**Template for the confidential annex to the Product Assessment Report of a biocidal product family for national/simplified/Union authorisation applications**

Version 1.0

**Document history**

|  |  |  |
| --- | --- | --- |
| **Version** | **Changes** | **Date** |
| 1.0 | First version | 26 November 2020at CG-44 |

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**CONFIDENTIAL ANNEX [FOR MSCAs ONLY] TO THE PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR [NATIONAL/SIMPLIFIED/UNION] AUTHORISATION APPLICATION**

(submitted by the [applicant / competent authority])



[Product family name]

Product type(s) [XX]

[Active substance(s)’ name(s)] as included in the Union list of approved active substances / Annex I of Regulation (EU) No 582/2012]

Case Number in R4BP: [XXX]

Competent Authority: [CA]

[Date: day Month year]

Table of Contents

[1 Biocidal product family composition and formulation 5](#_Toc73002616)

[1.1 Qualitative and quantitative information on the full composition of the biocidal product family 5](#_Toc73002617)

[1.1.1 Similarity of composition 5](#_Toc73002618)

[1.1.2 Full composition of the biocidal product family 5](#_Toc73002619)

[1.1.3 Qualitative and quantitative information on the composition of grouped non-active substance(s) 5](#_Toc73002620)

[1.2 Full composition of meta-SPC(s) and individual product(s) 6](#_Toc73002621)

[1.3 Information on worst/best case composition and composition of test products 7](#_Toc73002622)

[1.3.1 Subsets and extensions to the core 7](#_Toc73002623)

[1.4 Qualitative and quantitative information on the composition of the premix of the active substance(s) 7](#_Toc73002624)

[1.5 Qualitative and quantitative information on the composition of the non-active substance mixture [name] 8](#_Toc73002625)

[1.6 Comparison of composition in case of change of composition 9](#_Toc73002626)

[1.7 Qualitative and quantitative information on the full composition of the biocidal product(s) not authorised within the biocidal product family 11](#_Toc73002627)

[2 Identification of substance(s) of concern 12](#_Toc73002628)

[3 Assessment of endocrine-disrupting properties of non-active substance(s) 13](#_Toc73002629)

[3.1 Summary of the assessment of ED properties of non-active substances 13](#_Toc73002630)

[4 Human health assessment 14](#_Toc73002631)

[4.1 Calculations for classification 14](#_Toc73002632)

[4.2 Calculations related to the assessment of effects on human health 14](#_Toc73002633)

[5 Environmental risk assessment 14](#_Toc73002634)

[6 Other 14](#_Toc73002635)

# Biocidal product family composition and formulation

## Qualitative and quantitative information on the full composition of the biocidal product family

### Similarity of composition

All products contain the following active substance(s) and non-active substances, which *[– since the products are solvent based –]* are considered essential to formulate the products:

Table 1.1 Similarity of composition

| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)**  |
| --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance |  |  |  |  |
|  |  | *[Solvent]* |  |  |  |  |

*[Insert/delete rows accordingly.]*

Accordingly, all the products applied for are considered similar in composition.

### Full composition of the biocidal product family

Table 1.2 Full composition of the biocidal product family

| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)**[[1]](#footnote-2) |
| --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance[[2]](#footnote-3) |  |  |  |  |
|  |  | *[Describe the function of the non-active substance*[[3]](#footnote-4)*]* |  |  |  |  |

*[Insert/delete rows accordingly.]*

### Qualitative and quantitative information on the composition of grouped non-active substance(s)

*[If not relevant, do not delete this section, but indicate that it is not relevant.]*

**Group 1**

Table 1.3 Qualitative and quantitative information on the composition of grouped non-active substance(s)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) |  |  |  |  |

*[Repeat this section as many times as needed.]*

## Full composition of meta-SPC(s) and individual product(s)

**Meta-SPC [number]**

Table 1.4 Full composition of the meta-SPC

| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance |  |  |  |  |
|  |  | *[Describe the function of the non-active substance]*  |  |  |  |  |

*[Insert/delete rows accordingly.]*

**Composition of individual products in meta-SPC [number]**

*[Do not report the trade name(s) of the product here, since it is (they are) indicated in the SPC.]*

Table 1.5 Full composition of [Name of the product]

| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| --- | --- | --- | --- | --- | --- |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  |
|  |  | *[Describe the function of the non-active substance]*  |  |  |  |
| Total |  |  |  |  | 100% |

*[Insert/delete rows accordingly.]*

*[Repeat this section as many times as needed.]*

## Information on worst/best case composition and composition of test products

*[Include a detailed justification, why the worst-case composition, e.g. tested product, is representative for the whole product family (the core), taking into account that this worst-case composition might be different from area to area.]*

**Justification regarding physical, chemical and technical properties**

**Justification regarding physical hazards and respective characteristics**

**Justification regarding methods for detection and identification**

**Justification regarding efficacy**

**Justification regarding human health**

**Justification regarding environment**

### Subsets and extensions to the core

*[Indicate the reasons why subsets and/or extensions to the core were considered necessary and describe how they were derived. Report also the assessment.]*

## Qualitative and quantitative information on the composition of the premix of the active substance(s)

*[Report here the detailed composition of the premix of the active substance. If not relevant, do not delete this section, but indicate that it is not relevant.]*

Table 1.6 Qualitative and quantitative information on the composition of the premix of the active substance(s)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) |  |  |  |  |

*[Insert one line for each non-active substance.]*

## Qualitative and quantitative information on the composition of the non-active substance mixture [name]

*[Report here the composition of non-active substance mixtures available in the dossier (from MSDS, from suppliers, etc.). Where relevant, use separate tables for each non-active substance. If not relevant, do not delete this section, but indicate that it is not relevant.]*

