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

Version 2.0

**Document history**

|  |  |  |
| --- | --- | --- |
| **Version** | **Changes** | **Date** |
| 1.0 | First edition (original unnumbered version) | - |
| 2.0 | Main changes in the document:* Two templates have been created for single products and product families.
* The template can be used for national, simplified, and Union authorisation applications.
* Some editorial changes have been made to harmonise the style in the template.
* The general part has been simplified to avoid duplication of information in the PAR and the SPC.
* Pre-defined text has been added, where relevant, to simplify the compilation of the template.
* The content of the different sections of the assessment has been revised.
* The appendices have been revised.
* The confidential annex to the PAR has been generated as a separate document.
 | 26 November 2020at CG-44 |

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

**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]

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**Changes history table**

**Note for the applicant and the competent authority:**

The changes to the PAR are implemented as follows:

- For national authorisation, the changes should be introduced in the PAR *via* an addendum. The addendum will be a standalone document, displaying the same chapters’ structure of the PAR and reporting only the changes under the relevant chapters. At the renewal stage of the national authorisation, the PAR will be consolidated by incorporating the changes;

- For Union authorisation, it is recommended that the changes are introduced in a consolidated PAR and are clearly identified, for example, by highlighting them in yellow.

The competent authority should delete this note when finalising the PAR.

*[Provide in the table below the overview of the changes history by compiling all the changes made to the PAR since the initial authorisation. In case the change impacts several sections of the PAR, this can be indicated in the last column “Chapter/page”.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP |  |  | dd.mm.yyyy | *[Initial assessment]* |  |
| NA-AAT |  |  | dd.mm.yyyy | *[Change of expiry date to 31.08.2020]* |  |
| NA-MAC,UA-MAC |  |  | dd.mm.yyyy | *[Addition of the target organism]* |  |
| NA-MIC, UA-MIC |  |  | dd.mm.yyyy | *[Extension of shelf-life (24 to 48 months)]* |  |
| NA-RNL |  |  | dd.mm.yyyy | *[Renewal of the authorisation ]* |  |

# Conclusion

**Note for the applicant:**

The section “Conclusion” has to be compiled by the competent authority and should not be deleted.

**Note for the competent authority:**

The section “Conclusion” includes options in the form of a pre-defined text, among which the competent authority can choose, as appropriate.

The competent authority should delete this text box when finalising the PAR.

The BPF [Name of BPF] consists of products containing the active substance(s) [name of the active substance(s)]. The products are *[indicate the formulation type(s)]*. The BPF is used for *[indicate the use(s)]* by *[include the user categor(y/ies)]* for the control of *[include the general name(s) of the target organism(s), for example bacteria, virus, fungi, crawling insects]*.

The BPF consists of XX meta-SPC(s). *[In case of more than one meta-SPC, include:]* The structure of the BPF into meta-SPCs was based on *[briefly indicate the main points from section 2.3 of the PAR]*.

*[If national/Union authorisation is proposed, include:]*

The BPF falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s). *[In case of Union authorisation, include:]* The BPF is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore [can / may][[1]](#footnote-2) be authorised for the uses *[indicate the use(s) and user categor (y/ies)]*, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

*[If national/Union authorisation is not proposed, include:]*

The overall conclusion of the evaluation is that the BPF does not meet the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012, because *[indicate the grounds for non-authorisation]* and therefore [cannot / may not1] be authorised. The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

*[If simplified authorisation is proposed, include:]*

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses *[indicate the use(s) and user categor(y/ies)]*, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

*[If simplified authorisation is not proposed, include:]*

The overall conclusion of the evaluation is that the BPF does not meet the conditions laid down in Article 25 of Regulation (EU) No 528/2012, because *[indicate the grounds for non-authorisation]* and therefore cannot be authorised. The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended use(s) of the BPF as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the BPF and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals, and the environment are reported in sections 4 and 5 of the SPC.

*[For simplified authorisation, include the following paragraph and delete the other paragraphs of this section, as appropriate:]*

Following evaluation, the BPF [does meet / does not meet] the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance(s) [name of the active substance(s)] [is / are] listed in Annex I of Regulation (EU) 528/2012 [with no restrictions applied / and satisf(ies/y) the restriction that *[indicate the restriction]*];
2. The BPF does not contain any substance of concern;
3. The BPF does not contain any nanomaterials;
4. The BPF is sufficiently effective;
5. The handling of the BPF as part of its intended use does not require any personal protective equipment (PPE).

*[Where relevant, indicate why the BPF does not meet the conditions for simplified authorisation.]*

A classification according to Regulation (EC) No 1272/2008[[2]](#footnote-3) [is / is not] necessary. *[If classification is necessary, include the following paragraphs.]* Detailed information on classification and labelling is provided in section 2.9 of the PAR. The hazard and precautionary statements of the BPF according to Regulation (EC) No 1272/2008 are available in the SPC, in section 3 for each meta-SPC.

*[If the non-active substance(s) (is / are) not (a) substance(s) of concern, insert:]*

The BPF does not contain [any / a] non-active substance(s) (so called “co-formulant(s)”) which [are / is] considered as (a) substance(s) of concern.

*[If the non-active substance(s) (is / are) (a) substance(s) of concern, insert:]*

The BPF contains (a) non-active substance(s) (so called “co-formulant(s)”) which [is / are] considered as (a) substance(s) of concern *[in case of concern, indicate within brackets if the concern is for human health and/or for environment, e.g. (for human health and/or environment). Where relevant, indicate if the non-active substance(s) has/have endocrine disrupting properties]*. The non-active substance(s) considered as (a) substance(s) of concern [is / are] [name of the non-active substance(s)]. *[In case of substance(s) of concern, include the following paragraph:]* The assessment of the non-active substance(s) showed that *[briefly describe the outcome]*. More detailed information on the substance(s) of concern is provided in the confidential annex.

The BPF should be considered [to have / not to have] endocrine-disrupting properties*.*

*[Include and delete text in the following paragraph(s) as appropriate.]*

The BPF does not contain any active substances having endocrine-disrupting properties.

The BPF contains the active substance(s) *[include the name of the active substance(s)]* having endocrine-disrupting properties.

The BPF contains the active substance(s) *[include the name of the active substance(s)]*, which [has / have] not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

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 BPF.

Meta-SPC(s) *[specify the meta-SPC number]* contain(s) 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)] in meta-SPC(s) *[specify the meta-SPC number]* may have endocrine-disrupting properties and these will have to be further investigated[[3]](#footnote-4).

More information is available in section 2.8 of the PAR and in the confidential annex.

*[If the active substance(s) (is / are) not (a) candidate(s) for substitution, insert:]*

The BPF contains [name of the active substance(s)] which [does / do] not meet(s) the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and [is / are] not considered as (a) candidate(s)for substitution. Therefore, a comparative assessment of the BPF is not required.

*[If the active substance(s) (is / are) (a) candidate(s) for substitution, insert:]*

The BPF contains [name of the active substance(s)] which meet(s) the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and [is / are] considered as (a) candidate(s) for substitution based on the following criteria: [*briefly report here the criteria]*. Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[[4]](#footnote-5). The assessment is presented under section 3.10 of the PAR. The competent authority concluded that *[indicate a brief summary of the conclusions on the availability of other authorised biocidal product(s) / non chemical control or prevention method(s)]*.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the BPF is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal products [is / are] listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the BPF [are / are not] met. More information is available in sections 2.5 and 2.6 of the PAR. The manufacturer(s) of the active substance(s) [is / are] listed in section 1.5 of the SPC.

**Conclusions of the assessments for each area**

The intended use(s) as applied for by the applicant [has / have] been assessed and the conclusions of the assessments for each area are summarised below.

*[For simplified authorisation, indicate for each area when data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.]*

Physical, chemical and technical properties

The physico-chemical properties [are / are not] deemed acceptable for the appropriate use, storage and transportation of the biocidal products. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

*[If physical hazards are not identified, insert:]*

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

*[If physical hazard(s) (is / are) identified, insert:]*

(A) P(p)hysical hazard(s) (was / were) identified in meta-SPC(s) XXX. *[Indicate the hazard(s) identified.]* More information is available in section 3.3 of the PAR.

Methods for detection and identification

(A) V(v)alidated analytical method(s) for the determination of the concentration of the active substance(s), residues, relevant impurit(y/ies) and substances of concern [is / are] available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

(A) V(v)alidated analytical method(s) [is / are] provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The BPF has been shown to be efficacious against *[include the target organism(s)]* for all intended uses *[indicate if there are exceptions]*. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

*[If the BPF does not contain substances of concern, insert:]*

Since no substance of concern has been identified, the human health risk assessment is based on [name of the active substance(s)].

*[If the BPF contains (a) substance(s) of concern, insert:]*

Since [name of substance(s) of concern] [have / has] been identified as (a) substance(s) of concern, the human health risk assessment is based on [name of active substance(s)] and on [name of substance(s) of concern].

*[If the assessment shows acceptable risk, insert:]*

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable acute or chronic risk to professional users, non-professional users and professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

*[If the assessment shows unacceptable risk, insert:]*

The risk assessment has shown unacceptable risk in meta-SPC(s) XXX for *[indicate the use(s) and user categor(y/ies)]* and therefore [this use / these uses] [is / are] not proposed for authorisation.

Dietary risk assessment

*[If no dietary risk assessment is performed, insert:]*

Considering the use(s), food or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance(s) is considered as negligible, and no dietary risk assessment has been performed.

