Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance Name(s)[[1]](#footnote-2):**

**EC Number(s)[[2]](#footnote-3):**

**CAS Number(s):**

**Submitted by: [Name of the Member State/s]**

**Date:**

*The aim of this template is to provide support to the authorities involved in the development of Annex XV dossiers for the identification of substances of very high concern (SVHC) with regard to the structure and content of the Annex XV report. This support is complementary to the provisions of the legal text and the information already available in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern and the information and support available at* [*http://echa.europa.eu/web/guest/support/authorisation/substances-of-very-high-concern-identification*](http://echa.europa.eu/web/guest/support/authorisation/substances-of-very-high-concern-identification)*.*

This annotated template provides instructions on how to structure and present information in the Annex XV SVHC report. The aim of this structure is to provide clarity and avoid duplication, without requiring any further information than laid down in the REACH Regulation. Furthermore, this template includes some standard phrases, which may be useful in the preparation of the “Supporting Documents” for the meetings of the Member State Committee.

Authorities should use this template when preparing an Annex XV SVHC report, proposing the identification of a substance in the hazard classes:

* carcinogenicity category 1A or 1B;
* germ cell mutagenicity category 1A or 1B; or
* toxic for reproduction category 1A or 1B;
* as persistent, bioaccumulative and toxic (PBT) and/or
* very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII to the REACH Regulation;
* as a substance of equivalent concern, in accordance with Article 57(f) REACH.

Sub-headings which are not relevant for the substance in question should be deleted, but please maintain the Section headings (in blue) as part of the overall final structure. Items highlighted in green should be replaced with the specific substance information. All annotations in italics should also be deleted before finalisation.

*The* ***proposal*** *should provide the identity of the substance as it is proposed to be included in the Candidate List and a summary of how the substance meets the criteria set out in Article 57. Furthermore, the registration status of the substance should also be provided here. All* ***relevant (preferably public) information from the registration dossiers*** *must be taken into account in Part II of the Annex XV SVHC dossier and the dossier must respect the relevant confidentiality and intellectual property aspects. Therefore, it is recommended to source registration data from ECHA’s dissemination site where possible.*

**Part I** (“Justification”) should provide the information that is relevant to identify the substance(s) addressed as meeting one or more of the criteria of Article 57 REACH. Therefore, only information that is of immediate relevance for the identification of the SVHC properties should be included in this part.

Valid information on properties that is not of immediate relevance for the conclusion as to whether the substance concerned meets the Article 57 criteria but could be useful for exposure and hazard assessment or in the context of prioritisation for inclusion in Annex XIV to REACH should still be provided, but in Annexes to the report.

The formats for Sections 3 to 5 of Part I follow the chemical safety report (CSR) template which is based on the required standard headings of Annex I of REACH.

**Part II** (Information on use, exposure and alternatives) can be used to report available information in order to serve the next step of the authorisation procedure, namely, priority setting in the context of recommending substances for inclusion in Annex XIV and development of draft Annex XIV entries (transitional arrangements, review periods, exemptions of (categories of) uses). The (preferably public) information from the **registration dossiers** (and other REACH/CLP dossiers) are the **main source of information** for this part of the Annex XV report. It should be noted that the aim of Part II is not to provide an exposure assessment or to conduct an assessment of possible alternatives, but to support the priority setting process.

This document has been prepared according to template: TEM-0049.04

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ABBREVIATIONS

*for example – please add/delete as necessary*

GC/MS: gas chromatography/ mass spectrometry

LOD: level of detection

LOEC: Lowest Observed Effect Concentration

LOQ: level of quantification

NO(A)EL: no observed (adverse) effect level

OEL: occupational exposure limit

TWA: time weighted average

ROS: reactive oxygen species

SEv: substance evaluation

SVHC: substance of very high concern

WoE: weight of evidence

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

*The substance name, CAS and EC numbers listed below should be those foreseen to be included in the Candidate List.*

**Substance name(s):** Substance name

**EC number(s)[[3]](#footnote-4): xxx-xxx-xx**

**CAS number(s): xxx-xxx-xx**

*Please delete what is not relevant. If your substance is a CMR, please maintain the footnote.*

* The substance(s) is/are proposed to be identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1A or 1B[[4]](#footnote-5).
* The substance(s) is/are proposed to be identified as a substance meeting the criteria of Article 57 (b) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class germ cell mutagenicity category 1A or 1B4.
* The substance(s) is/are proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1A or 1B4.
* It is proposed to identify the substance(s) as persistent, bioaccumulative and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).
* It is proposed to identify the substance(s) as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).
* It is proposed to identify the substance(s) as a substance(s) of equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 (REACH) according to Article 57(f) of REACH Regulation.

**Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation**

***The aim of this section is to provide a summary of the information supporting the identification of the substance as meeting the criteria set out in Article 57 REACH. The summary needs to address and reflect the main conclusions of the assessment (from Section 6: Conclusions on the SVHC properties, in addition to a description of the basis on which the assessment was made (e.g. use of weight-of-evidence, read across) as well as a clear statement on which Article 57 criterion/criteria is/are met. Consistency with Section 6 (****Conclusions on the SVHC Properties****) of the Annex XV report should be ensured while drafting the summary, although*** *no bibliographic references should be included here****. It is important to keep in mind that this summary is used later in the process to document the agreement of the Member State Committee.***

*For substances meeting the criteria set out in points (a) to (c) of Article 57 REACH, please use the relevant paragraph(s) provided below. Delete what is not relevant.*

Substance name is covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1A or 1B (hazard statement H350: “May cause cancer”).

Substance nameis covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class germ cell mutagenicity category 1A or 1B (hazard statement H340: “May cause genetic defects”).

Substance name is covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1A or 1B (hazard statement[[5]](#footnote-6)).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class: (*please delete what is not relevant*)

* Carcinogenicity category 1A or 1B in accordance with Article 57 (a) of REACH.
* Germ cell mutagenicity category 1A or 1B in accordance with Article 57 (b) of REACH.
* Toxic for reproduction category 1A or 1B in accordance with Article 57 (c) of REACH.

*For substances meeting the criteria of Articles 57 (d) and/or (e) REACH:*

*A summary of the assessment of each property (persistence, bioaccumulation and where relevant, toxicity) must be provided, including a clear comparison with the criteria in Annex XIII of REACH, in addition to a concluding statement on whether the substance is identified as an SVHC based on Articles 57 (d) and/or (e) REACH. The identification as an SVHC can be based on the PBT/vPvB properties of relevant constituents (including impurities and additives) of a substance and/or relevant transformation and/or degradation products. In such cases, a summary of PBT and/or vPvB properties for relevant constituents of a substance and/or for its relevant transformation products must also be provided. This section should be entirely consistent with the contents of Section 6.2.2 (Summary and overall conclusions on the PBT and vPvB properties, i.e. the text from Section 6.2.2 should be copied here).*

*Please use the following paragraph (modified as necessary) to reflect the weight-of-evidence you have used:*

A weight-of-evidence determination according to the provisions of Annex XIII of REACH has been used to identify the substance as PBT/vPvB. All available relevant information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) was considered together in a weight-of-evidence approach.

*The following structure should be used to report the outcome of the assessment of substances meeting the criteria of Articles 57 (d) and/or (e) REACH. This structure could also be the starting point in cases where substances meet the criteria of Article 57 (f) as substances of equivalent level of concern to PBT/vPvB substances.*

Persistence

Bioaccumulation

Toxicity (only relevant for PBT substances)

Conclusion

In conclusion, substance name meets the criteria for aPBT and/or vPvBsubstance according to Article 57 (d) and/or (e)of the REACH Regulation*.*

*For substances meeting the criteria of Article 57 (f) REACH:*

***(i) Where*** *the basis for the proposal is a harmonised classification* ***and where the equivalent level of concern relates to a hazard class relevant for human health*** *(e.g. respiratory sensitisation) the following text can be used: (please amend as appropriate).*

Substance name is covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified as a [*respiratory sensitiser*]. Substance name is proposed to be identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with [*respiratory sensitising hazard*] for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

***(ii) Where*** *the basis for the proposal is an adverse effect for which no hazard class has been defined in Regulation (EC) No 1272/2008 (CLP Regulation)* ***and where the equivalent level of concern relates to a human health effect*** *(e.g. caused by the endocrine disrupting properties of the substance), the following text can be used: (please amend as appropriate).*

Substance name is proposed to be identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because *[through its degradation to (name(s) of degradation product(s))]* it is a substance with *[endocrine disrupting properties]* for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

*In addition, summary information must be provided on the basis of which the above conclusion has been drawn. Ideally, this should include a brief summary of the evidence from high quality studies/information.*

Based on the above conclusion, evidence that the substance is of an equivalent level of concern includes:

***Where the equivalent level of concern relates to a human health effect, the key information in the report should be summarised taking into account the relevant discussion points in section 6.3.2 (non-exhaustive).*** *The conclusions of the assessment (from section 6.3.3) must also be included here.*

***(iii) Where*** *the basis for the proposal is an adverse effect for which no hazard class has been defined in Regulation (EC) No 1272/2008 (CLP Regulation)* ***and where the equivalent level of concern relates to an environmental effect*** *(e.g. caused by the endocrine disrupting properties of the substance), the following text can be used: (please amend as appropriate).*

Substance name is proposed to be identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because *[through its degradation to (name(s) of degradation product(s))]* it is a substance with *[endocrine disrupting properties]* for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

*In addition, summary information must be provided on the basis of which the above conclusion has been drawn. Ideally, this should include a brief summary of the evidence from high quality studies/information.*

Based on the above conclusion, evidence that the substance is of an equivalent level of concern includes:

***Where the equivalent level of concern relates to an environmental effect, the key information in the report should be summarised taking into account the relevant discussion points in section 6.3.2 (non-exhaustive).*** *The conclusions of the assessment (from section 6.3.3) must also be included here.*

(iv) ***Where*** *the basis for the proposal is an adverse effect for which no hazard class has been defined in Regulation (EC) No 1272/2008 (CLP Regulation)* ***and where the equivalent level of concern relates to both environmental and human health effects*** *the following text can be used: (please amend as appropriate).*

Substance name is proposed to be identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) as there is scientific evidence of probable serious effects to the environment and human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

*A summary of the assessment of each property (fate, ecotoxicity, human health toxicity) must be provided. This section should be entirely consistent with the contents of the Summary and overall conclusions from Section 6. For example, the following structure could be used:*

*Intrinsic properties*

*(Where relevant, it is important to clearly distinguish between the environmental and human health intrinsic properties)*

*Scientific evidence of probable serious effects to human health and the environment*

*Equivalent level of concern*

*The level of concern is considered very high in particular due to the combination of the*

*following concern elements:…*

*In conclusion*

*The combined intrinsic properties justifying the inclusion as a substance for which there is*

*scientific evidence of probable serious effects to human health and the environment which*

