

13 September 2012

Screening of registration dossiers for intermediates

Background information

For intermediates the registration requirements laid down in Articles 17 and 18 of REACH apply, in particular limited information requirements on substance properties and no requirement to carry out a Chemical Safety Assessment. Substances used as an intermediate are intended to be transformed into another substance, and shall be manufactured and used under strictly controlled conditions at chemical manufacturing sites. Due to these special circumstances, the exposure to humans and the environment is considered to be minimised. On that basis, the REACH Regulation exempts the registration of isolated intermediates from certain information requirements (References 1 and 2). The transformation of the substance into another substance during chemical processing and the strict control of use conditions until its transformation has taken place are therefore key criteria for the opportunity of benefiting from reduced information requirements.

As a result of a continuous IT-based screening of registration dossiers, 2388 dossiers have been identified as containing information that put into question the transformation of the substance during chemical processing and/or the strict control of exposure until its transformation. This information thus indicates that the registration of the substance might not meet the conditions set out in Articles 3(15), 17 and/or 18 of the REACH Regulation. If this would be the case, the registration should include the information specified in Article 10 of the REACH Regulation.

For the reasons explained above, the following information, if reported in Section 3.5 of a technical dossier, is considered inconsistent with the registration as an intermediate¹.

1. Uses by industrial workers that contain one or more of the Process Categories listed in Annex 1 to this note. These categories describe a process or an activity that is inconsistent with the intermediate status, or is likely to be incompatible with strictly controlled conditions.
2. Uses by professional workers that contain one or more of the Process Categories listed in Annex 1 to this note. These categories describe a process or an activity that is inconsistent with the intermediate status, or is likely to be incompatible with strictly controlled conditions. Please note that wide dispersive uses (uses outside of industrial sites) are generally incompatible with the intermediate status.
3. Uses by industrial workers that contain one or more of the Environmental Release Categories listed in Annex 1 to this note.
4. Uses by professional workers that contain one or more of the Environmental Release Categories listed in Annex 1 to this note. Please note that wide dispersive uses (uses outside industrial sites) are generally incompatible with the intermediate status.
5. Uses by consumers. Consumer uses are by definition incompatible with the status of an intermediate as they do not take place at an industrial site for the manufacture of substances.
6. Technical functions being incompatible with the technical function of an intermediate. Such incompatible functions include for example: agents adsorbing and absorbing gases or liquids, binding agents, colouring agents, pigments, pH-regulating agents, bleaching agents, fertilisers, fillers, flame retardants, flotation agents, lubricants and lubricant additives, and tanning agents.

¹ This is based on the understanding as agreed by the Commission, Member States and ECHA on 4 May 2010 and as laid down in the Guidance on intermediates (Reference 2), and on the definitions laid down in IR & CSA Guidance Chapter R.12 (use descriptor system) (Reference 1).

7. Uses by workers that are reported with an Article Category and/or with one of the following Environmental Release Categories: 5, 8c, 8f, 10a, 10b, 11a, 11b, 12a and 12b. Inclusion of these categories in the use description in section 3.5 of the technical dossier suggests that a substance is transferred into or onto articles, which is by definition incompatible with the intermediate status.

The analysis of the use descriptor elements described above is performed by automated screening of the dossiers with particular filters on certain aspects of the use description. Other parts of the dossiers have not yet been screened.

ECHA will repeat its screening activity with the same or additional filtering criteria in periodic intervals, starting three months after the date of this News Alert. The absence of relevant updates of the technical dossiers may result in legally binding decisions requiring the submission of the information specified in Article 10 of the REACH Regulation.

Further information and advice how to describe the uses of an isolated intermediate in the technical dossier is contained in Annexes I and II of this document. In addition section 3 in Annex II provides instructions on how to update to a standard registration under Article 10 if the registrant considers that Article 17 or 18 of the REACH Regulation were actually not applicable to the uses he intended to register:

- Annex I provides further explanation as to why certain Process Categories and Environmental Release Categories are considered incompatible with a registration under Articles 17 and 18.
- Annex II provides some brief guidance on how to report the use description in section 3.5 of IUCLID 5.4 in the technical dossier for an intermediate. Please note that due to the recent upgrade of IUCLID from version 5.3 to 5.4, any updates of your technical dossier should be done using IUCLID 5.4, in which section 3 has been modified (See Reference 3 below) to allow a more structured documentation on the manufacture and use of a substance.