*[If dietary risk assessment is performed, insert:]*

Considering the use(s), food or feed contamination is expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance(s) has been assessed, and dietary risk assessment has been performed. *[Include the conclusions of the risk assessment.]* More information is available in section 3.6.8 of the PAR.

Risk assessment for animal health

*[If no exposure to animals is expected, insert:]*

Considering the use(s), exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

*[If exposure to animals is expected, insert:]*

A risk assessment for animal health has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.7 of the PAR.

*[If the assessment shows acceptable risk, insert:]*

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable risk for [companion animals / livestock animals], if the directions for use, as specified in the SPC, are followed.

*[If the assessment shows unacceptable risk, insert:]*

The risk assessment of *[indicate the use(s)]* has shown unacceptable risk in meta-SPC(s) XXX for [companion animals / livestock animals] and therefore [this use / these uses] [is / are] not proposed for authorisation.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

*[If the BPF does not contain substance(s) of concern, insert:]*

Since no substance of concern has been identified, the risk assessment for the environment is based on [name of the active substance(s)].

*[If the BPF contains substance(s) of concern, insert:]*

Since [name of substance(s) of concern] [have / has] been identified as (a) substance(s) of concern, the risk assessment for the environment is based on [name of the active substance(s)] and on [name of the substance(s) of concern].

*[If the assessment shows acceptable risk, insert:]*

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

*[If the assessment shows unacceptable risk, insert:]*

The risk assessment of *[indicate the use(s)]* has shown unacceptable risk in meta-SPC(s) XXX for *[indicate the compartment]* and therefore [this use / these uses] [is / are] not proposed for authorisation.

**Post-authorisation conditions**

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

|  |  |
| --- | --- |
| **Description** | **Due date** |
| *[indicate the data that the authorisation holder has to provide]*  | *[indicate the deadline to provide the data]*  |

# Information on the biocidal product family

## Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

|  |  |
| --- | --- |
| **Product type(s)** | *[PT2 for meta-SPC 1 and 3; PT4 for meta-SPC 2 and 4]* |
| **Type(s) of formulation** | *[AL-other liquids to be applied undiluted for meta-SPC 1, 2, 3 and 4]* |

*[Specify the product type(s) and the formulation type(s) per meta-SPC. An example of how to compile the fields is provided.]*

## Uses

**Note for the applicant:**

Compile the table below with the intended use(s) you apply for.

**Note for the competent authority:**

All the uses applied for and assessed by the competent authority have to be kept in the final PAR in table XX. When authorisation is not proposed, this should be indicated in the column “Conclusion” of table XX. Uses applied for but withdrawn by the applicant during the evaluation should not be reported in the table in the final PAR.

When preparing the PAR, indicate the acceptability for each intended use and update the SPC to include the uses you propose for authorisation.

The competent authority may insert a second table with the uses proposed for authorisation if the uses proposed for authorisation deviate considerably from the uses applied for by the applicant. This might be the case if more complex uses or meta-SPCs are applied for and it is not possible to indicate the authorised uses clearly within Table XX.

The competent authority should delete this text box when finalising the PAR.

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the BPF

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use number1** | **Use description2** | **PT3** | **Target organisms4** | **Application method5** | **Application rate6** **(min-max)** | **User category7** | **Conclusion****(by CA)8** | **Comment9** |
| *[1.1]* | *[Disinfection of cleanrooms by spraying and wiping]* | *[PT2]* | *[Bacteria* *Yeasts**Fungi**Viruses**Spores (bacterial)]* | *[Spraying and wiping]* | *[10-15 mL/m2]* | *[Professional]* | *[R]* | * *[Additional RMM (human health)]*
 |
| *[1.2]* | *[Disinfection of cleanrooms by mopping]*  | *[Mopping]* | *[15-20 mL/m2]* | *[R]* |
| *[2.1]* | *[Disinfection of surfaces by wiping]* | *[Wiping]*  | *[10 mL/m2]* | *[R]* | * *[Additional RMM (human health)]*
 |
| *[2.2]* | *[Disinfection of large surfaces by mopping]*  | *[Mopping]*  | *[15-20 mL/m2]* | *[R]* |
| *[3.1]* | *[Disinfection of small surfaces by wiping]*  | *[Wiping]*  | *[10 mL/m2]* | *[R]* | * *[Not efficacious against viruses]*
 |
| *[4.1]* | *[Disinfection of food contact surfaces by spraying]* | *[PT4]* | *[Spraying and wiping]* | *[10-15 mL/m2]* | *[A]* | *[None]* |

1 Use number (as applied for) to be indicated together with the meta-SPC number, as in the SPC (e.g. 1.2, where “1” is the meta-SPC and “2” is the use number within the meta-SPC)

2 Title of the specific use (as applied for), as indicated in the SPC

3 Product type(s) of the use(s)

4 Target organisms, group of organisms

5 Application method for all meta-SPCs for the specific use

6 Min-max. application rate of the product(s) for the specific use

7 User categor(y/ies), e.g. general public, non-professional, professional, industrial

8 eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

*Codes for indicating the acceptability for each use*

|  |  |
| --- | --- |
| A | Acceptable |
| R | Acceptable with further restriction or risk mitigation measures (RMM) |
| N | Not acceptable |

9 If the use or meta-SPC is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

## Similarity of the group of products for which the authorisation as a biocidal product family is sought

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health, and the environment, and the minimum level of efficacy.

All the products applied for include the same active substance(s) and are similar in composition. Information on the similarity of composition and the identified worst and best case composition are provided in the confidential annex.

Table 2.3 Overview regarding the similarity of the intended uses

|  |  |  |  |
| --- | --- | --- | --- |
| Use number | Producttype | Reference1 | Use pattern2 |
| *[1.1]* | *[PTXX]* | *[number]* | *[Use pattern]* |
| *[1.2]* | *[PTXX]* | *[number]* | *[Use pattern]* |
| *[n.n]* | *[PTXX]* | *[number]* | *[Use pattern]* |

1, 2 As indicated in the Note for Guidance “Implementing the concept of biocidal product family“ (CA-July19-Doc4.2-Final).

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled “Implementing the concept of biocidal product family”.

In accordance with the agreed general criteria, all the intended uses are considered similar uses, in line with the document CG-34-2019-12 AP 15.1 Assessment of similarity in BPF.docx (“Section 2 – Similarity of uses”). The corresponding justification(s) provided by the applicant are considered acceptable.

In order to reduce the number of applications to be prepared by the applicant and to be evaluated by the [refMS / eCA] furthermore the following use pattern(s) [was / were] exceptionally accepted within the BPF:

* [Exception 1 - Use pattern number XXX]
* [Exception 2 - Use pattern number XXX]

All the intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bear a consistent set of instructions for use, RMMs etc. (e.g. same RMMs from best to worst case composition), it was ensured that all products of the BPF have a similar level of risk and efficacy.

## Identity and composition

The identity and composition of the following product(s) within the BPF:

*[list the product(s) here]*

are

identical [ ]

not identical [ ]

to the identity and composition of the product(s) evaluated in connection with the [approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation (EU) No 528/2012].

*[For simplified authorisation of biocidal products containing active substance(s) included in categories 1, 2, 3, 4, 5 and 7 of Annex I of BPR, instead of the paragraph above, insert the following:]*

The determination whether the identity and composition of the biocidal product(s) within the BPF are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the meta-SPC(s) and of the individual product(s) is detailed in sections 2.1 and 7 of the SPC, respectively. Information on the full composition is provided in the confidential annex.

## Identity of the active substance(s)

*[If the BPF contains more than one active substance, repeat the following table for each active substance.]*

Table 2.4 Identity of the active substance(s)

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | *(as provided in the implementing regulation of the active substance approval)* |
| **Chemical name** | *(as provided in the implementing regulation of the active substance approval)* |
| **EC number** | *(as provided in the implementing regulation of the active substance approval)* |
| **CAS number** | *(as provided in the implementing regulation of the active substance approval)* |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | *(as provided in the implementing regulation of the active substance approval)* |
| **Structural formula** |  |

## Information on the source(s) of the active substance(s)

*[Indicate whether the source*[[5]](#footnote-6) *of the active substance is* *the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 or in connection with the inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012, by ticking the appropriate tick box. If the BPF contains more than one active substance, duplicate the question and the tick boxes for each active substance. If the active substance has more than one source, duplicate the question and the tick boxes for each source. Every time “No” is selected, include an explanation. Example: "The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number: XXX).”*

*A source reported in the list of active substance suppliers in accordance with Article 95 of the BPR is not sufficient to demonstrate that the active substance source would be authorized to formulate biocidal products. The R4BP 3 case/asset number and the results of the technical equivalence assessment done by ECHA should be reported to state if the source is indicated as reference source or is used following an assessment of the equivalency performed by ECHA.]*

Is the source of [name of the active substance] the same as the one(s) evaluated in connection with the [approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012]?

[ ]  Yes

[ ]  No

*[For simplified authorisation of biocidal products containing active substance(s) included in categories 1, 2, 3, 4, 5, and 7 of Annex I of BPR, instead of the paragraph above, insert the following:]*

The information on the source(s) of the active substance(s) is not applicable.

## Candidate(s) for substitution

The following candidate(s) for substitution [has / have] been identified:

* [name of candidate for substitution 1]
* [name of candidate for substitution 2]
* *[add names to the list, as needed]*

The following criteria for substitution are met *[examples are provided in the list below]*:

* *[Very persistent]*
* *[Toxic]*

## Assessment of the endocrine-disrupting properties of the biocidal product family

*[Include and delete text in the following paragraph(s) as appropriate.]*

The BPF does not contain any active substances having endocrine-disrupting properties.

