ECHA
EUROPEAN CHEMICALS AGENCY

# How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID

Practical Guide 16

ABC

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**How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID**
**Practical Guide 16**

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# The purpose and nature of practical guides

Practical guides aim to help duty holders fulfil their obligations in relation to the REACH regulation. They provide practical tips and advice and explain the Agency's processes and scientific approaches. Practical Guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH. However, they explain, in a practical way, specific issue(s) presented in the Guidance.

This practical guide aims to assist registrants of intermediates and the downstream users in assessing if the use of a substance complies with the definition of intermediate according to Article 3(15) of REACH. In addition it will assist the registrants to identify the relevant information to include in their registration dossiers in order to comply with their legal obligations. It also explains the information needed to document that an intermediate is used under strictly controlled conditions, as defined in Article 18(4)(a) to (f) of REACH.

This practical guide has been developed on the basis of:

- information provided to ECHA in the registration dossiers of intermediates,
- experience gathered from the evaluation of responses to requests for information from ECHA (Article 36 decisions) provided by the registrants of intermediates and
- input from the Forum for Exchange on Information on Enforcement – the body composed of representatives from the European national enforcement authorities for REACH (Article 86).
- Good practices in the area of intermediates' registration are emerging and developing, as experience in the implementation of REACH grows. This document will be reviewed and revised as necessary in the future to incorporate new developments.

ECHA invites interested parties to submit experiences and examples to be incorporated in future updates of this document. These can be submitted via the ECHA Information Desk at: http://echa.europa.eu/contact

# 1. Introduction

## 1.1 WHAT IS THIS DOCUMENT ABOUT AND WHO SHOULD READ IT

This document is addressed to registrants and downstream users (DUs) of intermediates. The aim is to provide practical advice on how to fulfil the legal obligations that apply to intermediates under REACH.

The definition of an intermediate under REACH is clarified here, as are the legal obligations relating to the use of the substance.

Registrants of intermediates may benefit from reduced information requirements if the intermediate is manufactured and/or used under strictly controlled conditions. Intermediates that are not manufactured and/or used under strictly controlled conditions are registered in full and are not subject to reduced information requirements.

This publication describes the relevant information that should be included in registration dossiers in order to demonstrate that these legal obligations are fulfilled. It gives practical advice on what should be checked, as a minimum, to assess, if legal requirements for intermediates are met and the type, scope and format of the information which should be provided in the registration dossier.

This practical guide may be used by enforcement authorities and ECHA when checking for compliance with REACH requirements for intermediates in addition to other information that may be requested on a case by case basis.

## 1.2 WHAT IS THE LEGAL BACKGROUND

An intermediate is defined in Article 3(15) of REACH as "*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (…)*". REACH identifies three types of intermediates[1]:

1) non-isolated intermediate (outside the scope of REACH; Article 2(1)(c));
2) on-site isolated intermediate – manufactured and used on the same site;
3) transported isolated intermediate – transported between or supplied to other sites where it is used .

The REACH provisions related to restrictions do not apply to on-site isolated intermediates (Article 68(1) of REACH). Intermediates uses are exempt from the provisions of REACH that concern Authorisation (Article 2(8)(b) of REACH).

In addition, substances registered as intermediates (both on-site and transported), and manufactured and used under strictly controlled conditions, are subject to:

- limited registration information requirements (Article 17(2) and Article 18(2) and (3) of REACH);
- reduced registration fee (Article 4 of Regulation EC No 340/2008);
- exemption from Dossier Evaluation and Substance Evaluation (this exemption does not apply to transported isolated intermediates, Article 49 of REACH).

Article 18(4)(a) to(f) of REACH defines strictly controlled conditions.

1 The definition of "intermediate" is available in Article 3 (15) of the REACH regulation, and further clarification on the definition is provided in the ECHA Guidance on intermediates.

## 1.3 HOW IS THIS DOCUMENT RELATED TO OTHER INFORMATION

This practical guide is published on the European Chemicals Agency's (ECHA) website (http://echa.europa.eu/publications_en.asp). It is specifically focusing on how to report information on intermediates in the registration dossier. It complements ECHA's Guidance on intermediates (Dec 2010)[2], and it is not intended as a comprehensive overview of all the obligations of the registrant of an intermediate. The examples shown in this practical guide are consistent with the information in the above mentioned ECHA Guidance on intermediates, specifically in Chapter 2 – registration of isolated intermediates, Appendix 3 – format for documenting information on risk management measures in a registration dossier for isolated on-site and transported intermediates, and Appendix 4 – definition of intermediates.

For the registration of intermediates under Article 10, the information in the ECHA Guidance on registration[3] also has to be taken into account.

For the registration of intermediates under strictly controlled conditions, use descriptors can be used to support the description of the conditions of use. This is in addition to the information on risk management measures that are required under Article 17.2 f) and Article 18.2 f) of REACH to justify strictly controlled conditions. In selecting use descriptors, registrants should be aware that some descriptors (e.g. PROCs and ERCs related to use by consumers or uses where the possibility for exposure is not negligible) may not be suitable for the registration of intermediates under strictly controlled conditions. Use descriptors are defined in Chapter R.12 of the ECHA Guidance on information requirements and chemical safety assessment[4].

## 1.4 REGISTRATION OF INTERMEDIATES

Different registration information requirements apply, depending on the type of intermediate use and, more specifically, on the conditions under which that substance is manufactured and used. In the case of on-site isolated intermediates registered under Article 17 of REACH, a registrant shall submit a registration dossier meeting the information requirements outlined in Article 17(2) of REACH, and in which the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions.

In the case of a transported isolated intermediates (TII) registered under Article 18 of REACH, a registrant shall submit a registration dossier that conforms to the information requirements in Article 18(2) of REACH. When the annual tonnage exceeds 1000 tonnes the registration shall additionally cover the requirements referred to in Article 18(3) of REACH. Any registration pursuant to Article 18 shall also confirm that the substance is only manufactured and used under strictly controlled conditions. Regarding the use by downstream users, the registrant may either confirm himself or alternatively state 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 specified strictly controlled conditions. In the first case (confirm himself), the registrant possesses knowledge on how the substance is used by downstream users. This may happen if downstream users have provided information on their uses to the registrant before the registration. In the second case (received confirmation), downstream users may have decided not to disclose details on their uses to the registrant (e.g. for reasons of confidentiality). In this situation downstream users are required to provide to the registrant a confirmation that the substance is used as an intermediate under strictly controlled conditions. Downstream users should provide appropriate documentation to the registrant either to describe their use and conditions of use, or to confirm that the substance is used as an intermediate under strictly controlled conditions. Registrants should keep this documentation at their site and provide it to the authorities if required.

2 http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

3 http://echa.europa.eu/documents/10162/13632/registration_en.pdf

4 http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

For both on-site and transported isolated intermediates, if the requirements for strictly controlled conditions are not fulfilled, the substance must meet the full registration requirements in accordance with Article 10 of REACH.

In all cases, the first task for the registrant of an intermediate (regardless of the conditions of manufacturing and use) is to determine if the substance is an isolated intermediate in accordance with Article 3(15) of REACH. In particular, the registrant has to confirm that the intermediate is only used for or consumed in chemical processing, by the registrant himself or by a user down the supply chain, in order to be transformed into another substance. The chemical processing involved refers to the manufacturing of that other substance as such but not to the production of an article. That other substance shall therefore normally be subject to registration requirements under REACH, unless otherwise exempted.

In addition, the registrant of an intermediate who wishes to benefit from reduced registration requirements, has to determine if his substance is manufactured and used under strictly controlled conditions (Article 18(4)(a) to (f)).

## 1.5 STRUCTURE OF THE DOCUMENT

In addition to the current introductory section (section 1), this document consists of three key sections (section 2, 3 and 4) and one appendix.

Sections 2 and 3 focus respectively on the "use" of a substance as an intermediate (independent of the conditions of use) and the "strictly controlled conditions" as defined in Article 18 of REACH. These sections include:

- a description of the key issues containing:
    - a short description of the legal requirements and some key questions that registrants and/or downstream users may ask themselves to find out which requirements are applicable;
    - a description of a step by step approach that a registrant and/or downstream user may apply to check if conditions are fulfilled;
- practical examples illustrating what type of information should be provided in the registration dossier to demonstrate that the registration requirements are fulfilled. This information should be also kept on-site and made available to authorities upon request. A format for reporting information in the dossier is provided, which in line with the ECHA Guidance on intermediates.

Section 4 presents an example of the information to be provided in the registration dossier (as an attachment in Section 13 of the IUCLID file).

The appendix contains a number of practical examples illustrating the type of information to be provided to demonstrate that the requirements on strictly controlled conditions are fulfilled.

# 2. Use of a substance as an intermediate

Before considering the conditions of use, it is important to establish that the substance is actually used as an intermediate according to the REACH definition. Therefore, the information in this section is relevant for both intermediates registered under Articles 17 and 18 of REACH (strictly controlled conditions are applied) and intermediates registered under Article 10 of REACH (general registration).

The aim of this section is to provide advice to registrants and downstream users of intermediates on:

- how to check if the use of the intermediate complies with the definition of intermediate under Article 3(15) of REACH, and
- the information to report in the registration dossier.

**Key issue**
Appendix 4 of the ECHA Guidance on intermediates provides clarification on the definition of an intermediate under REACH. It describes and exemplifies the circumstances when the use of a substance meets, or does not meet, the definition in Article 3(15).

As stated in this Appendix: "for the proper implementation of the REACH Regulation, the status of a substance as to whether it is an [...] intermediate or not should be unequivocal". In practice, determining the status of the substance as an intermediate requires a systematic and careful analysis of all the processes in which the substance is used.

**How to check if the conditions are fulfilled**
The following table lists key considerations to be made to determine whether a substance (A) is an intermediate or not under REACH. This list is intended to support and document a structured assessment of the status of a substance as an intermediate.

| Key considerations | Remarks |
|---|---|
| 1. What is the process that involves the use of the substance (A)?<br>a. Process<br>b. Processing steps | a. An intermediate – substance (A) - must be used in a manufacturing process of another substance (B).<br>b. An overview of the processing steps is normally necessary to establish the role of the substance (A) in the process. |
| 2. What are the relevant transformations to which the substance (A) is subject in that process? | An intermediate must be transformed into another manufactured substance.<br>A representation of the transformation, in the form of a reaction scheme with structural formula, should show how the chemical elements of substance (A) contribute to the identity of the substance (B) manufactured from it.<br>As indicated in Appendix 4, Chapter 3 of the Guidance on intermediates, the transformation from an intermediate (A) normally involves the chemical reaction of (A). However, in a limited number of cases, such as individual refining processes, substance (A) does not necessarily react in order to be transformed into another substance. |

| | |
|---|---|
| 3. What is the technical role of the substance (A) in the process? | The substance (A) must be used in the manufacturing process, in order to be itself transformed into another substance (B).<br>The use of a substance (A) in a manufacturing process involving transformations is not sufficient, as such, to qualify that substance (A) is an intermediate. Whenever the choice of using a substance (A) in a process is motivated by a technical reason other than the manufacturing of its transformation products, this would mean that substance (A) is not an intermediate. |
| 4. What is the regulatory status of the transformation product(s)<br>a. Chemical identity<br>b. Registration obligations under REACH | The transformation product (substance (B)) that results from the use of a substance (A) must itself be a substance as such, as defined in REACH, and subject to registration requirements, unless otherwise exempted. |

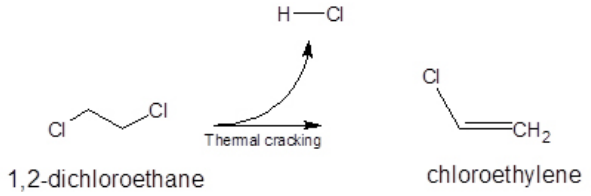
Three examples are provided in the following sections of this guide to illustrate how these key considerations can be used in practice to document the intermediate status of a substance. Given the possible complexity arising from documenting transformations involving UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials) compared with the case of well-defined substances, the examples provided in this practical guide address both substance types (a well-defined mono-constituent substance in Example 1 and a UVCB substance in Example 2). Where the same substance is used as an intermediate in different manufacturing processes, the structure illustrated in Example 3 can be followed.

