

August 2025

Brief voluntary guidance to Co-registrants to complete their co-registration IULID files

Following a successful update of the lead dossier for boron in August 2025, the Boron Consortium provides a "co-registrant template" to support subsequent updates of co-registrant dossiers when these are needed. An i6z IUCLID substance export file is provided, with some pre-filled information in sections 1-3. There is also a placeholder in section 13, where co-registrants of boron need to provide their own Part A of the CSR, while Part B is 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 contained in the co-registration dossiers.

The i6z file has been generated with IUCLID 6, Version 8.13.3 and considered the latest technical completeness check rules for those sections where content is provided.

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

A useful guide to preparing your co-registrant dossier is available in ECHA's Manual on preparing registration dossiers:

https://echa.europa.eu/documents/10162/1804633/manual regis and ppord en.pdf

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". Co-registrant (CoReg) to:

- change "Substance name" to appropriate name for their submission
- select own legal entity (replace "predefined legal entity")
- select their appropriate role in supply chain
- add their contact person details.

1.2

This section in the in the CoReg template contains six "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 powders that are hazard classified because of the borate impurity, 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, the co-registrant may create a copy of the boundary composition record that corresponds to his product, rename it, change the type of composition to "legal entity composition", and amend individual constituents and/or impurities as appropriate to his own product.

Important: The lead dossier contains the hazard data, - assessment and -conclusions for the boundary compositions. Boron powders that are hazard classified because of the borate impurity are now covered in the lead dossier. If a co-registrants composition does not fit within the boundary composition of boron, he may have to conduct his 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 compositions 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 their own analytical data to demonstrate substance identity, purity and quantification of impurities.

1.5

Pre-filled the name of the joint submission.

2.1

Two agreed hazard classification already included ("not classified" for boron in boron alloys and pure boron powder, classified boron powder due to borate impurity). Only to be changed by a Co-Registrant, if their 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

Co-Reg to complete with their appropriate own data on tonnages.

3.4 Information on mixtures

Pre-filled as per the lead dossier. Co-registrants should delete what is not appropriate from 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 August 2025 update of the lead dossier to fulfil the latest technical completeness check rules. Uses are now linked to compositions, which is required to demonstrate that only some uses have been identified as relevant for the hazard classified boron powders. **Each Co-Reg to review the entries and delete the ones that do not apply to you.** The Uses submitted in your Co-Reg dossier must only reflect <u>your</u> uses of the substance.

13.1

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

For more detailed information on dossier preparation/registration, please refer to ECHA's Manuals: How to prepare Registration and PPORD dossiers, October 2024:

https://echa.europa.eu/documents/10162/1804633/manual regis and ppord en.pdf

Guidance on Registration, Version 4, August 2021:

 $\frac{\text{https://echa.europa.eu/documents/10162/23036412/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2}{\text{pb34-8680944372f2}}$