*give rise to an equivalent level of concern are the following:….*

**Registration dossiers submitted for the substance: Yes/No**

PART I

*The purpose of this first part of the report is to provide a concise and scientifically sound justification that the substance(s) addressed by the dossier has properties that meet one or more of the criteria of REACH Article 57.*

***Any information or data not relevant for the identification of the substance(s) as SVHC in accordance with Article 57 REACH should not be provided in Part I of the report.***

*This is to render the SVHC identification process stipulated by Article 59 REACH as efficient as possible. This means avoiding as much as possible, discussion and comments on (i) already agreed information (e.g. harmonised classification and labelling) and (ii) on information that is not relevant for the conclusion on the SVHC properties.*

*Valid information on properties that is not of immediate relevance for the conclusion on the SVHC properties, but could be useful in the context of prioritisation for inclusion in Annex XIV to REACH, should be provided in Annexes to the report (where this is considered useful, a reference to this option is made in the section-specific instructions).*

*The format and the headings proposed for the justification follow the CSR template, based on the required standard headings of Annex I of REACH. All* ***relevant******information from the registration dossiers*** *must be included in the Annex XV report (whilst respecting the relevant confidentiality and intellectual property aspects).*

Justification

*The submitting authorities should evaluate the validity of the data used in the assessment and not rely solely on the assessment made by registrants in their registration dossier, where the information comes from the (preferably public) registration dossier(s). It should be indicated which studies are considered as the main studies for the conclusions drawn on each physicochemical, environmental fate, human health or ecotoxicological endpoint and which studies are included as supporting information. The reliability of each study should be discussed and reported (e.g. Klimisch code).*

*In case a read-across approach is used in the assessment, please report the rationale in detail according to the available guidance[[6]](#footnote-7). Where a weight-of-evidence approach is used in the assessment, all available relevant**information should be used even if the individual pieces of information may not be regarded as information sufficient to conclude on the properties/endpoints. A justification should be provided for each piece of information used in the weight-of-evidence approach[[7]](#footnote-8). Please note that pursuant to Annex XIII to REACH, for the identification of PBT and vPvB substances a weight-of-evidence determination using expert judgement must always be applied.*

*(Sub)headings or tables not relevant or for which no information is provided should be deleted.*

# Identity of the substance and physical and chemical properties

*The principal requirements for identification and naming of mono- or multi-constituent substances and UVCBs[[8]](#footnote-9) are laid down in the “Guidance for identification and naming of substances under REACH and CLP”[[9]](#footnote-10).*

*Constituents (including impurities and additives) or degradation/transformation products that are* ***relevant for classification*** *and/or the PBT/vPvB properties (i.e. SVHC properties in accordance with REACH Art. 57) of the substance shall be specified independently from their concentration (in Section 1.3 “Identity and composition of degradation products/metabolites relevant for the SVHC assessment*” *below). In practice, this means constituents (including impurities and additives) or degradation/transformation products (that are relevant for classification) for which a (harmonised) classification is available, the generic concentration limits (GCL) given in Annex I of Regulation (EC) No 1272/2008 (CLP Regulation)  or specific concentration limits, where such are warranted, should be specified in this section. For certain hazard classes, constituents present below the generic or, where relevant, specific concentration limits (S/GCL) but above generic cut off value (CLP table 1.1), should be taken into account.*

*In the case of constituents (including impurities and additives) with PBT or vPvB properties a concentration limit of 0.1% w/w applies. This limit of 0.1 % w/w is set based on a well-established practice recognised in European Union legislation[[10]](#footnote-11). However, there may be particular cases of PBT constituents (including impurities and additives) where it is necessary to specify a concentration limit below 0.1% w/w (i.e. when based on the toxicity criterion of the PBT constituent where a specific concentration limit lower than 0.1 % w/w has been assigned).*

*In the case of degradation/transformation products with PBT or vPvB properties, similar arguments apply. The PBT/vPvB assessment should normally be carried out for each* ***relevant*** *transformation or degradation product. It is not possible to draw an overall conclusion for the substance if the assessment of persistence has been concluded for one transformation/degradation product and the assessment of bioaccumulation or toxicity for another transformation/degradation product. The principles of the standard test guidelines for identifying relevant transformation and degradation products should be applied. However, it should be noted that authorities are not bound under the SVHC-identification process to the stipulations of the Test Methods Regulation or other standards for defining what is a relevant transformation/degradation product but have the possibility to use other types of justified (concentration or formation rate) limits to define on a case-by-case basis which transformation/degradation products are relevant for the PBT/vPvB assessment.*

*For complex (groups of) substances with unclear substance identities, it is recommended to contact ECHA (*[*annex-xv@echa.europa.eu*](mailto:annex-xv@echa.europa.eu)*) at the earliest opportunity to allow the SVHC team and the substance identity experts to support you in specifying the substance information in the best possible way in your proposal.*

## Name and other identifiers of the substance

*The name and other identifiers of the substance should designate the actual substance(s) proposed to be identified as SVHC.*

*For substances identified as SVHC based on the PBT/vPvB properties of their transformation and/or degradation products, the information on the name or other identifiers of the substance should still designate the substance proposed to be identified as SVHC. In addition, information on transformation products having PBT/vPvB properties should be provided in Section 1.3 below.*

**Table 1: Substance identity**

|  |  |
| --- | --- |
| EC number: |  |
| EC name: |  |
| CAS number (in the EC inventory): |  |
| CAS number: |  |
| IUPAC name: |  |
| Index number in Annex VI of the CLP Regulation |  |
| Molecular formula: |  |
| Molecular weight range: |  |
| Synonyms: |  |

**Structural formula:**

## 1.2 Composition of the substance

*This information is particularly important for the main constituent(s) and for the constituents (including impurities) which influence the outcome of the SVHC identification. The information should be tailored as far as possible to profile the requirements on the composition for the substance to present the SVHC property.*

*Please note that the identification of a* ***mono- or multi-constituent substance*** *as an SVHC in its own right is based on the identity of its main constituent(s). In this case, the composition expected to be reported should be limited to the identity and typical concentration of the main constituent(s). The identification of the main constituent(s) is based on the rules established in the “Guidance for identification and naming of substances under REACH and CLP”[[11]](#footnote-12). Accordingly, the main constituent of a mono-constituent substance normally has a typical concentration level ≥80% w/w, while the main constituents in a multi-constituent substance are typically present at a concentration ≥10% w/w and <80% w/w.*

*Other constituents (i.e. impurities or additives) which are not relevant for the identification of the substance(s) as SVHC should not be mentioned. Indeed, indicating the identity and concentration of further constituents may confuse suppliers (manufacturers, importers or downstream users) supplying/using these substances, but having different compositions. In such cases, they may wrongly conclude that their substance is not covered by the proposal. However, impurities and additives must be mentioned whenever they are relevant for the identification of the substance as SVHC.*

**Name:**

**Description:**

**Substance type: mono-constituent / multi-constituent / UVCB**[[12]](#footnote-13)

***Any tables that are not relevant for the identification of the substance can be deleted. Any table columns that are not relevant can also be deleted.***

**Table 2: Constituents other than impurities/additives**

|  |  |  |  |
| --- | --- | --- | --- |
| Constituents | Typical concentration | Concentration range | Remarks |
| Name and EC number |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Table 3: Impurities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Impurities** | **Typical concentration** | **Concentration range** | **Remarks** |
| Name and EC number |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Table 4: Additives**

|  |  |  |  |
| --- | --- | --- | --- |
| **Additives** | **Typical concentration** | **Concentration range** | **Remarks** |
| Name and EC number |  |  |  |
|  |  |  |  |
|  |  |  |  |

## 1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

*Degradation/transformation products and/or metabolites that are relevant for the SVHC properties of the substance shall always be specified, independently from their concentration. It is recommended to document the identity of the degradation/transformation product(s) or metabolite(s) of relevance for the SVHC properties in the following table and to report in addition, the structural formula as well as some information regarding the transformation process. Such a comprehensive table should be filled in for each relevant degradation/transformation product and/or metabolite.*

**Table 5: Degradation (transformation) product/metabolite**

|  |  |
| --- | --- |
| **EC number:** |  |
| **EC name:** |  |
| **SMILES:** |  |
| **CAS number (in the EC inventory):** |  |
| **CAS number:** |  |
| **IUPAC name:** |  |
| **Index number in Annex VI of the CLP Regulation** |  |
| **Molecular formula:** |  |
| **Molecular weight range:** |  |
| **Synonyms:** |  |

**Structural formula:**

**Indication of the process, organism and/or organ in which the transformation takes place:**

## 1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

*For each structurally related substance of relevance for the SVHC properties, the following tables should be filled in.*

**Table 6: Structurally related substance(s) identity**

|  |  |
| --- | --- |
| **EC number:** |  |
| **EC name:** |  |
| **SMILES:** |  |
| **CAS number (in the EC inventory):** |  |
| **CAS number:** |  |
| **IUPAC name:** |  |
| **Index number in Annex VI of the CLP Regulation** |  |
| **Molecular formula:** |  |
| **Molecular weight range:** |  |
| **Synonyms:** |  |

**Substance type: mono-constituent / multi-constituent / UVCB**

**Structurally related substance(s) formula:**

**Table 7: Constituents of structurally related substance(s)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Constituents** | **Typical concentration** | **Concentration range** | **Remarks** |
| *Name and EC number* |  |  |  |

**Table 8: Impurities of structurally related substance(s)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Impurities** | **Typical concentration** | **Concentration range** | **Remarks** |
| *Name and EC number* |  |  |  |

**Table 9: Additives of structurally related substance(s)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Additives** | **Typical concentration** | **Concentration range** | **Remarks** |
| *Name and EC number* |  |  |  |

## 1.5 Physicochemical properties

*Physicochemical properties should be provided here if they are relevant for the assessment of the SVHC criteria.*

If the objective of the Annex XV dossier is to identify an SVHC because it has been classified as a CMR in accordance with Article 57 (a) to (c) of the REACH Regulation, it is not necessary to provide data in this section. If this section is not relevant, the following phrase can be used:

Not relevant for the identification of the substance(s) as SVHC in accordance with Article 57 (a) to (f) of the REACH Regulation.