## 2.1 EXAMPLE 1: WELL-DEFINED SUBSTANCE USED AS AN INTERMEDIATE

**Case description**

This example illustrates the information which can be provided to support the identified use of 1,2-dichloroethane as an intermediate in the synthesis of chloroethylene.

| What to check | What to report |
|---|---|
| 1. The process involving the use of the substance<br>a. Process<br>b. Processing steps | **a. Process**<br>1,2-dichloroethane is used in the manufacturing of chloroethylene.<br>**b. Processing steps**<br>The chemical process used for the manufacture of chloroethylene consists of the following steps:<br>- Continuous feeding of 1,2-dichloroethane to the dehydrochlorination reactor;<br>- Transformation of 1,2-dichloroethane into chloroethylene in the dehydrochlorination reactor;<br>- Continuous purification (distillation) to isolate chloroethylene from the hydrogen chloride (HCl) simultaneously generated in the reactor. |

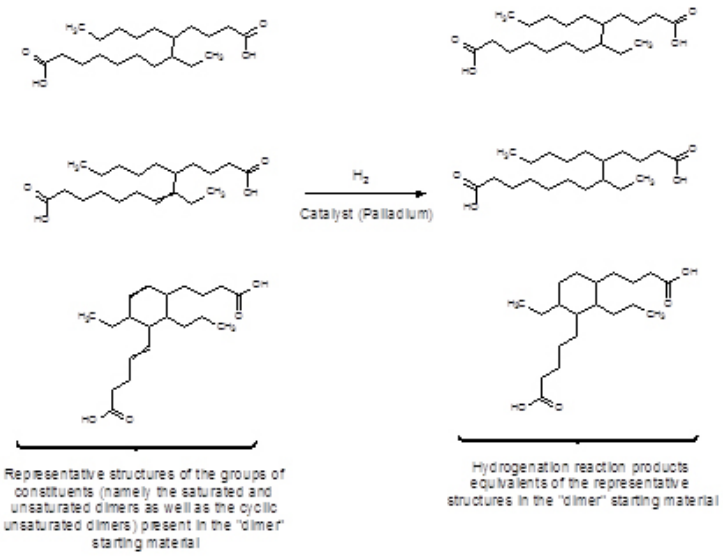
| | |
|---|---|
| 2. What are the relevant chemical reactions (transformations) which the substance is subject to in that process? | 1,2-dichloroethane reacts according to the following reaction scheme:<br>  <br><br>Side reactions may take place during the manufacture that result in the formation of ethylene, 1-butene, 2-butene and 1,3-butadiene. These end up in the composition of the manufactured substance (chloroethylene) as impurities. |
| 3. What is the technical role of the substance in the process? | The technical role of 1,2-dichloroethane is determined in relation to the manufacture of chloroethylene only. HCl is not taken into account because 1,2-dichloroethane is not used in order to manufacture HCl (its manufacture is not the aim of the process).<br>1,2-dichloroethane is subject to a chemical transformation in the chloroethylene manufacturing process. The chemical elements of the main constituent of chloroethylene (C, H, Cl) come from 1,2-dichloroethane.<br>Chloroethylene therefore cannot be manufactured without 1,2-dichloroethane.<br>1,2-dichloroethane has no other function than that of a reactant in the manufacturing process. |
| 4. What is the regulatory status of the transformation products from the substance? | **a. Chemical identity**<br>Substance type: mono-constituent substance<br>EC no.: 200-831-0<br>CAS no.: 75-01-4<br>IUPAC/chemical name: chloroethylene<br>Description: not applicable (well-defined substance) Substance on its own or in a mixture : substance on its own<br>**b. Registration obligations**<br>Chloroethylene is subject to registration requirements under REACH. The registrant of 1,2-dichloroethane has also registered chloroethylene (registration number XX-XXXXXXX-XXXX). |

## 2.2 EXAMPLE 2: UVCB SUBSTANCE USED AS AN INTERMEDIATE

**Case description**

This example illustrates the information which can be provided to support the identified use of the UVCB substance, "fatty acids, C10-unsaturated, dimers", as an intermediate, used in the synthesis of the UVCB substance "fatty acids, C10-unsaturated, dimers, hydrogenated".

| What to check | What to report |
|---|---|
| 1. The process involving the use of the substance<br>a. Process<br>b. Processing steps | **a. Process**<br>"Fatty acids, C10-unsaturated, dimers" (hereinafter "the dimer") is used in the manufacturing of "fatty acids, C10-unsaturated, dimers, hydrogenated" (hereinafter "the hydrogenated dimer").<br>**b. Processing steps**<br>The manufacturing process of the hydrogenated dimer entails the following steps:<br>- Loading of the dimer into the reaction vessel;<br>- Loading of the catalyst (palladium) into the reaction vessel;<br>- Pressurisation of the reaction vessel with hydrogen;<br>- Catalytic hydrogenation reaction;<br>- Filtration of the reaction medium upon completion of the hydrogenation reaction to separate the reaction products from the catalyst;<br>- Isolation of the hydrogenated dimer.<br>Two different substances result from the manufacturing process:<br>- The hydrogenated dimer which is the substance isolated from the manufacturing process;<br>- The solid residue collected from the filtration step. It consists of the spent catalyst as well as residual organic material. A separate process is applied to recover the palladium from the residue. |

| | |
|---|---|
| 2. What are the relevant chemical reactions (transformations) which the substance is subject to in that process? | "Fatty acids, C10-unsaturated, dimers" is a UVCB substance that results from the catalytic dimerization of a fatty acid substance presenting a narrow carbon number distribution (>90% (w/w) C10) with variable number, position and configuration (cis- and trans-) of unsaturations. The dimerization results in the formation of a covalent bond between the fatty acids. Due to the complexity of the composition of the dimer, it is not possible to fully identify it structurally by an exhaustive list of constituents. However, representative structures can be identified to represent its composition, namely saturated structures, unsaturated acyclic structures (representing the predominant group of constituents) and unsaturated cyclic structures. These three representative structures will be used to describe the chemical reactions involved for its use in the manufacturing of the hydrogenated dimer.[5]   |
| 3. What is the technical role of the substance in the process? | The technical role of the dimer is determined in relation to the manufacturing of the hydrogenated dimer which is the substance that results from the manufacturing process.<br><br>The dimer, as a substance, is subject to a chemical transformation in the hydrogenated dimer manufacturing process. The chemical elements of the constituents of the hydrogenated dimer (C, H, O) overall come from both the dimer and the hydrogen gas.<br><br>The hydrogenated dimer therefore cannot be manufactured without the dimer. The aim of the process is to manufacture a substance with a saturated backbone containing two primary carboxylic acids on a ramified saturated hydrocarbon backbone of a specific carbon number (C20). These transformation products from the dimer therefore are essential to the composition of the manufactured hydrogenated dimer.<br><br>In the hydrogenated dimer manufacturing process, the dimer is used in order to be itself transformed into the hydrogenated dimer. The dimer has no other function than that of a reactant in the manufacturing process. |

5 It should be noted that the manufacturing process involves a number of chemical reactions/interactions involving the catalyst, hydrogen and the constituents from "Fatty acids, C10-unsatd., dimers". These reactions/ chemical interactions solely represent interim chemical stages within the manufacturing process. These interim stages do not describe as such the transformation of "Fatty acids, C10-unsatd., dimers" into another substance. They are not relevant in the assessment of the status of "Fatty acids, C10-unsatd., dimers" as an intermediate.

| | |
|---|---|
| 4. What is the regulatory status of the transformation products from the substance? | **a. Chemical identity**<br>Substance type: UVCB<br>EC no.: not available<br>CAS no.: not available<br>Chemical name: Fatty acids, C10-unsatd., dimers, hydrogenated<br>Description: The reaction products from the complete catalytic hydrogenation of "fatty acids, C10-unsatd. Dimers" consists predominantly (≥80% (w/w)) of constituents presenting two C10 carboxylic acid building blocks connected to each other by a covalent bond. Includes also minor amounts of saturated C20 dicarboxylic acids with cyclic structures originating from the dimer starting material.<br>Substance on its own or in a mixture: Substance on its own<br>**b. Registration obligations**<br>The hydrogenated dimer is subject to registration requirements under REACH. The manufacturer will register this phase-in substance according to the June 2018 registration deadline. |

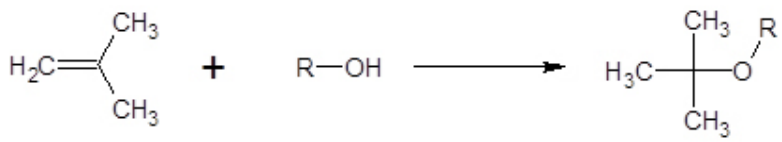
## 2.3 EXAMPLE 3: MANUFACTURING OF MULTIPLE SUBSTANCES FROM THE SAME INTERMEDIATE

**Case description**

The following example illustrates the information which can be provided to support the identified use of isobutylene as an intermediate, used in the manufacturing of several other substances.

Isobutylene is a substance manufactured by the registrant himself and then used both as a transported isolated and on-site isolated intermediate. The substance is used by the registrant to manufacture several tert-butyl ethers according to the same general manufacturing process. These ethers are then placed on the market. Given the similarities in the manufacturing processes wherein isobutylene is used, the assessment of its status as an intermediate can be documented all together in generic terms.

