Doc J removal - Instructions for applicants on data reporting in IUCLID

EFSA

CONTENTS

GENERAL INFORMATION

As of **IUCLID 6 Version 9**, the IUCLID document 'FLEXIBLE_RECORD.Manufacturer_EU_PPP' along with its field to provide the **Document J** attachment is no longer available for chemical active substance dossiers.

These instructions provide guidance to applicants on where in IUCLID to enter the data previously included in Document J.

All chemical active substance (a.s.) initial dossier submissions made after the release of IUCLID 6.9 must follow the updated data entry process in IUCLID, as outlined below. **Previously submitted dossiers will remain unchanged**, but any new submissions made after release of IUCLID 6.9, must comply with these updated requirements.

Important Note: Applicants must ensure that all information previously included in Document J is correctly reported in the designated IUCLID fields. Any attempt to attach Document J elsewhere should not be accepted by the RMS during the admissibility check. Also note that this change is only applicable to chemical active substance dossiers while for **microorganisms** this change will be implemented at a later stage.

Applicants should read these instructions in conjunction with the **Doc J - crosswalks.xlsx** mapping file, which provides additional guidance on where to enter specific data elements in IUCLID, and with the IUCLID Active Substance Applications Manual.

REQUIRED SECTIONS FOR DATA REPORTING

Applicants must enter data in the sections listed below. These instructions focus on describing the newly created fields and highlight some of the existing ones when particularly relevant in the context of removing Document J. Please note that the documents listed below should nonetheless be completed in full, as described in the IUCLID user manual.

Active substance dataset

- **Identity of the active substance and applicant**
- **Producer of the active substance**
- **Method of manufacture (synthesis pathway) of the active substance**
- **Specification of purity of the active substance (g/kg)**
- **Analytical profile of batches**
- **Analytical methods**
- **Impurities**
- **Batches and test material**

Product datasets

- **Identity of the plant protection product, trade name or proposed trade name, and applicant**

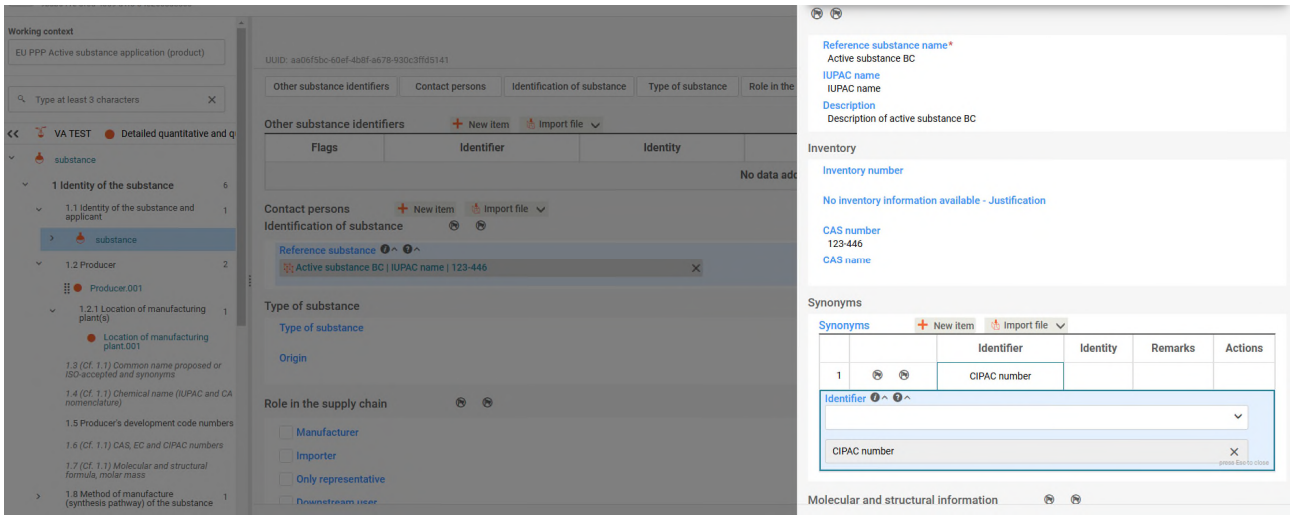
- **Producer of the plant protection product**
- **Detailed quantitative and qualitative information on the composition of the plant protection product**
- **Method of manufacture (synthesis pathway) of the plant protection product**

ACTIVE SUBSTANCE DATASET

IDENTITY OF THE ACTIVE SUBSTANCE AND APPLICANT

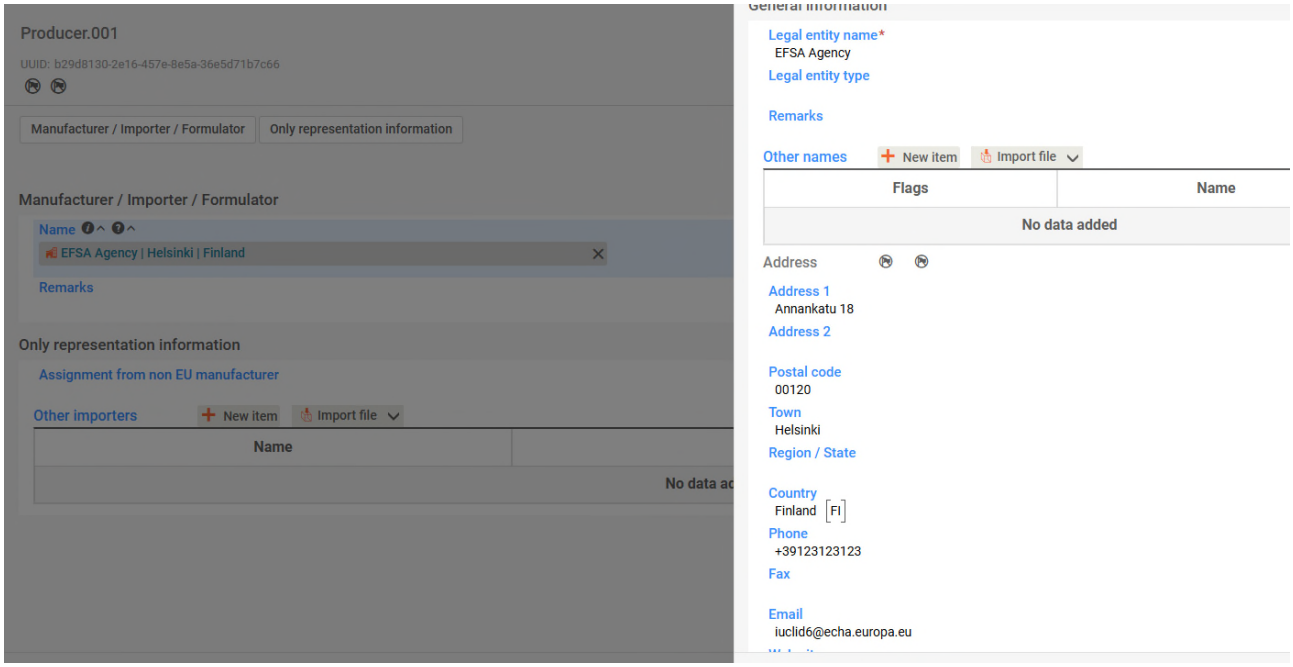
All relevant information on the identity of the active substance, such as chemical identifiers, and applicant (legal entity owner) must be provided in section *'1.1 Identity of the active substance and applicant'*.