The BPF contains the active substance(s) *[include the name of the active substance(s)]* having endocrine-disrupting properties on the basis of the scientific criteria in Regulation (EU) 2017/2100 (and) the active substance(s) *[include the name of the active substance(s)]* having endocrine-disrupting properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, (and) the active substance(s) *[include the name of the active substance(s)]* with an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s). The details on the endocrine-disrupting properties are available in the CAR(s) provided for the approval of the active substance(s).

The BPF contains the active substance(s) *[include the name of the active substance(s)]*, which [has / have] not yet been evaluated according to the scientific criteria set out in the Regulation (EU) No 2017/2100.

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

Meta-SPC(s) *[specify the meta-SPC number]* contain(s) 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. More detailed information is available in the confidential annex.

Based on the available information, there are significant indications that [name of the non-active substance(s)] in meta-SPC(s) *[specify the meta-SPC number]* may have endocrine-disrupting properties and these will have to be further investigated[[6]](#footnote-7). However, at this stage, it is not possible to conclude before the expiration of the legal deadline in the BPR (Articles 30(2), 34(4) and 44(1)) whether the non-active substance(s) should be considered to have endocrine-disrupting properties. More detailed information is available in the confidential annex.

## Classification and labelling

*[Please add additional tables in case of more meta-SPCs.*

*Classification of a BPF should be done at meta-SPC level. The hazard and precautionary statements must be the same for all products covered by one meta-SPC.*

*In this section, it should be also indicated if some P-statements triggered by the criteria in CLP have been excluded due to the risk assessment or use of the BPF.* ***Therefore, all P-statements should be included under the column “Classification”****, regardless of the number of the P-statements. Excluded P-statements should be marked with strikethrough and if necessary, justified under “notes”.]*

Table 2.5 Classification and labelling of the BPF

| ***[Meta SPC 1]*** | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | *[Eye Irrit. Cat 2**Aquatic acute Cat 1**Aquatic chronic Cat 1]* |  |
| **Hazard Pictograms** | *[GHS17, GHS08]* | [GHS08] |
| **Signal word(s)**  | *[Warning]* | [Warning] |
| **Hazard statements** | *[H319 - Causes serious eye irritation**H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects]* | *[H319- Causes serious eye irritation* *H410 Very toxic to aquatic life with long lasting effects]* |
| **Precautionary statements\*** | *[P264 - Wash hands thoroughly after handling.**P280 - Wear protective gloves.**P305+ P351+ P338- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P337 + P313- If eye irritation persists: Get medical advice.**P273 - Avoid release to the environment**P391 - Collect spillage**P501 - Dispose of contents and container in accordance with national regulation]* | The authorisation holder is responsible to choose the relevant P-statements to be included on the label. |
| **Supplemental hazard statements** | *[EUH208 - Contains XXX (CAS No. XXX). May produce an allergic reaction.]* |
| **Notes** | *[Where necessary, add a justification for excluding certain P-statements.]* |

**\***P-statements that are excluded based on the risk assessment or the intended use of the product(s)[[7]](#footnote-8), are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

## Letter of access

*[Indicate here whether a Letter of Access to the active substance(s) and/or to the products (has / have) been submitted. It must be clear in the Letter of Access to which data and to which authority access is granted.]*

## Data submitted in relation to product authorisation

*[Indicate here whether any new data on the active substance(s) and substance(s) of concern have been submitted.*

*Please note that for (the) active substance(s), only data for endpoints which were not contained in the original approved data set shall be added, i.e. ADS according to Annex II of the BPR.*

*Example: Due to a new use, additional active substance data according to the information requirements are mandatory.]*

## Similar conditions of use across the Union

*[For national and simplified authorisation applications, insert:]*

This section is not relevant.

*[For Union authorisation applications, insert:]*

The outcome of the consultation during the pre-submission phase indicated that the BPF [is / is not] deemed to have similar conditions of use across the Union.

# Assessment of the biocidal product family

*[For simplified authorisation, indicate for each area when data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.]*

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging1** | **Size/volume of the packaging2**  | **Material of the packaging3** | **Type and material of closure(s)** | **Intended user4** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| *[Sachets]* | *[(20; 30; 50; 100g) packed in:** + *Bags (paper or LDPE) (5, 10, 25 kg)*
	+ *Bucket (PE) (525kg)*
	+ *Carton box (carton) (5, 10, 50 kg)]*
 | *[LDPE]* | *[screw cap, HDPE]* |  |  |
| *[Can* *Barrel]* | *[5L**10L**20L**50L]* | *[Tin plate (with epoxyphenol varnish layer)]* |  |  |  |
| *[Rolls**Wipes]* | *[700\*50\*50mm**200 units (100g)]* |  |  |  |  |

1 Type of packaging e.g. bottle, rolls, can, barrel, tank.

2 Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage, and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.

For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height\*Length\*Width for rolls / number and weight of wipes.

3 For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.

4 Intended user, e.g. professional, non-professional

## Physical, chemical, and technical properties

*[Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*.]*

Information on the choice of the worst case composition for physical, chemical, and technical properties (e.g. representative test product(s)) and the justification for why the chosen test product(s) [is / are] considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

*[Note for the table: for storage stability test – long-term storage at ambient temperature, if no final report of the long-term shelf life study is available yet, an expected end date should be provided accompanied by proof that the study is running (e.g. protocol or, if available, interim data).]*

Table 3.2 Physical, chemical, and technical properties

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa |  |  |  |  |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa |  |  |  |  |
| 3.1.2. | Colour at 20 °C and 101.3 kPa |  |  |  |  |
| 3.1.3. | Odour at 20 °C and 101.3 kPa |  |  |  |  |
| 3.2. | Acidity, alkalinity, and pH value |  |  |  |  |
| 3.3. | Relative density / bulk density |  |  |  |  |
| 3.4.1.1. | Storage stability test – **accelerated storage** | *[All used test methods should be mentioned in this field, including the analytical method used to determine active substances and substances of concern.]* |  | *[Time/temperature and packaging (material and volume) tested should be reported.* *The test results of each property required in function of the formulation type should be reported before and after storage (e.g. appearance, packaging stability, leakproofness test of the packaging, sealing tightness test, active substance content, acidity/alkalinity).]*  |  |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | *[All used test methods should be mentioned in this field, including the analytical method used to determine active substances and substances of concern.]* |  | *[Time/temperature and packaging (material and volume) tested should be reported.* *The required tests for each formulation type should be performed before and after storage (e.g. appearance, packaging stability, leakproofness test of the packaging, sealing tightness test, active substance content, pH, acidity/alkalinity, suspensibility, particle size).]* |  |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** |  |  |  |  |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** |  |  |  |  |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  |  |  |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  |  |  |
| 3.5.1. | Wettability *[indicate the concentration tested]* |  |  |  |  |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]* |  |  |  |  |
| 3.5.3. | Wet sieve analysis and dry sieve test *[indicate the concentration tested]* |  |  |  |  |
| 3.5.4. | Emulsifiability, re-emulsifiability, and emulsion stability *[indicate the concentration tested]* |  |  |  |  |
| 3.5.5. | Disintegration time |  |  |  |  |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability *[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]* |  |  |  |  |
| 3.5.7. | Persistent foaming *[indicate the concentration tested]* |  |  |  |  |
| 3.5.8. | Flowability/pourability/dustability |  |  |  |  |
| 3.5.9. | Burning rate — smoke generators |  |  |  |  |
| 3.5.10. | Burning completeness — smoke generators |  |  |  |  |
| 3.5.11. | Composition of smoke — smoke generators |  |  | *[Indicate how the analysis was performed and report the qualitative and quantitative composition of smoke.]*  |  |
| 3.5.12. | Spraying pattern — aerosols / spray |  |  |  |  |
| 3.6.1. | Physical compatibility |  |  |  |  |
| 3.6.2. | Chemical compatibility |  |  |  |  |
| 3.7. | Degree of dissolution and dilution stability *(indicate the concentration tested)* |  |  |  |  |
| 3.8. | Surface tension *[indicate the conditions of the test and the concentration tested]* |  |  |  |  |
| 3.9. | Viscosity *[indicate the shear rate and the temperature tested]* |  |  |  |  |

Table 3.3 Conclusion on physical, chemical and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| *[Fill in for each meta-SPC]****:***The representative product(s) [Product name(s)] of meta-SPC XXX [is / are] a(n) *[indicate the formulation type]*. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.**Implications for labelling for meta-SPC XXX:** (e.g. 'protect from frost' or 'stir before use')*[include the implications for each meta-SPC.]* |

## Physical hazards and respective characteristics

*[Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*. All required tests should be performed according to CLP Regulation. If data is waived, it should be clearly explained why the meta-SPC is not classified. Note that waivers should be based on information in line with the CLP requirements.]*

Information on the choice of the worst case composition for physical hazards and respective characteristics (e.g. representative test product(s)) and the justification for why the chosen test product(s) [is / are] considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.4 Physical hazards and respective characteristics

