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Short analysis of the Practical Guide 16, as issued by ECHA, on: How to assess whether a substance is used as an intermediate under SCC and how to report the information for the intermediate registration in IUCLID

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Aim of this document:

- This publication describes the relevant information to be included in registration dossiers in order to demonstrate that legal obligations related to intermediates are fulfilled (reduced registration requirements if SCC can be demonstrated)
- It gives practical advice on what should be checked as a minimum to assess, if legal requirements for intermediates are met
- It gives practical advice on the type, scope and format of the information which should be provided in the registration dossier
- It includes examples that are consistent with the information in the ECHA Guidance on intermediates
- It refers to use descriptors, clarifying 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

The document **complements ECHA's Guidance on intermediates (Dec 2010),** and it is not intended as a comprehensive overview of all the obligations of the registrant of an intermediate

Note: this practical guide may be used by enforcement authorities and ECHA when checking for compliance with REACH requirements for intermediates

Structure of the document

The document is structured along the 'key steps' to be performed by the registrant of an intermediate: check if your substance is an intermediate as defined by REACH (section 2); b) check the conditions of use (section 3); c) report information in your dossier (section 4)

- **Section 2: check the use of the substance as intermediate (page 9 onwards)**, i.e. check if the substance is actually used as an intermediate according to the REACH definition (Article 3(15)

A table on page 9 reports the key considerations to be used here:

1. *What is the process that involves the use of the substance (A)?*
   a. Process
   b. Processing steps
2. *What are the relevant transformations to which the substance (A) is subject in that process ('transformed')?*
3. *What is the technical role of the substance (A) in the process?*
4. *What is the regulatory status of the transformation products?*

a. chemical identity
b. registration obligations under REACH (should be a substance)

These key considerations are in line with the Appendix 4 of the ECHA Guidance issued in 2010. Three simple, not contestable examples are provided using a well-defined substance as intermediate (with transformation illustrated by a reaction scheme), a UVCB used as intermediate (with a chemical transformation represented by representative structures), manufacturing of multiple substances using the same intermediate (with isobutylene transformed in tert-butyl ethers)

- **Section 3: check the conditions of use, i.e. are thos in line with the REACH Articles 17 and 18 requirements? (page 18 onwards)**

It starts by recalling that SCC is a combination of technical measures underpinned by operating procedures and management systems:

- *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*
- *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.*

Interesting notes (for example, clarifying further what was briefly mentioned in the ECHA Guidance 2010: obligations M/I and DU, use of Personal Protective Equipment…)

- 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

- The registrant has to confirm that the synthesis of another substance from that intermediate takes place on other sites under 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….It is recommended to include this information (the list of DUs and the confirmations received) in the registration dossier of intermediates. (note: this is also stressed on page 7: *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*).

- 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. (note: mandatory use of PPE like for Pb is not mentioned here)*

- They propose to check if the conditions are fulfilled for the following process steps/process associated steps:
    - Normal operation
    - Cleaning and maintenance
    - Sampling
    - Control of emissions to the environment

For each of these steps the guide explains more in detail (or less ambiguous way) what was already stressed in the ECHA 2010 guidance. For example on page 20 they mention clearly that ***any process step where the substance is not contained by technical means cannot be regarded as rigorously contained.*** There is no mention to hazard knowledge!

When addressing control of emission to the environment they state that: *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 Guide includes a section on how **monitoring data can be used to confirm SCC**

A distinction is made between monitoring of the process, workers exposure monitoring, monitoring of releases to the environment?

The monitoring of the process (page 24) is seen from the following perspective: *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 containment7 of the substance. All transfers of the intermediate are through pipework. As such they propose to monitor the pressure in the pipework and to detect leaks*

Workers' monitoring (page 24):

- Air sampling: 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:
    - workers involved in processes of: loading /unloading, sampling, maintenance and operators and supervisors of the (closed) production process (all 'sensitive' tasks) must be included in the monitoring
    - The samples taken should be analysed by an accredited laboratory

- 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.

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.

- Biological monitoring: may be possible and / or required as a part of a health surveillance programme. If it is performed, the indications should be explained, together with the health effect targeted 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. 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.

But

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.

- **Section 4: how to register: an example of the information to provide in the dossier (page 27 onwards)**

The example is based on the 'Annex 3' of the 2010 ECHA guidance but written out with the information to provide as attachment to section 13 of IUCLID