

## Registration guidance for intermediates

REACH defines intermediates as substances which is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. Three types of intermediates are involved in REACH, included: non-isolated intermediates, on-site isolated intermediates and transported isolated intermediates.

### Intermediates

NON-ISOLATED INTERMEDIATES: Intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, or pipe work for transfer from one vessel to another place, but it **excludes** tanks or other vessels in which the substance(s) are stored after the manufacture.

ON-SITE ISOLATED INTERMEDIATES: Intermediate that is not classify as a non-isolated intermediate and where the manufacture process of the intermediate takes place on the same site. (A site means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.)

TRANSPORTED ISOLATED INTERMEDIATES: Intermediates that are not classifies as a non-isolated intermediate and transported between or supplied to other sites. Lifecycle of an isolated intermediate start from the substance manufacture and ends with the use of the substance in the mixture process for the manufacture of another substance.

Residues of the isolated intermediate: If the substance disposed of as waste and not recycled as a non-isolated or isolated intermediate, they are not in the scope of REACH. However, if the residues of the intermediate are found in the mixture substance, they are defined as an impurity.

### Task and obligations

1. NON-ISOLATED INTERMEDIATES: There are **no obligations** for the use of a substance under REACH
2. ON-SITE ISOLATED INTERMEDIATES: A manufacturer has to do the registration if the on-site isolated intermediates in quantity of 1 ton or more per year and to submit the information for standard registration purposes.
  - **Registration obligations** - An on-site intermediate will be defined as a standard substance if it is a monomer used for polymerization. A full data package is required according to the tonnage level if the substance is not strictly controlled.
  - **Exemptions** - If the substance is manufactured and used under strictly controlled condition and a full study report is available, the manufacturer only submit a study summaries and the **substance intrinsic properties information can be reduced**. If the manufacturer/importer had submitted a notification under Directive



67/548/EEC covering the relevant use, registration is not required.

- **Classification and labeling** - If an on-site isolated intermediate is a phase-in substance that will be put on the market and it has not been registered, the manufacturer must notify ECHA the information related to its classification and labeling. If the substance is classified as dangerous, even if the substances are less than one tonne per year, the manufacturer must notify ECHA the information related to its classification and labeling. The deadline for above actions is 1 December 2010 for substances already on the market. If the substance is not yet on the market on the date, then notification must be done before putting on the market.
  - **Dossier and substance evaluation** - Evaluation of dossier and substance do not apply for on-site isolated intermediates.
  - **Authorization/Restriction** - Authorization does not apply on intermediates. It includes the intermediates used as monomers for the mixture of polymers. However, downstream user must check if it is covered by any restriction in Annex XVII of REACH.
3. TRANSPORTED ISOLATED INTERMEDIATES: The information that manufacturer or importer has to be submitted for standard registration also referred to *Article 10 and Section 1.8.1 of the Guidance on Registration*.
- **Registration obligations** - The quantity for transported isolated intermediates may be larger than on-site intermediates. If the annual quantity of substance is over 1000 tonnes, the substance intrinsic properties must be included. A full data package is required according to the tonnage level if the substance is not strictly controlled.
  - **Exemptions** - A reduction of registration information can be submitted if the substances are strictly controlled. If the substance is manufactured and used under strictly controlled condition, the usage is less than 1000 tonnes per year and a full study report is available, the manufacturer only submit a study summaries and the substance intrinsic properties information can be reduced.
  - **Classification and labeling** - Same as on-site intermediates
  - **Dossier and substance evaluation** - Evaluation of dossier and substance apply to transported isolated intermediates. Manufacturer or importer may be requested to submit additional information during evaluation process.
  - **Authorization/Restriction** - Same as on-site intermediates



## Registration of isolated intermediates

Isolated intermediates (on-site as well as transported intermediates) are within the scope of REACH although specific requirements apply for their registration. Same as other substances, the tonnage of intermediates for manufacturer or transported over 1 tonne are within the scope of REACH. If the intermediates are not under strictly controlled, a "standard" registration dossier has to be submitted by registrant. It should be noted, though, that monomers used as on-site isolated intermediates or transported isolated intermediates are not exempted from standard registration requirements allowed for intermediates and have to be registered

### **Example 1** Tonnage to consider for the registration dossier of a substance both used as isolated intermediate and non-intermediate

A company manufactures 2300 tonnes of substance A, of which 1700 tonnes are used as intermediate in strictly controlled conditions. This company will submit a standard registration dossier for substance A, where the volume of the remaining 600 tonnes not used as intermediate is used to determine the information requirements. This means that the information requirements for 100-1000t substances will be used as a basis for this standard dossier. The fact that the substance is also used as an intermediate should be indicated in the dossier and the volume of 1700 tonnes used as intermediates will need to be documented in the dossier.