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product / batch (AS% (w/w)** | **Results** |
| --- | --- | --- | --- | --- |
| 4.1. | Explosives |  |  |  |
| 4.2. | Flammable gases |  |  |  |
| 4.3. | Flammable aerosols |  |  |  |
| 4.4. | Oxidising gases |  |  |  |
| 4.5. | Gases under pressure |  |  |  |
| 4.6. | Flammable liquids |  |  |  |
| 4.7. | Flammable solids |  |  |  |
| 4.8. | Self-reactive substances and mixtures |  |  |  |
| 4.9. | Pyrophoric liquids |  |  |  |
| 4.10. | Pyrophoric solids |  |  |  |
| 4.11. | Self-heating substances and mixtures |  |  |  |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases |  |  |  |
| 4.13. | Oxidising liquids |  |  |  |
| 4.14. | Oxidising solids |  |  |  |
| 4.15. | Organic peroxides |  |  |  |
| 4.16. | Corrosive to metals |  |  |  |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) |  |  |  |
| 4.17.2. | Relative self-ignition temperature for solids |  |  |  |
| 4.17.3. | Dust explosion hazard |  |  |  |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| *[Fill in for each meta-SPC]****:***Based on the assessment of the representative product(s), meta-SPC XXX [is not classified for the physical hazards/ is classified as *[indicate the classification (hazard class, category code and hazard statement)]*]. |

## Methods for detection and identification

*[Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*. Describe the analytical methods used for the analysis of the active substance(s), residues, relevant impurit(y/ies), and substance(s) of concern in the BPF.]*

Information on the choice of the worst case composition for methods for detection and identification (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities, and residues** |
| Principle of the method *[reference method]: [Describe the analytical methods used for the analysis of the active substance(s), relevant impurit(y/ies), and substance(s) of concern in the BPF, e.g. “5 mg sample are taken and dissolved in 20 mL mobile phase (methanol/water 5/95 v/v) in a 50 mL volumetric flask, sonicated and filled up to the mark. Analysis is done by HPLC-UV at 254 nm with a C18 column and mobile phase using gradient/isocratic elution (specify gradient).”]* |
| **Analyte** (type of analyte e.g. active substance) | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of Quantification LOQ** *– only for impurit(y/ies)* | **Reference** |
| Level | Number of measurements | Range | Mean | RSD | Concentration tested | Number of replicates |
|  | *[Include the range of concentration, number of samples, correlation coefficient r²]* | *[Interference present or not >3% of peak sample area.**Chromatograms / mass spectra provided or not (formulation and solvent blanks, fortified samples, linearity samples …).]* |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[If new data are provided, add the following tables for each matrix. Otherwise, delete the tables.]*

Table 3.7 Analytical methods for soil

|  |
| --- |
| **Analytical methods for soil** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 3.8 Analytical methods for air

|  |
| --- |
| **Analytical methods for air** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 3.9 Analytical methods for water

|  |
| --- |
| **Analytical methods for water** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 3.10 Analytical methods for animal and human body fluids and tissues

|  |
| --- |
| **Analytical methods for animal and human body fluids and tissues** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 3.11 Analytical methods for monitoring of active substances and residues in food and feeding stuff

|  |
| --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 3.12 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification**  |
| (An) A(a)nalytical method(s) *[include the reference]* for the determination of [name of the active substance(s) and/or impurit(y/ies)] [is / are] available. Specificity, linearity, accuracy and precision were checked and found acceptable.(An) A(a)nalytical method(s) *[include the reference]* for the determination of [name of the substance(s) of concern] [is / are] available. Specificity, linearity, accuracy and precision [were checked and found acceptable or are not submitted as the [name of the substance(s) of concern] [does / do] not change in [its / their] concentration / [is / are] not formed during storage].Methods for the detection of [active substance(s)] in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required.*(Add the following, where necessary)* * The products are not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required.
* As no MRL were fixed, no analytical method for the determination of active substance in food/feed of plant and animal origin is required.
* As the active substance(s) [is / are] readily degradable in soil/water/air, no analytical method is required in this matri(x/ces).
 |

##

## Assessment of efficacy against target organisms

*[Refer to the Guidance on the BPR: Volume II Efficacy (Part A), as well as (Parts B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*. Please also consult the documents agreed at BPC WG meetings, including Technical Agreements for Biocides that are available in CIRCABC at* [*https://webgate.ec.europa.eu/s-circabc/w/browse/4047dcc1-ff35-45e1-894c-8647639f9ae8*](https://webgate.ec.europa.eu/s-circabc/w/browse/4047dcc1-ff35-45e1-894c-8647639f9ae8)*.]*

### Function (organisms to be controlled) and field of use (products or objects to be protected)

*[Include (in text format):*

* *Description of the function, e.g. fungicide, rodenticide, insecticide, bactericide (the function should be described in terms of a problem formulation: which problem is caused by the unwanted organisms?, e.g. prevents the spread of …);*
* *Field of use of the biocidal product (the respective field of use, i.e. indoor/outdoor together with detailed description should be included here);*
* *Description of the organisms to be controlled (provide both the common name and the scientific name, when possible, and also the sex, strain, and stadia, where relevant and appropriate. In cases where groups of organisms are to be controlled, generic names that are representative of the group must be indicated, e.g. bacteria, flying insects. If relevant, indicate in which parts of EU the organisms to be controlled exist.);*
* *Products, organisms or objects to be protected.]*

### Mode of action and effects on target organisms, including unacceptable suffering

*[Describe the mode of action in terms of biological, biochemical, and physiological mechanisms, including the time delay and the effects of the biocidal product on (the) target organism(s).]*

##

### Efficacy data

*[Include in the table below any experimental data on the efficacy of the biocidal product(s) against target organism(s) for each meta-SPC. If needed, in order to make it easier to check the efficacy data, several tables may be provided in order to cover all uses and PTs. In the column “Test results: effects”, include information regarding e.g. log reduction, contact time, temperature, soiling. Some examples are provided and should be considered as suggestions on how to fill in the table. When filling the column “Number in IUCLID section 6.7/Test report title”, ensure that that the references are aligned between the PAR and the IUCLID file, i.e. the same number/title is used to indicate the same study in the PAR and in the IUCLID file.]*

**Note for the competent authority:**

In the column “Test results: effects”, indicate if the efficacy criteria has been validated. In case of unknown or in-house methods, list the validation criteria.

The competent authority should delete this text box when finalising the PAR.

Table 3.13 Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects***[address here results related to efficacy of the test product and validity of the test]* | **Reference**  | **Number in IUCLID section 6.7/Test report title** |
| *[PT1**Use 1.1: Hand disinfection]*  | *[Prod1**X% (w/w) AS]* | *[Bactericidal /E. coli K12]* | *[EN 1500 (2013) phase 2, step 2 test**Concentrations tested: 50%, 100% (v/v)**Contact time: 30 seconds**Temperature 20°C ± 1°C]* | *[Passed concentration: 100 % (v/v)**Acceptance criteria for test results, as given in chapter 5.7.1. of EN 1500, fulfilled.]* | *[XX et al. 2018**study N°XXX]* |  |
| *[PT3**Use 1.1: Disinfection of hard surfaces]* | *[Prod3**Z% (w/w) AS]* | *[Fungicidal activity / Aspergillus brasiliensis and Candida albicans**Yeasticidal activity / Candida albicans]* | *[EN 16438 (2014) phase 2, step 2 test**Concentrations tested: 0.25%, 0.75%, 1 % (v/v)**Interfering substances tested: Low level soiling 3 g/l BSA, High level soiling 10g/l yeast extract + 10g/l BSA**Contact times tested: 5 min+10 s and 30 min+10 s**Temperature: 10°C + 1°C]* | *[Concentration 0.75% (v/v) passed (3.5 log reduction)Clean conditions5 min contact timeTemperature 10°CConcentration 1 % (v/v) passed (3.2 log reduction)Dirty conditions30 min contact timeTemperature 10°C**The validity criteria of the test method are fulfilled (test suspension, dilution-neutralisation, water control.]* | *[XX et al. 2016**study N°XXX]* |  |
| *[PT8**Use 4.5: Preventive treatment against fungi]* | *[Prod4**X% (w/w) AS]* | *[C. puteanaG. trabeumP. placentaC. versicolor]* | *[EN 113 after EN 73 (evaporation)* *The product was applied by vacuum impregnation** *6 blocks tested for each treatment and each fungal strain. C. puteana, G. trabeum and P. placenta are tested on pine. C. versicolor is tested on beech replicates*
* *Number of replicates: 6 replicates for each treatment and each fungal strain.*

*CONTROLS** *Untreated controls: one non-treated control block included with the treated block in each test. Six virulence control blocks for each fungal strain.*

*The effect investigated is mass loss of the test blocks, induced by the fungal development**The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.** *Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains.]*
 | *[The study is validated as more than 20 % of mass loss is observed in the control (>X % in each control)**Mid toxic values of the test product:** *Cannot be determined for C. puteana, G. trabeum and C. versicolor, but the toxic values were lower than X, Y and Z kg/m3 respectively.*
* *Against P. placenta: X kg/m3 or Xg/m².*

*Thus, the biological reference value of the test product X for brown and white rot fungi, on softwood and hardwood after evaporative ageing procedure, is X kg/m3 or XX g/m² of wood.]* | *[XX et al., 2015**study N°XXX]* |  |
| *[PT14**Use 1.3:**IndoorOutdoor]* | *[Prod5**25% AS]* | *[Mice**5 females and 5 males* | *[Laboratory test**Pre-treatment 3 days in individual cage at room temperature.**Day 0: reference food and bait biocidal product have been given:** *X g per animal of reference food for the assessment of palatability,*
* *X g per animal of biocidal product during 3 consecutive days with daily consumption measurements.*

*Mortality was observed during 14 days every 24 hours or until the death of all animals.* | *[Palatability= >20%**Mortality = 100%**Validity criteria of the test (list of criteria used) fulfilled.* | *[S-2017-00457-2 study N°XXX* |  |
| *Black rats**Estimated population]* | *Field test**Site location:**Census baiting technique, which involved the following phases:* * *Pre-treatment census : 14 days pre-treatment lag phase : 4 days*
* *Treatment census : 15 days*
* *Post-treatment lag phase : 3 days*
* *Post-treatment census : 5 days*