Isobutylene is also sold to one specific customer who transforms this substance into 2,6-di-tert-butyl-p-cresol. For that different type of use, the assessment must be carried out and reported separately.

| Use type 1: Use of isobutylene in the manufacturing of tert-butyl ethers | |
|---|---|
| **What to check** | **What to report** |
| 1. The process involving the use of the substance<br>a. Process<br>b. Processing steps | **a. Process**<br>Isobutylene is used in the manufacturing of three different tert-butyl ether substances.<br>**b. Processing steps**<br>The processing steps involved in the manufacture of the different tert-butyl ethers are overall the same. They only differ in terms of the alcohol reactant used.<br>- Isobutylene and an alcohol (R-OH) are continuously fed into a mixing column. This mixing step leads to a formulation of reactants in which there is a large excess of alcohol over the isobutylene;<br>- This formulation of reactants passes through a heated reactor packed with a porous solid acid catalyst under pressure to maintain the reactants in the liquid phase;<br>- The alcohol is recovered by distillation;<br>- High purity grade tert-butyl ether is isolated from the process. |
| 2. What are the relevant chemical reactions (transformations) which the substance is subject to in that process? | Under the reaction conditions used in the process, addition of the alcohol to isobutylene takes place according to the overall reaction scheme:[6]<br>  |



6 It should be pointed out that the catalytic reaction mechanism involves the formation of a protonated isobutylene cationic interim structure (H3C)3C+ with which the alcohol R-OH reacts. The proton that is involved in the formation of the isobutylene cationic structure is regenerated in the course of the reaction with the alcohol. These interim steps are not relevant since these ionic structures do not represent constituents of a substance.

| | |
|---|---|
| | Side reactions also take place during the manufacturing of the tert-butyl ethers:<br>- Dimerisation of isobutylene into diisobutenes (i.e. of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene);<br>- Reaction of isobutylene with residual water from the feedstock, which result in the formation of tert-butanol.<br>The diisobutene isomers end up as impurities in the isolated tert-butyl ethers while the tert-butanol remains in the recovered alcohol. These side reactions are not considered relevant for the assessment of the status of isobutylene as an intermediate because they do not represent the transformation that the manufacturing process aims at. |
| 3. What is the technical role of the substance in the process? | The technical role of isobutylene is determined in relation to the manufacturing of the tert-butyl ether which is the substance resulting from the manufacturing process.<br>Isobutylene is subject to a chemical transformation in the tert-butyl ether manufacturing process. The tert-butyl block from the manufactured tert-butyl ethers originates from isobutylene.<br>The tert-butyl ethers therefore cannot be manufactured without isobutylene.<br>Isobutylene is used in order to be itself transformed into the tert-butyl ethers. Isobutylene has no other function than that of a reactant in the manufacturing process. |
| 4. What is the regulatory status of the transformation products from the substance? | **Process where the alcohol (R-OH) used is methanol**<br>**a. Chemical identity**<br>Substance type: mono-constituent substance<br>EC no.: 216-653-1<br>CAS no.: 1634-04-4<br>Chemical name: tert-butyl methyl ether<br>Description: not applicable (well-defined substance)<br>Substance on its own or in mixture: substance on its own<br>**b. Registration obligations**<br>The substance is subject to registration requirements under REACH. The registrant of isobutylene has also registered tert-butyl methyl ether (registration number XX-XXXXXXX-XXXX).<br>**Process where the alcohol (R-OH) used is ethanol**<br>**a. Chemical identity**<br>Substance type: mono-constituent substance<br>EC no.: 211-309-7<br>CAS no.: 637-92-3<br>Chemical name: tert-butyl ethyl ether<br>Description: not applicable (well-defined substance)<br>Substance on its own or in mixture: Substance on its own<br>**b. Registration obligations**<br>The substance is not subject to registration requirements under REACH because the annual tonnage is below 1 tonne per year. |

| | |
|---|---|
| | **Process where the alcohol (R-OH) used is isopropanol**<br>**c. Chemical identity**<br>Substance type: mono-constituent substance<br>EC no.: 241-373-1<br>CAS no.: 17348-59-3<br>Chemical name: 2-isopropoxy-2-methylpropane<br>Description: not applicable (well-defined substance)<br>Substance on its own or in mixture: substance on its own<br>**d. Registration obligations**<br>The substance is subject to registration requirements under REACH. The manufacturer will register this phase-in substance according to the June 2018 registration deadline. |

| Use type 2: Use of isobutylene in the manufacturing of 2,6-di-tert-butyl-p-cresol | |
|---|---|
| **What to check** | **What to report** |
| … | The same approach as in e.g. example 1 above can be followed. |

# 3. Strictly controlled conditions

Registration of substances as on-site isolated intermediates or transported isolated intermediates pursuant to Articles 17 and 18 of REACH requires that strictly controlled conditions are implemented, and that information is provided that demonstrates that the requirements of Articles 17 and 18 of REACH have been fulfilled. REACH requires that the registration of an on-site isolated intermediate shall include "details of the risk management measures (RMM) applied" (Article 17(2)(f) of REACH) and, for transported isolated intermediates, "information on risk management measures applied and recommended to the user" (Article 18(2)(f) of REACH).

## 3.1 KEY ISSUE

Strictly controlled conditions are defined in Article 18(4) (a) to (f) of REACH. The Guidance on intermediates (section 2.1) defines strictly controlled conditions as "a combination of technical measures that are underpinned by operating procedures and management systems". These measures include:

- Rigorous containment of the substance by technical means, supported by procedural and control technologies in place, used to minimise emissions and resulting exposure during the whole life cycle of the intermediate, i.e.:
    - manufacture of the intermediate and further purification steps
    - use in the synthesis of (an)other substance(s)
    - cleaning and maintenance,
    - sampling and analysis,
    - loading and unloading of equipment/vessels,
    - waste disposal/purification and storage

- Handling of the substance performed by trained, authorised and supervised personnel in accordance with well documented procedures
- Special procedures in place for cleaning and maintenance,
- Procedural and/or control technologies to deal with accidents and waste management.

Registrants of intermediates have to verify that all these conditions are fulfilled in order to benefit from reduced information requirements on registrations, as foreseen in Articles 17 and 18 of REACH.

In the case of an on-site isolated intermediate, manufacturing and use of the intermediate take place at the same site. The registrant of the intermediate has to verify that technical and organisational measures are in place to ensure that exposure to workers and the environment is minimised during the manufacturing and use of the intermediate, including during sampling, cleaning and maintenance.

Registrants of a transported isolated intermediate are either manufacturers or importers of the substance. In this case, the use of the intermediate (with the purpose of being transformed into another substance) can take place at the registrant's site and/or at the sites of downstream users. For transported isolated intermediates Article 18 requirements apply. If the registrant is both manufacturer and user of the intermediate (to manufacture another substance) he has to implement the strictly controlled conditions at his own site during the manufacturing and use of the substance. If the substance is manufactured outside of the EU and it is imported by the registrant, requirements on strictly controlled conditions do not apply to the manufacturing and any operation taking place outside the territory of the European Union.

If the registrant supplies the intermediate to downstream users in the EU, he has to recommend specific risk management measures to those downstream users. The registrant has to confirm that the synthesis of another substance from that intermediate takes place on other sities udner strictly controlled condition, However, if the registrant is not able to know precisely how the substance is used by the downstream users, he has to receive confirmation from these operators that the substance is used as an intermediate and under strictly controlled conditions. REACH requires that the registrant either confirms himself in his dossier or state that has received confirmation from the downstream users that the substance is used as intermediate under strictly controlled conditions.

Suppliers of intermediates have to keep information on the identity of downstream users as well as confirmations received from them, and provide them to authorities upon request. It is recommended to include this information (the list of DUs and the confirmations received) in the registration dossier of intermediates. The reason for providing information on downstream users in the dossier is to demonstrate that a system is in place to fulfil the requirements related to strictly controlled conditions for transported isolated intermediates, as laid down in Article 18(4) of REACH.

Operational procedures and the management system play a key role when the plant has to be opened or entered for cleaning and maintenance. Article 18(4)(d) of REACH requires that "special procedures" such as purging and washing are to be applied before the plant is opened. These "special procedures" should be described in the dossier. They should take into account:

- how purging and washing have to be carried out in order to minimise possible exposure for workers when the system is opened, and
- how waste water or air emissions from washing and purging are treated / collected in order to minimise eventual releases of the substance into the environment.

Rigorous containment should be achieved without taking into account the use of personal protective equipment (PPE). This means that PPE cannot be used to prevent exposure to the substance resulting from "lack of" or "inadequacy of", rigorous containment under normal operating conditions. However, it does not mean that PPE cannot be used at all. ECHA Guidance on intermediates clarifies that PPE can be a part of strictly controlled conditions, as far as it aims to limit exposure resulting from accidents and incidents or maintenance and cleaning, provided that "special procedures" (see reference above) are applied before the system is opened or entered.). PPE may also be used as 'good practice', an additional line of protection, in addition to sufficient engineering controls applied.

## 3.2 HOW TO CHECK IF CONDITIONS ARE FULFILLED

The following sections present a description and examples of key elements that should be checked on-site to verify, if strictly controlled conditions are fulfilled, that the substance is rigorously contained by technical means during its whole lifecycle. This includes the manufacture and the use, including the different steps of the processing, where the substance may be present and exposure may occur. These steps will be described under the following headings:

- normal operation (including loading and unloading)
- cleaning and maintenance
- sampling
- control of the emissions to the environment.

There is also a section describing how monitoring data can be used to help to demonstrate that strictly controlled conditions are implemented.

In the final part of the section some practical examples are presented to illustrate how the assessment of strictly controlled conditions could be performed in different stages and for different steps of the use of an intermediate.

### 3.2.1 Normal operations (including loading and unloading)

Assessment of strictly controlled conditions during normal operations in the manufacturing and use of the intermediate includes checking of the following elements:

- rigorous containment of the manufacturing system by technical means;
- procedural and control technologies in place that minimise emission and any resulting exposure;
- the management system, including training and supervision of the personnel.

Rigorous containment is required to ensure that for all the steps from when the intermediate is manufactured until it is completely transformed into another substance, including during loading and unloading, there is no likelihood of exposure for humans and the environment. It is defined in ECHA Guidance on intermediates (chapter 2) as control achieved by technical design. It is applicable to the handling of intermediates on any scale and it aims to minimise releases – and the possibility of exposure – through the design of the process and the equipment.

Procedural and control technologies have to be integral parts of the management system (which includes training and supervision of the personnel) to ensure that the containment remains effective during normal operation (e.g. the system has to be maintained, operated and checked periodically to ensure its integrity and reliable functioning). In addition, procedural and control technologies ensure strictly controlled conditions during tasks which are not part of the normal operation (e.g. cleaning, maintenance, sampling, accidents etc.).

The following points should be taken into account, when establishing the strictly controlled conditions in the handling of an intermediate:

- The system has to be designed in such a way as to minimise potential for exposure to workers and the environment during loading and unloading operations. This may include e.g. use of glove box, closed coupling connections, double isolation valves, vapour recovery systems, vacuum transfer, dry lock couplings etc.
- Vessels, pipelines, pumps and any other ancillary equipment must be designed and installed in a way that would ensure substance containment during normal operation. The principle of the "rigorous containment" has to be maintained even during connecting or disconnecting for loading / unloading. Any process step where the substance is not contained by technical means cannot be regarded as rigorously contained.
- Releases to the environment from the process have to be minimised (see section 2.3.4 of the Guidance on intermediates for further details).
- There may be residual releases from the plant during specific tasks (for example, during sampling or maintenance). These emissions, and any resulting exposure, have to be minimised by procedural and control technologies. The means to achieve the required minimisation of exposure may vary depending on the physicochemical properties of the substance.
- The personnel handling the intermediate have to be appropriately trained and supervised. Training and supervision should be a documented part of a systematic programme (not an isolated event).

