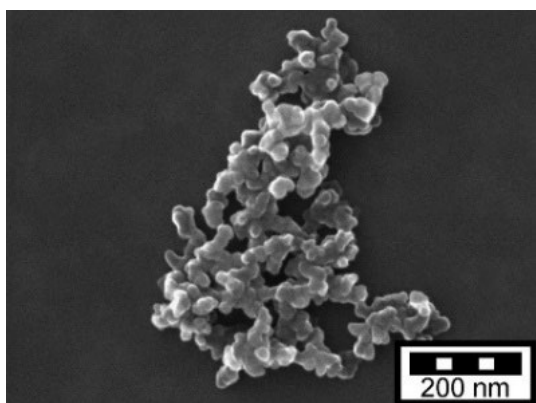


Figure 5: A SEM image of a fumed nano SAS

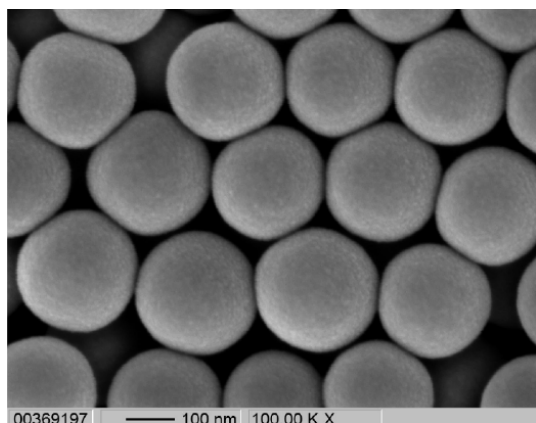


Figure 6: A SEM image of a colloidal bulk SAS