All relevant chemical identifiers of the active substance such as the CAS number, EC number, IUPAC name, molecular and structural formula, SMILE, InChI, ISO common name, and CIPAC number must be provided in the REFERENCE_SUBSTANCE entity linked to the 'Reference substance' field.

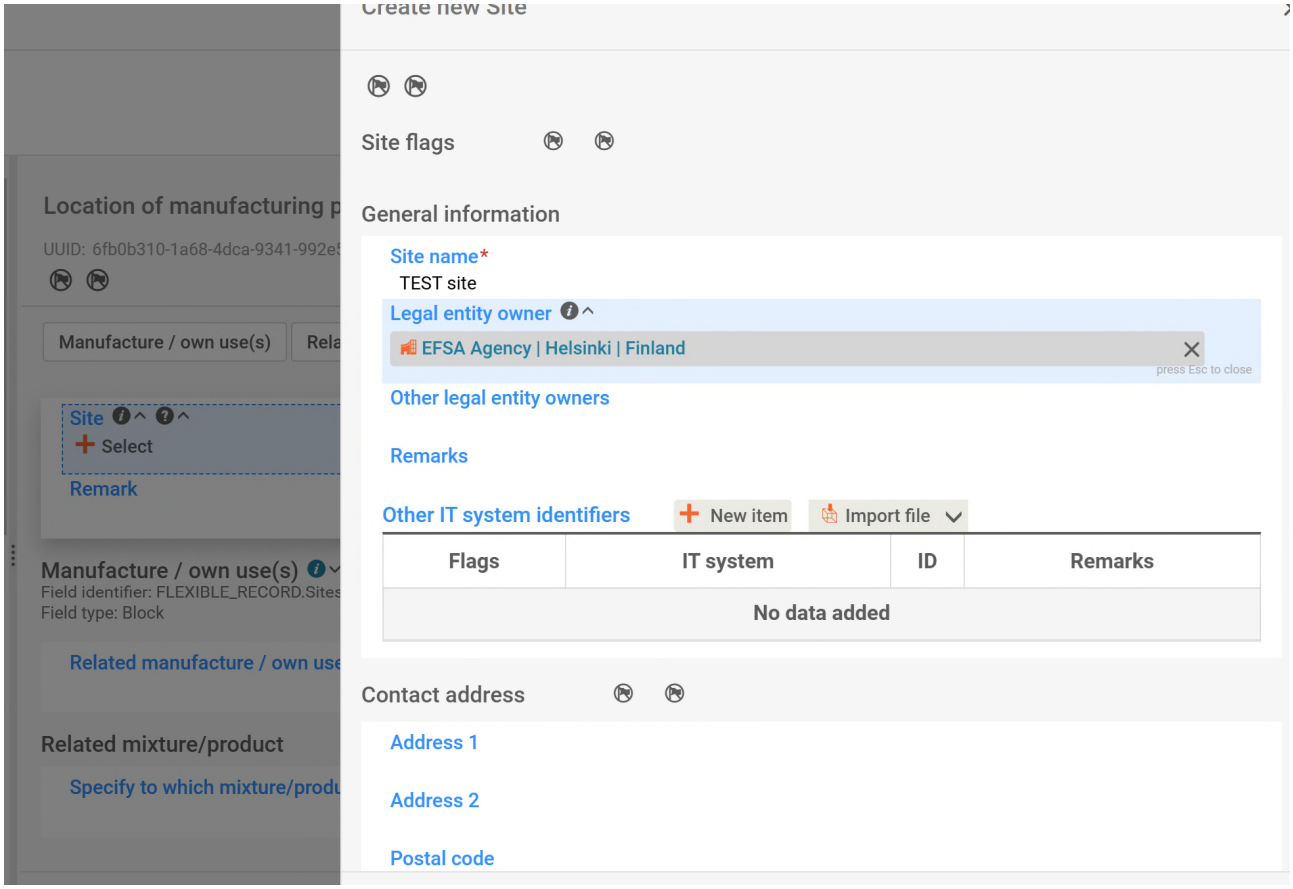


PRODUCER

The name, address and other contact information of the producer of the active substance must be provided in the FLEXIBLE_RECORD.Suppliers of section *'1.2 Producer'*, by referencing the LEGAL_ENTITY under the 'Name' field.



Detailed information on the location and contacts of each manufacturing plant (address, region, phone, email, etc) are to be provided in the FLEXIBLE_RECORD.Sites in section '1.2.1 Location of manufacturing plant(s)', by referencing a SITE entity in the 'Site' field.



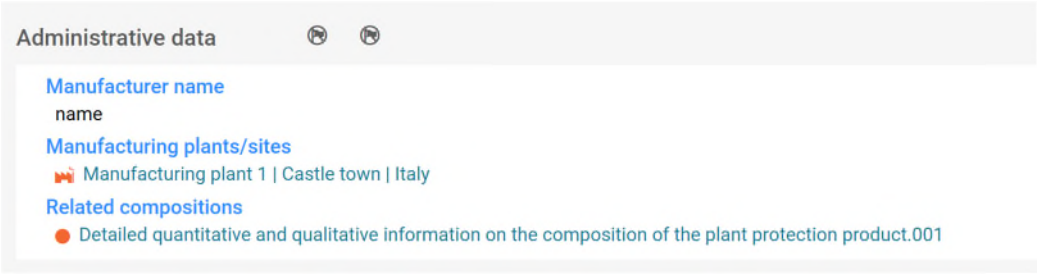
In case of more than one producer and/or manufacturing sites, a separate document for each of them must be created in these sections.