References

1. Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system, Version: 2, March 2010, http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf
2. Guidance on intermediates, Version 2, May 2012, http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf
3. IUCLID 5.4 changes and impact on submission and dissemination of information, Questions and Answers, http://echa.europa.eu/documents/10162/13651/questions_and_answers_iuclid5_4_en.pdf, and IUCLID 5 FAQ, <http://www.iuclid.eu/index.php?useaction=home.faq>

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Non suitable use descriptors in the technical dossier of intermediates registered under Article 17 or 18 of the REACH Regulation

Table 1: Non suitable process categories in intermediate dossiers (reference: Guidance R.12, Appendix R.12-3, explanation of the process category)

Proc	Process Categories	Reasoning
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC5	Mixing or blending in batch processes for formulation of preparations* and articles (multistage and/or significant contact)	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC6	Calendering operations	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC7	Industrial spraying	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities.	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC10	Roller application or brushing	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC11	Non industrial spraying	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC12	Use of blowing agents in manufacture of foam	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC13	Treatment of articles by dipping and pouring	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.

Table 1: Non suitable process categories in intermediate dossiers (reference: Guidance R.12, Appendix R.12-3, explanation of the process category)

Proc	Process Categories	Reasoning
PROC17	Lubrication at high energy conditions and in partly open process	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC18	Greasing at high energy conditions	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC19	Hand-mixing with intimate contact and only PPE available	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC20	Heat and pressure transfer fluids in dispersive, professional use but closed systems	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC21	Low energy manipulation of substances bound in materials and/or articles	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC23	Open processing and transfer operations with minerals/metals at elevated temperature	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC25	Other hot work operations with metals	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
PROC26	Handling of solid inorganic substances at ambient temperature	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions. as set out in Article 17(3) and 18(4) of REACH.
PROC27a	Production of metal powders (hot processes)	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC27b	Production of metal powders (wet processes)	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.

Table 2: Non suitable environmental release categories in intermediate dossiers (reference: Guidance R.12, Appendix R.12-4, explanation of the environmental release category and REACH Regulation, Article 6(2) for ERC 6c)

ERC Number	Name	Reasoning
ERC3	Formulation in materials	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC4	Industrial use of processing aids in processes and products, not becoming part of articles	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. Processing aids are not used in order to be themselves converted into another substance, and the manufactured substance is not formed from the processing aid;
ERC5	Industrial use resulting in inclusion into or onto a matrix	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC6b	Industrial use of reactive processing aids	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. Processing aids are not used in order to be themselves converted into another substance, and the manufactured substance is not formed from the processing aid.
ERC6c	Industrial use of monomers for manufacture of thermoplastics	For monomers that are used as on-site isolated intermediates or transported isolated intermediates the reduced information requirements of Articles 17 and 18 do not apply.
ERC7	Industrial use of substances in closed systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. ERC 7 describes the use of functional fluids.
ERC8a	Wide dispersive indoor use of processing aids in open systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. Processing aids are not used in order to be themselves converted into another substance, and the manufactured substance is not formed from the processing aid.
ERC8b	Wide dispersive indoor use of reactive substances in open systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. This category refers to the use of the substance in a process where it reacts, but there is no manufacturing of another substance (there is no "synthesis");
ERC8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC8d	Wide dispersive outdoor use of processing aids in open systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. Processing aids are not used in order to be themselves converted into another substance and the manufactured

Table 2: Non suitable environmental release categories in intermediate dossiers (reference: Guidance R.12, Appendix R.12-4, explanation of the environmental release category and REACH Regulation, Article 6(2) for ERC 6c)

ERC Number	Name	Reasoning
		substance is not formed from the processing aid;
ERC8e	Wide dispersive outdoor use of reactive substances in open systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH. This category refers to the use of the substance in a process where it reacts, but there is no manufacturing of another substance (there is no "synthesis");
ERC8f	Wide dispersive outdoor use resulting in inclusion into or onto a matrix	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC9a	Wide dispersive indoor use of substances in closed systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC9b	Wide dispersive outdoor use of substances in closed systems	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC10a	Wide dispersive outdoor use of long-life articles and materials with low release	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC10b	Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC11a	Wide dispersive indoor use of long-life articles and materials with low release	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC11b	Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC12a	Industrial processing of articles with abrasive techniques (low release)	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.
ERC12b	Industrial processing of articles with abrasive techniques (high release)	This category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.

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How to describe identified uses in section 3.5 of the technical dossier of an intermediate registered under Articles 17 or 18 of the REACH Regulation

Section 1 of this annex briefly summarises the basic principles for determining i) whether a substance has the status of an intermediate under REACH and ii) whether the actual conditions of use justify benefiting from the reduced information requirements for a registration under Article 17 or 18 of REACH.

Section 2 provides practical advice on how to describe the uses of an intermediate in section 3.5 of the technical dossier when the intermediate is registered under Article 17 or 18 of REACH.

1. Background information

a) Intermediate legal definition (Article 3(15))

REACH defines an intermediate as *a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance*.