*For substances proposed to be identified as SVHC based on the PBT/vPvB-properties, physicochemical data are necessary for the assessment and should be provided here, particularly the vapour pressure, water solubility, partition coefficient n-octanol/water and dissociation constants (ionising substances).*

*If the Annex XV dossier aims to identify a substance as having properties giving rise to an equivalent level of concern, in accordance with Article 57 (f) REACH, other physicochemical properties might be important and the relevancy of such endpoints should be assessed on a case-by-case basis.*

*When reporting the physicochemical properties in the following table, please specify, when relevant the test conditions (e.g. temperature, pH, including the correct units of measurement).*

*Where the source of the physicochemical data is ECHA’s dissemination website, please note that information published on ECHA’s dissemination site is not necessarily checked for its’ correctness. Therefore, in order to ensure that the information included in your Annex XV SVHC report is accurate, it is recommended that you assess the original data accordingly or base the information on other, reliable sources.*

**Table 10: Overview of physicochemical properties**

|  |  |  |  |
| --- | --- | --- | --- |
| Property | Description of key information | Value [Unit] | Reference/source of information |
| Physical state at 20°C and 101.3 kPa | short description of key information | Value used in the assessment |  |
| Melting/freezing point | idem | idem |  |
| Boiling point | idem | idem |  |
| Vapour pressure | idem | e.g. xx Pa at xy °C |  |
| Density | idem | e.g. xx kg/m3 at xy °C |  |
| Water solubility | idem | e.g. Xx mg/l at xy °C |  |
| Partition coefficient n-octanol/water (log value) | idem | e.g. log Kow xx at xy °C |  |
| [Enter other property, if relevant. Add rows if needed, or delete row as appropriate.] | idem | idem |  |

# Harmonised classification and labelling

*In this section, only harmonised classification and labelling should be reported as included in Part 3 of Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).*

*The harmonised classification reported in this section provides the basis for the conclusion that the substance(s) addressed fulfil(s) the criteria for being considered as carcinogenic, mutagenic or toxic for reproduction (category 1A or 1B) in accordance with Article 57 (a) to (c) REACH.*

*Reference to Annex VI of the CLP Regulation may be necessary to provide evidence that the T-criterion of REACH Annex XIII (with regard to human health effects) is met. Reference to Annex VI of the CLP Regulation may also be necessary for cases in accordance with Article 57(f) REACH which are based on harmonised classification and labelling (e.g. respiratory sensitisers).*

*In cases where the classification is based on the presence of a constituent or an impurity (and if relevant, additives), this should be stated clearly, along with the identity of the constituent/impurity and the concentration of the constituent/impurity in the substance leading to the classification.*

*The information provided should include the index number, specific concentration limits/M-factors and the notes listed in Annex VI of the CLP Regulation. ECHA would therefore recommend reproducing in this section the entry as given in Annex VI of the CLP Regulation.*

Substance name is covered by Index number xxx-xxx-xx-x in part 3 of Annex VI to the CLP Regulation as follows:

**Table 11: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Index No | Chemical name | EC No | CAS No | Classification | | Labelling | | | Spec. Conc. Limits, M-factors and ATEs[[13]](#footnote-14) | Notes |
| Hazard Class and Category Code(s) | Hazard statement code(s) | Pictogram, Signal Word Code(s) | Hazard statement code(s) | Suppl. Hazard statement code(s) |
|  |  |  |  |  |  |  |  |  |  |  |

# Environmental fate properties

*If the Annex XV SVHC dossier aims to identify a substance as having PBT or vPvB properties or, as having properties giving rise to an equivalent level of concern (environment), in accordance with Article 57 (d) to (f) REACH, Sections 3.1 and 3.4 including the relevant sub-sections, need to be filled in, as a minimum. It is necessary to document the data and considerations that result in the conclusions in Section 6 “Conclusions on the SVHC Properties” as to whether the substance meets the P/vP and B/vB criteria of Annex XIII to REACH or, as to whether it has properties leading to an equivalent level of concern. It should be noted that a comparison with the Annex XIII criteria is foreseen for Section 3 (Environmental fate properties) and should also be included in Section 6.2****.2.***

*For substances identified as SVHC based on the PBT/vPvB-properties of relevant transformation and/or degradation products, the environmental fate properties of each relevant transformation product need to be provided here (****or as part of an Annex to the Annex XV report)****. The environmental fate properties of the parent substance (respectively its relevant constituents, impurities and additives) should be reported in this section also (****or as part of an annex to the Annex XV report)****. The relevance of the degradation and/or transformation products in question also needs to be described and discussed in this section in a quantitative and/or qualitative way (e.g., reflecting the probability and rate of formation of the degradation and/or transformation products in question).*

*Sub-headings which are not relevant for the substance in question should be deleted.*

If the objective of the Annex XV dossier is to identify an SVHC because it has been classified as a CMR in accordance with Article 57 (a) to (c) REACH, it is not necessary to provide data in this section. If this section is not relevant, the following phrase can be used:

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (f) of the REACH Regulation.

## 3.1 Degradation

*In this section, information relevant for assessing the degradation potential of the substance can be included. The information needs to be presented in such a level of detail that the reader is able to make their own basic judgement about the reliability of the information. The dossier submitter should also provide their conclusions on the reliability of the information. Furthermore, the relevance and adequacy of the presented information for the purpose of the assessment needs to be described. This information will form the basis for the conclusion whether the substance is considered to fulfil the P or vP criteria according to Annex XIII to REACH. A summary and discussion on the main conclusions on both abiotic and biotic degradation should be included in the following sections. This section may also be relevant for substances proposed to be identified in accordance with Article 57 (f) REACH.*

*When using a weight-of-evidence approach, please consider also reporting in the different sub-sections of Section 3.1 “Degradation”, detailed information on the studies and describing the necessary details of the weight-of-evidence approach. Examples and principles of weight-of-evidence determinations for the PBT/vPvB assessment are provided in Section R.11.4 of the “Guidance on information requirements and chemical safety assessment: Chapter R.11: PBT/vPvB assessment[[14]](#footnote-15)”.*

*In addition, the Weight of Evidence/Uncertainty Analysis Template[[15]](#footnote-16)” and “Background document & Examples”[[16]](#footnote-17) provide information on building a weight-of-evidence approach.*

*In Section “3.1.4 Summary and discussion of degradation” the relevant information on degradation (having relevant weight as part of the weight-of-evidence) must be summarised.*

*In addition, conclusions regarding the overall degradation potential of the substance must be drawn and reported in Section 3.1.4. This information will form the basis for the conclusion whether the substance fulfils the P or vP criteria according to Annex XIII to REACH and as documented in Section 6 of the Annex XV report. The comparison with Annex XIII criteria is foreseen in Section 3.1 and should also be included in Section 6.2.2 and further copied to the proposal section: “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation".***

***The same applies when concluding on substances proposed to be identified in accordance with Article 57(f) REACH.***

### 3.1.1 Abiotic degradation

#### 3.1.1.1 Hydrolysis

#### 3.1.1.2 Oxidation

#### 3.1.1.3 Phototransformation/photolysis

##### 3.1.1.3.1 Phototransformation in air

##### 3.1.1.3.2 Phototransformation in water

##### 3.1.1.3.3 Phototransformation in soil

#### 3.1.1.4 Summary on abiotic degradation

### 3.1.2 Biodegradation

#### 3.1.2.1 Biodegradation in aqueous media or aqueous environment

##### 3.1.2.1.1 Estimated data

##### 3.1.2.1.2 Screening tests

##### 3.1.2.1.3 Simulation tests

###### 3.1.2.1.3.1 Biodegradation in water

###### 3.1.2.1.3.2 Biodegradation in sediment

#### 3.1.2.2 Biodegradation in soil

##### 3.1.2.2.1 Simulation tests in soil

#### 3.1.2.3 Summary and discussion on biodegradation

### 3.1.3 Field data

### 3.1.4 Summary and discussion of degradation

## 3.2 Environmental distribution

### 3.2.1 Adsorption/desorption

### 3.2.2 Volatilisation

### 3.2.3 Distribution modelling

### 3.2.4 Field data

### 3.2.5 Summary and discussion of environmental distribution

## 3.3 Data indicating potential for long-range transport

*Regarding the long-range transport potential of the substance, relevant information such as screening information as set out in the Stockholm Convention on Persistent Organic Pollutants (POPs) can be reported in this section (cf. screening criteria for potential for long-range environmental transport in Annex D, Section 1 (d) of the Stockholm Convention[[17]](#footnote-18)).* For substances fulfilling the vP, vB and T criteria according to Annex XIII, it is strongly recommended to assess the long-range transport potential of the substance as this will facilitate screening for and identification of potential POP candidates under the Stockholm Convention.

## 3.4 Bioaccumulation

*In this section, information relevant for identifying the bioaccumulation potential of the substance can be included. The information needs to be presented in such a level of detail that the reader is able to make their own basic judgement about the reliability of the information. The dossier submitter also should provide their conclusions on the reliability of the information. Furthermore, the relevance and adequacy of the presented information for the purpose of the assessment needs to be described. This information will be the basis for the conclusion on whether the substance is considered to fulfil the B or vB criteria according to Annex XIII. The information to be used in support of the assessment of the bioaccumulation potential is listed under Annex XIII to REACH, Sections 3.1.2 and 3.2.2. Please note that information related to bioaccumulation in humans and toxicokinetics should be reported under Section 4 of the Annex XV report, as Section 3.4 is intended to describe the environmental bioaccumulation potential. However, a reference to the data on bioaccumulation in humans and toxicokinetics in Section 4 can be included here if it is relevant for assessing bioaccumulation in air breathing wildlife. Data on protein binding can also be included in Section 3.4 if relevant for the bioaccumulation assessment. This section may also be relevant for substances proposed to be identified in accordance with Article 57(f) of REACH.*

*When using a weight-of-evidence approach, please consider reporting in the different sub-sections of Section 3.4 (Bioaccumulation) detailed information on the studies and describing in accordance with the “Weight of Evidence/Uncertainty Analysis Template[[18]](#footnote-19)” the necessary details of the weight-of-evidence approach.*

*In Section 3.4.4 “Summary and discussion of bioaccumulation” the relevant information on bioaccumulation (having relevant weight as part of the weight-of-evidence) must be summarised and a comparison to the Annex XIII criteria conducted. A summary and discussion on the main conclusions on aquatic and terrestrial bioaccumulation should be included in the following sections.*

*In addition, conclusions regarding the overall bioaccumulation potential of the substance should be drawn and reported in Section 3.4.4. This information will be the basis for the conclusions whether the substance fulfils the B or vB criteria according to Annex XIII to REACH. The comparison with the criteria/conclusions should also be reported in Section 6.2.2 and copied to the proposal section: “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation".***

***The same applies when concluding on substances proposed to be identified in accordance with Article 57(f) of the REACH Regulation.***

### 3.4.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

### 3.4.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

### 3.4.3 Field data

### 3.4.4 Summary and discussion of bioaccumulation

3.5 **Summary and discussion of environmental fate properties**

# Human health hazard assessment

If the dossier aims to identify the substance addressed in the hazard classes carcinogenicity, germ cell mutagenicity or toxic for reproduction, category 1 A/B based on Annex VI of the CLP Regulation, in accordance with REACH Article 57 (a) to (c), the section on human health hazard assessment is not relevant and therefore does not need to be filled in. It is sufficient to provide the respective harmonised classification and labelling in Section 2. **If environmental data is used as part of the human health hazard assessment, please ensure that this is noted/referenced in this chapter.**

If this section is not relevant, the following phrase can be used:

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (c) or (f) of the REACH Regulation.

If a harmonised classification for the respective effect(s) is not available, it is strongly recommended to first submit to the Agency a proposal for harmonised classification and labelling in accordance with Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) and wait for a decision taken in accordance with the procedure set out in Article 37 of the CLP Regulation.

