

23 June 2023

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

The Iron Platform 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 Iron Platform co-registration templates were created in March 2023 using IUCLID 6 version 6.27.7, build of 24/02/2023 16:13. The content provided by the Iron Platform in this i6z passes the validation assistant. You will need to ensure there are no TCC *failures* after you have completed the template and before you generate the dossier.

The life-cycle information IUCLID section 3.5 was updated in June 2023 to ensure no TCC issues even with the very latest IUCLID 6 Version 7.0.4 and remains in line with current ECHA guidance.

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 Iron Platform 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 CoReg 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.

1.3

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

1.4

Iron Platform 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

Iron Platform has already entered the name of the joint submission.

2.1

Iron Platform 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.

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.

3.5

The Uses Section contains **all** identified *uses* identified and supported by Iron Platform. **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.

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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 2022:

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