REACH additionally defines different types of intermediates:

- A **non-isolated intermediate** is *an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe-work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture (Article 3(15)(a))*.
- An **on-site isolated intermediate** means *an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities (Article 3(15)(b))*.
- A **transported isolated intermediate** is *an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites (Article 3(15)(c))*.

b) Clarification of the circumstances under which a substance may or may not be regarded as an intermediate under REACH¹

The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing.

Article 3(15)(b) of REACH defines on-site isolated intermediates as intermediates not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities. Therefore, these substances are by definition first isolated before being “used for” chemical processing to be transformed into another substance. In accordance with the definition, an isolated intermediate is a substance that is manufactured for the purpose of being transformed into another

¹ Definition of intermediates as agreed by the Commission, Member States and ECHA on 4 May 2012. http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC. See also Reference 2, Appendix 4 (ECHA's guidance on intermediates).

substance in a subsequent step. The definition also specifies that the substance should effectively be used (i.e. transformed into another substance) in such a subsequent step, in order to be regarded as an intermediate. The same consideration applies to transported isolated intermediate: the intermediate is first isolated before being transported to a different site and subsequently used for chemical processing to be transformed into another substance.

The reference to “site” in Article 3(15) emphasises that an intermediate is used within industrial processes. The definition of “site” in Article 3(16)² suggests that it is a location, in which “manufacturing” (of the intermediate or of other substance) takes place. Hence, chemical processes involving the use of isolated intermediates are regarded as “manufacturing” activities under REACH.

An isolated intermediate is used in the manufacturing of another substance where it is itself transformed into that other substance. This other “manufactured” substance should be different from the intermediate used in the process. The definition of “intermediate” substance should therefore be understood to cover such transformation of this intermediate into another substance which is considered as “manufacturing” of that other substance in the sense of Article 3(8) REACH.

The lifecycle of an isolated intermediate therefore begins with its manufacture and ends with the use of the substance in the synthesis process for the manufacture of another substance (with its own life cycle).

c) Requirements for uses under strictly controlled conditions (legal text)

Articles 17 and 18 specify the conditions of use justifying the reduced information requirements for an intermediate registration. These include:

- Rigorous containment by technical means during the whole life cycle of the intermediate.
- Procedural and control technologies minimising emissions and any resulting exposure.

In the light of these requirements certain types of processes or activities as defined in the Use Descriptor System (IR&CSA Guidance Chapter R.12) are not compatible with a registration under Article 17 or 18. For further explanation see Annex 1.

2. Practical advice on how to report uses of intermediates in IUCLID

In June 2012, ECHA released a new version of IUCLID (IUCLID version 5.4), that introduces major changes in section 3.5. This section is now called “Life Cycle description”. The information in this Annex refers to IUCLID 5.4, as this version of the software is to be used for updating the technical dossier.

When opening a registration dossier (originally made in IUCLID 5.3) in IUCLID 5.4 the description of uses is automatically migrated from the IUCLID 5.3 structure into the IUCLID 5.4 structure. Here the use description will look different:

- Any uses reported under “Uses by workers in industrial setting” with the assignment of ERC 1, 2 or 3 in Version 5.3 have been moved or copied into the new “Manufacture” (ERC 1) and/or “Formulation” (ERC 2 and 3) table in IUCLID 5.4.

² **A site** means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared (Article 3(16)).

- Any uses reported under “Uses by workers in industrial setting” or “Uses by professional workers” in Version 5.3 and which contain an Article Category (AC) are copied to the new “Article Service Life” table in IUCLID 5.4. This does not apply however for uses with the assignment of ERC 5, 8c, 8f, 10a, 10b, 11a, 12a or 12b (indicating that the substance is incorporated into or onto an article) but which do not contain an Article Category (AC).

As a consequence of this migration, the number of uses in your current IUCLID dossier and the number of uses counted in ECHA’s automated screening may differ.

The following advice aims to promote consistency between the use description in section 3.5 of your IUCLID dossier and i) the definition of an intermediate under REACH and ii) the conditions of manufacture and use under which the registrant can benefit from the particular registration requirements laid down in Articles 17 and 18.

