Online dossier creation in REACH-IT: required information sheet

Conditions

- Initial dossier
- Member of a joint submission
- Substance defined by one composition
- You do not intend to opt out and provide your own study records or the study summaries are not provided by the lead
- You do not intend to report more than one classification and labelling that differs from the one provided by the lead
- You are not involved in a data-sharing dispute for this substance
- You do not intend to submit a 1 to 10 tonnes registration dossier with physicochemical requirements only
- You are not involved in any legal entity change due to a merger in REACH-IT
Minimum required information in a member dossier

1. Main constituents

Know if your substance is a well-defined substance (mono or multi-constituent) or a UVCB.

- If your substance is a well-defined substance you need:
  - Molecular formula, molecular weight and structural formula
- If your substance is UVCB you need:
  - Molecular formula, molecular weight

2. Trade name and analytical information

You need:
- Analytical information to cover at least one quantification and one identification approach
- Analysis type (e.g. chromatography – GC, chromatography – HPLC, MS, NMR, UV/Vis, etc.) of the quantification and of the identification approach
- Either the methods or results must be attached. In case the result is not determined, a justification is needed clearly stating the reasons for not providing the information

3. Substance composition

You need:
- Degree of purity
- Concentration range of your constituent
- In case of using stabilisers:
  - Identity of the stabiliser
  - Structural formula
  - Molecular formula
  - Molecular weight
  - Concentration range
  - Function (antioxidant, inhibitor, UV absorber, other)
- In case of impurities:
  - Identity of the impurity
  - Structural formula
  - Molecular formula
  - Molecular weight
  - Concentration range

4. Supply chain

You need to provide your role in the supply chain (manufacturer, importer, only representative or downstream user).

If you are a manufacturer, you need to indicate the details of your production site:
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- Site name
- Address

5. Administrative information

You need:

- Tonnage band you want to register (standard requirements, on-site isolated intermediates or transported isolated intermediates)
- Phase-in status of the substance

6. Classification and labelling inventory

If you do not agree with the classification and labelling provided by the lead of the joint submission, you need to indicate your own.

7. Uses

Bring your uses. Depending on the kind of use you are reporting, you need to submit different information. At least one contributing activity/technique for the environment and one contributing activity/technique for workers must be provided for each use.

Use maps can help you to describe the uses in a standardised way based on the information from downstream user sectors.

More

8. Advised against uses

If you have identified advised against uses, you should add a record for each one in the corresponding life cycle stage subsections.

9. Use information

You need:

- Information on the tonnage manufactured, imported and used in as such or in articles that are subject to registration per calendar year
- Information on mixtures including the substance which is subject to registration

10. Assessment reports

- Bring your chemical safety report (CSR), if you are registering more than 10 tonnes per year and the lead registrant is not providing it on your behalf. In cases where the lead is not providing the report on your behalf, you need to:
  - Provide your own PBT assessment
  - Make sure that the chemical safety report
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- is referred to your company
- is related to the composition of your own substance
- includes tonnage information in case your company has the role of manufacturer
- reflects your own uses

For joint submissions, the guidance on safe use can be provided jointly by the lead registrant on behalf of all members, or by each member individually. If you wish to provide your own guidance on safe use, you will need:
- First-aid measures
- Fire-fighting measures
- Accidental release measures
- Information on handling and storage

Additionally, if you are providing your own guidance on safe use and if the chemical safety report is not needed, you will need:
- Exposure controls and personal protection
- Stability and reactivity
- Disposal considerations

11. Confidentiality claims

If you are planning to claim a part of your dossier confidential, you need to provide a justification. There is help in the tool explaining how to do it.

12. Contact person

We need the contact details of the person that will be responsible for following up the dossier.