Table 1.7 Qualitative and quantitative information on the composition of the non-active substance mixture [name]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) |  |  |  |  |

*[Insert additional lines, if needed.]*

## Comparison of composition in case of change of composition

*[If not relevant, do not delete this section, but indicate that it is not relevant. Repeat the tables as many times as needed.]*

**Meta-SPC [number****]**

Table 1.8 Comparison of composition in case of change of composition

| **Old composition** | **New composition** |
| --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** | **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| **Min** | **Max** | **Min** | **Max** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  |  | (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  |  |
|  |  | *[Describe the function of the non-active substance]* |  |  |  |  |  |  | *[Describe the function of the non-active substance]*  |  |  |  |  |

**[Name of the product]**

Table 1.9 Comparison of composition in case of change of composition

| **Old composition** | **New composition** |
| --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** | **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  | (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  |
|  |  | *[Describe the function of the non-active substance]* |  |  |  |  |  | *[Describe the function of the non-active substance]*  |  |  |  |
| Total |  |  |  |  | 100% |  |  |  |  |  | 100% |

##

## Qualitative and quantitative information on the full composition of the biocidal product(s) not authorised within the biocidal product family

*[Include in the table(s) below the composition of the biocidal product(s) applied for by the applicant, but not authorised by the competent authority. Please also include a brief explanation on why each product could not be authorised. Repeat the section below as many times as needed. If not relevant in the PAR, do not delete this section, but indicate that it is not relevant.]*

**Composition of individual products in meta-SPC [number]**

[Name of the product]

The biocidal product could not be authorised for the following reason(s): *[include here briefly the explanation.]*

Table 1.10 Qualitative and quantitative information on the full composition of the biocidal product(s) not authorised within the biocidal product family

| Common name | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| --- | --- | --- | --- | --- | --- |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance |  |  |  |
|  |  |  |  |  |  |
|  |  | *[Describe the function of the non-active substance]* |  |  |  |
| Total |  |  |  |  | 100% |

*[Insert/delete rows accordingly.]*

# Identification of substance(s) of concern

*[If the BPF does not contain substances of concern, indicate this and delete the table below. Do not delete this section.]*

Table 2.1 Identification of substance(s) of concern

|  |  |
| --- | --- |
| Common name |  |
| Chemical name |  |
| CAS number |  |
| EC number |  |
| Concentration (maximum, g/kg) |  |
| Classification and Labelling according to Regulation (EC) No 1272/2008: |  |
| Relevant toxicological/ecotoxicological information to support the identification of the substance of concern |  |
| Other grounds for concern |  |
| Identified as substance of concern  | [indicate Yes/No] |
| Detailed description on identification*[Provide the detailed description on the identification of the substance of concern.]* |

*[Repeat this table as many times as needed.]*

# Assessment of endocrine-disrupting properties of non-active substance(s)

*[The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides. It means that ED hazard assessment should be included in the confidential annex to the PAR. To this end applicants should perform screening for non-active substances contained in the product, and where an alert is identified, perform further ED evaluation. The screening and/or evaluation should be carried out in accordance with the EFSA/ECHA ED guidance (*[*http://www.efsa.europa.eu/en/press/news/180607*](http://www.efsa.europa.eu/en/press/news/180607)*) and reported in the confidential annex to the PAR by describing the process, databases used, information gathered and weight of evidence taken for each non-active substance. Furthermore, the Biocides competent Authorities have agreed in March 2021 on a practical way forward for the assessment of the endocrine disrupting properties of the non-active substances contained in the biocidal products. The document agreed is available on ECHA’s website at* [*https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products*](https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products)*.]*

*[Include the full assessment of endocrine-disrupting (ED) properties of the non-active substance(s).]*

## Summary of the assessment of ED properties of non-active substances

*[Include and delete text in the following paragraphs as appropriate.]*

The biocidal product contains the non-active substance(s) *[include the name of the non-active substance(s)]* having endocrine-disrupting properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006.

Based on the available information, there are significant indications that [name of the non-active substance(s)] may have endocrine-disrupting properties and these will have to be further investigated[[4]](#footnote-5).

Based on the available information, there are indications that [name of the non-active substance(s)] may have endocrine-disrupting properties and these will have to be further investigated.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

# Human health assessment

*[Do not embed the calculation sheets in the confidential annex to the PAR.]*

## Calculations for classification

*[Include the calculations when the calculation rules according to Regulation (EC) No 1272/2008 are used.]*

## Calculations related to the assessment of effects on human health

*[Include the calculations related to the assessment of effects on human health.]*

# Environmental risk assessment

*[Include the description of the scenario(s) based on tonnage data.]*

# Other

*[Include any further information which has not been covered by the previous chapters, e.g. read across of dermal absorption data, withdrawals of single products and/or uses by the applicant during the evaluation phase, reference to the confidential annex restricted to authorities.]*

1. It is highly recommended to use % w/w. % v/v is allowed in exceptional cases only. [↑](#footnote-ref-2)
2. The purity of the active substance indicated in the approval regulation is: [X] % w/w. [↑](#footnote-ref-3)
3. So called “co-formulant”. [↑](#footnote-ref-4)
4. Please see the document CA-March21-Doc.4.4 (“Approach on providing information in public documents on non-active substances with indications of endocrine-disrupting properties”) available in CIRCABC at <https://circabc.europa.eu/w/browse/f28c5951-e162-4571-af1f-d2dc27992455>. [↑](#footnote-ref-5)