In case a harmonised classification has been established, supplementary information on the leading health effect(s), toxicodynamics (i.e. threshold or non-threshold MoA) and potency, if available/relevant, should not be reported in this section but in an Annex to the report (using the structure and relevant headings proposed for this section). These data may be useful to further assess the hazard potential of the substance and could be useful in the application for authorisation (AfA) phase.

This section also provides the basis for reporting information in the context of a proposal to identify a substance as giving rise to an equivalent level of concern in accordance with Article 57(f) REACH if the relevant effects relate to toxicological endpoints (See also Section 6.3 for further reporting on Art 57(f) aspects).

**PBT considerations regarding human health hazard assessment:**

The information provided in this section can form the basis for the conclusion as to whether the substance addressed fulfils the T-criterion in accordance with Annex XIII to REACH (on the basis of toxicological effects). If the dossier proposes to conclude on the T-criterion in accordance with Section 1.1.3 (b) or (c) of Annex XIII and a harmonised classification for the respective effect(s) is not available, it is strongly recommended that a proposal for harmonised classification and labelling in accordance with Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) is first submitted to the Agency and a decision taken in accordance with the procedure set out in Article 37 of the CLP Regulation is awaited.

This section can also be relevant for reporting information relevant for the assessment of the bioaccumulation potential of the substance, such as the toxicokinetic behaviour or data from scientific analysis in human body fluids. In such case, the information needs to be presented in such a level of detail that the reader is able to make their own basic judgement about the reliability of the information. The dossier submitter should also provide their conclusions on the reliability of the information. Furthermore, the relevance and adequacy of the presented information for the purpose of the assessment need to be described. A summary and discussion on the main conclusions regarding the toxicokinetic behaviour of the substance and the bioaccumulation potential of the substance in humans should be reported in the relevant sections below. Please note that information related to bioaccumulation in aquatic and terrestrial species should be reported under Section 3.4.

*This information will be the basis for the conclusions whether the substance fulfils the B or vB criteria according to Annex XIII to REACH. The comparison with Annex XIII criteria is foreseen here and should also be reported in Section 6.2 and copied to the proposal section: “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation".***

*Sub-headings which are not relevant for the substance in question should be deleted.*

**Endocrine disruption**

*The evaluation of endocrine disrupting properties is carried out based on the WHO/IPCS definition of an endocrine disruptor (WHO/IPCS, 2002) as interpreted by the JRC Endocrine Expert Advisory Group (2013). In addition, the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA/EFSA 2018) is, inter alia, taken into account.*

*The ECHA/EFSA document for the identification of endocrine disruptors is intended to provide guidance to applicants and assessors of the competent regulatory authorities on the implementation of the scientific criteria for the determination of endocrine disrupting properties of biocidal products and plant protection products. Here, a similar approach is proposed for REACH substances in order to provide a systematic overview of the available data.*

*Consequently, the justification part of the report is accompanied by the summary in Section 4.10 below and the suggested five annexes, which can be filled in as set out in the respective chapters of the Guidance for the identification of endocrine disruptors. In order to facilitate assembling and analysis of lines of evidence it is in particular recommended to use the Excel template for reporting the available information relevant for ED assessment.*

*Suggested Annexes:*

* *Annex III - Detailed study information*
* *Annex IV – Data overview (Excel template for reporting the available information relevant for ED assessment)*
* *Annex V – Lines of evidence for adverse effects and endocrine activity*
* *Annex VI – Mode of action analysis*
* *Annex VII – Human epidemiology studies*

*A summary overview of available studies should be given in Section 4.10 but study details can be presented in Annexes III to VII.*

## 4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

*For guidance on the information to be provided in support of the bioaccumulation assessment under PBT assessment, please refer to the R.11 guidance on PBT assessment[[19]](#footnote-20).*

### 4.1.1 Non-human information

### 4.1.2 Human information (including bioaccumulation in humans)

### 4.1.3 Conclusion on toxicokinetics (and bioaccumulation in humans)

## 4.2 Acute toxicity

### 4.2.1 Non-human information

#### 4.2.1.1 Acute toxicity: oral

#### 4.2.1.2 Acute toxicity: inhalation

#### 4.2.1.3 Acute toxicity: dermal

#### 4.2.1.4 Acute toxicity: other routes

### 4.2.2 Human information

### 4.2.3 Summary and discussion of acute toxicity

## 4.3 Irritation

## 4.4 Corrosivity

## 4.5 Sensitisation

### 4.5.1 Skin

#### 4.5.1.1 Non-human information

#### 4.5.1.2 Human information

### 4.5.2 Respiratory system

#### 4.5.2.1 Non-human information

#### 4.5.2.2 Human information

### 4.5.3 Summary and discussion of sensitisation

## 4.6 Repeated dose toxicity

### 4.6.1 Non-human information

#### 4.6.1.1 Repeated dose toxicity: oral

#### 4.6.1.2 Repeated dose toxicity: inhalation

#### 4.6.1.3 Repeated dose toxicity: dermal

#### 4.6.1.4 Repeated dose toxicity: other routes

### 4.6.2 Human information

### 4.6.3 Summary and discussion of repeated dose toxicity

## 4.7 Mutagenicity

### 4.7.1 Non-human information

#### 4.7.1.1 In vitro data

#### 4.7.1.2 In vivo data

### 4.7.2 Human information

### 4.7.3 Summary and discussion of mutagenicity

## 4.8 Carcinogenicity

### 4.8.1 Non-human information

#### 4.8.1.1 Carcinogenicity: oral

#### 4.8.1.2 Carcinogenicity: inhalation

#### 4.8.1.3 Carcinogenicity: dermal

#### 4.8.1.4 Carcinogenicity: other routes

### 4.8.2 Human information

### 4.8.3 Summary and discussion of carcinogenicity

## 4.9 Toxicity for reproduction

### 4.9.1 Effects on fertility

#### 4.9.1.1 Non-human information

#### 4.9.1.2 Human information

### 4.9.2 Developmental toxicity

#### 4.9.2.1 Non-human information

#### 4.9.2.2 Human information

### 4.9.3 Summary and discussion of reproductive toxicity

## 4.10 Endocrine disruption (Human Health)[[20]](#footnote-21)

### 4.10.1 Lines of evidence (LoE)- EAS[[21]](#footnote-22) modalities

#### 4.10.1.1 LoE Adversity - EAS

#### 4.10.1.2 LoE Endocrine Activity - EAS

#### 4.10.1.3 Assembling and integration of LoE for Endocrine Activity and Adversity – EAS

### 4.10.2 Lines of evidence - T[[22]](#footnote-23) modality

#### 4.10.2.1 LoE Adversity - T

#### 4.10.2.2 LoE Endocrine Activity - T

#### 4.10.2.3 Assembling and integration of LoE for Endocrine Activity and Adversity – T

### 4.10.3 Lines of Evidence - Other modalities

#### 4.10.3.1 LoE Adversity – Other

#### 4.10.3.2 LoE Endocrine Activity – Other

#### 4.10.3.3 Assembling and integration of LoE for Endocrine Activity and Adversity - Other

*Lines of evidence should ideally be assembled, assessed, integrated and reported as described in section 3.3. of the ED guidance. Information according to levels 4 and 5 (potentially also levels 1 and 3) of the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals (revised version 2018) may be used to inform on adverse endocrine related effects of the substance whereas information in accordance with levels 2 to 5 (potentially also level 1) of the Conceptual Framework may be used to inform on endocrine activity exerted by the substance.*

*The EAS and T (i.e. EATS) modalities are currently the pathways for which there is a relatively good mechanistic understanding of how substance-induced perturbations may lead to adverse effects via an endocrine disrupting MoA. In addition, only for these modalities there are at present standardised test guidelines for in vivo and in vitro testing available where there is broad scientific agreement on the interpretation of the effects observed on the investigated parameters. However, there are other endocrine (i.e. non-EATS) modalities. Although the existing knowledge for those modalities is not as advanced as for the EATS modalities, it may, in some cases, be already possible to reach a conclusion on a non-EATS endocrine modality, e.g. where literature data provide mechanistic information, which can be linked to adverse effects measured in standard tests. Such information should be reported in section 4.10.3, applying the same assessment principles as for EATS modalities (e.g. Chapter 3 of ED guidance).*

### 4.10.4 Mode of Action (MoA) analysis

*Guidance on how to postulate and conclude on MoA(s), assess the biological plausibility of a link between endocrine activity and adverse effects as well as to identify which further information could help to clarify the postulated MoA(s) is provided in Section 3.5 of the ED guidance.*

#### 4.10.4.1 Postulation of MoA(s)

#### 4.10.4.2 Assessment of biological plausibility of the link between endocrine activity and adverse effect(s)

#### 4.10.4.3 Human relevance of MoA

*Human relevance of MoA is assumed by default unless there is indication that this may not be the case. Hence, only if there is such indication, assessment of relevance for humans of the postulated MoA(s) needs to be carried out here. Cf. sections 3.5.4.4 & 3.3.1.3 of ED guidance.*

#### 4.10.4.4 Conclusion on the Mode of Action analysis

*Consider guidance provided in section 3.5.6 of the ED guidance.*

### 4.10.5 Overall conclusion on endocrine disruption with regards to human health

## 4.11 Other effects: *[type of effect]*

### 4.11.1 Non-human information

#### 4.11.1.1 Neurotoxicity

#### 4.11.1.2 Immunotoxicity

#### 4.11.1.3 Specific investigations: other studies

### 4.11.2 Human information

### 4.11.3 Summary and discussion of other effects – human health

## **4.12 Summary and discussion of human health hazard assessment**

*If environmental data is used as part of the human health hazard assessment, please ensure that this is noted/referenced in this chapter.*

# **Environmental hazard assessment**

If the dossier aims to identify the substance addressed in the hazard classes carcinogenicity, germ cell mutagenicity or toxic for reproduction, category 1 A/B, in accordance with Article 57 (a) to (c) REACH, the section on environmental hazard assessment is not relevant and therefore does not need to be filled in. The same applies in the context of a proposal to identify a substance as giving rise to an equivalent level of concern in accordance with Article 57 (f) REACH if the relevant effects relate only to human health endpoints. If this section is not relevant, the following phrase can be used:

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (c) or (f) REACH.

**However, if human health data (e.g. mammalian toxicity data) is used as part of the environmental hazard assessment, please ensure that this is noted/referenced in this chapter.** The information provided in this section forms the basis for the conclusion as to whether the substance addressed fulfils the T-criterion in accordance with Annex XIII to REACH (on the basis of ecotoxicological effects). This section also provides the basis for reporting information in the context of a proposal to identify a substance as giving rise to an equivalent level of concern in accordance with Article 57(f) REACH if the relevant effects relate to ecotoxicological endpoints (or other environmental concerns). (See also Section 6.3 for further reporting on Art 57(f) aspects).

For these purposes, the information needs to be presented in such a level of detail that the reader is able to make their own basic judgement about the reliability of the information. The dossier submitter should also provide their conclusions on the reliability of the information. Furthermore, the relevance and adequacy of the presented information for the purpose of the assessment needs to be described.