*During each assessment, the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.]** *Pre-treatment: X g of wheat per station per day*
* *Treatment: X g of bait per day in each lockable bait station – total X bait stations*
* *Post-baiting: X g of wheat per station per day*
 | *Estimated efficacy = 100%**Pre-baiting plateau = 1185.8 g/day**Post-baiting = 0g**Observed mortality : 1 rat**Validity criteria of the test (list of criteria used) fulfilled]* | *[study N° XXX]* |  |
| *[PT19**Use 1.2: Skin repellent]* | *[Prod6**25% AS**Spray Application**Or* *Roller**Or**…]* | *[Repellent or Attractant**Organisms or objects to be protected**Species (Aedes albopictus, Stomoxys calcitrans, …)**Development Stages* *Sex, age, starves, or no…**Number tested Number of replicates]*  | *[Laboratory/Simulated used test/Field Test**Indoor or Outdoor**Corresponding Standard* *For each type of method, test system:** *Location*
* *Temperature*
* *Humidity*
* *Doses tested*
* *Light cycle*
* *Number of replication per modality*

*Method of application: By spraying (sprays number)**Example of test design:**Based on WHO/HTM/NTD/ WHOPES/2009.4; Guideline for efficacy testing of mosquito repellents for human skin - § 2.2* *Laboratory test.**Arm-in-cage study.* *10 volunteers/3 volunteers and 3 replicates per volunteer.* *Size of cage**Product applied on one forearm of each volunteer, the other untreated one being used as a control.**Dose of product XX mg/cm² of skin (i.e. XX g/600 cm² forearm).**The trial began 30 minutes after the product had been applied. The control forearm was inserted into the cage for 30 seconds and after validation of this control (10 landings), the treated forearm was inserted into the cage for 3 minutes/5 minutes (exposure time).**The same procedure was repeated every hour until XX hours or inefficacy.* *Landings and bites were counted during each exposure time.**Climatic conditions: temperature 27 + 2 °C; relative humidity 62 % + 10%]* | *[The methodology is validated (description of validation criteria).** *Efficacy in samples tested with product AND in control*
* *Efficacy data for each species and/or time tested*
* *Time delay and residual efficacy*
* *Efficacy criteria*

*Conclusion:**After application of the product at XX mg/cm² of skin, the duration of protection was:* *- X hours for C. pipiens* *- X hours for A. albopictus* *- X hours for A. aegypti* *- X hours for A. gambiae* *Based on the less sensitive species, the protection duration of the product is X hours when the product is applied on skin.]* | *[XX et al. 2016**study N°XXX]* |  |

*[Insert/delete rows according to the number of studies.]*

### Efficacy assessment

Information on the choice of the worst case composition for efficacy (e.g. representative test product(s) and expert judgement/bridging studies where applicable) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for. *[Indicate if there are exceptions.]*

*[Provide an efficacy assessment for* *the core and eventual subsets/extensions, if relevant.]*

### Conclusion on efficacy

*[Insert the efficacy conclusion in relation to the claims made for all the intended uses as applied for by the applicant and indicate for which uses efficacy is not demonstrated.]*

### Occurrence of resistance and resistance management

*[Describe the occurrence or possible occurrence of the development of resistance and appropriate management strategies.]*

### Known limitations

*[Describe any known limitations on efficacy, including observations on undesirable or unintended side effects.]*

### Relevant information if the BPF is intended to be authorised for use with other biocidal products

*[Indicate whether the BPF is intended to be used in combination with other biocidal products.]*

## Risk assessment for human health

*[Refer to the Guidance on the BPR: Volume III Human Health (Part A) as well as (Parts B+C) and the Biocides Human Health Exposure Methodology when compiling this section. Both documents are available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*.*

*Indicate in the following sections whether new data/information on human health effects for the active substance(s) listed in the Union list of approved active substances under Regulation (EU) No 528/2012 have become available since the approval. In case of bridging of data between the representative product(s) in the CAR and similar products of the BPF applied for authorisation, a justification for bridging should be provided including a quantitative comparison of the composition of the respective products.*

*If no new data/information is required and if the products applied for authorisation are identical to the representative products in the CAR, a very short summary of the human health effects assessment and the human health exposure and risk assessment can be presented here which could be copied from the assessment report or from the CAR.]*

Table 3.14 Overview table of the concentrations of the active substance(s) and substance(s) of concern contained in the BPF

|  |
| --- |
| **Concentration range of the BPF (%)** |
| **meta-SPC number** | **1** | **2** | **…** | **…** |
| **Active substance 1** |  |  |  |  |
| **Active substance 2** |  |  |  |  |
| **Substance of concern 1** |  |  |  |  |
| **Substance of concern 2** |  |  |  |  |

*[Indicate the concentration range of the active substance(s) and substance(s) of concern for each meta-SPC.]*

Information on the choice of the worst case composition for human health risk assessment (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products chosen, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

### Assessment of effects on human health

*[If no endpoints have been submitted, include:]*

There are no human health data available for the products. The assessment, classification, and labelling are based on the agreed endpoint(s) for the active substance(s) and available information for the non-active substance(s).

*[If no data is provided, delete the table for the relevant endpoint and indicate the justification for the adaptation/waiving of the data requirement(s), including a reference to the IUCLID data point. When using the calculation rules in accordance with Regulation (EC) No 1272/2008, include calculations in the confidential annex for the meta-SPC, using the harmonised classification, if any, and MSDS for the non-active substances according to the current standards. If the applicant deviates from the C&L as given in the MSDS of its supplier, a justification should be provided. Classification for actual products as placed on the market should derived rather than a classification based on the raw materials. This would mean that e.g. content in raw materials or acid/base reactions need to be considered for the actual products.*

*The hazard must be determined at meta-SPC level rather than at product level and must be identical for all products covered by one meta-SPC. Otherwise, they should be allocated to different meta-SPCs. Thus, for the determination of the toxicological profile of the meta-SPC, its specific composition range should be taken into account.]*

#### Skin corrosion and irritation

Table 3.15 Summary table of in vitro studies on skin corrosion/irritation

| **Summary table of in vitro studies on skin corrosion/irritation** |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.16 Summary table of animal studies on skin corrosion/irritation

|  |
| --- |
| **Summary table of animal studies on skin corrosion/irritation** |
| **Method, Guideline,** **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results***Average score**(24, 48, 72h)/**observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological**findings* | **Remarks** *(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.17 Summary table of human data on skin corrosion/irritation

| **Summary table of human data on skin corrosion/irritation** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

Table 3.18 Conclusion used in Risk Assessment – Skin corrosion and irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.19 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Eye irritation

Table 3.20 Summary table of in vitro studies on serious eye damage and eye irritation

| **Summary table of in vitro studies on serious eye damage and eye irritation**  |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.21 Summary table of animal studies on serious eye damage and eye irritation

|  |
| --- |
| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Dose levels, Duration of exposure** | **Results***Average score (24, 48, 72h)/**observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.22 Summary table of human data on serious eye damage and eye irritation

| **Summary table of human data on serious eye damage and eye irritation** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows according to the available information.]*

Table 3.23 Conclusion used in Risk Assessment – Eye irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.24 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Respiratory tract irritation

Table 3.25 Summary table of animal studies on respiratory tract irritation

| **Summary table of animal studies on respiratory tract irritation** |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance****Dose levels, Duration of exposure** | **Results***Clinical signs, histopathology, reversibility* | **Remarks***(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.26 Summary table of human data on respiratory tract irritation

| **Summary table of human data on respiratory tract irritation** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

Table 3.27 Conclusion used in the Risk Assessment – Respiratory tract irritation

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.28 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Skin sensitization

Table 3.29 Summary table of in vitro studies on skin sensitisation

| **Summary table of in vitro studies on skin sensitisation** |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.30 Summary table of animal studies on skin sensitisation

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks***(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.31 Summary table of human data on skin sensitisation

| **Summary table of human data on skin sensitisation** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.32 Conclusion used in Risk Assessment – Skin sensitisation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.33 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Respiratory sensitization

Table 3.34 Summary table of animal data on respiratory sensitisation

| **Summary table of animal data on respiratory sensitisation** |
| --- |
| **Method, Guideline, GLP status, Reliability** | **Species, strain, Sex, No/group** | **Test substance****Dose levels, Duration of exposure** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.35 Summary table of human data on respiratory sensitisation

| **Summary table of human data on respiratory sensitisation** |
| --- |
| **Type of data/ report, Reliability**  | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.36 Conclusion used in Risk Assessment – Respiratory sensitisation

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.37 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Acute oral toxicity

Table 3.38 Summary table of animal studies on acute oral toxicity

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline GLP status, Reliability**  | **Species, Strain, Sex, No/group** | **Test substance****Dose levels, Type of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **Value LD50** | **Remarks** *(e.g. major deviations)* | **Reference**  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.39 Summary table of human data on acute oral toxicity

| **Summary table of human data on acute oral toxicity** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows as needed. If not relevant, delete the table and include a statement that no human data is available.]*

Table 3.40 Value used in the Risk Assessment – Acute oral toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value |  |
| Justification for the selected value |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.41 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Acute inhalation toxicity

Table 3.42 Summary table of animal studies on acute inhalation toxicity

|  |
| --- |
| **Summary table of animal studies on acute inhalation toxicity** |
| **Method, Guideline,** **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD)****Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LC50** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.43 Summary table of human data on acute inhalation toxicity

| **Summary table of human data on acute inhalation toxicity** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows as needed. If not relevant, delete the table and include a statement that no human data is available.]*

