20 June 2024

Voluntary guidance for Co-registrants to assist in completing their co-registration IUCLID files

The Boron Consortium provides a "co-registrant template", which is an i6z IUCLID substance export file, with some pre-filled information in sections 1-3. The further sections 4-7, 11 and 13, i.e. including Guidance on Safe Use (GoSU) and the Chemical Safety Report (CSR), are submitted "jointly" by the lead registrant on behalf of all members of the joint submission. These do not need to be included in the co-registration dossiers. The GoSU is included in the i6z file in section 11 for you to download and retain for your use.

Note that ECHA periodically updates its technical completeness check (TCC), which includes an automated check upon submission of a dossier via REACH-IT, and more recently also an additional manual check.

The current Boron Consortium co-registration templates were created in June 2024 using IUCLID 6 version 7.0.7. The content provided by the Boron Consortium in this i6z passes the validation assistant (also checked with the latest IUCLID 6 version 8.0.2, build of 26/04/2024). You will need to ensure there are no TCC *failures* after you have completed the template and before you generate the dossier.

Actions for co-registrants:

Each co-registrant must 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), see below.

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

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

IUCLID sections in Boron Consortium co-registrant templates:

1.1

This section is pre-filled with the correct *reference substance* for the registration and "type of substance". The *reference substance* was originally taken from the EC inventory, but has been modified to include updated information. It is therefore recommended that co-registrants use the *reference substance* provided in this i6z file for their registration.

Co-registrant 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, and add their contact person details

1.2

This section in the co-registrant template contains the "Boundary Composition(s)". This is the SIEF/Consortium-agreed composition within which should fit all the compositions of the individual

registrants. 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 boundary composition.

Important: The lead dossier contains the hazard data, - assessment and -conclusions for the boundary composition. If a co-registrants composition does not fit within the boundary composition, the co-registrant may have to conduct their 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 composition and that may impact on the hazard conclusions.

Note that the dossier contains two boundary compositions for phosphorus, and two corresponding C&L entries (see 2.1 below).

If your registration for phosphorus is (only) for phosphorus imported in alloys, or produced during the manufacture of alloys, your legal entity composition should have phosphorus as the only constituent, with a typical concentration of 100% (and the concentration range also 100-100%).

1.3
Each Co-registrant to complete with their own ECHA (pre-)registration number or ECHA inquiry number as appropriate.

1.4
Boron Consortium has pre-selected the "No" for optical activity, **but each Co-Registrant must add their own analytical data for their substance to demonstrate substance identity, purity and quantification of impurities.**

1.5
Boron Consortium has already entered the name of the joint submission.

2.1
Boron Consortium agreed hazard classification conclusions are already included. Only to be changed by a Co-Registrant if their composition includes constituents, impurities (or additives) that change the hazard classification.

Note that the dossier contains two boundary compositions, and two corresponding C&L entries: one with the harmonised classification of phosphorus (Index No. 015-001-00-1) and one with the self-classification by the Consortium. The only difference is that the self-classification is more severe for Acute Oral Toxicity. Available study data in the dossier indicates that the classification should be Acute Tox 1 oral. The current harmonised classification (translated from the pre-CLP Dangerous Substances Directive) is Acute Tox 2.

2.3
The appropriate remark explaining why PBT is not required, is already included.

3.2

Each registrant to complete with its own tonnage data. It can be useful to include data for the last three years, since that data can be used to calculate the tonnage band of the registration. That said, to pass the TCC only one record referring to the current or previous year is required.

3.4

This information on mixtures is not mandatory, but included a suggestion for those registering phosphorus in alloys:

You may amend this for your own dossier, as appropriate, or delete.

3.5

The Uses Section contains **all** identified *uses* identified and supported by Boron Consortium. **Each Co-Reg must review the entries and delete the ones that do not apply to you.** The Uses submitted in your Co- Reg dossier must only reflect **your** Uses of the substance. Or in the case of an Only Representative, the EU uses of the supply chain of the non-EU company you represent.

11

The GoSU is included in the i6z file in section 11 for you to download and retain for your use. This does not need to be submitted by co-registrants, because it is submitted by the lead.

For more detailed information on dossier preparation/registration, please refer to ECHA's Manuals:
How to prepare Registration and PPORD dossiers, October 2023:
https://echa.europa.eu/documents/10162/1804633/manual_regis_and_ppord_en.pdf
Guidance on Registration, Version 4, August 2021:
https://echa.europa.eu/documents/10162/23036412/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2