*When using a weight-of-evidence approach, please consider reporting in the different sub-sections detailed information on the studies and describing in accordance with the Practical Guide on “How to use alternatives to animal testing to fulfil your information requirements for REACH registration” the necessary details of the weight-of-evidence approach.*

*In Section 5.6 (Summary and discussion of toxic effects) the relevant information (having relevant weight as part of the weight-of-evidence) must be summarised.*

*For substances identified as SVHC based on the PBT/vPvB-properties of relevant transformation and/or degradation products, the environmental toxicity properties of each relevant transformation and/or degradation product should be provided here (****or as part of an Annex to the Annex XV report)****. The environmental toxicity properties of the parent substance and constituents (including impurities and additives) should be reported in this section also (****or as part of an Annex to the Annex XV report)****.*

*A summary and discussion on the main conclusions of the specific toxicity of the substance to organisms in the different environmental compartments should be included in the compartment specific (sub)-sections (i.e. sub-sections 5.1 – 5.6, as relevant).*

*In addition, conclusions regarding the overall toxicity of the substance to organisms living in the different environmental compartments should be reported in Section 5.9 (Summary and discussion of the environmental hazard assessment). This information will form the basis for the conclusion whether the substance fulfils the T criteria according to Annex XIII as needs to be documented in Section 6 (Conclusions on the SVHC Properties) of the Annex XV report. The comparison with Annex XIII criteria is foreseen to be included in Section 5.9. The comparison to the criteria/conclusion should also be reported in Section 6.2.2 and copied to the proposal section: “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation". The same applies when concluding on substances proposed to be identified in accordance with Article 57(f) of REACH.***

*Sub-headings which are not relevant for the substance in question should be deleted.*

**Endocrine disruption**

*The evaluation of endocrine disrupting properties is carried out based on the WHO/IPCS definition of an endocrine disruptor (WHO/IPCS, 2002) as interpreted by the JRC Endocrine Expert Advisory Group (2013). In addition, the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA/EFSA 2018) is, inter alia, taken into account.*

*The ECHA/EFSA document is intended to provide guidance to applicants and assessors of the competent regulatory authorities on the implementation of the scientific criteria for the determination of endocrine disrupting properties of biocidal products and plant protection products. Here, a similar approach is proposed for REACH substances in order to provide a systematic overview of the available data.*

*Consequently, the justification part of the report is accompanied by the summary in Section 5.7 below and the suggested four annexes, which can be filled in as set out in the respective chapters of the Guidance for the identification of endocrine disruptors. In order to facilitate assembling and analysis of lines of evidence it is in particular recommended to use the Excel template for reporting the available information relevant for ED assessment.*

*Suggested Annexes:*

* *Annex III - Detailed study information*
* *Annex IV – Data overview (Excel template for reporting the available information relevant for ED assessment)*
* *Annex V – Lines of evidence for adverse effects and endocrine activity*
* *Annex VI – Mode of action analysis*

*A summary overview of available studies is given in Section 5.7 but study details are presented in Annexes III and IV.*

## 5.1 Aquatic compartment (including sediment)

### 5.1.1 Fish

#### 5.1.1.1 Short-term toxicity to fish

#### 5.1.1.2 Long-term toxicity to fish

### 5.1.2 Aquatic invertebrates

#### 5.1.2.1 Short-term toxicity to aquatic invertebrates

#### 5.1.2.2 Long-term toxicity to aquatic invertebrates

### 5.1.3 Algae and aquatic plants

### 5.1.4 Sediment organisms

### 5.1.5 Other aquatic organisms

## 5.2 Terrestrial compartment

### 5.2.1 Toxicity to soil macro-organisms

### 5.2.2 Toxicity to terrestrial plants

### 5.2.3 Toxicity to soil micro-organisms

### 5.2.4 Toxicity to other terrestrial organisms

## 5.3 Atmospheric compartment

*Relevant information, such as concentrations of the substance measured in ambient air (indoor and outdoor air, including in dust) can be reported in this section. It should be reported if the samples refer to the concentration of the substance in the gas- and/or the particle phase and/or to the bulk concentrations (sum of gas and particle phases).*

## 5.4 Microbiological activity in sewage treatment systems

## 5.5 Toxicity to birds

## 5.6 Mammalian wildlife

*[If the hazards described in Section 4 are also relevant for mammalian wildlife, briefly refer to this here.]*

## 5.7 Endocrine disruption (Environment)[[23]](#footnote-24)

### 5.7.1 Lines of evidence (LoE)- EAS[[24]](#footnote-25) modalities

#### 5.7.1.1 LoE Adversity

#### 5.7.1.2 LoE Endocrine Activity - EAS

#### 5.7.1.3 Assembling and integration of LoE for Endocrine Activity and Adversity – EAS

### 5.7.2 Lines of evidence – T[[25]](#footnote-26) modality

#### 5.7.2.1 LoE Adversity - T

#### 5.7.2.2 LoE Endocrine Activity - T

#### 5.7.2.3 Assembling and integration of LoE for Endocrine Activity and Adversity – T

### 5.7.3 Lines of Evidence – Other modalities

#### 5.7.3.1 LoE Adversity – Other

#### 5.7.3.2 LoE Endocrine Activity – Other

#### 5.7.3.3 Assembling and integration of LoE for Endocrine Activity and Adversity - Other

*Lines of evidence should ideally be assembled, assessed, integrated and reported as described in section 3.3. of the ED guidance. Information according to levels 4 and 5 (potentially also levels 1 and 3) of the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals (revised version 2018) may be used to inform on adverse endocrine related effects of the substance whereas information in accordance with levels 2 to 5 (potentially also level 1) of the Conceptual Framework may be used to inform on endocrine activity exerted by the substance.*

*The EAS and T (i.e. EATS) modalities are currently the pathways for which there is a relatively good mechanistic understanding of how substance-induced perturbations may lead to adverse effects via an endocrine disrupting MoA. In addition, only for these modalities there are at present standardised test guidelines for in vivo and in vitro testing available where there is broad scientific agreement on the interpretation of the effects observed on the investigated parameters. However, there are other endocrine (i.e. non-EATS) modalities. Although the existing knowledge for those modalities is not as advanced as for the EATS modalities, it may, in some cases, be already possible to reach a conclusion on a non-EATS endocrine modality, e.g. where literature data provide mechanistic information, which can be linked to adverse effects measured in standard tests. Such information should be reported in section 4.10.3, applying the same assessment principles as for EATS modalities (e.g. Chapter 3 of ED guidance).*

### 5.7.4 Mode of Action (MoA) analysis

*Guidance on how to postulate and conclude on MoA(s), assess the biological plausibility of a link between endocrine activity and adverse effects as well as to identify which further information could help to clarify the postulated MoA(s) is provided in Section 3.5 of the ED guidance.*

#### 5.7.4.1 Postulation of MoA(s)

#### 5.7.4.2 Assessment of biological plausibility of the link between endocrine activity and adverse effect(s)

#### 5.7.4.3 Population relevance of MoA

*Population relevance for environmental animals of the postulated MoA needs to be assessed in particular if the postulated ED MoA is based on mammalian data from studies carried out in the context of human health assessment. Advice on assessment of population relevance is provided in section 3.3.1.4 of the ED guidance.*

#### 5.7.4.4 Conclusion on the Mode of Action analysis

*Consider guidance provided in section 3.5.6 of the ED guidance.*

### 5.7.5 Overall conclusion on endocrine disruption with regards to environment

## 5.8 Other effects: *[type of effect]*

### 5.8.1 Adverse effects (non-ED)

### 5.8.2 Summary and discussion of other effects – environment

## 5.9 Summary and discussion of the environmental hazard assessment

*If human health data (e.g. mammalian toxicity data) is used as part of the environmental hazard assessment, please ensure that this is noted/referenced in this chapter.*

# 6. Conclusions on the SVHC Properties

## 6.1 CMR assessment

*This section is only relevant if the intention of the Annex XV (SVHC) dossier is to identify the substance as a CMR in accordance with Article 57 (a) to (c) REACH. A reference to the respective harmonised classification as included in Annex VI of Regulation (EC) No 1272/2008* (*CLP* *Regulation) and provided for in Section 2 of the dossier is sufficient.* *Therefore*, *for substances meeting the criteria of Articles 57 (a) to (c) REACH please use one of the paragraphs provided below. Delete what is not relevant.*

Substance name is covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1A or 1B (hazard statement H350: “May cause cancer”).

Substance nameis covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class germ cell mutagenicity category 1A or 1B (hazard statement H340: “May cause genetic defects”).

Substance name is covered by index number xxx-xxx-xx-x of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1A or 1B (hazard statement[[26]](#footnote-27)).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class: (*please delete what is not relevant*)

* carcinogenicity category 1A or 1B in accordance with Article 57 (a) of REACH.
* germ cell mutagenicity category 1A or 1B in accordance with Article 57 (b) of REACH.
* toxic for reproduction category 1A or 1B in accordance with Article 57 (c) of REACH.

If this section is not relevant the following text can be used:

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (f) of the REACH Regulation.

## 6.2 PBT and vPvB assessment

This section is only relevant if the intention of the Annex XV (SVHC) dossier is to identify the substance as a PBT or a vPvB in accordance with Article 57 (d) or (e). This section is not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (c) and (f) of the REACH Regulation.

The data provided in Sections 2 to 5 must be compared to the criteria of Annex XIII and an overall conclusion drawn on the PBT or vPvB properties of the substance. Information on whether the Annex XIII criteria are fulfilled should be also be reported here in Section 6.2.

*The comparison with the Annex XIII criteria need not be done for the purpose of an Annex XV SVHC dossier for each constituent/impurity/additive of the substance or for each relevant transformation/degradation product formed, as it is sufficient to demonstrate the comparison for at least one constituent/impurity/additive present in concentration above 0.1% w/w or at least one degradation or transformation product formed.*

For the purpose of comparison of the relevant information with the Annex XIII criteria a weight-of-evidence approach is necessary in accordance with the introductory section of Annex XIII to the REACH Regulation. Any description/justification for the approach taken which in particular serves the stage of comparison of the information with the Annex XIII criteria should be added under the relevant sub-sections of the corresponding chapter. However, it should be noted that the detailed discussion on relevance and weight of each piece of information among all the available relevant information) e.g. whether the Annex XIII criteria are met) should be presented in Section 3, while the overall comparison with the Annex XIII criteria and conclusion should be reported in Chapter 6.

*For substances where it is concluded that they can be identified in accordance with Article 57 (d) and/or (e): please copy the summary and overall conclusion contained in Section 6.2.2 to the proposal, section: “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation".***

### 6.2.1 Assessment of PBT/vPvB properties

*Please use the following paragraph (modified as necessary) to reflect the weight-of-evidence you have used:*

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance as PBT/vPvB. All available information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) was considered together in a weight-of-evidence approach.