METHOD OF MANUFACTURE (SYNTHESIS PATHWAY) OF THE ACTIVE SUBSTANCE

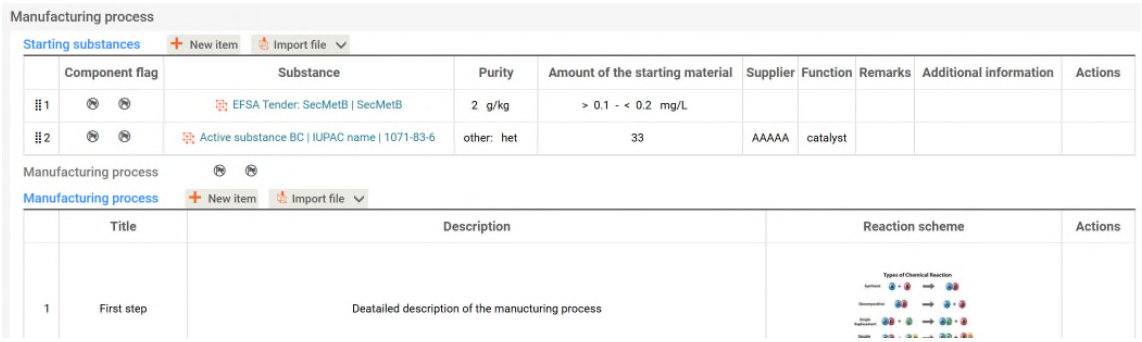
All information related with the manufacturing process must be reported in the document 'FLEXIBLE_RECORD.Manufacturer_EFSA' in section '1.8 Method of manufacture (synthesis pathway) of the active substance'. This document replaces the previous 'FLEXIBLE_RECORD.Manufacturer_EU_PPP' as of IUCLID 6.9.

This document includes three main blocks with structured fields that must be completed:

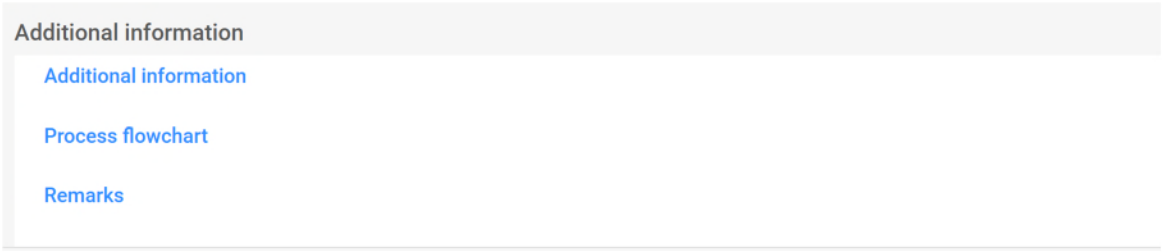
- **Administrative data** to report the manufacturer name and plants/sites. Multiple manufacturing plants/sites can be linked to the same manufacturing process. The related composition (result of the manufacturing process) should be linked here.



- **Manufacturing process:**
  - For each starting material a 'Reference substance' record should be created including all required identifiers (e.g. name, CAS number, structural formula). Purity and commercial availability of each starting material should be reported in the dedicated column of the 'starting substances' section.
  - A detailed description of the different steps of the production should be reported in the 'manufacturing process' section. The option to attach a reaction scheme (as an image) is available.



- **Additional information** to provide any additional information related to the manufacturing process. The process flowchart can be attached in this section.



N.B. One document per manufacturing process must be created. **If multiple manufacturing processes need to be reported, a dedicated document must be created for each manufacturing process.**

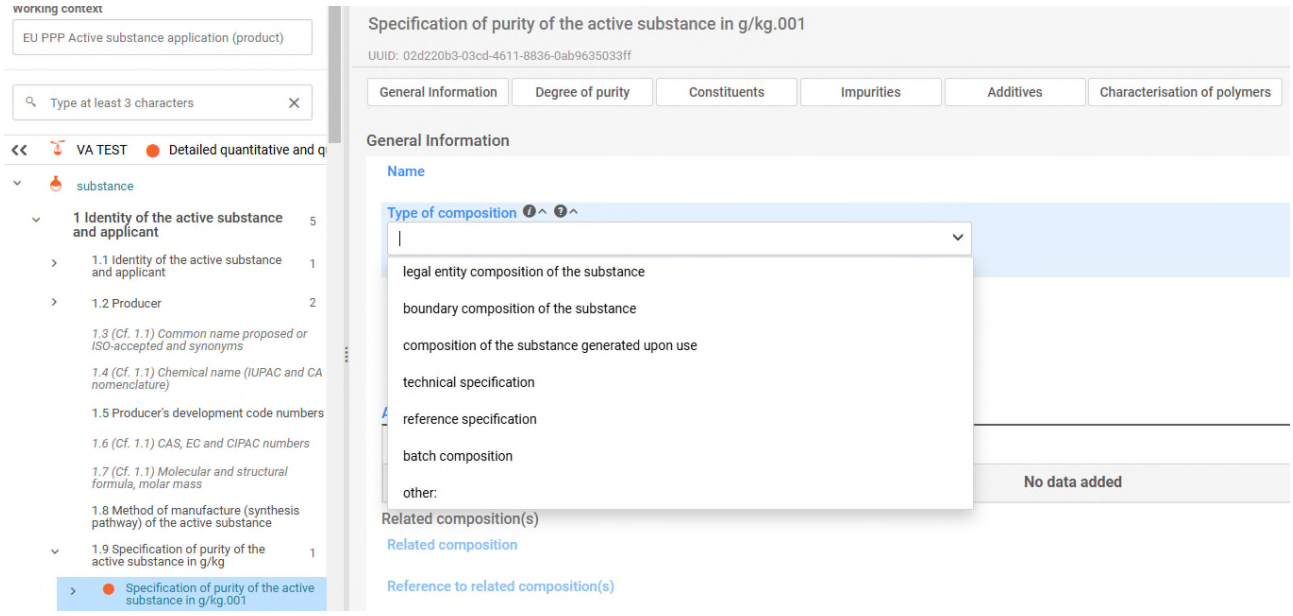
SPECIFICATION OF PURITY OF THE ACTIVE SUBSTANCE (G/KG)

The 'FLEXIBLE_RECORD.SubstanceComposition' document in section '1.9 Specification of purity of the active substance in g/kg' should be used to report the technical specification(s), the reference specification(s) and each batch composition used in the batch analysis (minimum 5 representative batches). As of IUCLID 6.9, the following three picklist values applicable to pesticides are available in the 'Type of composition' field:

- **Batch composition** to be used to report the composition of individual batches which are part of the analysis of the representative batches
- **Technical specification** to be used to report the proposed specification based on batch data and supporting data (if any) for a particular manufacturing site
- **Reference specification** to be used to report the (proposed) reference specification (e.g. agreed at the first Approval and to be maintained also for the renewal procedure or proposed reference specification in case of a new active substance)

Note: For active substances manufactured as technical concentrates, separate documents should be created with the relevant type of composition (e.g. "technical specification") to report the composition of the technical concentrate and composition in the theoretical dry weight material.

To provide the reference specification of the previous assessment, if available to the applicant, a document with the type of composition "Reference specification" should be created. In this document the applicant should indicate where the reference specification is located e.g. DAR/Month/Year in the 'Description' field.



