

**SASFORREACH Consortium**

**Information Letter 3**

**Aluminatesilicate (AS1), EC # 215-475-1, CAS # 1327-36-2**

**Dossier update 2023**

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 19<sup>th</sup> October 2023, the lead registrant BASF submitted on behalf of the joint submission an update of the joint registration dossier. The update introduced the NEW boundary composition for a nano form of Aluminatesilicate (AS1) including new study data and read-across justification.

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

- Nano-form of AS1
- Bulk-form AS1

Two forms of AS1 (bulk and nano) are currently part of the joint submission dossier.

Therefore, all registrants must check whether their member registration is referring to correct boundary composition for nano, bulk or both AS1 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 non-compliant 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 of the nano-form(s). In case of a nano-form, the reference to the new established NANO boundary composition must be included in the legal entity composition of the member dossier by submitting a member dossier update. 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 BULK boundary composition which has been changed with this update 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 bulk form of the registered substance.

No additional costs would be incurred for the time being, if member registrants still chose the bulk-form only. Member registrants of the nano-form may need to contribute to the costs of the dossier generation and additional studies which are done on nano AS1 to fulfill their registration obligations. This information will be available once the process has been completed and registrants have communicated their intention to register the nano-form to the Consortium.

**Obligation of each registrant**

Each registrant is responsible for registering the nanoforms that they manufacture or import themselves. Therefore, each registrant has the obligation to characterize the nanoforms to ensure that a specific hazard data set is provided for each nanoform.

The information required by REACH Annex VI, including the characterization of nanoforms, must always be submitted separately by each registrant in their IUCLID dossier.

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 nanoforms with the relevant Annex VII-X information in the lead dossier. This is done by referring to the corresponding boundary composition name 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**