#### 6.2.1.1 Persistence

#### 6.2.1.2 Bioaccumulation

#### 6.2.1.3 Toxicity

### 6.2.2 Summary and overall conclusions on the PBT and vPvB properties

***In this section information should be summarised as to why the substance meets the PBT, and/or the vPvP criteria. Additionally, the summary should address and reflect the relevant facts of the assessment.***

*A summary of the assessment for each criterion (property), a comparison with the Annex XIII criteria and the overall conclusion should be included in this section. Please include the following text when concluding on the assessment:*

In conclusion, the [substance name] is proposed to be identified as a PBT/vPvB substance according to Art. 57(d)/(e) of REACH by comparing all relevant and available information listed in Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

## 6.3 Assessment under Article 57(f)

This section is only relevant if the intention of the Annex XV (SVHC) dossier is to identify the substance as a substance giving rise to an equivalent level of concern in accordance with Article 57(f) REACH, i.e. for which there is scientific evidence of probable serious effects to human health or the environment which gives rise to an equivalent level of concern to those of other substances listed in (a) to (e) of Article 57 of the REACH Regulation.

This section is not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) to (e) of the REACH Regulation.

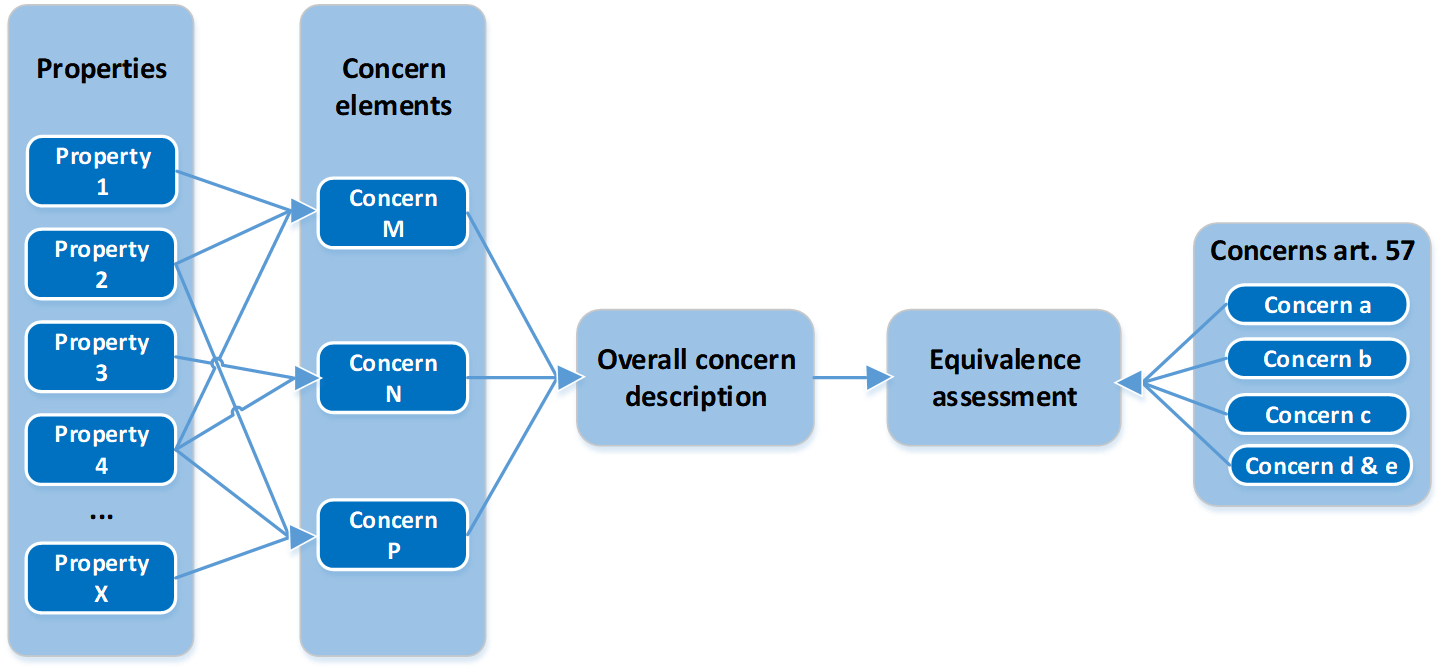
### 6.3.1 *Summary of the data on the intrinsic/hazardous properties (providing scientific evidence of probable serious effects to HH and/or ENV)*

*A summary of the data provided in Sections 2 to 5 (and a description of any further supporting information) which leads to the conclusion that there is scientific evidence of probable serious effects to human health or the environment (including evidence that the substance is an endocrine disruptor, is classified as a respiratory sensitiser etc.) should be included here. Statement(s) should be included in this section that the effects arising from the intrinsic/hazardous properties of the substance are probable (i.e. that the substance can have the effects described on HH and/or the ENV) and that they are serious (to avoid duplication, this can be done with reference to the appropriate part of the ELoC assessment in Section 6.3.2 where the seriousness of the effects are described).*

### 6.3.2 Equivalent level of concern assessment

The assessment as to why the substance gives rise to an equivalent level of concern to the substances listed in Art 57 (a) to (e) REACH should be made here.

*For cases where, based on weight-of-evidence from a combination of properties, the arguments demonstrate that there is scientific evidence of probable serious adverse effects of a substance (group) to the environment and/or human health, which gives rise to an equivalent level of concern, the structure of the ELoC assessment can be further differentiated (see Figure 1 as an example).*



**Figure 1:** Overview of an example assessment for ELoC concerning a combination of properties

*In the case of substance(s) having environmental concern elements the conclusions should be provided following the structure given in Section 6.2 of this template.* *Please note that the (non-exhaustive) list of discussion topics provided below are intended as potential starting points (see also example table(s) of how the equivalent level of concern assessment may be summarised and presented in Annex VIII).*

#### 6.3.2.1 Human health

***Where the equivalent level of concern relates to a human health effect, the key information in the report should be summarised, taking into account where relevant, the following (non-exhaustive) list of discussion points:***

* + *Health effects:*
    - *Type and potential severity of possible health effects*
    - *Irreversibility of health effects*
    - *Delay of health effects*
  + *Other factors:* 
    - *Quality of life affected*
    - *Societal concern*
    - *Is derivation of a ‘safe concentration’ possible?*

#### 6.3.2.2 Environment

***Where the equivalent level of concern relates to an environmental effect, the key information in the dossier should be discussed and summarised as to why the information justifies an equivalent level of concern. This may, if relevant, take into account one or several of the following (non-exhaustive list of) discussion points:***

* + *Possible adverse environmental effects related to:*

*o Severity, e.g.:*

*- Delay of effects*

*- Inter-generational effects*

*- Impact on migratory species (spatial effects)*

*- Impact of short-term exposure (long-term effects)*

*- Potential to impair population level structure and recruitment or ecosystem function and stability*

*• Other factors:*

*o Is derivation of a ‘safe concentration’ possible?*

* + - *Societal concern*
    - *Is derivation of a ‘safe concentration’ possible?*

**Where the equivalent level of concern relates to both a human health effect and an environmental effect, the key information in the report should be summarised taking into account the relevant discussion points in (6.3.2.1) and (6.3.2.2) above.**

#### 6.3.2.3 Summary of the ELoC assessment

*Examples of ELoC summary reporting (in tabular form) are included in Annex VIII*

### 6.3.3 Conclusion on the Article 57(f) assessment

*An overall conclusion on the substance properties leading to the conclusion that there is scientific evidence of probable serious effects to human health or the environment giving rise to an equivalent level of concern should be provided here and copied to the proposal section “****Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation"****.*

Part II

The purpose of this second part is to report information which will serve the next steps of the authorisation procedure. This relates to priority setting in the context of the recommendation of substances to be included in Annex XIV, the development of the draft Annex XIV entries (transitional arrangements, review periods, exemptions of (categories of) uses) and later, applications for authorisation (AfA). Part II of the dossier provides the available information on use, tonnage and alternatives. This is consistent with the requirement of Annex XV, section II.2 of the REACH regulation that states: “The available use and exposure information and information on alternative substances and techniques shall be provided.”

In particular, sections 8 (total tonnage of the substance) and 9 (information on uses of the substance) are intended to cover the use and exposure aspects. This information is used in the prioritisation process for Annex XIV if the substance is already included in the Candidate List (i.e. identified as an SVHC). It should be noted that the aim of Part II is not to provide an exposure assessment or to conduct an assessment of possible alternatives as this goes beyond the scope of the prioritisation setting step in the authorisation process.

Article 58(3) of REACH sets out three criteria regarding the substances to which priority for inclusion in Annex XIV to REACH shall normally be given. These are substances with

1. *PBT or vPvB properties, or*
2. *wide dispersive use, or*
3. *high volumes.*

The approach for prioritisation was agreed between the Member State Committee (MSC) and ECHA and can be accessed on ECHA’s web site[[27]](#footnote-28).

Combined with the information on intrinsic properties from Part I, the information on tonnage and uses based on (preferably public) registration data (e.g. industrial/professional/consumer) and volume of the substance used within the scope of the authorisation requirement will be used for prioritisation. The assessment of priority is performed in a substance-specific (case-by-case) manner since the inclusion in Annex XIV is per substance. Information on the uses of the substance is necessary in order to conduct this assessment. The description of the uses and the actors involved in a supply chain are an essential source of information for the development of the draft Annex XIV entry, and in particular for deciding on the sunset and latest application dates to be recommended[[28]](#footnote-29).

Information on existing EU legislation that applies to the substance in question can be considered as supplementary information that might be relevant for possible exemptions. Information on the potential for other substances on the Candidate List (including Candidate List substances that are already recommended) to substitute or be substituted by the substance in (some of) the uses is an additional factor to be considered when assessing the priority of a substance. Any information collected by way of consultation is also welcome and can be included in the relevant section.

The **registration dossiers** are the **main source of information** for the priority assessment.

*Overall, information provided on uses should allow its’ reliability and representativeness to be assessed. Therefore, information should where possible be accompanied by a description which clarifies the source of the information, the time period covered, the sector(s) / the share of the market / the number of users it represents and any other description which is relevant for the assessment of the reliability and representativeness of the information. As for Part I, it would be useful to provide a systematic documentation of uncertainties in each section, as appropriate.*

*Please ensure that only publicly available information is included in the body of the Annex XV SVHC report, i.e. sourced from ECHA’s dissemination site.* ***All confidential information should be included in an Annex to the report.*** *For a general list of issues to check when generating documents for which information from REACH registration dossiers is used, a document named “Checklist of confidentiality aspects in using Registration data” is available at the S-CIRCABC Regulatory Risk Management Interest Group in the “General Information” folder. In the Annex XV SVHC report, please avoid using trade-marks/brand names under which certain substances are marketed, unless there is a real need or justification why they should appear here, instead of the chemical substance name.*

*Headings / sub-headings not relevant for the substance in question should be deleted.*

In summary, the information collected under this section will provide ECHA with:

* data needed for the prioritisation of substances to be recommended for inclusion in Annex XIV
* data for defining the transitional arrangements to be recommended
* data to be able to decide if exemption(s) of uses should be recommended based on existing EU legislation.