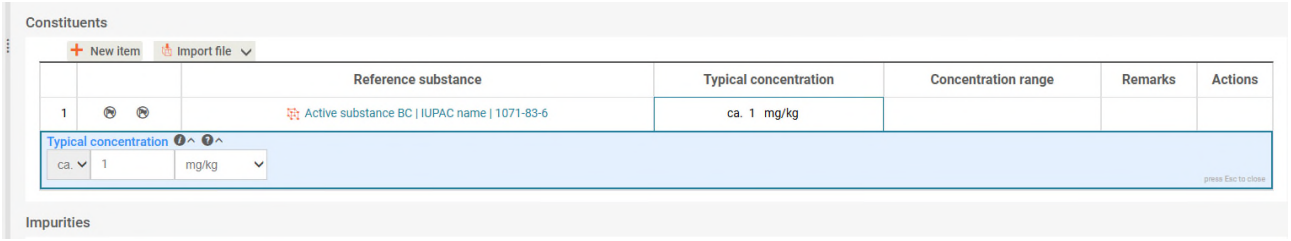
The minimum purity of the active substance is to be reported in the 'Degree of purity' field.

For each 'Type of composition' (i.e. batch composition, proposed (technical) specification and reference specification) the designated table sections 'constituents', 'impurities' and 'additives' must be completed:

Constituents: to report the identity and the content of the active substance in the composition. It is a repeatable block which allows the reporting of more than one constituent of the active substance if needed (e.g. in case the active substance is a defined mixture of two isomers).

Note: When the type of composition is 'Technical' or 'Reference specification', the (proposed) minimum content of the active substance in the technical material should be reported in the field 'Typical concentration'.

In case of technical concentrate, the minimum and maximum content of the active substance in the technical concentrate should be reported in the 'Concentration range' field. For 'Batch composition' in the field 'Typical concentration' the measured amount of the active substance in the relevant (individual) batches is to be reported.



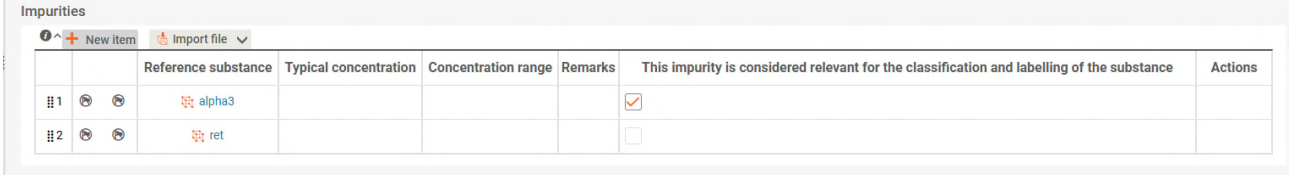
The 'Remarks' field should be used to report any additional information on the specification of purity of the active substance as manufactured.

Impurities: to report the identity and the content of each impurity in the composition.

Note: When the Type of composition is 'Technical' and 'Reference specification' the (proposed) maximum content of the impurities in the technical material or technical concentrate should be

reported in the 'Typical concentration' field. For "batch composition" the measured amount of the impurities in the relevant (individual) batches should be reported in the 'Typical concentration' field.

The checkbox 'This impurity is considered relevant for the classification and labelling of the substance' should be used to indicate that the impurity has an impact on the classification and labelling of the substance.


Impurities

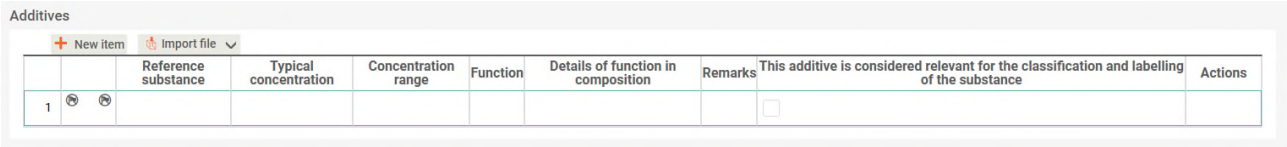
New item | Import file

		Reference substance	Typical concentration	Concentration range	Remarks	This impurity is considered relevant for the classification and labelling of the substance	Actions
1		alpha3				☑	
2		ret				☐	

All impurities reported in this document should also be included in the 'Impurities' document in which more details on the impurities e.g. type of impurities (e.g. significant, relevant, etc), origin, etc can be provided (see dedicated paragraph below)**.**

Additives: to report the identity and the content of Additives in the composition. This is a repeatable block subsection which enables the applicant to provide details on all additives (if more than one) of the active substance as manufactured.

Use the 'Concentration range' field to report the minimum and maximum content of each additive in the technical and/or reference specification type of composition, and use "Typical concentration" to report the exact measured value for the "batch composition" if applicable.


Additives

New item | Import file

		Reference substance	Typical concentration	Concentration range	Function	Details of function in composition	Remarks	This additive is considered relevant for the classification and labelling of the substance	Actions
1								☐	

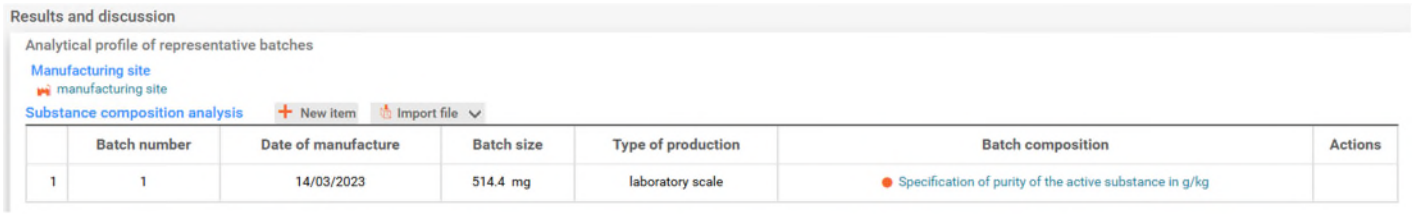
ANALYTICAL PROFILE OF BATCHES

As of IUCLID 6.9, two types of documents should be created under section '1.11 Analytical profile of batches':