Table 3.44 Value used in the Risk Assessment – Acute inhalation toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value |  |
| Justification for the selected value |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.45 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

#### Acute dermal toxicity

Table 3.46 Summary table of animal studies on acute dermal toxicity

|  |
| --- |
| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline, GLP status,****Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.47 Summary table of human data on acute dermal toxicity

| **Summary table of human data on acute dermal toxicity** |
| --- |
| **Type of data/ report, reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows as needed. If not relevant, delete the table and include a statement that no human data is available.]*

Table 3.48 Value used in the Risk Assessment – Acute dermal toxicity

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value |  |
| Justification for the selected value |  |
| Classification of the product(s) according to CLP  | *[Include a proposal, if relevant, and indicate the concerned meta-SPC(s).]* |

Table 3.49 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table. This table is considered relevant when classification is based on read across or when based on the calculation rules.]*

### Information on dermal absorption

*[If no data is provided, delete the table and indicate the justification for the adaptation/waiving of the data requirement(s), including a reference to the IUCLID data point. In case of bridging of data between similar products, a justification for bridging should be provided including a quantitative comparison of the composition of the respective products conforming to the EFSA Guidance on Dermal Absorption (2017) (*[*https://www.efsa.europa.eu/en/efsajournal/pub/4873*](https://www.efsa.europa.eu/en/efsajournal/pub/4873)*). Also, when using default values for dermal absorption a clear justification needs to be provided. A default dermal absorption of 100 % should be indicated for corrosive concentrations unless there is data indicating lower dermal absorption. This is included in the technical agreements on biocides (*[*https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups*](https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups)*, page 57).]*

Table 3.50 Summary table of in vitro studies on dermal absorption

| **Summary table of in vitro studies on dermal absorption** |
| --- |
| **Method, guideline, GLP status, reliability** | **Species, number of skin samples tested per dose, other relevant information about the study** | **Test substance, doses** | **Absorption data for each compartment and final absorption value** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.51 Summary table of animal studies on dermal absorption

|  |
| --- |
| **Summary table of animal studies on dermal absorption** |
| **Method, guideline,****GLP status, reliability** | **Species, strain, sex, no/group** | **Concentration of test substance/label, duration of exposure** | **Absorption data for each compartment and final absorption value**  | **Signs of toxicity** | **Remarks** *(e.g. major deviations)* | **Reference** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[Insert/delete rows according to the number of studies.]*

Table 3.52 Value(s) used in the Risk Assessment – Dermal absorption

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance |  |
| Value(s) | *[Include the concentration range(s) the values are applicable for, if relevant.]* |
| Justification for the selected value(s) |  |

Table 3.53 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement |  |
| Justification |  |

*[If not relevant, delete the table.]*

### Available toxicological data relating to substance(s) of concern

*[Present all available information, including relevant information to be used in the risk assessment (AEL or a European validated value, if an AEL is not available). The substances of concern guidance for human health toxicology is described in CA-Nov14-Doc.5.11 – SoC guidance\_final.doc published in the CIRCABC Interest Group “Biocides - Regulation 528/2012 – Public”. Furthermore, the text of this CA document is included in the BPR guidance (Volume III Human Health - Assessment & Evaluation (Parts B+C)). Address the substances of concern in line with the guidance for the identification and evaluation of substances of concern guidance as indicated above, clearly stating why substances are identified as substances of concern. Also make sure that the substances of concern(s) listed in the table below are consistent with the confidential annex to the PAR and the supporting document “Overview of the biocidal product family”.]*

*[If the BPF does not contain substances of concern, include:]*

No substances of concern regarding human health were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Consequently, only the active substance(s) [was /were] addressed in the human health risk assessment.

*[If the BPF contains (a) substance(s) of concern, include:]*

According to the criteria as set in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)), the following substance(s) need(s) to be considered as (a) substance(s) of concern regarding human health:

Table 3.54 Available toxicological data relating to substance(s) of concern

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Meta-SPC** | **Substance of concern** | **Criterion for the identification as a substance of concern** | **Band** | **Type of risk assessment performed** |
| *[Meta-SPC X]* | *[No substance of concern identified]* | *[Not relevant]* | *[Not relevant]* | *[Not relevant]* |
| *[Meta-SPC Y]*  | *[Chemical name of the substance of concern (max. conc. XX%)]* | *[i.e. BPR, Art. 3 (f)" or "other grounds of concern* *as in Guidance Vol III Human Health Parts B+C”]* | *[indicate the relevant band from the banding approach]* | *[e.g. qualitative assessment, (semi-)quantitative assessment (based on product classification), quantitative assessment (using AEL, OEL of XXX)]* |

*[Insert/delete rows as needed.]*

### Other

*[Include any relevant information and considerations not covered above, e.g. classification for endpoints not covered in the previous sections, food and feeding stuffs studies, effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal products and other test(s) related to the exposure to humans. If not relevant, do not delete this section nor the following sub-sections, but indicate that they are not relevant.]*

#### Food and feeding stuffs studies

#### Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal products

#### Other test(s) related to the exposure to humans

### Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of (the) non-active substance(s), refer to the respective section of the confidential annex.

### Exposure assessment and risk characterisation for human health

*[Assess primary and secondary exposure for each active substance and substance of concern in case of exposure to several active substances or substances of concern.]*

#### Introductory remarks

*[Provide a short description on how the following points are addressed in the human health risk assessment.]*

Relevant guidance documents consulted for human health risk assessment

*[List the guidance documents used.]*

Relevant exposure models or exposure studies used for human health risk assessment

*[List the exposure models or exposure studies used.]*

Strategy for human health risk assessment

*[Briefly describe:*

* *The mode of action of the active substance(s) (systemic, local);*
* *The type of assessment performed (quantitative, (semi-)quantitative, qualitative or combinations thereof).]*

*[Briefly present the human health risk assessment strategy, e.g. per user category, PT, use, worst case approach or combinations thereof.]*

Considerations on volatility of the active substance(s) and substance(s) of concern

*[Include any relevant consideration on the volatility of the active substance(s) and substance(s) of concern, i.e. the need to consider exposure towards vapours.]*

Strategy for livestock exposure and/or dietary risk assessment

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

Strategy for the assessment of substance(s) of concern

*[Briefly present the substance(s) of concern assessment strategy, including the type of assessment performed, e.g. quantitative, (semi-)quantitative, qualitative or combinations thereof. Please also consider dietary risk assessment (DRA), if relevant.]*

Strategy for disinfectant by-products assessment

*[Briefly present the strategy. If not relevant, do not delete this section, but indicate that it is not relevant. Please also consider DRA, if relevant.]*

#### Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the BPF

Table 3.55 Summary table: main paths of human exposure

| **Summary table: main paths of human exposure** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Professional users** (including industrial users and trained professional users) | **Non-professional users** | **Professional users** (including industrial users and trained professional users) | **Non-professional bystanders/General public** | **Via food** |
| Oral |  |  |  |  |  |
| Dermal |  |  |  |  |  |
| Inhalation |  |  |  |  |  |

*[Indicate the main paths of human exposure by stating “yes”, “no” or “n/a” (not applicable) for each cell.]*

#### List of exposure scenarios

*[This list should contain all scenarios for professional, non-professional, and secondary exposure, but should exclude dietary exposure. Exposure shall be assessed along the life-cycle of the product, i.e. exposure associated with production, formulation, use and disposal of the product. Refrain from including scenarios already covered by other legislations such as REACH.*

*A brief description of the scenarios should be provided in the table. Models used for calculations and detailed description of the scenarios should not be included in the table. If exposure may take place to one person performing different tasks (e.g. mixing and loading, application and post-application), include a separate line for each type of task and sum up, where relevant. If the same person may be exposed in several scenarios, there may be the need to evaluate the combined exposure occurring when performing these combined scenarios and related tasks.*

*Refer to the “Biocides Human Health Exposure Methodology Document”*[[8]](#footnote-9) *(parts regularly updated by HEAdhoc Recommendations No 6) for the recommended exposure scenarios for each product type and their respective numbers.]*

Table 3.56 Summary table: exposure scenarios

| **Summary table: exposure scenarios** |
| --- |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group**(e.g. professionals, non-professionals, professional bystanders, non-professional bystanders/general public) |
| **Primary exposure** |
| **[Scenario number]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |
| Task number | *[Include the name of the task.]* |  |
| Task number | *[Include the name of the task.]* |  |
| **[Scenario number]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |
| Task number | *[Include the name of the task.]* |  |
| Task number | *[Include the name of the task.]* |  |
| **[Scenario number]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |
| Task number | *[Include the name of the task.]* |  |
| Task number | *[Include the name of the task.]* |  |
| **Combined primary exposure** |
| **[Scenarios’ numbers]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |
| Task number | *[Include the name of the task.]* |  |
| Task number | *[Include the name of the task.]* |  |
| **Secondary exposure** |
| **[Scenario number]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |  |
| **[Scenario number]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |  |
| **Combined secondary exposure** |
| **[Scenarios’ numbers]** | ***[Include the name of the scenario as in the Biocides Human Health Exposure Methodology Document]*** |

*[Insert/delete rows as needed.]*

#### Overview of BPF: worst case uses and corresponding exposure scenarios

*[Present an overview of uses and corresponding meta-SPCs in the table below.]*

Table 3.57 Overview of the BPF: worst case uses and corresponding exposure scenarios

|  |
| --- |
| **Overview of the BPF: worst case uses and corresponding exposure scenarios**  |
| **Use number1** | **Exposure scenarios2**  | **Application method3** | **Maximum in-use concentration of the active substance(s)4** | **Maximum in-use concentration of substance(s) of concern5** | **Application frequency6** | **User category7** |
| *[1.1]**[2.1]* |  | *[Spraying]* | *[AS1:]*  | *[SoC1:]* |  |  |
|  | *[AS2:]* | *[SoC2:]* |
| *[1.2]**[2.2]* |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1 Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.