- The tables “Uses by professional workers”, “Consumer uses” and “Article service life” should be empty. Any use reported in these tables is inconsistent with the intermediate status of the substance. **If such uses exist and you wish to cover them in your registration, a full registration under Article 10 would be required.**
- For uses reported in the table “Uses at industrial sites”, the checkbox “Subsequent service life relevant” should be ticked to “no”. Please note that the life cycle of an intermediate ends when the intermediate has been transformed into another manufactured substance (which can again be an isolated intermediate). The uses of this other substance shall not be reported in the technical dossier of the intermediate.
- Several use descriptors (Process Category, PROC, and Environmental Release Category, ERC) are not compatible with the intermediate status and/or the requirement of strictly controlled conditions. Therefore, when filling in the tables “Manufacture”, “Formulation” and/or “Uses at industrial sites” in IUCLID, usually only the following descriptors (for definition see IR&CSA Guidance Chapter R.12) are applicable:
 - PROC 1, 2, 3
 - PROC 8a, 8b
 - PROC 9
 - PROC 15
 - PROC 26, 27a, 27b
 - ERC 1, 2, 6a, 6d
- For the categories PROC 8a, 26 and 27 particular explanation on the applied technical process is required in the field “Brief description of the process” in order to justify that strictly controlled conditions can be met. Please note that more detailed information on the process and the strictly controlled conditions should be provided in the attachment [*RMM detail*] to the technical dossier (see points 1 to 6 of Appendix 3 to the Guidance on Intermediates).
- For repair, cleaning and maintenance PROC 0 may be most appropriate. The same applies for storage. Please note that the current use category system as contained in Chapter R.12 of the IR&CSA Guidance does not include a suitable, specific category for these activities.
- When filling in the table “Uses at industrial sites” the following information is expected for each of the uses reported:

- Field "Use Name": Describe the most common types of synthesis (or other types of chemical processing) for which the intermediate is used, e.g. "Use in the synthesis of" or "Transformation into".
- In the field "Brief description of the use process" (not mandatory under current TCC rules), summary information may be provided on the technological process. Please note that further information on the process should be provided in the attachment [*RMM detail*] to the IUCLID dossier (see point 1 and 2 of Appendix 3 to the Guidance on Intermediates). If this option is used, include a remark "further information is included under point 1 and 2 in the attachment *RMM detail* to the IUCLID dossier". In addition, information on the strictly controlled conditions as set out in Article 17 and 18 is required under point 3 to 6 of Appendix 3 to the Guidance on Intermediates.
- Field "Tonnage of substance per use" (not mandatory under current TCC rules).
- Field "Technical function of the substance": select the option "Intermediates". Please note that various substance functions include a reaction on end-use, and thus the substance is consumed during use. However the consumed substance is not an intermediate, as it is not transformed into another manufactured substance.
- Field "Substance supplied to that use in the form of" (not mandatory under current TCC rules): select the option "As such" or "in mixture"
- Field "Subsequent service life relevant for that use?": select option "no"
- Field "Number of use sites" (not mandatory under current TCC rules): select the number of site range you are aware of.
- Field "Product category" (not mandatory under current TCC rules): select option PC19 (Intermediate)
- Field Sector of End-use: SU 9,10 or 14 are categories consistent with the intermediate status (transformation at a chemical manufacturing site)
- The following field is not expected to be filled for a substance registered as an intermediate under Articles 17 or 18:
 - Use covered in CSR.

Updating of the information in section 3.5 of your IUCLID dossier should be carried out in three steps:

1. Reconsider whether you intended to register i) an intermediate or ii) a substance for which other uses should also be covered in the registration. If i) continue with step 2. If ii) a registration under Article 10 may be required (see section 3 below).
2. Remove all use descriptions from section 3.5 in order to start from a clean section.
3. Enter the use description for your intermediate taking into account the advice above.

3. Instructions on how to update the registration of your intermediate to a standard registration under Article 10

Registrants who consider that Article 17 or 18 of the REACH Regulation were actually not applicable to the uses they intended to register, will need to create a new dossier containing all the information required by the REACH Regulation for the relevant tonnage band. Additionally, they will need to enter the registration number in section 1.3 of the IUCLID dossier. At step 6 in the 'dossier creation wizard', it must be indicated that the dossier is an update in the dossier header, and the latest submission number needs to be provided in the corresponding field. The box 'spontaneous update' should then be ticked and as a justification for the update 'change of tonnage band' should be selected. This reason for updating has to be selected due to technical constraints even if there is no actual change of tonnage band.

Finally, before submitting the dossier through REACH-IT, the Technical Completeness Check tool should be run to ensure that all the required information is included in the updated dossier.

4. Additional helpful sources of information

1. Guidance on information requirements and chemical safety assessment (IR&CSA Guidance), Chapter R.12: Use descriptor system, Version: 2, March 2010, http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf
2. Guidance on intermediates, Version 2, May 2012, http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf
3. IUCLID 5.4 changes and impact on submission and dissemination of information, Questions and Answers http://echa.europa.eu/documents/10162/13651/questions_and_answers_iuclid5_4_en.pdf, and IUCLID 5 FAQ, <http://www.iuclid.eu/index.php?useaction=home.faq>
4. "Data Submission Manual – Part 05 - How to complete a technical dossier for registrations and PPORD notifications" (version 3.0, 07/2012). http://www.echa.europa.eu/documents/10162/13653/compl_tech_dossier_manual_en.pdf