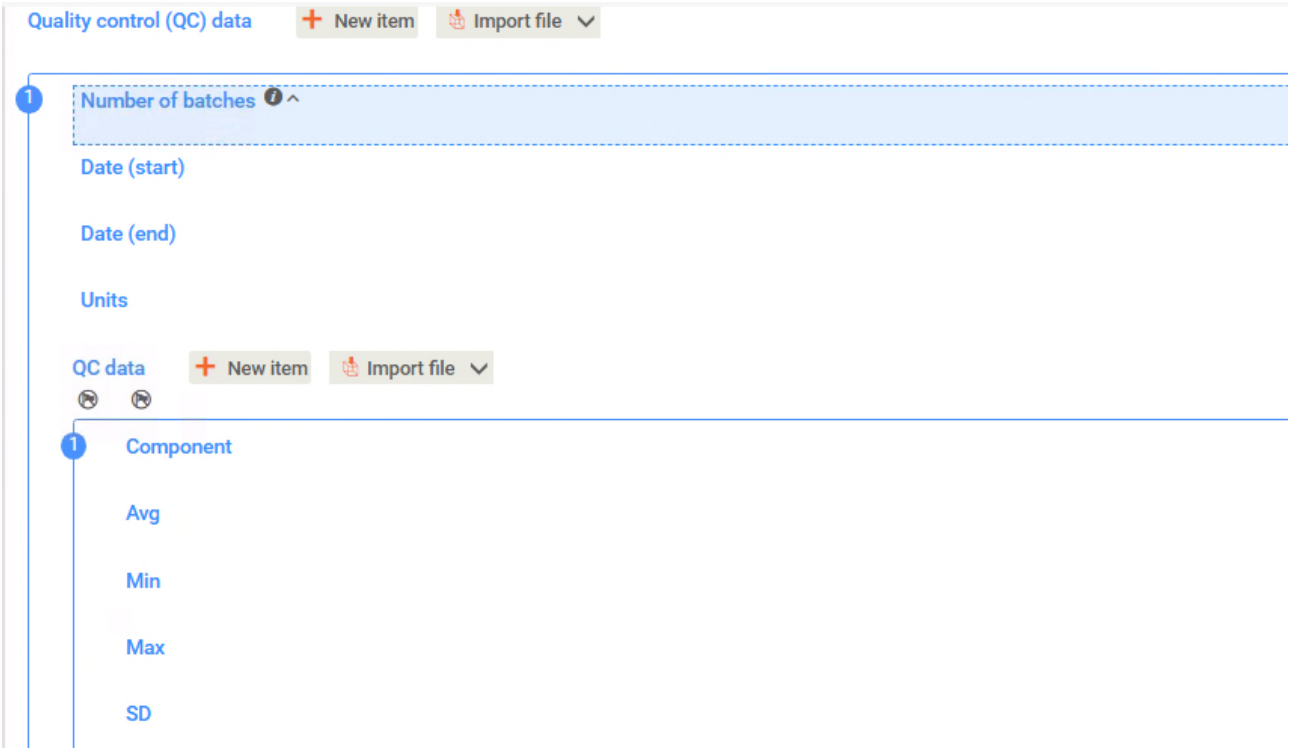
- **An endpoint study record ('ENDPOINT_STUDY_RECORD.AnalyticalProfileOfBatches') for each manufacturing plant and/or for each 5-batch analysis (5BA)**.
  All standard fields common to endpoint study records should be dully completed, including the data source linking the study report.

  Importantly, the 'Results and discussion' > 'Analytical profile of representative batches' section should be fully completed, including:

  - Link to the Manufacturing site entity, including address, contact details, etc.
  - One entry per batch within the repeatable table 'Substance composition analysis', provifding all the batchspecific data and linking the corresponding 'Substance composition' document for the batch (type = 'batch composition') as described in section 1.9



- Quality control (QC) data for the same manufacturing site, including quantitative information for each of the analysed substances (average, min, max, SD). More than one quality control dataset can be provided, if applicable.

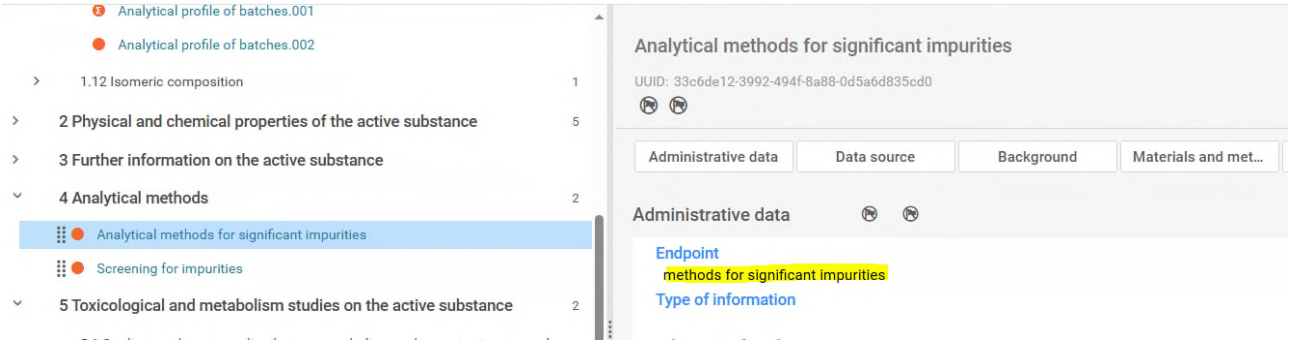


- Link to the 'Substance composition' document for the proposed technical specification (type = "technical specification", see section 1.9) derived from the batch analysis and QC data reported in this document

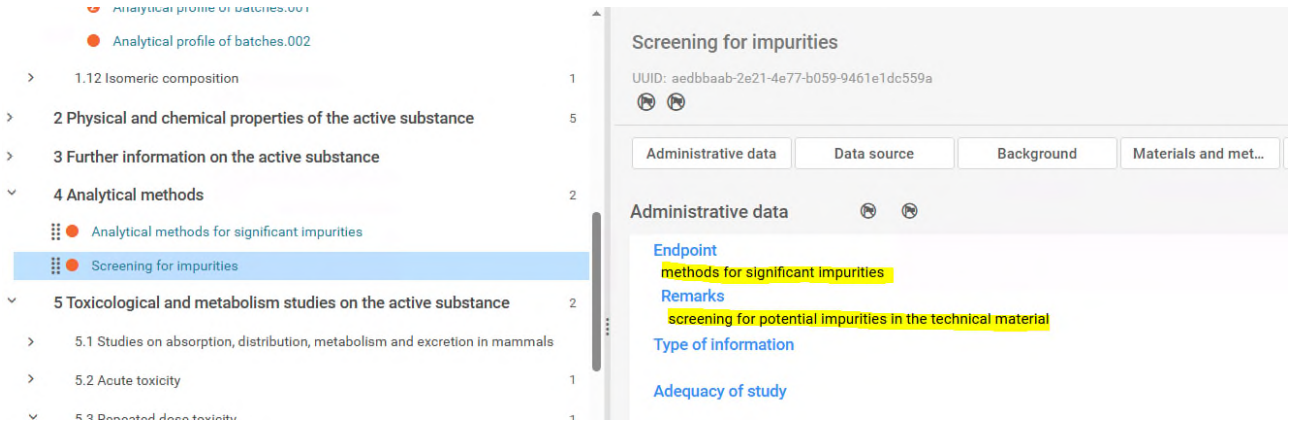
- **An endpoint summary (ENDPOINT_SUMMARY.AnalyticalProfileOfBatches) to collect the outcome of all the 5BAs submitted for the active substance**, to sum up all the technical aspects and lead to a conclusion on the specifications. All relevant endpoint study records detailing the 5-batch analysis must be linked in the dedicated field 'Link to relevant study record(s)' of the endpoint summary.