2 Indicate the number of the scenarios according to section 3.6.6.3.

3 Indicate the worst case application method or n/a if not relevant.

4 For the respective use indicate the maximum concentration for all active substances. Add or delete rows according to the number of active substances.

5 Maximum concentration of the substance(s) of concern if relevant for the use. Add more columns for other substances of concern, if needed.

6 Worst case application frequency for exposure assessment.

7 Worst case user category for the exposure assessment.

#### Reference values to be used in risk characterisation

Table 3.58 Reference values to be used in risk characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL) or NOAEC (LOAEC)** | **AF** | **Correction for absorption** | **Value** |
| AELshort-term |  |  |  |  |  |
| AELmedium-term |  |  |  |  |  |
| AELlong-term |  |  |  |  |  |
| AECdermal |  |  |  | n.r. |  |
| AECinhalation |  |  |  | n.r. |  |
| ARfD |  |  |  |  |  |
| ADI |  |  |  |  |  |

#### Specific reference value for groundwater

*[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, include the argumentation and the calculations here. If not relevant, do not delete this section, but indicate that it is not relevant.]*

#### Professional users (including industrial users and trained professional users)

*[Professional users, including industrial users and trained professional users, use biocides in the course of their job or business and they have received suitable information, instruction and training in their use. Industrial users are involved in manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products. Professional users use end-products outside manufacturing industry. Include a section for each scenario where primary or secondary professional exposure is foreseen. If no professional exposure is foreseen, then only indicate this and delete the tables and text. For the scenario number [n], refer to section 3.6.6.3 List of exposure scenarios.]*

Scenario [n]: [Include the name of the scenario.]

Description and input parameters

Table 3.59 Description and input parameters

| **Description of Scenario [n]** |
| --- |
| *[Give detailed information on the scenario and tasks, exposed worker, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure; concentration of active substance(s) in the product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used, and a justification should be provided why the selected models and parameters are the most appropriate for the BPF.]* |

| **Input parameters for Scenario [n]** |
| --- |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

2 Only include the parameters changed with respect to the previous Tier. Tier 1 assessments should reflect the exposure for an unprotected person, normally only in higher tier assessments the use of PPE and/or RPE may be included as a refinement.

3 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Outcome of systemic exposure and risk characterisation

Table 3.60 Summary table: estimated systemic exposure and risk characterisation for professional users

| **Summary table: estimated systemic exposure and risk characterisation for professional users** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Combined scenarios

*[Combined scenarios are relevant only for the quantitative systemic assessment, but not for the (semi-)quantitative local assessment).]*

Outcome of combined systemic exposure and risk characterisation

Table 3.61 Summary table: combined systemic exposure and risk characterisation for professional users

| **Summary table: combined systemic exposure and risk characterisation for professional users** |
| --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] + Scenario [p], …] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of (semi-)quantitative local exposure and risk characterisation

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. Combined scenarios are not relevant for the (semi-)quantitative local assessment).]*

Table 3.62 Summary table: estimated local exposure and risk characterisation for professional users

| **Summary table: estimated local exposure and risk characterisation for professional users** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated dermal exposure****[%]** | **Estimated inhalation exposure****[%]** | **Estimated total exposure****[mg/m3 or %]** | **Estimated exposure / AEC** **(%)**AECdermal = XX %AECinhalation = XX mg/m3 | **Acceptable****(yes/no)** |
| Scenario [n] | 1/no PPE |  |  | Dermal:Inhalation: |  |  |
| 2*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of qualitative local risk assessment

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. In addition to a quantitative assessment, if applicable, a qualitative local assessment needs to be included. For qualitative local risk assessment, use the template table presented in the BPR guidance (see page 255, table 27 of the Guidance on BPR: Vol III Parts B+C version 4.0). For example, also refer to Appendix 4-5: risk characterization for local effects including sensitization presented in the Guidance on the BPR: Vol III Parts B+C version 4.0.]*

Table 3.63 Outcome of qualitative local risk assessment

|  |  |  |
| --- | --- | --- |
| **Hazard**  | **Exposure information** | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMMs & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[Insert/delete rows as needed.]*

Conclusion

*[Include a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

#### Non-professional users

*[Include a section for each scenario where primary or secondary non-professional exposure is foreseen. If non-professional exposure is not foreseen, then only indicate this and delete the tables and text. For the scenario number [n], refer to section 3.6.6.3 List of exposure scenarios.]*

Scenario [n]: [Include the name of the scenario.]

Description and input parameters

Table 3.64 Description and input parameters

| **Description of Scenario [n]** |
| --- |
| *[Give detailed information on the scenario and tasks, exposed person, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure; concentration of active substance(s) in the product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used, and a justification should be provided why the selected models and parameters are the most appropriate for the BPF.]* |

| **Input parameters for Scenario [n]** |
| --- |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

2 Only include the parameters changed with respect to the previous Tier. Tier 1 assessments should reflect the exposure for an unprotected person, normally only in higher tier assessments the use of PPE and/or RPE may be included as a refinement.

3 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Outcome of systemic exposure and risk characterisation

Table 3.65 Summary table: estimated systemic exposure and risk characterisation for non-professional users

| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Combined scenarios

*[Combined scenarios are relevant only for the quantitative systemic assessment, but not for the (semi-)quantitative local assessment).]*

Outcome of combined systemic exposure and risk characterisation

Table 3.66 Summary table: combined systemic exposure and risk characterisation for non-professional users

| **Summary table: combined systemic exposure and risk characterisation for non-professional users** |
| --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] + Scenario [p], …] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of (semi-)quantitative local exposure and risk characterisation

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. Combined scenarios are not relevant for the (semi-)quantitative local assessment).]*

Table 3.67 Summary table: estimated local exposure and risk characterisation for non-professional users

| **Summary table: estimated local exposure and risk characterisation for non-professional users** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated dermal exposure****[%]** | **Estimated inhalation exposure****[%]** | **Estimated total exposure****[mg/m3 or %]** | **Estimated exposure / AEC** **(%)**AECdermal = XX %AECinhalation = XX mg/m3 | **Acceptable****(yes/no)** |
| Scenario [n] | 1/no PPE |  |  | Dermal: |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE* |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of qualitative local risk assessment

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. In addition to a quantitative assessment, if applicable, a qualitative local assessment needs to be included. For qualitative local risk assessment, use the template table presented in the BPR guidance (see page 255, table 27 of the Guidance on BPR: Vol III Parts B+C version 4.0). For examples, also refer to Appendix 4-5: risk characterization for local effects including sensitization presented in the Guidance on the BPR: Vol III Parts B+C version 4.0.]*

Table 3.68 Outcome of qualitative local risk assessment

|  |  |  |
| --- | --- | --- |
| **Hazard**  | **Exposure information** | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMMs & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[Insert/delete rows as needed.]*

Conclusion

*[Include a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

#### Secondary exposure to professional bystanders and non-professional bystanders/general public

*[Include a section for each scenario where secondary non-professional bystanders/general public is foreseen. If no exposure for non-professional bystanders/general public is foreseen, then only indicate this and delete the tables and text. For the scenario number [n], refer to section 3.6.6.2 List of exposure scenarios.]*

Scenario [n]: [Include the name of the scenario.]

Description and input parameters

Table 3.69 Description and input parameters

| **Description of Scenario [n]** |
| --- |
| *[Give detailed information on the scenario and tasks, exposed person, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure; concentration of active substance(s) in the product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used, and a justification should be provided why the selected models and parameters are the most appropriate for the BPF.]* |

| **Input parameters for Scenario [n]** |
| --- |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |
| *[Indicate the exposure path, e.g. oral, dermal, inhalation. Include new rows for each exposure path.]* |
|  | Parameters1 | Value | Reference and justification3 |
| Tier 1 (no PPE) |  |  |  |
|  |  |  |
|  |  |  |
| Tier 22 *[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3 *[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |
|  |  |  |
|  |  |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

2 Only include the parameters changed with respect to the previous Tier. Tier 1 assessments should reflect the exposure for an unprotected person, normally only in higher tier assessments the use of PPE and/or RPE may be included as a refinement.