### 3.2.2 Cleaning and maintenance

Article 18(4)(d) of REACH requires that special procedures are applied before the system is opened and entered for cleaning or maintenance. The intention is that, as far as possible, all traces of the intermediate should be removed prior to the cleaning and maintenance phase and exposure to the intermediate is thereby minimised. In practice, a range of options may be available to decontaminate the plant. The options will depend on the chemical and physical properties of the intermediate substance. Following the isolation of the plant (or section of the plant) some of the options presented below may be chosen:

- Draining the plant to empty it of the substance;
- Purging the plant with a suitable gas or vapour (e.g. nitrogen or steam);
- Flushing the plant with a suitable liquid (e.g. water);
- Chemical degradation of the intermediate using appropriate reactants with subsequent flushing;
- High temperature operation to decompose the intermediate (or residues) with subsequent flushing.

For gaseous or vapour phase intermediates, it may be appropriate to purge the system using an inert diluent gas. For non-volatile or low volatility intermediates, it will be necessary to wash or chemically decontaminate the system prior to opening it. Monitoring systems should be in place to ensure the absence of the intermediate throughout the isolated part of the plant. Any waste generated will also need to be contained and adequately disposed of to meet the requirements for strictly controlled conditions.

In some cases it may be possible to completely ensure absence of the intermediate substance during the cleaning or maintenance phase and normal site arrangements can be followed. The key to safe operation during cleaning and maintenance is an understanding to what extent the plant has been decontaminated, and the nature of the residual risk of contact with any remaining intermediate.

It is anticipated that cleaning and maintenance will be coupled with well controlled access arrangements such as permit-to-work procedures. The number of workers with access should be kept to the minimum required for safe operational procedures. Workers will have to be competent, qualified and trained to carry out their specific tasks. The tasks will, ideally, be subject to safety method statements as part of permit to work. A 'safety method statement' is a written procedure covering non-routine tasks and will take account of all the risks associated with the work activity, including potential exposure arising from presence of the intermediate substance.

A safety method statement should be clear, concise and contain the following information:

- a description of the task and where it is to be carried out;
- the sequence and method of the work;
- the hazards identified during the assessment of the risk;
- the skills required to deal with the task and the hazards;
- the precautions required;
- references to specific safety procedures;
- details of any isolations and related procedures;
- methods of disposal of waste and debris;
- details of the state or condition the plant will be left in at the end of the work.

If residues of the intermediate are still present, it will be necessary for workers to have access to suitable and adequate personal protective equipment (PPE). The use of PPE is also subject to supervisory control that ensures its correct use, the prevention of the spread of contamination, and the safe disposal or cleaning under strictly controlled conditions.

### 3.2.3 Sampling

According to the Article 18(4)(a) of REACH, the substance has to be rigorously contained by technical means during its whole lifecycle. This explicitly covers sampling.

It is not uncommon in a process that samples are taken at the following stages in the operation:

1) From the raw material (intermediate) to confirm the purity of the substance. One sample can be taken from each batch delivered, if delivery is in drums, or from a tanker load, before the production process starts.
2) During the reaction stage to verify the degree of transformation or conversion; and
3) From the final product of the reaction to confirm that there is no residue of the intermediate left or that any residue left (impurity) is in a concentration in accordance with the product specifications.

Other sampling points can be established, depending on the needs of the individual process.

In appendix I of this document additional information is available to illustrate the level of detail that should be provided to demonstrate that strictly controlled conditions have been implemented.

### 3.2.4 Control of emissions to the environment

When strictly controlled conditions are in place, releases of the intermediate to the environment are minimised. The implementation of risk management measures (RMM) to control releases to the environment below threshold values (e.g. local PNECs or values specified in a water discharge permit issued by the local environmental authority) is not sufficient to justify strictly controlled conditions. Technical measures have to be in place in addition to the regular emission reduction measures in order to demonstrate that releases are effectively minimised. The following sections provide some examples of aspects that require consideration related to control of emissions to the environment, in a regime of strictly controlled conditions.

#### 3.2.4.1 Air

**Solids**
Exhaust ventilation is used to control the possible emissions from the process. Exhausted air, containing particles of the intermediate, can be treated in a two-step process. Firstly, the exhausted air would be passed through a single cyclone. The recovered solids would be collected in closed drums (automatic closure with no contact possible with workers) and disposed of as hazardous waste. The cyclone should be changed by trained personnel following special procedures and using appropriate PPE. As a second cleaning step, a fabric filter could be used. The dust collected by the filter should be a subject to the same procedures applicable to hazardous waste disposal as those applied to the dust collected by the cyclone. Used filters should be collected by trained personnel following special procedures using suitable PPE.

The information on the efficiency in relation to the specific particle size should be provided for both the cyclone and fabric filter.

**Liquids (organic) and gases**
All collected off gases (from the loading/unloading section, sampling station, laboratory and during maintenance/cleaning procedures) should be sent via enclosed pipelines to the on-site incineration facility (temperature in the combustion chamber, and the duration of its application, should be suitable for the disintegration of the chemical structure of the specific intermediate) where the organic intermediate is fully destroyed.

#### 3.2.4.2 Water

Contaminated water (originating from, for example, purging of the system) after pre-treatment (stripping with steam) can be transferred to the on-site wastewater treatment plant (WWTP). Any intermediate recovered during pre-treatment may be sent back to the process. Chemical (oxidation) and biological treatment could be applied to the wastewater at the on-site WWTP. All the sludge from WWTP should be incinerated under conditions applicable to hazardous waste incineration. Effluent of WWTP must be monitored for the residues of the intermediate. If any residual concentration of the intermediate is detected in the effluent, the release of effluent should be terminated, with following assessment and adjustment of WWTP. Waste water during termination period should be collected in special reservoirs and are not released from the site.

If the intermediate is not fully consumed during the synthesis of another substance (standard consumption rate is 75-80%), a recovery of the non-reacted intermediate, for example steam-stripping followed by condensation, should be applied. Recovered substance could be recycled back to the synthesis process. Residues of the intermediate (confirmed by regular analyses) can be present in the waste water. Waste water should be transferred to the on-site WWTP. Before applying biological treatment, waste water could be passed through a closed aeration tank, where off gases would be collected and sent for combustion at the on-site incineration plant. Effluent from the WWTP must be monitored for residues of the intermediate. In case it is detected in the effluent, recovery and WWTP treatment processes would be adjusted to improve recovery/removal efficiency of the intermediate.

#### 3.2.4.3 Waste

Waste can be generated in different steps of the lifecycle of the intermediate. During the manufacturing and use of the intermediate (in the synthesis of another substance) residues from production (by-products not put on the market), maintenance, cleaning or other ancillary processes can be collected to be disposed of as waste. From the worker and environmental protection perspective, the handling of waste is subject to the same requirements as the handling of the intermediate. For this reason, collection of waste has to be rigorously contained.

Methodologies used may include:

- Collection of waste in sealed drums in a dedicated filling station, equipped with glove box and an integrated LEV.
- Collection of liquid waste in road tankers. Loading and unloading of truck tanks taking place in dedicated stations. Tanks to be provided with vapour recovery systems, connection of tanks to loading system through flexible hoses, using dry-break couplings. Hoses to be drained and purged before they are connected and/or disconnected. Systems are provided with integrated LEV or other air-dynamic barriers.
- Collection of solid waste in special containers. Containers should be filled automatically (via mechanical arms located in confined spaces). In case manual handling is required, systems should be contained (level of containment depending on physicochemical properties) and special procedures have to be in place for management of waste.

Disposal of waste has to ensure that the substance is not released to the environment. Appropriate waste disposal technologies applicable for strictly controlled conditions include incineration and disposal in landfill for hazardous waste.

## 3.3 HOW MONITORING DATA CAN BE USED TO CONFIRM THAT STRICTLY CONTROLLED CONDITIONS ARE FULFILLED

Monitoring of the process for the presence of emissions and releases, and measuring of the exposure of workers can be used to confirm the integrity and effectiveness of the rigorous containment methods that are implemented.

**Monitoring of the process**
Monitoring of the integrity of the plant (e.g. monitoring of the pressure in the system) provides an early detection system of breaks in the integrity of the system.

The manufacturing process, from loading the reactors to the packing of the final product, is expected to be conducted in a system designed to ensure rigorous containment[7] of the substance. All transfers of the intermediate are through pipework. The integrity of this system can be monitored by two complementary systems:

1) The pressure in the transfer pipework and vessels can be monitored;
2) Leak detection sensors can be installed at identified sensitive points in the plant (e.g. at sample collection valves, connection points of pipelines, connection to the reactor etc.).

Both pressure gauges and detection sensors should be connected to control room monitors, and give audible alarms when the pressure changes unexpectedly or presence of the substance is detected outside of the containment system.

The monitoring equipment should be regularly inspected and maintained to ensure continuous and reliable operation. Alarms – detection of intermediate or drop in pressure, indicating a potential leakage – would result in the activation of emergency procedures.

The causes of all alarms should be investigated and remedial action taken to minimise the potential for reoccurrence of a problem, and possible false alarms. Records of investigations and follow-up actions should be kept.

**Worker exposure monitoring (personal and static)**
The role of the air sampling (assessment of workplace atmosphere) is to (within reason) prove the absence of the substance in the workplace air and develop an understanding of the need for additional risk management measures, such as portable LEV or PPE, in the circumstances that may be encountered. Worker monitoring should be conducted with the frequency prescribed by the national legislation related to workers' health and safety. It is to be conducted by the company specialising in the assessments of workers' exposure, in accordance with the national or international standard (e.g. PN-Z-0400807: 2008 or CSN EN 689). Both static and personal sampling methods may be used. The monitoring should be conducted on a typical working day, when all relevant industrial processes are on-going. The static sampling is to be conducted in the areas where the potential for exposure may occur. Workers involved in the processes of: loading /unloading, sampling, maintenance and operators and supervisors of the (closed) production process (all 'sensitive' tasks) must be included in the monitoring. Maintenance workers performing larger scale, planned work can be included in an additional/separate static and personal monitoring programme.

The samples taken should be analysed by an accredited laboratory, in accordance with the national/ international standards. Worker exposure monitoring information should be kept on-site and could be used by a registrant or a downstream user to confirm strictly controlled conditions.

7 http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

Such information should include:

- details of the technological process monitored, including substances involved
- task descriptions and durations,
- number of workers in the area where sampling is performed
- duration of sampling
- results of the monitoring.

The Guidance on Information requirements and chemical safety assessment, Chapter R. 14: Occupational exposure estimation, provides some useful information about sampling strategies and sample sizes considered to be representative.

To confirm the use of the intermediate under strictly controlled conditions, the air concentrations of the substance measured are expected to be at or below the limits of detection of the method for the majority of samples. If there are exposures measured, additional measures should be put in place to:

- identify those tasks linked to the exposures measured
- take corrective action, including, for example, for maintenance tasks – additional purging and ventilation time, for sampling - additional use of portable LEV, use of PPE to second level of protection against exposure (attenuation level / effectiveness of all RMMs used should be given)
- analyse changes in the pattern or number of the measured exposures over time.

For some substances, also biological monitoring, as a part of a health surveillance programme, may be possible and / or required. If it is performed, the indications should be explained, together with the health effect targeted (for example, skin or respiratory sensitisation). The conclusions of the series of biomonitoring / health surveillance, performed, over some years, can be presented as a confirmation of the control (or absence) of exposure.

**Monitoring of releases to the environment**

Measurement of the releases of substances to different environmental compartments may be required to demonstrate compliance with environmental legislations such as the IED directive (Directive 2010/75/EU replacing the IPPC directive), water discharge permits, air emission permits etc.

