

# Information Sheet: Update on Transported Isolated Intermediates:

## Executive Summary

Transported isolated intermediate (TII) means any chemical which is exported as an intermediate to Europe & is put to further chemical processing on the European manufacturing site. During this chemical processing, the intermediate chemical completely loses its chemical identity, though there may be traces of the intermediate in the substance formed, as a result of the chemical reaction.

Within REACH, if a substance qualifies as a TII, the information requirement to be submitted to ECHA at the time of REACH registration of the TII is very less. If the TII is exported in less than 1000 tons per annum only basic information needs to be provided (as described below). For TII exported in greater than 1000 tons per annum, in addition to the basic information, additional information as mentioned in annex VII of the REACH regulation apply.

However, to benefit from the reduced information requirements, the manufacturers of the TII have to get an undertaking from all their European suppliers, who buy a particular TII chemical that they fulfill all the controlled condition on their manufacturing sites as required within the REACH regulation.

**It is important to note that ECHA is shortly expected to come out with an update with respect to TII. ECHA is expected to come up with clarification on how the substances will be treated when they have both TII and non-TII applications / uses**

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## Applicable Section of REACH Regulation:

### Article 3(15) (Definition of Intermediates – Isolated Transported Intermediate)

Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

- (a) non-isolated intermediate: means an 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, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
- (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
- (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

**Article 3(16)** Site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

### Article 18

#### Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.
2. A registration for a transported isolated intermediate shall include all the following information:
  - (a) the identity of the manufacturer or importer as specified in Section 1 of Annex VI;
  - (b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
  - (c) the classification of the intermediate as specified in Section 4 of Annex VI;
  - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
  - (e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
  - (f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarized under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.
4. For the generation of this information, Article 13 shall apply. 4. Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

- (a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
- (b) procedural and control technologies shall be used that minimize emission and any resulting exposure;
- (c) only properly trained and authorized personnel handle the substance;
- (d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- (e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimize emissions and the resulting exposure during purification or cleaning and maintenance procedures;
- (f) substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

## Explanation:

**Important – This Provision is not applicable to Monomers: It should be noted, though, that monomers used as on-site isolated intermediates or transported isolated intermediates do not benefit from the exemption from standard registration requirements which normally applies to intermediates and have to be registered following the registration requirements described in Article 10 (Article 6(2)).**

In the light of the above information, if your Pre-registered substances happen to qualify as transported isolated intermediate(s) the following requirements will apply to you

Registration obligation; *with reduced information requirements*, **subject to certain conditions being fulfilled.**

### Reduced Information for < 1000 tons per annum

**Information requirements for registration of transported isolated intermediates exported less than 1000 tonnes per year per manufacturer:**

- The identity of the manufacturer
- The identity of the intermediate which includes the following:

Name or other identifier of each substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)  
 Other names (usual name, trade name, abbreviation)  
 EINECS or ELINCS number (if available and appropriate)  
 CAS name and CAS number (if available)  
 Other identity code (if available)

Information related to molecular and structural formula of each substance

Molecular and structural formula (including SMILES notation, if available)  
 Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)  
 Molecular weight or molecular weight range

Composition of each substance

Degree of purity  
 Nature of impurities, including isomers and by-products  
 Percentage of (significant) main impurities

Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

- The classification and labelling of the intermediate in accordance with Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC (**This information shall be compiled by the OR**)
- Any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted
- A brief general description of the identified use(s)
- Information on the risk management measures applied and recommended to the user

### **Reduced Information for > 1000 tons per annum**

#### ***Information requirements for registration of transported isolated intermediates exported Greater than 1000 tonnes per year per manufacturer:***

A registration for a transported isolated intermediate in quantities of more than 1,000 tonnes per year per manufacturer shall include the above information and information specified in Annex VII (**REACH Regulation - Annex VII Table is furnished below – end of this info sheet**)

## **Conditions Necessary for Benefiting from this Provision**

**Important – This Provision is not applicable to Monomers:** It should be noted, though, that monomers used as on-site isolated intermediates or transported isolated intermediates do not benefit from the exemption from standard registration requirements which normally applies to intermediates and have to be registered following the registration requirements described in Article 10 (Article 6(2)).

**However, it is important to note that reduced information requirement for transported isolated intermediate(s) will only apply if the manufacturer or importer confirms that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:**

- The substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage
- Procedural and control technologies shall be used that minimize emission and any resulting exposure
- Only properly trained and authorized personnel handle the substance
- In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered
- In cases of accident and where waste is generated, procedural and/or control technologies are used to minimize emissions and the resulting exposure during purification or cleaning and maintenance procedures
- Substance-handling procedures are well documented and strictly supervised by the site operator

**If the conditions listed above are not fulfilled, the reduced information requirements will not apply** (registration shall include the information specified in Article 10).

It is important to note that both the registrant and the users are each liable for their own statement regarding the strictly controlled conditions.

