



The REACH Boron Consortium, December 2020

Brief voluntary guidance to Co-registrants to complete their co-registration IUCLID dossiers

Following a successful update of the lead dossier for boron (231-151-2) in October 2020, the REACH Boron Consortium is now making available a “co-registrant template” to support subsequent updates of co-registrant dossiers when needed. This is an i6z IUCLID substance export file, with some pre-filled information in sections 1-3. There is a placeholder in section 13, where co-registrants of boron must provide their own Part A of the CSR, Part B having been submitted by the Lead Registrant.

Section 4-7 and 11, i.e. the details on physico-chemical, toxicological and ecotoxicological information and including *guidance on safe use* have been submitted “jointly” by the Lead Registrant on behalf of all members of the joint submission. These do not need to be included in co-registrants’ dossiers.

The i6z file has been generated with IUCLID 6, Version 4.14.2 and passed the latest technical completeness check rules for those sections where content is provided.

However, each co-registrant still needs to complete its own registration dossier with company specific information, such as the legal entity composition, analytical data and the recent tonnage data (estimated quantities), see below.

Please ensure that you run the latest validation assistant on your dossier and remedy any failure before submitting the dossier to ECHA!

IUCLID sections in Boron co-registrant template:

1.1

Pre-filled with the correct *reference substance* for the registration and “type of substance” and some trade names.

Co-registrant to change “Substance name” to appropriate name for their submission.

Co-Registrant to select own legal entity (replace “predefined legal entity”).

Co-Registrant to select its appropriate role in supply chain.

Co-Registrant to add its contact person details.

1.2

This section in the in the Co-registrant template contains five “Boundary compositions”. These are the SIEF/Consortium-agreed compositions that should cover the compositions of all individual registrants. There are separate boundary compositions for boron powder, boron in master-alloys and boron in ferro-alloys (powder and massive forms). Each Co-Registrant needs to create at least one record in this IUCLID section that gives his “legal entity composition”, which should fit within the corresponding boundary composition.

In practice, each co-registrant should create a copy of the boundary composition record that corresponds to its product, rename it, change the type of composition to “legal entity composition”, and amend individual constituents and/or impurities as appropriate to its own product.

Important: The lead dossier contains the hazard data, assessment and conclusions for the boundary compositions. If a co-registrant’s composition does not fit within the boundary composition of boron, it may have to conduct its own hazard assessment. For example, this could be the case if a product contains further constituents or impurities that are not included in the boundary

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composition and that may impact on the hazard conclusions. In such cases, please liaise with the Consortium secretariat.

1.3

Each Co-registrant to complete with own registration number.

1.4

Pre-selected the “No” for optical activity, **but each Co-Registrant must add its own analytical data to demonstrate substance identity, purity and quantification of impurities.**

1.5

Pre-filled with the name of the joint submission.

2.1

Agreed hazard classification already included (“not classified” for boron). Only to be changed by a Co-Registrant if its composition includes impurities (or additives) that change the classification.

2.3

The appropriate remark explaining why PBT is not required is already included.

3.2

Empty record fields for 2017, 2018, 2019 are already created for each Co-registrant to complete with its own tonnage data.

3.4 Information on mixtures

Pre-filled as per the lead dossier. Co-registrants should delete what is not appropriate for them (e.g. registrants of pure boron do not need to provide information here on boron in alloys).

3.5

Use section pre-completed with all identified *uses* identified and supported by the Consortium. These have been updated for the October 2020 update of the lead dossier to fulfil the latest technical completeness check rules. **Each Co-Reg should review the entries and delete those that do not apply to it.** The Uses submitted in the Co-registrant dossier must reflect only the Co-registrant’s uses of the substance.

13.1

Placeholder for own Part A of the CSR, to be prepared by each co-registrant.

Please feel free to contact the Consortium secretariat in case of need for further guidance.