# 7. Registration and C&L notification status

## Registration status

**Table 12 Registration status**

|  |  |
| --- | --- |
| **From the ECHA dissemination site[[29]](#footnote-30)** | |
| Registrations | ☒ Full registration(s)  (Art. 10)  ☒ Intermediate registration(s)  (Art. 17 and/or 18) |

## 7.2 CLP notification status

**Table 13: CLP notifications**

|  |  |
| --- | --- |
|  | **CLP Notifications[[30]](#footnote-31)** |
| Number of aggregated notifications | xxx |
| Total number of notifiers | xxx |

# 

# 8. Total tonnage of the substance

*The total tonnage band for a substance displayed on ECHA’s dissemination website is compiled from all registration dossiers with two exceptions: (i) tonnages that are claimed confidential and (ii) any quantity that is used as an intermediate to manufacture another substance. Please do not include confidential tonnage information in this section, but rather in a confidential annex (e.g. information on the breakdown of import/export tonnage and/or tonnage/use information).*

**Table 14: Tonnage status**

|  |  |
| --- | --- |
| Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)[[31]](#footnote-32) | xx-xxxxxx t/pa |
| Tonnage information from public sources other than registration dossiers (if available)[[32]](#footnote-33) | xxxxxx t/pa |

# 9. Information on uses of the substance

*Please report the available information on the uses of the substance in the table below including (confidential information can be included in a confidential annex, where considered necessary:*

* + Whether it is (i) a registered use or (ii) a non-registered use likely to occur in the EU (including the source of the information and its’ reliability and representativeness);
  + description of the different uses (tonnage per use if available can be included in a confidential annex) and
    - the function(s) of the substance (e.g. binding agent, plasticiser, flame-retardant); (please note - the technical function as listed in IUCLID may be flagged as confidential information)
    - the type of applications in which the substance is used, e.g. types of mixtures in which it is formulated (e.g. adhesives, sealants, paints, textile dyes, polymer mixtures…),
    - the sector(s) of use (e.g. building and construction work, metal production and working, plastics industry, agriculture, textile industry, aeronautics…),
* *the sector(s) into which the final products are distributed,*

* + - the type of articles in which the substance is incorporated (and if releases are intended or likely/unlikely)
  + whether the substance is used at industrial sites only, or whether it is also used by professionals outside industrial sites and/or consumers, and if yes, in which applications;
  + whether the use appears to be in the scope of the authorisation requirement, e.g. in which concentration (range) is the substance present in the respective mixtures or, whether it falls under the generic exemptions[[33]](#footnote-34) from authorisation;
  + whether there are downstream user reports for the substance.

**Table 15: Uses**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Use(s)** | **Registered use**  *(If not, specify the source of the information)* | **Use likely to be in the scope of Authorisation** |
| **Uses as intermediate** |  | Yes/No | Yes/No |
| **Formulation or repacking** |  | Yes/No | Yes/No |
| **Uses at industrial sites** |  | Yes/No | Yes/No  Yes/No |
| **Uses by professional workers** |  | Yes/No | Yes/No |
| **Consumer uses** |  | Yes/No | Yes/No |
| **Article service life** |  | Yes/No | Yes/No |

# 10. Information on structure of the supply chain

Information on the structure and complexity of the supply chains can support the determination of the draft Annex XIV entries, in particular defining Latest Application Dates (LADs) and Sunset Dates (SDs)[[34]](#footnote-35). **Where possible**, please include a description of supply chain(s), e.g. an estimation of the number and diversity of the actors therein, such as manufacturers / importers, distributors, levels of downstream users (including industrial, professional, and consumers), recyclers etc. The practical implementation document[[35]](#footnote-36) describes the factors that ECHA holistically takes into account for setting LADs, therefore all information that can be used to assess the complexity of supply chain (e.g. life-cycle stages, sector of uses, types of product, type of article, number of industrial use sites) is very welcome.

# 11. Additional information

*The types of information to be considered for this section include:*

## 11.1 Substances with similar hazard and use profiles on the Candidate List

*Information on substances with similar hazard and use profiles allows ECHA to take into account certain aspects that may affect regulatory coherence and effectiveness as well as practicality at the application for authorisation phase when prioritising substances to avoid regrettable substitution and defining the transitional arrangements.*

*If available, please report information on substances with similar hazard and use profiles, i.e.:*

* + *Information on whether the substance could potentially replace or be replaced by other substances on the Candidate List for (some of) their uses, and the basis for this assumption. The basis for such assumptions is normally either explicit information obtained from industry (or experts / literature) about the potential for using the two substances in the same type(s) of applications or, a combination of structural similarities and common uses. Please note that a thorough assessment is not required here.*
* Any data which could illustrate wide dispersiveness of the uses.
  + *Other Candidate List substances that together with the substance could potentially fulfil the definition of a group in Section 1.5 of Annex XI of REACH. As a joint application for authorisation can be submitted for substances that meet the above definition, therefore it can be meaningful to allocate them to the same latest application date slot.*

## 11.2 Alternatives

*The term “alternatives” refers to either the use of an alternative substance, or an alternative technique or technology, or a combination of both, including changes that make the process step involving the use of the substance redundant (for further information see the general prioritisation approach[[36]](#footnote-37)). If available, the following type of information on alternatives is considered useful:*

* information on the work already done by companies in seeking an alternative, including information on R&D activities;
* *any information on practical experiences with alternatives and main conclusions.*

## 11.3 Existing EU legislation

*Please report any information on existing EU legislation that applies to the substance in question (at any lifecycle stage of the substance). This will be used particularly in the development of draft Annex XIV entries (exemptions of (categories of) uses).*

## 11.4 Previous assessments by other authorities/ongoing regulatory activities

References

# References for Part I

*Please use the format provided below when including references*

Journal articles:

Author Last name I.I., Author Last name I.I. & Author Last name I.I. (YYYY): Article title. Full Journal title, XX[Journal number], xxx-xxx[start – end page].

Books:

Author Last name I.I., Last name I.I. & Last name I.I. (YYYY): Book title. Editor, Country.

Web page:

Author Last name I.I., Last name I.I. & Last name I.I. (undated): Web page title. Available at <http://URL> (accessed on DD Month YYYY).

# References for Part II

*Examples:*

*Please use the format provided below when including references*

Arrieta C., David E., Dolez P. & Vu-Khanh T. (2011): Hydrolytic and photochemical aging studies of a Kevlar-PBI blend. Polymer degradation and Stability, 96, 1411-1419.

Pyromark (2008): The Art of Pyrotechnics, available at <http://www.pyromark.com/pyrotechnics.html> (accessed on 22 April 2011).

Baltussen E. (2010): Determination of physico-chemical properties of 4,4’-methylene bis (2-chloroaniline). NOTOX B.V., 's-Hertogenbosch, The Netherlands.

ECHA (2011): [4,4'-methylenebis[2-chloroaniline]](http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d935cd5-ed84-0f57-e044-00144f67d249/DISS-9d935cd5-ed84-0f57-e044-00144f67d249_DISS-9d935cd5-ed84-0f57-e044-00144f67d249.html). Information on registered substances, published on ECHA’s website <http://apps.echa.europa.eu/registered/registered-sub.aspx#search> (accessed on 8 July 2011).

EU (2004). Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version). Official Journal of the European Union, L158: 50-76.

EU(2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.

EU (2007). Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L136: 3-280.

EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.

EU (2009). Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 as regards of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII. Official Journal of the European Union, L164: 7-31.

# Annex I - Additional information on read across approach

In case of a read-across approach, detailed information on the approach (analogue or category) and the relevant information of source(s) and target could be given here[[37]](#footnote-38).

*In general, the read-across approach can be applied using substances with physicochemical and/or toxicological and/or ecotoxicological properties that are likely to be similar to the substance in question, or follow a regular pattern as a result of structural similarity. Those substances may be considered as a group or a category of substances. According to ECHA`s Practical Guide 6 “How to report read-across and categories[[38]](#footnote-39)” similarities may be due to a common functional group, common precursor or breakdown products, constant pattern in changing potency or common constituents or chemical class.*

* Structural similarities of source(s) and target
* Dissociation of the source(s) and target in aqueous media/air/….
* Physicochemical properties and partition coefficients of source(s) and target
* ….

A matrix with the relevant information of the source(s) and the identified gaps should be included here.

# Annex II - Confidential data on substance identity

# Annex III – Detailed study information *(suggested)*

***In vivo* studies**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure Period** | **Reference** | **Year** | **System** | **Method** | **Relevant Endpoints & Effects (Effects Are Annotated With Arrows Or 'Affected')** | **Effects** | **NOEL/LOEL** | **Comments/Notes** | **Klimisch Score** |
| **Specify life stage** |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

***In vitro* studies**

*Please adjust the table as necessary*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Category** | **Reference** | **Year** | **System & Method** | **Relevant endpoints & Effects** | **Comments/notes** | **Modality** |
| **Specify type of endocrine activity** |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

# Annex IV - Data overview (ED Guidance table) *(suggested)*

To open the embedded Excel worksheet:

1. Open the Attachments panel on the left hand side.
2. In the Attachments panel, double-click the listed attachment.

****

# Annex V - Lines of evidence for adverse effects and endocrine activity *(suggested)*

*Please amend/delete the suggested table headings below as necessary. Separate tables can be provided for different types of endocrine activity.*

***Table X1: Lines of evidence for endocrine activity in silico by [substance name]***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Reference*** | ***Grouping*** | ***Line of evidence*** | ***Species/cell lines*** | ***Observed effects (positive/negative)*** | ***Assessment of each line of evidence*** |
| ***Ref 1*** |  |  |  |  |  |
| ***Ref 2*** |  |  |  |  |  |

***Table X2: Lines of evidence for endocrine activity in vitro by [substance name]***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Reference*** | ***Grouping*** | ***Line of evidence*** | ***Species/cell lines*** | ***Observed effects (positive/negative)*** | ***Assessment of each line of evidence*** |
| ***Ref 1*** |  |  |  |  |  |
| ***Ref 2*** |  |  |  |  |  |

***Table X3: Lines of evidence for endocrine activity in vivo and adversity by [substance name]***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Reference*** | ***Grouping*** | ***Line of evidence*** | ***Species/cell lines*** | ***Observed effects (positive/negative)*** | ***Assessment of each line of evidence (e.g. supporting data, sufficient evidence)*** |
| ***Ref 1*** |  |  |  |  |  |
| ***Ref 2*** |  |  |  |  |  |

# Annex VI – Mode of action analysis *(suggested)*

**Introduction**

*Please amend/repeat/delete the suggested table headings below as necessary. Separate tables can be provided for different endocrine modes of action.*

**Table Y1: Summary table on key events for mode of action of [substance name]**

|  |  |  |
| --- | --- | --- |
| Summary of hypothesis: | | |
|  | **Brief description of key event (KE)** | **Supporting evidence** |
| e.g. MIE | e.g. Molecular: Activation of estrogen receptor |  |
| KE1 |  |  |
| KE2 |  |  |