## REACH Regulation Annex VII (Applicable in case of Transported Isolated Intermediates > 1000 tons)

### INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

Column 1 Standard Information Required	Column 2 Specific Rules for Adaptation from Column 1
7.1. State of the substance at 20 °C and 101,3 kPa	
7.2. Melting/freezing point	7.2. The study does not need to be conducted below a lower limit of 20 °C.
7.3. Boiling point	7.3. The study does not need to be conducted: <ul style="list-style-type: none"> <li>— for gases, or</li> <li>— for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured, or</li> <li>— for substances which decompose before boiling (e.g. Auto-oxidation, rearrangement, degradation, decomposition, etc.).</li> </ul>
7.4. Relative density	7.4. The study does not need to be conducted if: <ul style="list-style-type: none"> <li>— the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient, or the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.</li> </ul>
7.5. Vapour pressure	7.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
7.6. Surface tension	7.6. The study need only be conducted if: <ul style="list-style-type: none"> <li>— based on structure, surface activity is expected or can be predicted, or</li> <li>— surface activity is a desired property of</li> </ul>

		the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
7.7. Water solubility		7.7. The study does not need to be conducted if: —the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or —the substance is readily oxidisable in water. If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed.
7.8. Partition coefficient n- octanol/ water		7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.
7.9. Flash-point		7.9. The study does not need to be conducted if: — the substance is inorganic, or — the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions, or — the estimated flash-point is above 200 °C, or — the flash-point can be accurately predicted by interpolation from existing characterised materials.
7.10. Flammability		7.10. The study does not need to be conducted: — if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability, or — for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit, or for substances which spontaneously ignite when in contact with air.
7.11. Explosive properties		7.11. The study does not need to be

	<p>conducted if:</p> <ul style="list-style-type: none"> <li>— there are no chemical groups associated with explosive properties present in the molecule, or</li> <li>— the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200, or</li> <li>— the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C, or</li> <li>— for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> <li>— less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard),</li> <li>— less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard).</li> </ul> </li> </ul> <p>Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>
7.12. Self-ignition temperature	<p>7.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>— if the substance is explosive or ignites spontaneously with air at room temperature, or</li> <li>— for liquids non flammable in air, e.g. no flash point up to 200 C, or</li> <li>— for gases having no flammable range, or for solids, if the substance has a melting point <math>\leq 160</math> °C, or if preliminary results exclude self-heating of the substance up to 400 °C.</li> </ul>
7.13. Oxidising properties	<p>7.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is explosive, or</li> <li>— the substance is highly flammable, or</li> <li>— the substance is an organic peroxide, or</li> <li>— the substance is incapable of reacting</li> </ul>

	<p>exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms).</p> <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
7.14. Granulometry	7.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.

**TOXICOLOGICAL INFORMATION**

<p align="center"><b>Column 1</b></p> <p><b>Standard Information Required</b></p>	<p align="center"><b>Column 2</b></p> <p><b>Specific Rules for Adaptation from Column 1</b></p>
<p>8.1. Skin irritation or skin corrosion</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <ol style="list-style-type: none"> <li>(1) an assessment of the available human and animal data,</li> <li>(2) an assessment of the acid or alkaline reserve,</li> <li>(3) in vitro study for skin corrosion,</li> <li>(4) in vitro study for skin irritation.</li> </ol>	<p>8.1. Steps 3 and 4 do not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes, or</li> <li>— the substance is flammable in air at room temperature, or</li> <li>— the substance is classified as very toxic in contact with skin, or</li> <li>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).</li> </ul>

<p>8.2. Eye irritation</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human and animal data,</p> <p>(2) an assessment of the acid or alkaline reserve,</p> <p>(3) in vitro study for eye irritation.</p>	<p>8.2. Step 3 does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes, or</li> <li>— the substance is flammable in air at room temperature;</li> </ul>
<p>8.3. Skin sensitisation</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human, animal and alternative data,</p> <p>(2) In vivo testing</p>	<p>8.3. Step 2 does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or</li> <li>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or</li> <li>— the substance is flammable in air at room temperature.</li> </ul> <p>The Murine Local Lymph Node Assay (LLNA) is the first-choice method for in vivo testing. Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.</p>
<p>8.4. Mutagenicity</p> <p>8.4.1. In vitro gene mutation study in bacteria</p>	<p>8.4. Further mutagenicity studies shall be considered in case of a positive result.</p>
<p>8.5. Acute toxicity</p> <p>8.5.1. By oral route</p>	<p>8.5. The study/ies do(es) not generally need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as corrosive to the skin.</li> </ul> <p>The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available.</p>

#### ECOTOXICOLOGICAL INFORMATION

<p style="text-align: center;"><b>Column 1</b></p> <p><b>Standard Information Required</b></p>	<p style="text-align: center;"><b>Column 2</b></p> <p><b>Specific Rules for Adaptation from Column 1</b></p>
<p>9.1. Aquatic toxicity</p> <p>9.1.1. Short-term toxicity testing on invertebrates (preferred species Daphnia)</p> <p>The registrant may consider long term toxicity testing instead of short-term.</p> <p>9.1.2. Growth inhibition study aquatic plants (algae preferred)</p>	<p>9.1.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or</li> <li>— a long-term aquatic toxicity study on invertebrates is available, or adequate information for environmental classification and labelling is</li> </ul>

	<p>available.</p> <p>The long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.</p> <p>9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.</p>
<p>9.2. Degradation  9.2.1. Biotic  9.2.1.1. Ready biodegradability</p>	<p>9.2.1.1. The study does not need to be conducted if the substance is inorganic.</p>

**Any other relevant physicochemical, toxicological and eco-toxicological information that is available shall be provided**