ANALYTICAL METHODS

In order to facilitate further extraction of the analytical method(s) related to analysis of the impurities (other than relevant impurities) in a Confidential report[1] all analytical methods for significant impurities must have 'Methods for significant impurities' in the 'Endpoint' field as shown below.



To report studies on the screening for impurities, applicants should also use Section 4 Analytical methods, with the same Endpoint = 'Methods for significant impurities', clarifying in the Remarks that the study is a screening.



The documents should be duly filled in, including all the dedicated structured fields for the Materials and methods and Results sections, as described in the IUCLID manual.

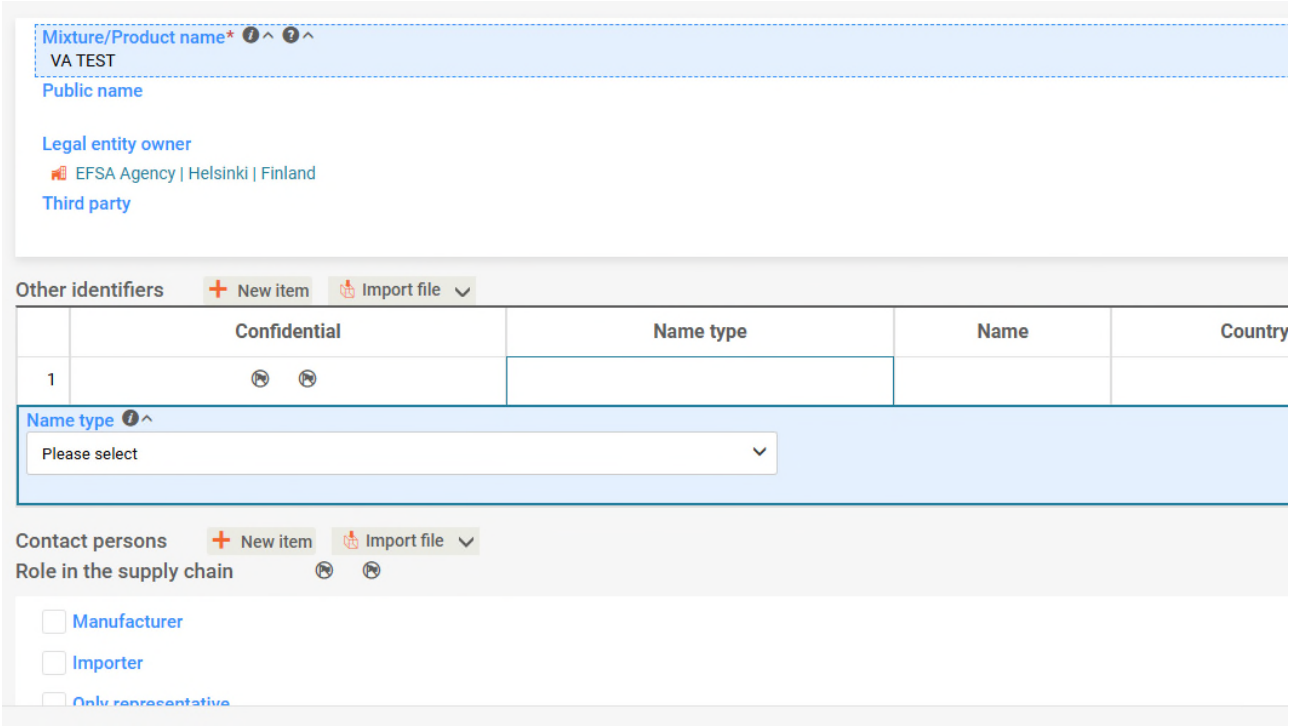
[1] To replace Document J

PRODUCT DATASET

This section refers both to the main/representative product and to any other representative product(s) that the applicant may have included in the dossier (Section 1.4.5 "Other Representative Products").

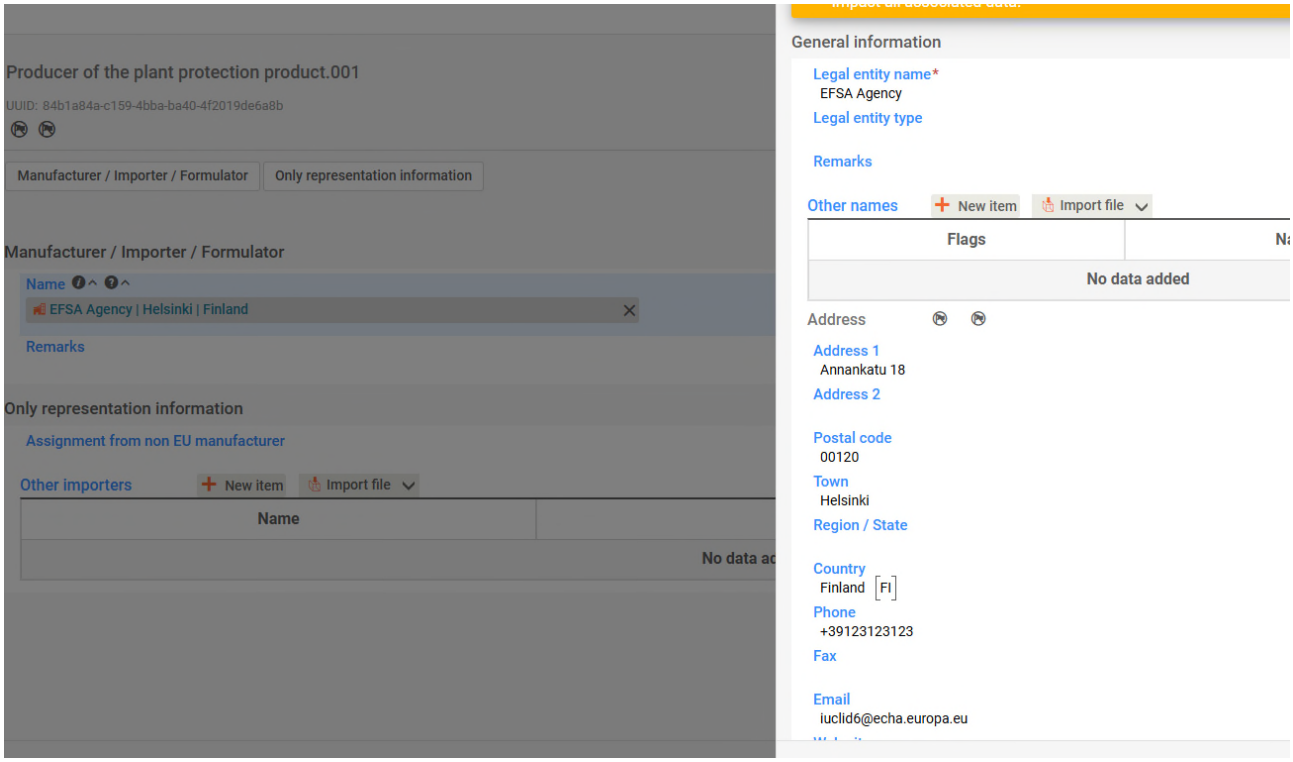
IDENTITY OF THE PLANT PROTECTION PRODUCT, TRADE NAME OR PROPOSED TRADE NAME, AND APPLICANT

This document must be completed to report information on the Legal Entity owner and contact person for the plant protection product. The trade name or proposed trade name and producer's development code number of the plant protection product can also be provided.