The data requirements for the registration of isolated intermediates manufactured in quantities of 1 tonne or more per year **depend on whether they are transported or not**. For transported intermediates, those requirements depend on the volume manufactured or imported. Compared to the data requirements for the registration of a "standard" substance, there are reduced information requirements for isolated intermediates, as long as the registrant confirms that strictly controlled conditions are applied during manufacture and use of the substance on-site but also, in case of transported intermediates, that he has received confirmation from the user that strictly controlled conditions are applied on other sites.

**On-site isolated intermediates**, registrant shall gather all existing available information on physicochemical, human health or environmental properties of the substance for which he submits a registration dossier.

**Transported isolated intermediates** need to be submitted as same as on-site isolated intermediates. Besides, the registrant needs to submit additional information if the tonnage over 1000 tonnes per year.

In order to know what kinds of dossier have to submit, the registrant should determine the substance is isolated intermediate or not, on-site isolated or transported isolated, and is the intermediate **under strictly controlled conditions**.



### **Strictly controlled conditions**

Registrants can provide a reduced set of information if the substance is in strictly controlled conditions. A reduced set of information can be provided if: **On-site isolated intermediates** - The substance are confirmed as manufactured only and used under strictly controlled condition in that it is rigorously contained by technical means during its whole lifecycle. **Transported isolated intermediates** - A confirmation from the downstream user that the mixture of other substance from that intermediate that will take place on other sites under strictly controlled conditions. It is also apply to the manufacturer outside EU. The registrants should assess the intermediates are treated under strictly controlled conditions on the site or not. It can be reported during filling the registration dossier at IUCLID 5.

For both isolated intermediate, there is no need to include the explanation of the strictly controlled condition in the registration, but the assessment of the use of intermediate should be documented within a company in case there is a request from ECHA. The contents of document should include justification for the assignment of use as an intermediate to the substance. Customers' statement includes for transported isolated. Second is the relevant operating condition. Third is the risk management measures implemented in the company and recommended to external customers. Forth is the corresponding exposure considerations. The last is reference or derivation of any relevant threshold value, the relevant physicochemical, toxicological and ecotoxicological data, and the data from substance grouping. The registration dossier should also include the details of the risk management measures applied and recommended to the user. Actually, it reflects the strictly controlled conditions. The registrants can use the existing legislative frameworks or industry standards.

### **Registration requirements for on-site isolated intermediates**

- The identity of the manufacturer or importer (section 8.2.2.3 of the [Guidance on registration](#)).
- The identity of the intermediate (section 8.2.2.3 of the [Guidance on registration](#)), but analytical methods descriptions is **not** required.
- The classification of the intermediate (section 8.2.2.4 of the [Guidance on registration](#)).
- The information on physicochemical, human health or environmental properties of the intermediate. (Section 8.2.2.6 of the [Guidance on registration](#)).
- A brief general description of the use. (Section 8.2.2.5 of the [Guidance on registration](#)).
- Details of the risk management measures applied and recommended to the user. (Section 8.2.2.3 of the [Guidance on registration](#) and section 8.2.2.5 of the [Guidance on registration](#)).

If it is not strictly controlled, a full registration is required according to Article 10 of the Regulation.

### **Registration requirements for transported isolated intermediates**

It divided into two classes, **1 to 1000 tonnes per year** and **over 1000 tonnes per year**.

- 1 to 1000 tonnes per year requires registrants to submit the following information. It is same as the requirement for on-site isolated intermediates that mentioned in section 2.2
- 1000 tonnes or more per year requires some addition information included in Annex VII of the Regulation. If it is not strictly controlled, a full registration is required.

### **Preparation of a registration dossier for isolated intermediates**

The technical dossier must be in IUCLID format. IUCLID can be downloaded freely by registrant. IUCLID 5 will guide the registrant to provide the information for intermediates. For on-site isolated intermediates, it is up to 1000 tonnes per year. For transported isolated intermediates, every classes of tonnage can also be fulfilled.

### **Joint submission of data on isolated intermediates by multiple registrants**

If a substance is pre-registered by many registrants and classified as isolated intermediate, either the intermediate is on-site or transported, joint registration must be required. The details are mentioned in section 1.8.4 in the [Guidance on registration](#). Article 19 states the rules of intermediates to registrants.

Two types of information need to submit for joint registration. First, joint information includes the classification of the intermediate, any available existing information on physicochemical, human health and environment properties of the intermediate. Second, separate information includes identity of manufacturer, identity of intermediate, a brief general description of the use and details of the risk management measures. However, the registrant can submit the joint information separately, in case the cost of joint submission is larger than separate submission. Also the information that will disclosure commercially sensitive and cause the registrant substantial commercial detriment or the registrant disagrees with the lead registrant on the selection of this information.

### **Registration fee**

A registration fee will be specified in a Commission Regulation one year after entry into force REACH Regulation.