**Table Y4: Analysis of biological plausibility of mode of action of [substance name]**

|  |  |  |
| --- | --- | --- |
| Summary of hypothesis: | | |
|  | **Brief description of key event (KE)** | **Supporting evidence** |
|  |  |  |
|  |  |  |
|  |  |  |

**Table Y7: Other considerations for key event relationships**

|  |  |
| --- | --- |
| **Factors** | **Comment** |
| Dose |  |
| Temporal concordance |  |
| **Essentiality** |  |
|  |
| **Human relevance** |  |
|  |
| **Identified uncertainties** |  |

# Annex VII – Human epidemiology studies *(suggested)*

*Sample format provided below – please adapt/repeat as necessary*

|  |  |  |
| --- | --- | --- |
| **Study name:** |  |  |
| **Paper title:** |  |  |
| **Authors:** |  |  |
| **Publication year:** |  |  |
|  |  |  |
|  |  | **Score** |
| **Study design and conduct** |  |  |
| study type |  |  |
| study year |  |  |
| additional comments related to study design |  |  |
| **Study population** |  |  |
| sampling method |  |  |
| study size |  |  |
| age range |  |  |
| sex |  |  |
| other population characteristics |  |  |
| quality of provided information on population characteristics |  |  |
| additional comments related to study population |  |  |
| **Exposure assessment** |  |  |
| method(s) used for exposure assessment |  |  |
| Validated methods used? |  |  |
| Is the timing between exposure and outcomes assessment appropriate? |  |  |
| **If HBM:** |  |  |
| matrix and sample type |  |  |
| Validated biomarker measured? |  |  |
| Adjusted for urinary dilution? |  |  |
| measured concentrations (median, range) |  |  |
| % samples with BP <LOD/LOQ |  |  |
| LOD/LOQ for BP |  |  |
| additional comment related to exposure assessment |  |  |
|  |  | **Score** |
| **Outcome assessment** |  |  |
| outcome(s) assessed |  |  |
| quality of outcome assessment |  |  |
| additional comment related to outcome assessment |  |  |
| **Confounder control** |  |  |
| Is information available for confounders relevant to the scientific questions asked? (comment if needed) |  |  |
|  |  |
| Are confounders clearly indicated? |  |  |
| Are confounders adequately controlled for? |  |  |
| additional comment related to confounder control |  |  |
| **Statistical analysis** |  |  |
| methods used for investigating associations |  |  |
| Suitability of used methods? |  |  |
| Maximised use of data? |  |  |
| only descriptive statistics or/and bivariate analysis |  |  |
| Appropriate control for confounders? |  |  |
| Unadjusted and adjusted estimates presented? |  |  |
| Sensitivity tests and interaction analysis conducted? |  |  |
| multiple testing issues |  |  |
| additional comment related to the statistical analysis |  |  |
|  |  | **Score** |
| **Reporting** |  |  |
| Key elements of M&M and results are reported in sufficient detail? |  |  |
| A plausible mechanism for the association under investigation is provided? |  |  |
| Are the conclusion made justified by the data shown? |  |  |
| additional comment related to the reporting of the study |  |  |
| **Key findings** |  |  |
| What are the key findings? |  |  |
| Any secondary findings? |  |  |
| effect size in relation to biological relevance |  |  |
|  |  |  |

# Annex VIII - Examples of ELoC summary reporting

*Concern elements which are not relevant can be deleted and other concern elements relevant to the case can be included.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Effect 1 - name | Effect 1 - name | Effect 1 - name | Effect 1 - name | Overall conclusion |
| Possible/Probable serious health effects?\* |  |  |  |  |  |
| Delay of health effects? |  |  |  |  |  |
| Irreversibility of health effects? |  |  |  |  |  |
| Quality of life impaired? |  |  |  |  |  |
| Societal concern? |  |  |  |  |  |
| Is derivation of a ‘safe concentration’ possible? |  |  |  |  |  |

*\*This factor is intended to discuss the severity of the effects and not their probability*

|  |  |
| --- | --- |
| **EXAMPLES OF ELEMENTS OF CONCERN**  **Irreversibility of the exposure of wildlife and man via the environment** | Very high potential/high potential |
| **Potential for rapid and wide geographic scale contamination** |  |
| **Potential to continuous increase of exposures** |  |
| **Potential for causing serious effects although those would not be observed in standard tests** |  |
| **Potential for causing serious effects on human health (known and unknown), and the environment (including the potential for irreversible effects)** |  |
| **Delay of effects** |  |
| **Potential to cause combined effects (co-exposure)** |  |
| **Uncertainties in deriving safe concentration limits** |  |
| **Possibility to remedy effects** |  |
| **Uncertainties in quantifying exposures with sufficient certainty** |  |
| **Potential to impair humans and the environment at large** |  |
| **Intergenerational effects** |  |
| **Societal concern** |  |

# Annex IX - Confidential data on tonnage, import and export

Tonnage per use, if available, could be included here.

# Annex X - Confidential data on uses

1. *The substance name, EC and CAS numbers provided should be publicly available. All confidential information should be included in an Annex.* [↑](#footnote-ref-2)
2. *If the proposed entry covers a group of substances, no numerical identifiers should be reported in this page. If available, any known numerical identifiers should be provided in the substance identity chapter.* [↑](#footnote-ref-3)
3. If the proposed entry covers a group of substances, no numerical identifiers should be reported in this page. If available, any known numerical identifiers should be provided in the substance identity chapter. [↑](#footnote-ref-4)
4. Classification in accordance with section …… of Annex I to Regulation (EC) No 1272/2008. [↑](#footnote-ref-5)
5. Please use the relevant hazard statement *i.e.* H360 ‘May damage fertility or the unborn child’; H360F ‘May damage fertility’; H360D: ‘May damage the unborn child’; H360FD: ‘May damage fertility. May damage the unborn child’; H360Fd: ‘May damage fertility. Suspected of damaging the unborn child’; H360Df: ‘May damage the unborn child. Suspected of damaging fertility’. [↑](#footnote-ref-6)
6. <http://echa.europa.eu/documents/10162/13628/raaf_en.pdf>

   <http://echa.europa.eu/support/grouping-of-substances-and-read-across> [↑](#footnote-ref-7)
7. <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities> [↑](#footnote-ref-8)
8. Substances of Unknown or Variable composition, Complex reaction products or Biological materials [↑](#footnote-ref-9)
9. <https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-identification-and-naming-of-substances-under-reach-and-clp> [↑](#footnote-ref-10)
10. *For example, for another category of substances of very high concern according to Article 57 of REACH, the default concentration of Carcinogenic/Mutagenic (category 1A/1B) ingredients in a mixture requiring a Carcinogen/Mutagen (1A/1B) classification of the mixture under Regulation (EC) No 1272/2008 is 0.1% (w/w). Furthermore, Articles 14(2)(f), 31(3)(b) and 56(6)(a) of REACH apply a similar principle and the same concentration limit for PBT/vPvB substances in mixtures regarding some obligations under REACH. By analogy, the Judgments of the General Court (Seventh Chamber, extended composition) of 7 March 2013 in cases T-93/10, T-94/10, T-95/10 and T-96/10 (see in particular paragraphs 117 to 121) confirmed the validity of this approach for PBT/vPvB constituents of a substance.* [↑](#footnote-ref-11)
11. <https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-identification-and-naming-of-substances-under-reach-and-clp> [↑](#footnote-ref-12)
12. Substances of Unknown or Variable composition, Complex reaction products or Biological materials [↑](#footnote-ref-13)
13. Acute Toxicity Estimate [↑](#footnote-ref-14)
14. <https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f> [↑](#footnote-ref-15)
15. <https://echa.europa.eu/documents/10162/17169198/template_for_weight_of_evidence_en.docx/eb183c2e-c360-cbce-7a58-ad2d1270e5bd> [↑](#footnote-ref-16)
16. <https://echa.europa.eu/documents/10162/17169198/wo_eu_uncertainty_background_en.docx/4f2b49ab-ade0-6ee3-e977-8abe00c21c23> [↑](#footnote-ref-17)
17. The criteria for LRTP in Annex D Section 1: (d) Potential for long-range environmental transport:

    (i) Measured levels of the chemical in locations distant from the sources of its release that are of potential concern;

    (ii) Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or

    (iii) Environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days. [↑](#footnote-ref-18)
18. <https://echa.europa.eu/documents/10162/17169198/template_for_weight_of_evidence_en.docx/eb183c2e-c360-cbce-7a58-ad2d1270e5bd> [↑](#footnote-ref-19)
19. <http://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf> [↑](#footnote-ref-20)
20. When presenting the endocrine disrupting properties of substances for human health, the relevance of environmental information related to this hazard property should also be considered. [↑](#footnote-ref-21)
21. EAS – estrogenic, androgenic and/or steroidogenic [↑](#footnote-ref-22)
22. T - thyroidal [↑](#footnote-ref-23)
23. When presenting the endocrine disrupting properties of substances for the environment, the relevance of human health information related to this hazard property should also be considered. [↑](#footnote-ref-24)
24. EAS – estrogenic, androgenic and/or steroidogenic [↑](#footnote-ref-25)
25. T - thyroidal [↑](#footnote-ref-26)
26. Please use the relevant hazard statement *i.e.* H360 ‘May damage fertility or the unborn child’; H360F ‘May damage fertility’; H360D: ‘May damage the unborn child’; H360FD: ‘May damage fertility. May damage the unborn child’; H360Fd: ‘May damage fertility. Suspected of damaging the unborn child’; H360Df: ‘May damage the unborn child. Suspected of damaging fertility’. [↑](#footnote-ref-27)
27. Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) <https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930> [↑](#footnote-ref-28)
28. <https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf/533e3d4a-b1d2-b024-c724-64715c2f6e8a> [↑](#footnote-ref-29)
29. *Please include here the link to the substance specific entry on the dissemination site (and the date accessed)* [↑](#footnote-ref-30)
30. C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed xx xxxx 20xx) [↑](#footnote-ref-31)
31. *Please include here the link to the substance specific entry on ECHA’s dissemination site (and the date accessed)* [↑](#footnote-ref-32)
32. *Please include a link to the source of the information (and the date accessed) or, cite it in the reference section.* [↑](#footnote-ref-33)
33. <https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf> [↑](#footnote-ref-34)
34. <http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf> [↑](#footnote-ref-35)
35. <https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf/533e3d4a-b1d2-b024-c724-64715c2f6e8a> [↑](#footnote-ref-36)
36. Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) <https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930> [↑](#footnote-ref-37)
37. <http://echa.europa.eu/documents/10162/13628/raaf_en.pdf>

    <http://echa.europa.eu/support/grouping-of-substances-and-read-across> [↑](#footnote-ref-38)
38. <http://echa.europa.eu/documents/10162/13655/pg_report_readacross_en.pdf> [↑](#footnote-ref-39)