In some cases, for example, of waste water, releases of certain substances into the environment are indirectly monitored through tests such as COD or TOC[8] or generic tests such as toxicity test, total suspended solids. Similar consideration may apply to air emissions (e.g. monitoring of volatile organic compounds). The above mentioned non-specific analytical methods provide information on release of a group of substances (e.g. organic compounds) in aggregated form. However, there may be cases where the measuring of releases of single substances is required by permits or it is performed by a company voluntarily.

A registrant can use monitoring data to demonstrate that a substance is not released into the environment (e.g. measured concentration of the substance in the effluents below the detection limit of an analytical method which is low enough to confirm negligible releases, if any) The number and type of samples have to be representative of typical release conditions. Sampling methods and analysis of samples should comply with national/international standards. Samples should be analysed by accredited labs. Environmental monitoring information should be kept on-site and could be used by a registrant or a downstream user to confirm strictly controlled conditions.

8 COD stands for Chemical Oxygen Demand and TOC stands for Total Organic Carbon. These tests are commonly used to measure the amount of organic compounds in water.

Such information should include:

- a description of the process generating the release including the risk management measures and operation conditions and the substances involved
- the type and characteristics of the emission to be monitored
- the duration and frequency of the release
- the sampling points, methods/standards used for sampling and analysis, the duration of sampling
- laboratory information (name, accreditation etc)
- the results of the monitoring.

Monitoring data may also be used to quantify possible residual releases of the substance into the environment after all minimisation technologies are applied.

Use of monitoring data to demonstrate that the release of the intermediate into the environment is in compliance with requirements from waste water and/or air emission permits itself is not sufficient as justification for strictly controlled conditions, if it is not demonstrated that rigorous containment is in place and residual releases are effectively minimised.

The presence of the substance in the waste does not necessarily imply that the substance is released into the environment. This is not the case where the handling and treatment/disposal of waste is performed in accordance with the requirements for strictly controlled conditions (e.g. incineration).

## 3.4 WHAT TO REPORT IN THE REGISTRATION DOSSIER

The ECHA guidance on intermediates indicates that to confirm manufacturing and use under strictly controlled conditions, information provided must include a description of the effectiveness of all Risk Management Measures (RMM) applied, sufficient to demonstrate that the substance is rigorously contained during its whole life cycle. In Appendix 3 of the ECHA guidance on intermediates a template is provided that can be used to document information on risk management measures in the registration of intermediates. This template is based on the requirements laid down in Article 17(3) and Article 18(4)(a) to (f) of REACH. This information should be provided in the form of an attachment in the section 13 of the IUCLID registration dossier. In the appendix II of this document, some examples are presented that relate to the manufacture of the intermediate and the use of the intermediate during the synthesis of a new substance. They have been set out according to the physicochemical properties of the intermediate.

# 4. Registration of a transported isolated intermediate: an example of the information to be provided in the dossier

This section presents the information on risk management measures that registrants are required to provide in order to fulfil the information requirements of the registration of an intermediate under Article 18 of REACH. This section also identifies further information that ECHA recommends that registrants provide in their dossiers. It provides an example of the information which should be prepared for the registration of a transported isolated intermediate. The example shows how to practically use the format for documenting information on risk management measures, proposed in Annex 3 of the Guidance on intermediates.
This information should be provided as an attachment to section 13 of the IUCLID registration dossier. Information provided in this section takes into account and illustrates all the considerations set out in the previous sections.

Through this information, it is expected that the registrant will demonstrate that:

- The substance is an intermediate, as defined in Article 3(15) of REACH,
- The requirements for strictly controlled conditions are fulfilled (Article 18(4)(a) to (f) of REACH) by the manufacturer / supplier and downstream users.

**Description of the case**
Substance A-B is manufactured in the EU and used in the synthesis of substance A-C. The registrant is the manufacturer of substance A-B. Part of the quantity of the manufactured substance A-B is used by the registrant himself to manufacture substance A-C. The rest is placed on the market and used also for manufacturing of substance A-C by 3 different legal entities, all of them located in the EU.

The registrant has registered the intermediate, substance A-B, both as an OSII and a TII at the quantity of over 1000 tonnes per year.

**Information on the status of the transported isolated intermediate**

| Item | Information |
|---|---|
| The process involving the use of the substance<br>a. Process<br>b. Processing steps | **a. Process**<br>Substance A-B is used in the manufacturing of substance A-C.<br>**b. Processing steps (flow chart may be included)**<br>The chemical process used for the manufacturing of substance A-C consists of the following steps:<br>- Batch feeding of substance A-B (in liquid form) and C to a primary batch chemical reactor.<br>- Chemical transformation of A-B into A-C in the primary chemical reactor by applying thermal energy.<br>- Purification steps (distillation) to isolate the manufactured substance A-C from reaction residues B. Reaction residues from the purification unit are disposed of as hazardous waste and sent to outside incinerator. |

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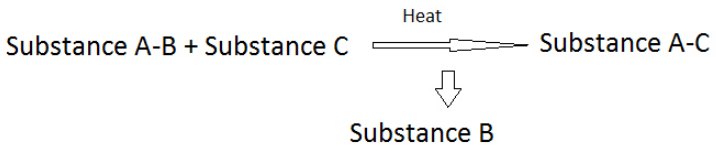
|---|---|
| The relevant chemical reactions (transformations) which the substance is subject to in that process | Substance A-B reacts according to the following reaction scheme:<br>  <br><br>Side reactions take place during the manufacturing process that result in the formation of other compounds ending up in the manufactured substance A-C as impurities. |
| The technical role of the substance in the process | The technical role of substance A-B in the process is determined in relation to the manufacture of substance A-C only. B is not taken into account because substance A-B is not used in order to manufacture B.<br>Substance A-B is subject to a chemical transformation in the manufacturing process resulting in substance A-C. The chemical elements of the main constituent of A-C come from A-B.<br>Substance A-C therefore cannot be manufactured without substance A-B. |
| The regulatory status of the transformation products from the substance | **Chemical identity**<br>Substance type: mono-constituent substance<br>EC no.: XXX-YYY-Z<br>CAS no.: AXZ-RR-T<br>Chemical name: Substance A-C<br>Description: not applicable (well-defined substance)<br>Substance on its own/in mixture: substance on its own<br>**Registration obligations**<br>The substance A-C is subject to registration requirements under REACH. The registrant of substance A-C already registered the substance (registration number XX-XXXXXXX-XXXX) |

**Information on the risk management measures**[9]

| Item | Information |
|---|---|
| Life-cycle stage(s) covered | Manufacture of the intermediate (substance A-B), industrial use (transformation into substance A-C), maintenance and cleaning, sampling, waste management. |
| Brief description of technological process applied in manufacture of the intermediate | **Process steps**<br>1. Raw material is charged into a batch reactor through fixed pipelines.<br>2. When reaction is completed the reactor is automatically discharged through fixed pipelines, using sealed pumps.<br>3. Reaction products are transferred from the reactor directly to on-site storage tanks.<br>4. From storage tanks the intermediate is transferred to truck and train tanks in dedicated loading stations.<br>**Sampling**<br>Sampling by dedicated enclosed vacuum sampler. The sample is transferred to a sample bottle under local exhaust ventilation. |
| Brief description of technological processes applied in use of the intermediate. | **Process steps**<br>1. Deliver of the intermediate (substance A-B) on site via pipeline (OSII) truck or by train tanks (TII).<br>2. Connection of tanks to the site delivery system in dedicated loading stations from where the intermediate is transferred to internal storage tanks.<br>3. Batch transfer of the intermediate from storage tanks to reaction vessel where the chemical transformation to substance A-C takes place.<br>4. Automatic discharge of the reacted intermediate (substance A-C) from reaction vessel when reaction is completed and transfer of the reacted intermediate (substance A-C) to the purification unit where impurities are removed from the substance by distillation.<br>5. Transfer of the purified substance A-C to the drums filling station. Substance A-C is stored and delivered to customers in 200 liters polyethylene drums.<br>6. Residues from purification are disposed of as hazardous waste.<br>7. Sampling (see manufacturing section) |
| Means of rigorous containment and minimisation technologies applied during manufacturing and/or used:<br>a. by the registrant<br>b. recommended to the user<br>c. to minimise emission and resulting exposure | **a. Measures applied by the registrant during manufacturing of the intermediate**<br>Process is carried out in pressurized reaction vessel.<br>- Reaction vessel is pressurized with Nitrogen and equipped with vapour recovery system to avoid releases of gases to the environment. Off gas from the reaction are sent to the on-site incinerator, via fixed pipelines.<br>- All substance handling is automated through fixed installations (pipes, vessels).<br>- Unloading of the intermediate from reaction vessel and transport to on-site storage tanks take place via fixed pipelines using sealed pumps. |

9 This template is based on the format proposed in Annex 3 of the ECHA Guidance on intermediates

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| | - On-site storage tanks are pressurized with Nitrogen and provided with enclosed gas recirculation system. No emission to the environment is expected.<br>- Transfer of the intermediate from storage tanks to truck/train tanks (for external transportation) takes place in dedicated loading stations.<br>- Truck/train tanks are equipped with vapour recovery system. They are connected to the loading system by dedicated flexible pipelines which are equipped with shut-off valves and are automatically emptied and purged with inert gas after a tank is filled up.<br>- Loading lines are washed and purged automatically prior to connection to transport tanks. Waste water from washing is itself collected as hazardous waste for disposal. Purging gas is incinerated in on-site gas incinerator.<br>- The air from all process steps is extracted from the system. This air is passed to an on-site incinerator where possible residuals of the intermediates are removed.<br>- Parameters (temperature and pressure) are controlled by a SCADA[10] system which shuts down the process when parameters are exceeded. |
| | **b. Measures applied by registrant and recommended to the user during use of the intermediate**<br>- The process is carried out at elevated temperature in a fully contained area. All substance handling is automated through fixed installations (pipes, vessels, sealed pumps).<br>- Loading stations are enclosed and equipped with a vapour recovery system for the connection of trailers supply system. No dermal or inhalation exposure is expected for workers in these steps during normal operations.<br>- The exhaust air from all the process steps is extracted from the system, including the filling-off in drums. Exhaust air from the device is sent to an on-site abatement system (incineration or activated carbon system) to eliminate possible residual content of intermediate.<br>- Parameters (temperature and pressure) are controlled by a SCADA system which shuts down the process when parameters are exceeded.<br>- Liquid waste from process and waste water from cleaning of the equipment to be disposed as hazardous waste for off-site incineration.<br>- Drums and other materials contaminated with theintermediate are collected and disposed of as hazardous waste, through incineration. |
| | **c. Procedural and control technologies used to minimise any emissions/ exposure**<br>- Pressure in the plant is continuously monitored to enable an early detection of loss of integrity and initiation of corrective action. Sensors installed at critical points (e.g. sampling valves) to detect vapour emissions.<br>- System is continuously monitored by the plant operating system/ control room. Storage tanks and reaction vessels are provided by containment system to avoid releases to soil or waste water in case of leakage. In case of spills or leakages procedures are in place to collect spilled substances. Contaminated materials used for spill cleaning are collected for disposal as hazardous waste and incinerated. |

10 SCADA stands for "Supervisory Control and Data Acquisition". It is a computer system for gathering and analyzing real time data.