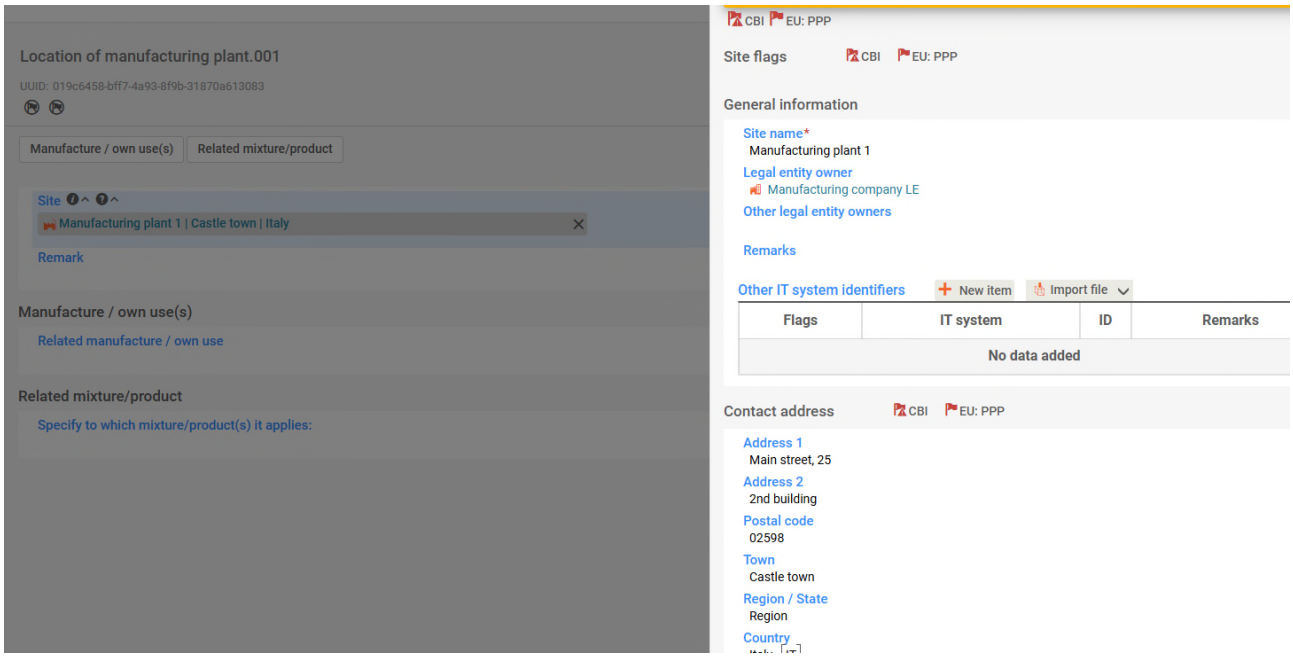


PRODUCER OF THE PLANT PROTECTION PRODUCT

Information on the producer of the plant protection product, including contact details of the supplier must be provided in this document.

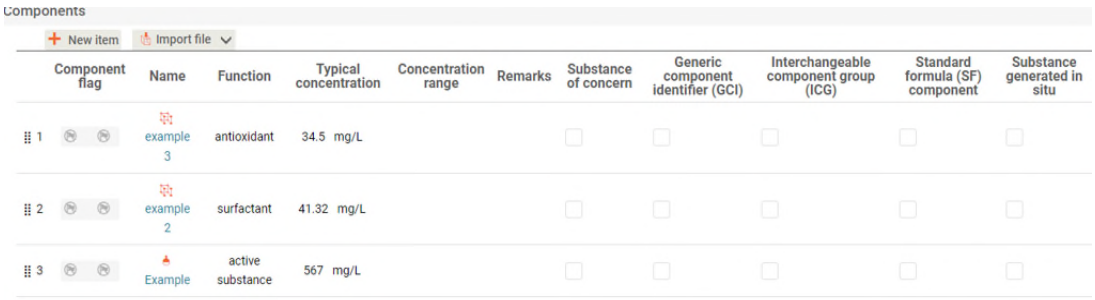


Whereas information on the manufacturing plant of the plant protection product must be provided in the 'Location of manufacturing plant' document.



DETAILED QUANTITATIVE AND QUALITATIVE INFORMATION ON THE COMPOSITION OF THE PLANT PROTECTION PRODUCT

The full composition of the plant protection product as laid down in the applicable data requirements must be provided in this document, including information on co-formulants and relevant impurities.


Components

New item | Import file

	Component flag	Name	Function	Typical concentration	Concentration range	Remarks	Substance of concern	Generic component identifier (GCI)	Interchangeable component group (ICG)	Standard formula (SF) component	Substance generated in situ
1		example 3	antioxidant	34.5 mg/L							
2		example 2	surfactant	41.32 mg/L							
3		Example	active substance	567 mg/L							

Any Safety Data Sheets (SDS) related to co-formulants should be provided and included in the FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP Document (section 13)

