August 2017

Requesting information on the manufacturing process of UVCB substances from non-EU manufacturers/suppliers

Background

Under the REACH and CLP regulations of the European Union, substances of “unknown or variable composition, complex reaction products or biological materials” (UVCB substances) are identified by, among other things, the description of the manufacturing process.

This description must be included in the respective IUCLID dossier for regulatory submissions to ECHA concerning:

- PPORD notification;
- Inquiry;
- Registration; and
- CLP notification

If you are an EU importer of a UVCB substance and you encounter difficulties getting hold of the information from the non-EU manufacturer/supplier, we recommend that you ask him to complete the **form below** and to return it to you. The information on the manufacturing process as requested in this form is usually sufficient.

Once you receive the duly completed form from the non-EU manufacturer/supplier, you will need to enter manually this information in the IUCLID dossier as follows:

- Type all the information on the manufacturing process in the "Description of composition" free text field of IUCLID Section 1.2.

- If the manufacturing process description includes figures, such as reaction schemes or process workflow, you must also attach these figures in the section under the "Attached description" heading of IUCLID Section 1.2.

If you submit a registration without sufficient information on the manufacturing process, your dossier will fail the technical completeness check undertaken by ECHA. You must therefore check that the non-EU manufacturer/supplier provided you with all the necessary elements of the manufacturing process before submitting your dossier.

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Form for reporting or requesting information on manufacturing process of UVCB substances

1. Identity of source material(s), reactant(s) or starting material(s) in terms of their chemical identifiers such as IUPAC name, EC/CAS number and as much information as possible on their composition (e.g. purity profile):

2. Ratio of source material(s), reactants(s) or starting material(s):

3. Description of the relevant manufacturing steps in the order they occur including any reaction step and extraction (e.g. fractionation and/or purification step). For each step the following should be specified:

- **the relevant process type (type of chemical reaction(s) or extraction(s) e.g. esterification/distillation)**

and

- **the operating parameters applied to that step (e.g. temperature, pressure, solvent, catalysis type…).**