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| Special procedures applied before cleaning and maintenance | - Procedures documented in a management system certified ISO 9001 and ISO 14000. Personnel are trained and closely supervised.<br>- For cleaning the plant is flushed with organic solvent and water and purged with nitrogen prior to opening. The contact with solvent and water leads to removal of all residual substance. Solvent and water used for cleaning are collected in a recovery system and disposed of as hazardous waste for incineration. Contaminated purging gas is sent to on-site gas incineration system. |
| Activities and type of PPE used in case of accidents, incidents, maintenance and cleaning or other activities<br>Applied by registrant and recommended to the user. | **Normal operation**<br>- Workers use PPE, specified in the standard operating procedures, when there may be a possibility of exposure: loading and unloading.<br>- Workers use skin protection during all operations (as a precautionary measure).<br>- Procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br>**Maintenance and cleaning**<br>- Workers use additional PPE for cleaning the reaction vessel. PPE is specified in the permit-to-work system.<br>**Sampling**<br>- PPE are not required for sampling however workers wear gloves and safety goggles as precautionary good practice.<br>**Accident and incidents**<br>- A fully trained Emergency Response Team (ERT) is in place to react in case of accidents and incidents resulting in unexpected releases of the intermediate in order to minimize risks of exposures to humans and the environment.<br>- Components of the ERT are selected among senior site operators and technicians and are periodically trained and certified to respond to emergencies. Trainings and certifications of members ERT are subject to periodical revisions and approval by Local Fire Department.<br>- PPE as specified in emergency procedures and training are required in case of accidents and incidents. PPE may include respirator, gloves body protection etc. Procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br>*Please note that it is expected that the type of gloves material, breakthrough time and type of respiratory protection and other PPE used will be specified (appropriate for the substance)* |
| Waste information | The following wastes are generated during manufacturing and use of the intermediate:<br>- air emissions from vessels and process;<br>- rinsing water and other liquid waste collected during cleaning of the system;<br>- residues from manufacturing process;<br>- waste generated during maintenance (empty containers contaminated with the intermediate, consumables, filters, contaminated parts etc.);<br>- by-products from synthesis containing unreacted intermediate. |

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| | **Treatment of waste on site**<br>- Water: no release to the environment via the waste water system expected.<br>- Air: no release via air as all air from the system and gaseous by products containing the intermediate are passed to an on-site thermal abatement system that removes all substance residues from the air.<br>- Soil: No direct and indirect (via STP sludge or air) release to soil as no contact to this medium exists.<br>**Treatment of waste off site**<br>Any waste generated which contains residues of the intermediate is stored under SCC and removed from site for treatment as hazardous waste by an authorized company according to EU provisions on disposal of hazardous wastes. |
| How strictly controlled conditions are confirmed | **Process monitoring**<br>- The integrity of the manufacturing plant is continuously monitored.<br>- The results consistently indicate that the pressure in the system is maintained, and there are no fugitive emissions, resulting from malfunction or breach of physical integrity of the plant.<br>**Worker exposure**<br>- Inhalation: The results of personal and static monitoring performed annually confirm that there is no measurable exposure via air.<br>- Results of regular bio-monitoring (health surveillance) confirm that the workers are not exposed to the intermediate.<br>**Environment**<br>- Measurements performed on waste water and air emissions show no presence of the substance above detection limits, therefore it can be considered that the substance is used under strictly controlled conditions with regards to the environment. No analytical confirmation is needed in regards to releases to soil either directly or indirectly (sludge from waste water treatment) as it is unlikely that the substance is released to soil under conditions of use described above. |

**Information on the use of the intermediate by downstream users**
The intermediate is supplied by the company XWZ (manufacturer) to the following downstream users who provided written confirmation that substance A-B supplied to them by company XWZ is used as intermediate (as defined in Article 3 (15) of REACH) and under strictly controlled conditions according to the provisions set forth in Article 18(4)(a) to (f) of Regulation EC 1907/2006 (REACH). This information is correct on the date of XX/XX/XXXX.

Name of Company 1:
Address:
Country:
Contact details: (web link etc)

Name of Company 2:
Address:
Country:
Contact details: (web link etc)
.
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-
Name of Company N:
Address:
Country:
Contact details: (web link etc)

# Appendix I

## Strictly controlled conditions: examples of techniques for sampling

### Liquid substances

*Sample of raw material (the intermediate)*

Delivery by tanker truck: samples could be collected during the delivery, when the intermediate is pumped from a tanker into the on-site storage facility.

Delivery in drums: samples could be collected when the intermediate is pumped from a drum into an on-site storage tank or the reaction vessel.

The sampling container should be attached (leak-proof) to a valve, which is opened only when the container is in place. At the sampling point a (preferably integrated) LEV (local exhaust ventilation) system has to be provided to minimise exposure of the worker when the sampling bottle is filled. Once the designated volume of the sample of the product is poured into the container, the sampling valve closes, allowing for all the substance in the tube to enter the sampling container and avoid drips / spillages. The worker collecting the sample is expected to wear gloves as a precautionary measure in case of leakage. If the intermediate is volatile, respiratory protection should be used to minimise the potential for exposure, before the container is sealed, especially if the sample is collected indoors.

*Sample of reaction product*

The reaction product is a new substance, different from the intermediate, for which specific registration obligations apply. Depending to the type of registration (full registration or intermediate registration), strictly controlled conditions may or may not be required. If the reaction product is registered as intermediate under strictly controlled conditions, the same considerations as for sampling of raw material apply.

### Solid substances

*Sample of raw material (the intermediate)*

The packaging of the solid substances depends on a number of factors. One of them is volume of consumption in a single process. It dictates the type and size of the container. The substances may be delivered in bags weighing a few kilogrammes or in bulk containers. The methodology used to take a sample from an individual container would vary, depending on the size and type of the container. The actual methods of sample collection and risk management measures depend on the dustiness of the substance (i.e. different for fine powder than granular form). It has to be remembered, though, that the exposure of workers has to be minimised. The work method must minimise the dust generation. Skin and respiratory protection has to be used, in conjunction with portable LEV, if it was deemed to be necessary (by, for example, the results of exposure measurement performed for the task). Samples of the intermediate may also be taken during the loading of the substance into the production line. An automated system may be installed, with a glove box: while the powder is being poured into the reactor, a sample of the intermediate is poured into the container installed on the turntable inside of the hopper. When the pouring is finished, the turntable brings the container outside of the hopper, to the glove-box, in which the sample is sealed and container cleaned of any residues by local exhaust ventilation. The worker collecting the sample is wearing gloves and a respirator (as a precautionary good practice).

*Sample of reaction product*

See previous case.

**Analysis of the sample**

The analysis of the sample is usually conducted in an industrial laboratory. The provisions of the Article 18.4 a) to f) apply to the process. The laboratory best practice principles should be applied, eliminating / minimising the exposure potential through use of high efficiency extraction systems over laboratory benches, work practices that minimise the possibility of direct contact with the substance and the use of appropriate personal protective equipment.

# Appendix II

## Strictly controlled conditions: examples of information to be provided in the dossier

The cases shown in this appendix illustrate the type of information which should be provided in the dossiers to demonstrate that the manufacture and use of the intermediate takes place under strictly controlled conditions. The examples relate to substances with the following characteristics:

- Powder of high dustiness
- Non-dusty solid
- Volatile liquid
- Non-volatile liquid

To provide a general perspective, all examples are related to the registration of Transported Isolated Intermediates, manufactured and used by the registrant on-site, and also distributed to downstream users to be used for the same purpose.

**Case 1: Describing strictly controlled conditions in the manufacture and use of the intermediate: powder of high dustiness**

*Case description*

This case describes the manufacture and use of a solid substance with high exposure potential (powder of high dustiness), and the information that could be provided in IUCLID Section 13 to support an intermediate registration, with regard to a description of the strictly controlled conditions. The example covers all process steps (i.e. loading and unloading, storage, chemical transformation, maintenance and cleaning, sampling, control of emissions to the environment).

| What to check | What to report |
|---|---|
| Life-cycle stage(s) covered: | All, including manufacture of the intermediate, industrial use, maintenance and cleaning, sampling, waste management. |
| Brief description of technological process applied in manufacture of the intermediate | **Process steps**<br>1 Raw materials are loaded into a reactor where the intermediate is manufactured<br>2 The intermediate is discharged from the reactor and by means of a closed piping system transported to other units for further processing<br>3 Further processing (including evaporation, drying, milling etc.) is carried out in a system designed to ensure rigorous containment of the intermediate<br>4. The refined intermediate is loaded into big bags[11] through a glove box system.<br>All process operations are automated with electronic control systems. |

11 Big bags are industrial containers made of flexible materials (e.g. fabric) used for storing and transporting solid dry products (e.g. sand, fertilisers, granules etc) in bulk quantities.

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| | **Sampling**<br>Samples of the intermediate are taken during manufacture and use at various stages of the process (e.g. loading of the intermediate into the production line, unloading of the product, reaction stage etc.). A dedicated sampling system is installed, with a glove box: while the powder is being transferred into the reactor, a sample of the intermediate is directed into the container installed on the turntable inside of the hopper. When the transfer is finished, the turntable brings the container outside of the hopper, to the glove-box, in which the sample is sealed and container cleaned of any residues by local extraction ventilation |
| Brief description of technological processes applied in use of the intermediate. | **Process steps**<br>1. The intermediate is transported to site in big bags.<br>2. Workers transfer the intermediate into the reaction vessel where the synthesis takes place (loading station, including glove box, is located on top of reaction vessel).<br>3. Products of reaction are discharged from reaction vessel by means of centrifugal pumps and transported to a purification and recovery unit.<br>All process operations are performed automatically with electronic control systems.<br>**Sampling**: see section above. |
| Means of rigorous containment and minimisation technologies applied during manufacturing and/or used:<br>a. by the registrant<br>b. recommended to the user<br>c. to minimise emission and resulting exposure | **a. Measures applied by the registrant during manufacturing**<br>- All vessels are connected via fixed pipes.<br>- All pumps, valves and metering equipment are fully sealed.<br>- Extracted air from the process is directed to an incinerator.<br>- Waste water from the process and from cleaning and maintenance, is pre-treated in a stripping column, where any intermediate content is removed, before the waste water is sent to the on-site (biological) waste water treatment plant (WWTP).<br>- Closing and disconnecting of the big bags is done through a glove box.<br>- All steps after the intermediate is manufactured are carried out in systems designed to ensure rigorous containment of the substance.<br>**b. Measures applied by registrant and recommended to the user during use of the intermediate**<br>- Opening and connection of big bags to loading/unloading equipment is done in a glove box.<br>- All vessels are connected via fixed pipes.<br>- All valves, pumps and metering equipment are fully sealed.<br>- Exhausted air from filling process is filtered and incinerated subsequently.<br>- Waste water from the process is pre-treated in a steam distillation column where all unreacted substance is removed (it is below detection limits), before being sent to an onsite biological waste water treatment plant (WWTP). |