METHOD OF MANUFACTURE (SYNTHESIS PATHWAY) OF THE PLANT PROTECTION PRODUCT

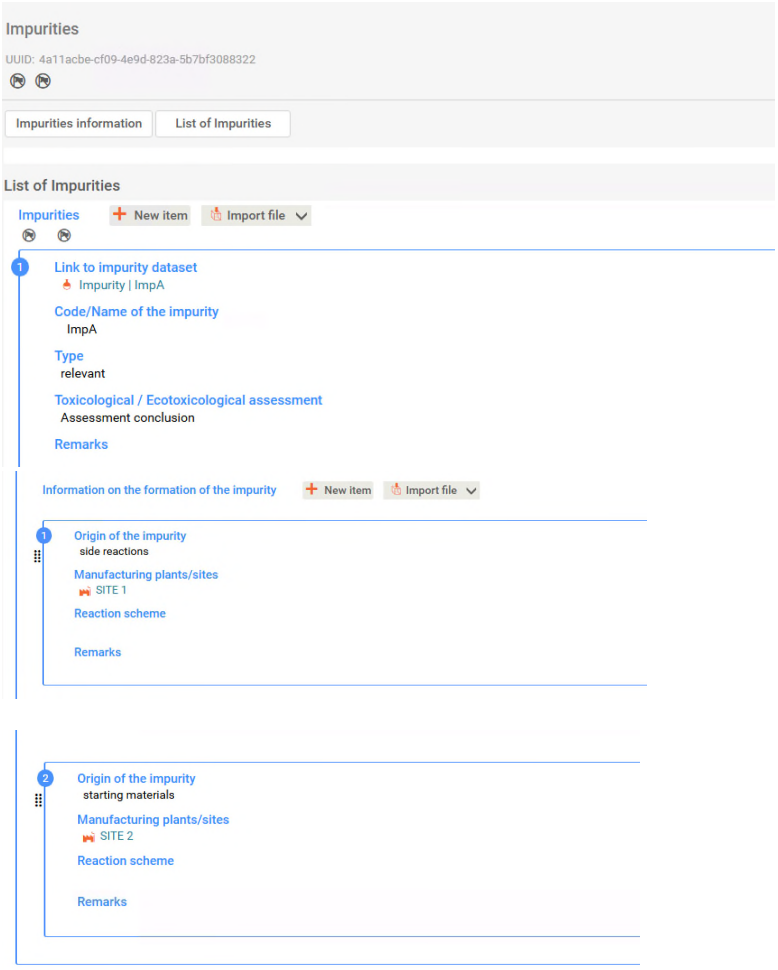
The FLEXIBLE_RECORD.Manufacturer_EFSA (introduced in IUCLID 6.9) must be used for providing detailed information on each step in the manufacturing process of the plant protection product, including the reaction schema. The related composition of the plant protection product must be provided in section 1.4 (as described in the above paragraph) and referenced in the 'Related compositions' field of this document.

IMPURITIES

Relevant information on all impurities of the active substance must be included in this document including:

- A link to the impurity data:
  - If no studies for the impurity are to be reported, a Reference substance entity must be created including all required chemical identifiers (e.g. name, CAS number, molecular and structural formula, SMILES, etc)
  - If studies for the impurity are to be reported, a substance dataset must be created, including i) the Reference substance entity with all required chemical identifiers (e.g. name, CAS number, molecular and structural formula, SMILES, etc), and ii) all relevant studies performed with the impurity
- The type of the impurity, i.e. significant, relevant, non-significant or theoretical

- A high-level toxicological and ecotoxicological assessment and conclusion for the impurity (introduced in IUCLID 6.9)
- Details on the origin of the impurity, including the link to the Manufacturing plant and an image of the chemical reaction, if available. The link to the Manufacturing plant is key to connecting the impurity to the corresponding manufacturing process and batch analysis information. If the impurity has different origins at different manufacturing processes, more than one entry should be created in the repeatable block.

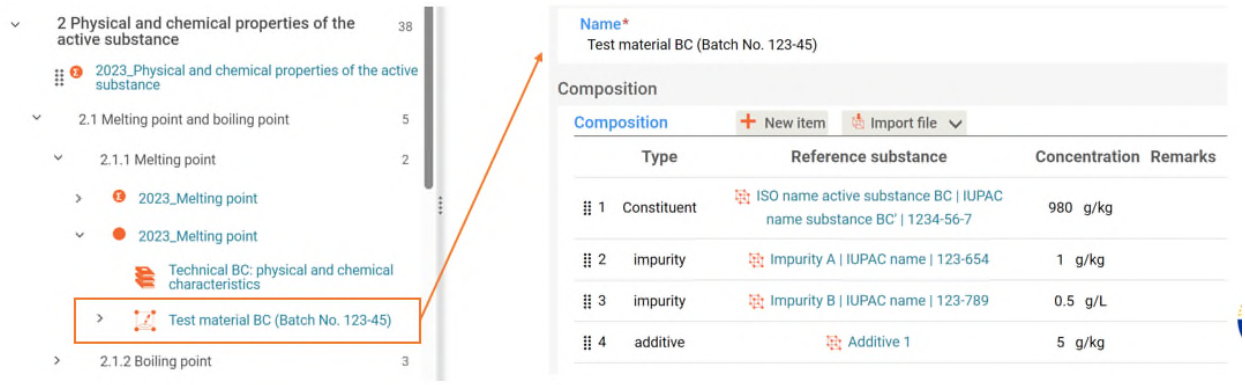


Relevant, significant, and non-significant impurities (if applicable) reported within this document should correspond to the impurities listed in the 1.9 Specification of purity of the active substance.

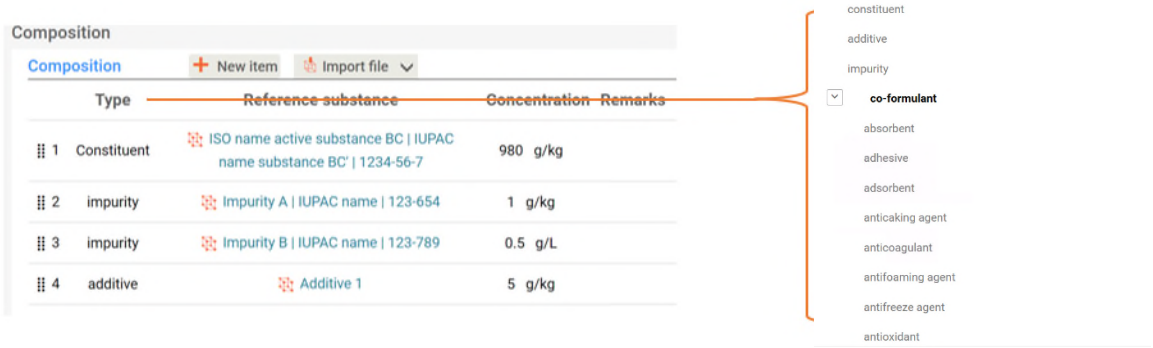
Relevant impurities should also be part of the product composition in section 1.4

TEST MATERIALS

Each study submitted for the active substance and the formulation must include a reference to a duly completed **TEST_MATERIAL_INFORMATION** document, including the identity and content of all components of the test material. These can be constituents (e.g. the active substance, a metabolite), impurities, additives, and co-formulants (for the formulation).



In the case of co-formulants, safeners and synergists, from IUCLID 6.9 the specific function must be selected from the 'Type' picklist, as shown below.



Duly completing the TEST_MATERIAL_INFORMATION documents will be key in order to aggregate and compare the compositions of i) the batches used in toxicological and ecotoxicological studies and the proposed technical / reference specification of the active substance, and ii) the formulations used in studies and the formulation for representative uses.