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| | **c. Procedural and control technologies used to minimise any emissions/ exposure**<br>- Pressure in the plant is continuously monitored to ensure early detection of loss of integrity and initiate corrective action.<br>- Workers use PPE, specified in the standard operating procedures, as good practice when there may be a potential of exposure: e.g. during charging of the reaction vessel and storage tanks, cleaning and maintenance, sampling, discharging at end of the reaction etc; procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br>- Extracted air is passed to an on-site incinerator.<br>- Solid and liquid wastes containing the intermediate are collected and handled in systems designed to ensure rigorous containment of the substance, and eventually removed by an authorised company for treatment at an off-site WTP (incineration). |
| Special procedures applied before cleaning and maintenance | - Procedures documented in a management system which has received ISO9001 accreditation. Personnel are trained, tested and supervised.<br>- Residual release to environment (water) via WWTP: below detectable levels.<br>- Permit-to-work is required to initiate maintenance activities. Permit granted only to trained and authorised personnel equipped with specified PPE.<br>- The system is washed with water and purged with inert gas before it is opened. Residual levels of the substance are checked for before the system is opened for maintenance.<br>- System is opened only when residual levels are below detectable levels.<br>- Water used for washing is treated as liquid waste. |
| Activities and type of PPE used in case of accidents, incidents, maintenance and cleaning or other activities<br>Applied by registrant and recommended to the user. | **Normal operation**<br>- Workers use PPE as a good practice to minimise possible exposures from minor accidental leaks during loading and unloading the reaction vessel, even though rigorous containment is ensured through technical means;<br>- Procedures in place for disposal or cleaning of contaminated PPE, as appropriate.<br>**Maintenance and cleaning**<br>- Special PPE specified in permit to work system. To enter the system full respirator is required and full body protection.<br>**Sampling**<br>- The worker collecting the sample is wearing gloves and a respirator (as a precautionary good practice). |

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| | **Accident and incidents**<br>- A fully trained Emergency Response Team (ERT) is in place to react in case of accidents and incidents resulting in unexpected releases of the intermediate in order to minimize risks of exposures to humans and the environment. Components of the ERT are selected among senior site operators and technicians and are periodically trained and certified to respond to emergencies. Trainings and certifications of members ERT are subject to periodical revisions and approval by Local Fire Department<br>- PPE as specified in emergency procedures and training are required in case of accidents and incidents. Type of PPE depends on the nature of the accident or the incident. PPE may include respirator, gloves and chemical-resistant clothing, etc. Procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br>*Please note that it is expected that the type of gloves material, breakthrough time and type of respiratory protection and other PPE used will be specified (appropriate for the substance)* |
| Waste information | Waste is generated in the following stages during the manufacturing and use of the intermediate<br>- waste water from process;<br>- air emissions from vessels and process;<br>- water and other liquid waste collected during cleaning of the system;<br>- by-products from manufacturing process;<br>- wastes generated during maintenance (empty containers contaminated with the intermediate, consumables, filters, contaminated parts etc);<br>- by-products from synthesis containing unreacted intermediate.<br>**Treatment of waste on-site**<br>- Waste water from manufacturing and use processes is pre-treated in steam distillation column where all unreacted substance is removed below detection limit before being sent to an on-site biological waste water treatment plant (WWTP);<br>- Exhausted air from filling process is filtered and incinerated subsequently.<br>**Treatment of waste off-site**<br>- Any waste generated which contains residues of the intermediate is stored under SCC and removed from site for treatment as hazardous waste by an authorised company. |
| How strictly controlled conditions are confirmed | **Process monitoring**<br>- The integrity of the manufacturing plant is continuously monitored.<br>- The results consistently indicate that the pressure in the system is maintained, and there are no fugitive emissions, resulting from malfunction or breach of physical integrity of the plant.<br>**Worker/workplace monitoring**<br>- Regularly measured on-site exposure confirms that workers are not exposed to the substance during any of the normal operations, or for operations requiring a permit-to-work, above the detection limit of the measuring method. |

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| | **Environment**<br>- Measurements performed on waste water show no presence of the substance above detection limits; therefore it can be considered that the substance is used under strictly controlled conditions with regards to the environment. Analytical confirmation of no releases to soil is not considered necessary due to negligible likelihood that the substance is released to soil either directly or indirectly (sludge from waste water treatment) under given operational conditions. |

### Case 2: Describing strictly controlled conditions in the manufacture and use of the intermediate: non-dusty solid

*Case description*

This case describes the manufacture and use of a solid substance with low exposure potential (non-dusty solid, e.g. granules or pellets), and the information that could be provided in IUCLID Section 13 to support an intermediate registration, with regard to a description of the strictly controlled conditions. The example covers all process steps (i.e. loading and unloading, chemical transformation, maintenance and cleaning, sampling, control of emissions to the environment).

| What to check | What to report |
|---|---|
| Life-cycle stage(s) covered: | All, including manufacture of the intermediate, industrial use, maintenance and cleaning, sampling, waste management. |
| Brief description of technological process applied in manufacture of the intermediate | **Process steps**<br>The manufacture of the intermediate takes place in a system designed to ensure rigorous containment of the substance which includes the charging of the reaction vessel, the reaction step and the discharging of the intermediate from the reactor. The product of reaction is constituted by wet granules that are further dried in dedicated low pressure drying units and packaged into plastic containers through an automatic fully contained packaging system which is physically isolated from workers by the mean of mechanical barriers. The packaging system is also provided by integrated LEV.<br>Subsequent processing of the intermediate is also within a system designed to ensure rigorous containment of the substance, and the final product is discharged into big bags through a purpose-built glove box system.<br>**Sampling**<br>See case 1 |
| Brief description of technological processes applied in use of the intermediate. | **Process steps**<br>The transformation into a new substance takes place in a rigorously contained process which includes:<br>1. transfer of raw material from storage,<br>2. charging of reaction vessel,<br>3. reaction step, and<br>4. discharging of reaction mass from the reactor.<br>The new substance is obtained in a granular form.<br>**Sampling**<br>See case 1 |
| Means of rigorous containment and minimisation technologies applied during manufacturing and/or used:<br>a. by the registrant<br>b. recommended to the user<br>c. to minimise emission and resulting exposure | **a. Measures applied by the registrant during manufacturing**<br>See case 1 |

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| | **b. Measures applied by registrant and recommended to the user during use of the intermediate**<br>- The plastic containers are charged and discharged at specially designed charging points that include a glove box and mechanically integrated LEVs where vacuum ensures dust removal.<br>- The unloading of the granular substance is carried out using a crane equipped with a closed cabin equipped with a filtered ventilation system. The operation is supervised from a control room as well as by visual inspections in the area.<br>- The refinement of the granular matte by milling is operated from a control room and the milling area is entered once a week for cleaning and maintenance (after cleaning)<br>- Workers involved use a full set of protective clothing, including skin protection adding respiratory protection (half-face respirator with a particulate filter) when there may be a potential for exposure (not in the control room) as a good practice.<br>- Refining of granular matte is done in a ball mixer equipped with an integrated dust collection system and filters to minimise emission to air.<br>- All transport processes are automated and enclosed and remotely operated. The reaction step where the intermediate is transformed into the new substance takes place in a closed reaction vessel.<br>- All exhaust air passes a bag filter before release to air. Exhausted filters are disposed of as hazardous waste and incinerated.<br>- Residual waste from the process and waste water from cleaning of equipment is disposed of as hazardous waste and incinerated.<br>**c. Procedural and control technologies used to minimise any emissions/ exposure**<br>- Pressure in the plant is continuously monitored to ensure early detection of loss of integrity and initiation of corrective action.<br>- Extracted air is passed to an on-site incinerator.<br>- Solid and liquid wastes are collected and handled in systems designed to ensure rigorous containment of the substance, and are eventually removed by an authorised specialist for treatment at an off-site WTP |
| Special procedures applied before cleaning and maintenance | - Procedures documented in a management system which has received ISO9001 and ISO14000 accreditations.<br>- Personnel are trained, tested and supervised.<br>- Residual release to environment (water) via WWTP: non detectable.<br>- Standard operating procedures are in place for maintenance activities.<br>- Such procedures include the steps to follow for the activities to avoid that workers and the environment are exposed to the substance during maintenance e.g.:<br>  - PPE required;<br>  - Flushing and purging of the system prior to opening<br>  - Handling of contaminate parts<br>  - Disposal of contaminated equipment |

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| | - Maintenance is performed by trained and certified personnel.<br>- The system is washed with low concentration alkaline solution (sodium based) and purged with N2 for at least 3 hours before it is opened. Residual concentration of the substance in the purging solution is checked before the system is opened for maintenance. System is opened only when residual contents are below detection value.<br>- Solution used for washing is treated as a hazardous liquid waste. |
| Activities and type of PPE used in case of accidents, incidents, maintenance and cleaning or other activities<br>Applied by registrant and recommended to the user. | **Normal operation**<br>See case 1<br>**Maintenance and cleaning**<br>See case 1<br>**Sampling**<br>See case 1<br>**Accident and incidents.**<br>- Dedicated personnel is trained and equipped to react in case of accidents and incidents to minimize risk to humans and the environment resulting from unexpected release of the substance.<br>- PPE: see case 1 |
| Waste information | Waste information : see case 1<br>**Treatment of waste on site**<br>- Waste water from the process and from the scrubbers is treated on-site with chemical and physical methods/techniques. The intermediate is removed from the waste water to a level below detection limits before discharge.<br>- All exhaust air passes a bag filter before release to air. Exhausted filters are disposed of as hazardous waste and incinerated.<br>**Treatment of waste off site**<br>See case 1 |
| How strictly controlled conditions are confirmed | See case 1 |

**Case 3: Describing strictly controlled conditions in the manufacture and use of the intermediate: volatile liquid**

*Case description*

This case describes the manufacture and use of a substance in liquid form with high exposure potential (volatile liquid), and the information that could be provided in IUCLID Section 13 to support an intermediate registration, with regard to a description of the strictly controlled conditions. The example covers all process steps (i.e. loading and unloading, chemical transformation, maintenance and cleaning, sampling, control of emissions to the environment).

| What to check | What to report |
|---|---|
| Life-cycle stage(s) covered: | All, including manufacture of the intermediate, industrial use, maintenance and cleaning, sampling, waste management. |
| Brief description of technological process applied in manufacture of the intermediate | **Process steps**<br>Manufacture of liquid intermediate in a closed batch process under sub-atmospheric pressure<br>1. The raw materials are charged into a batch reactor through fixed pipelines.<br>2. When reaction is completed the reactor is automatically discharged through fixed pipelines.<br>3. Filling of plastic drums is carried out at dedicated loading stations with integrated precision weighing scales and built-in fume hood at the lance for vapour collection.<br>4. Drums are transported off-site on pallets.<br>**Sampling**<br>Samples are collected when the intermediate is pumped from a drum into the reaction vessel. Sampling valve is only opened when the container is in place. Sampling by dedicated enclosed vacuum sampler. The sample is transferred to a sample bottle under local exhaust ventilation. The portable LEV is used to minimise potential for exposure, before the container is sealed if the pumping is done indoor. |
| Brief description of technological processes applied in use of the intermediate. | **Process steps**<br>Synthesis of a new substance from an intermediate in a closed multi-stage batch process under vacuum.<br>The intermediate is delivered on site in 200 litre plastic drums.<br>1. Drums arrive at the unloading stations where they are connected into the plant's piping system through high integrity flexible hoses with dry-break couplings.<br>2. Loading stations are connected to reaction vessels through fixed pipes.<br>3. Centrifugal pumps are used to transport the intermediate from loading station to reaction vessel.<br>4. The discharge of the reactor is automated and controlled from the control room when the reaction is completed.<br>5. The product is transferred to containers for shipping (plastic drums or bulk shipping in truck trailers) at dedicated loading stations.<br>**Sampling**<br>See above |

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| Means of rigorous containment and minimisation technologies applied during manufacturing and/or used:<br>a. by the registrant<br>b. recommended to the user<br>c. to minimise emission and resulting exposure | **a. Measures applied by the registrant during manufacturing**<br>- The process is carried out under vacuum. All substance-handling is automated through fixed installations (pipes, vessels).<br>- Loading/ unloading stations are enclosed and provided with integrated local exhaust ventilation and glove box for connection of drums to the reactor.<br>- The air from all process steps is extracted from the system, including the filling of drums. This air is passed to a wet scrubber (possible residual content of the substance is therefore removed because it is unstable in water).<br>- Parameters (temperature and pressure) are controlled by a SCADA5 system which shuts down the process when parameters are exceeded.<br>**b. Measures applied by registrant and recommended to the user during use of the intermediate**<br>- The process is carried out under vacuum, in a fully contained system. All substance handling is automated through fixed installations (pipes, vessels).<br>- The reactor loading station is enclosed and equipped with an integrated local exhaust ventilation system and glove box for the connection of the drums to the transfer system.<br>- The exhaust air from all the process steps is extracted from the system, including the filling-off in drums.<br>- Exhaust air from the system is passed to a wet scrubber where any possible residual content of intermediate substance is therefore removed because it is unstable in water.<br>- Parameters (temperature and pressure) are controlled by a SCADA system which shuts down the process when parameters are exceeded.<br>- Workers use protective clothing, including skin protection and respiratory protection (half-face respirator with a particulate filter) when there may be a potential for exposure as a good practice.<br>**c. Procedural and control technologies used to minimise any emissions/ exposure**<br>- Pressure in the plant is continuously monitored to ensure early detection of loss of integrity and initiation of corrective action. Sensors are installed at critical points (e.g. sampling valves) to detect vapour emissions.<br>- Both systems are continuously monitored by the plant operating system/control room. |
| Special procedures applied before cleaning and maintenance | - Procedures documented in a management system which has received ISO9001 accreditation.<br>- Personnel are trained and closely supervised.<br>- The maintenance (including the cleaning step) is part of a permit-to-work system requiring<br>- Risk assessment to minimise exposure to workers and to the environment;<br>- supervisor authorization. |

12 SCADA stands for "Supervisory Control and Data Acquisition". It is a computer system for gathering and analyzing real time data

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| | - The permit would specify<br>  - any special procedures and<br>  - PPE<br>  - required for carrying out the work.<br>- In addition, for general cleaning, the relevant equipment (including associated piping) is flushed with water prior to opening until the level of the intermediate in flushing water is no longer detectable. The contact with water leads to destruction of all residual substance. The water is collected in an interceptor pit and is only discharged after testing for compliance with the consent to discharge. |
| Activities and type of PPE used in case of accidents, incidents, maintenance and cleaning or other activities<br><br>Applied by registrant and recommended to the user. | **Normal operation**<br><br>See case 1<br><br>**Maintenance and cleaning**<br><br>- Workers use PPE (eye, skin and respiratory protection) for cleaning the reaction vessel. The required PPE is specified in the permit-to-work system.<br>- Procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br><br>**Sampling**<br><br>PPE are not required for sampling, but the worker collecting the sample wears gloves as good practice. Respiratory protective equipment is also used.<br><br>**Accident and incidents.**<br><br>See case 1 |
| Waste information | Waste is generated in the following stages of the manufacturing and use of the intermediate:<br><br>- waste water from chemical process;<br>- air emissions from vessels and process;<br>- water and other liquid waste collected during cleaning of the system;<br>- by-products from the manufacturing process;<br>- waste generated during maintenance (empty containers contaminated with the intermediate, consumables, filters, contaminated parts etc;);<br>- by-products from synthesis containing unreacted intermediate.<br><br>**Treatment of waste on-site**<br><br>- Water: No release via water as water has to be eliminated from the process because the substance is highly unstable in that medium.<br>- Air: No release via air as all air from the system is passed to a wet scrubber removing all substance residues from the air.<br>- Soil: No direct and indirect (via STP sludge or air) release to soil as no contact to this medium exists.<br>- General: breakdown products after reaction with water of the substance are not hazardous for human health and environment.<br><br>**Treatment of waste off-site**<br><br>See Case 1 |

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| How strictly controlled conditions are confirmed | **Process monitoring**<br>See Case 1<br>**Worker monitoring**<br>- The results of personal and static monitoring – all results below detection limits – confirm that no exposure via air occurs.<br>- Results of regular workplace monitoring and bio-monitoring (health surveillance) confirm that the workers are not exposed to the intermediate.<br>**Environment**<br>See case 1 |

**Case 4: Describing strictly controlled conditions in the manufacture and use of the intermediate: non-volatile liquid**

*Case description*

This case describes the manufacture and use of a substance - complex C4-10 aliphatic hydrocarbon - in liquid form with low exposure potential (non-volatile liquid), and the information that could be provided in IUCLID Section 13 to support an intermediate registration, with regard to a description of the strictly controlled conditions. The example covers all process steps (i.e. loading and unloading, chemical transformation, maintenance and cleaning, sampling, control of emissions to the environment).

| What to check | What to report |
|---|---|
| Life-cycle stage(s) covered: | All, including manufacture of the intermediate, industrial use, maintenance and cleaning, sampling, waste management. |
| Brief description of technological process applied in manufacture of the intermediate | **Process steps**<br>The manufacture of the intermediate is done through the fractional distillation of petroleum (a continuous steady-state process). There are extensive engineering (including dedicated recovery and waste treatment systems) and operational controls in place.<br>1. The petroleum arrives on-site by a fixed pipeline.<br>2. The petroleum is processed via a fractional distillation column, where one of the streams is a product stream for the intermediate.<br>3. The intermediate product stream is further processed for increased purification.<br>4. The final product (the purified intermediate) is sent to the on-site storage facility.<br>5. The intermediate is transferred via a special (purpose-built) loading system from the storage into road tankers for transportation to customers.<br>**Sampling**<br>Samples are collected through a designated valve during the pumping of the substance into the storage. Vacuum sampler is used. As the transfer is done outdoor, LEV is not used. |
| Brief description of technological processes applied in use of the intermediate. | The transformation into a new substance takes place in a continuous, closed, multi-stage manufacturing process, which includes on and off-site storage and transport. There are extensive engineering (including dedicated recovery and waste treatment systems) and operational controls in place.<br>**Process steps**<br>1. The substance (intermediate) is transported on-site by road tanker<br>2. Road tankers are connected by workers to the loading station where the intermediate is discharged from the tanker to a storage tank by means of centrifugal pumps.<br>3. Storage tanks are connected to reaction units by fixed pipes. Pneumatic pumps are used to transfer and load the substance into the reaction unit. |

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| | 4. A reaction unit consists of a reaction vessel and a series of three purification units (stripping columns) where the manufactured substance is refined. Reaction residues are either recycled back or disposed of as hazardous waste. The reaction vessel and stripping columns are connected by fixed pipes. The substance is moved from one purification unit to the next one via differential pressure.<br>5. The purified manufactured substance is collected in outdoor storage tanks for further uses.<br>**Sampling**<br>See above |
| Means of rigorous containment and minimisation technologies applied during manufacturing and/or used:<br>a. by the registrant<br>b. recommended to the user<br>c. to minimise emission and resulting exposure | **a. Measures applied by the registrant during manufacturing**<br>- All vessels are connected via fixed pipes.<br>- All pumps, valves and metering equipment are fully sealed.<br>- All steps after the intermediate is produced are carried out in systems designed to ensure rigorous containment of the substance.<br>- Storage tanks and reaction vessels are provided with "inert gas blankets" to both reduce the risk of fire and control fugitive emissions.<br>- Loading from the storage to tankers is done through a special loading system equipped with a vapour recovery system/extraction etc.<br>- Exhaust gases are incinerated on-site.<br>**b. Measures applied by registrant and recommended to the user during use of the intermediate**<br>- Connection of road tanker to loading station is performed via dry-break couplings. Flexible hoses/pipes are emptied and purged with nitrogen before disconnecting. Purging gas is sent to a local gas abatement system and incinerated.<br>- Bottom unloading of tankers is performed with a pump. Tankers are equipped with a vapour recovery system to contain and recycle vapour.<br>- Storage tanks, reaction vessels and recovery units are all connected via fixed pipes (ensuring rigorous containment of the substance). All equipment (such as pumps, valves, compressors etc.) is sealed.<br>- Storage tanks and reaction vessels are equipped with an "inert gas blankets" to control fugitive emissions.<br>- Exhaust gases from the process are incinerated.<br>- Waste water from the process is pre-treated in stripping columns prior to being sent to the on-site biological STP. The stripping unit is able to recover up to 99.9% of the unreacted intermediate from waste water which is then recycled back to the synthesis unit. The fraction containing the non-recovered intermediate substance is disposed of as waste.<br>**c. Procedural and control technologies used to minimise any emissions/ exposure**<br>- The system is monitored for early detection of leaks and releases. In case of loss of integrity, automatic shutdown is initiated and emergency procedures are in place to minimize exposure to workers and the environment.<br>- The plant is contained by a dike from which any releases are collected and sent to a special sewer for treatment of hazardous waste. Special procedures are in place to minimize exposure to the environment in case accidental emissions occur. |

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| Special procedures applied before cleaning and maintenance | See Case 3 |
| Activities and type of PPE used in case of accidents, incidents, maintenance and cleaning or other activities<br><br>Applied by registrant and recommended to the user. | **Normal operation**<br><br>See case 1<br><br>**Maintenance and cleaning**<br><br>- Workers use additional PPE for cleaning the reaction vessel. PPE should be specified in the permit-to-work system.<br><br>- A short exposure may occur during a maintenance operation, involving opening of a section of the pipeline connecting the reactor with loading station due to accidental presence of a residue of diluted intermediate that may lead to skin exposure. As a result, workers are given a specific work instruction on how to open this section, and are required to use high-efficiency PPE for skin and respiratory protection, as a precautionary and protective measure during all maintenance work, where there is a potential for exposure. PPE type is specified in the permit-to-work documents.<br><br>- Procedures are in place for disposal or cleaning of contaminated PPE, as appropriate.<br><br>**Sampling**<br><br>PPE not required for sampling, but gloves and safety glasses are used as good practice. |
| Accident and incidents. | See case 1 |
| Waste information | See case 3 |
| How strictly controlled conditions are confirmed | **Process monitoring**<br><br>See Case 1<br><br>**Worker monitoring**<br><br>- The results of personal and static monitoring – all results below detection limits – confirm that no exposure via air occurs during normal operation.<br><br>- Static monitoring performed during maintenance operation indicates a potential for exposure during work on the section of the plant identified in the permit-for-work. However, the duration of exposure is very short (few minutes) and during this time the work method used and the use of PPE control exposure.<br><br>- Results of regular workplace monitoring and bio-monitoring (health surveillance) confirm that the workers are not exposed to the intermediate.<br><br>**Environment**<br><br>See case 1 |

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