3 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed)

Outcome of systemic exposure and risk characterisation

Table 3.70 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

| **Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE]* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Combined scenarios

*[Combined scenarios are relevant only for the quantitative systemic assessment, but not for the (semi-)quantitative local assessment).]*

Outcome of combined systemic exposure and risk characterisation

Table 3.71 Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

| **Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** |
| --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [n] + Scenario [p], …] | 1/no PPE |  |  |  |  |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE* |  |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of (semi-)quantitative local exposure and risk characterisation

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. Combined scenarios are not relevant for the (semi-)quantitative local assessment).*

Table 3.72 Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

| **Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated dermal exposure****[%]** | **Estimated inhalation exposure****[%]** | **Estimated total exposure****[mg/m3 or %]** | **Estimated exposure / AEC** **(%)**AECdermal = XX %AECinhalation = XX mg/m3 | **Acceptable****(yes/no)** |
| Scenario [n] | 1/no PPE |  |  | Dermal: |  |  |
| 2/*[describe the type of PPE required, e.g. gloves and coated coverall]* |  |  |  |  |  |
| 3/*[describe the type of PPE required, e.g. gloves, coated coverall, and RPE* |  |  |  |  |  |

*[Insert/delete rows as needed. Output tables from exposure assessment tools and detailed exposure calculations should be included in Appendix 4.1.1 to complement the table.]*

Outcome of qualitative local risk assessment

*[If no exposure is foreseen and/or there is no need to consider local effects separately, then indicate this and delete the tables below. In addition to a quantitative assessment, if applicable, a qualitative local assessment needs to be included. For qualitative local risk assessment, use the template table presented in the BPR guidance (see page 255, table 27 of the Guidance on BPR: Vol III Parts B+C version 4.0). For examples, also refer to Appendix 4-5: risk characterization for local effects including sensitization presented in the Guidance on the BPR: Vol III Parts B+C version 4.0.]*

Table 3.73 Outcome of qualitative local risk assessment

|  |  |  |
| --- | --- | --- |
| **Hazard**  | **Exposure information** | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMMs & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[Insert/delete rows as needed.]*

Conclusion

*[Include a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

### Monitoring data

*[Add any information on surveys or exposure studies (e.g. Tier-3 field studies) with an actual product or with a surrogate.]*

### Dietary risk assessment

*[Include a section for each scenario where food, drinking water or livestock exposure is foreseen. If no exposure is foreseen, then only indicate this and delete the tables and text. Number the scenarios in the tables using the abbreviation DRA followed by running numbers (e.g. DRA-1, DRA-2, DRA-3 and so on). Some examples are provided and should be considered as suggestions on how to fill in the tables.]*

#### Information of non-biocidal use of the active substance and residue definitions

*[Include a section for each area of other (non-biocidal) use of the active substance(s). Include the residue definitions for monitoring and/or risk assessment for each sector of use. If not relevant, do not delete this section, but indicate that it is not relevant.]*

Table 3.74 Summary table of other (non-biocidal) uses

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use** | **Residue definition** | **Sample matrix** | **Reference regulation** | **Reference** |
| 1. | *[e.g. plant protection products, veterinary use, food or feed additives]* |  | *[e.g. food of plant origin, food of animal origin or single matrices]* | *[e.g. Regulation (EC) No 1107/2009]* | *[Insert the link to the legal act]* |
|  |  |  |  |  |  |

*[Insert/delete rows as needed.]*

#### Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

**List of scenarios**

*[Include a section for each relevant scenario. If not relevant, then only indicate this and delete the tables and text. Perform exposure assessment according to the “Guidance on estimating livestock exposure to active substances used in biocidal products” included in Guidance for Human Health Risk Assessment, Volume III, Part B+C.]*

Table 3.75 Summary table of main representative exposure scenarios

| **Summary table of main representative exposure scenarios** |
| --- |
| Scenario number | Type of use1 | Description of scenario | Subject of exposure2 |
| DRA-[n] | *[Professional use in animal husbandry]* | *[Livestock exposure assessment and dietary exposure of general public (WCCE)]* | *[food]* |
| DRA-[n] |  |  |  |
| DRA-[n] |  |  |  |

1 e.g. animal husbandry, food industry, professional use, residential use

2 e.g. food (chicken, milk, beer)

*[Insert/delete rows as needed.]*

**DRA-[n]:** *[Include the name of the scenario after “DRA-[n]”.]*

Table 3.76 Input parameters for DRA-[n]

| **Input parameters for DRA-[n]** |
| --- |
| Tier | Parameters | Value | Reference and justification2 |
| Tier 1 |  |  |  |
| Tier 21 |  |  |  |
| Tier 31 |  |  |  |

1 Only include the parameters changed with respect to the previous Tier.

2 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

*[Insert/delete rows as needed.]*

Results of calculations for estimating livestock and consumer exposure for DRA-[n]

*[Include any relevant calculations here. In case of a livestock exposure assessment at great length, report calculations in Appendix 4.1.2 and include a summary table reporting the results of the various tiers for the relevant animal species here. If not relevant, do not delete this section, but indicate it is not relevant.]*

Table 3.77 Internal dose received by the animal and consumer WCCE

| **Internal dose received by the animal and consumer WCCE1** |
| --- |
| [Indicate the model/calculations/database used] |
| Parameters2 | Livestock inhalation exposure | Livestock dermal exposure | Livestock oral exposure | Livestocktotal exposure | Estimated residues in animal edible tissues | Consumer WCCE |
|  |  |  |  |  | [*List relevant livestock species, tissues/eggs/milk, residue levels]* |  |
|  |  |  |  |  |  |  |

1 Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300g muscle, 100g liver, 50g or 90g fat (for mammal or poultry respectively), 50g or 10g kidney (for mammal or poultry, respectively) plus 1500g milk, 100g eggs and 20g honey)

2 Describe the parameters used to derive the WCCE. Use footnotes for references and justifications.

*[Insert/delete rows as needed.]*

Further information and considerations on DRA-[n]

*[Include relevant information and considerations not covered above.]*

**Conclusion**

*[Provide a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

#### Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

**List of scenarios**

*[Include for each intended representative use scenario a description of scenario; assumptions, parameters, and data used for exposure estimation, including refinements if applicable; calculations and results.]*

Table 3.78 Summary table of main representative exposure scenarios

| **Summary table of main representative exposure scenarios** |
| --- |
| Scenario number | Type of use1 | Description of scenario | Subject of exposure2 |
| DRA-[n] | *[Professional use in food industry]* | *[Dietary exposure assessment of general public]* | *[food]* |
| DRA-[n] |  |  |  |

1 e.g. animal husbandry, food industry, professional use, residential use

2 e.g. food (chicken, milk, beer)

*[Insert/delete rows as needed.]*

**DRA-[n]:** *[Include the name of the scenario after “DRA-[n]”.]*

Table 3.79 Input parameters for DRA-[n]

| **Input parameters for DRA-[n]** |
| --- |
| Tier | Parameters | Value | Reference and justification2 |
| Tier 1 |  |  |  |
| Tier 21 |  |  |  |
| Tier 31 |  |  |  |

1 Only include the parameters changed with respect to the previous Tier.

2 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

*[Insert/delete rows as needed.]*

Dietary exposure and risk characterisation for DRA-[n]

Table 3.80 Dietary exposure and risk characterisation for DRA-[n]

| **Tier** | **Acute/chronic** | **Estimated uptake (mg/kg bw/day)** | **ADI/ ARfD** **(%)** | **Acceptable****(yes/no)** |
| --- | --- | --- | --- | --- |
| Tier 1 |  |  |  |  |
| Tier 2 |  |  |  |  |
| Tier 3 |  |  |  |  |

*[Insert/delete rows as needed.]*

Further information and considerations on DRA-[n]

*[Include relevant information and considerations not covered above.]*

**Combined scenarios:**

Table 3.81 Combined scenarios

| **Scenarios combined** | **Acute/chronic** | **Estimated uptake (mg/kg bw/day)** | **ADI/ ARfD** **(%)** | **Acceptable****(yes/no)** |
| --- | --- | --- | --- | --- |
| DRA-[n] + DRA-[n]\* |  |  |  |  |
| DRA-[n] + DRA-[n]\* |  |  |  |  |
| DRA-[n] + DRA-[n]\* |  |  |  |  |

\* Include the Tier where relevant

*[Insert/delete rows as needed.]*

Conclusion

*[Provide a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

#### Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

**List of scenarios**

*[Include for each intended use scenario a description of scenario; assumptions, parameters, and data used for exposure estimation; calculations and result.*

*Perform exposure assessment according to “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” included in Guidance for Human Health Risk Assessment, Volume III, Part B +C.]*

Table 3.82 Summary table of main representative exposure scenarios

| **Summary table of main representative exposure scenarios** |
| --- |
| Scenario number | Type of use1 | Description of scenario | Subject of exposure2 |
| DRA-[n] | *[Non-professional use in kitchen]* | *[Dietary exposure assessment of general public]* | *[food]* |
| DRA-[n] |  |  |  |

1 e.g. animal husbandry, food industry, professional use, residential use

2 e.g. food (chicken, milk, beer)

*[Insert/delete rows as needed.]*

**DRA-**[**n]:** *[Include the name of the scenario after “DRA-[n]”.]*

Table 3.83 Input parameters for DRA-[n]

| **Input parameters for DRA-[n]** |
| --- |
| Tier | Parameters | Value | Reference and justification2 |
| Tier 1 |  |  |  |
| Tier 21 |  |  |  |
| Tier 31 |  |  |  |

1 Only include the parameters changed with respect to the previous Tier.

2 Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

*[Insert/delete rows as needed.]*

Dietary exposure and risk characterisation for DRA-[n]

*[Include any relevant calculations here. In case of many details, report calculations in Appendix 4.1.2 and include here a summary table with the results of the various tiers. If not relevant, do not delete this section, but indicate it is not relevant.]*

Table 3.84 Dietary exposure and risk characterisation for DRA-[n]

| **Tier** | **Acute/chronic** | **Estimated uptake (mg/kg bw/day)** | **ADI/ ARfD** **(%)** | **Acceptable****(yes/no)** |
| --- | --- | --- | --- | --- |
| Tier 1 |  |  |  |  |
| Tier 2 |  |  |  |  |
| Tier 3 |  |  |  |  |

*[Insert/delete rows as needed.]*

Further information and considerations on DRA-[n]

*[Include relevant information and considerations not covered above.]*

**Combined scenarios:**

Table 3.85 Combined scenarios

| **Scenarios combined** | **Acute/chronic** | **Estimated uptake (mg/kg bw/day)** | **ADI/ ARfD** **(%)** | **Acceptable****(yes/no)** |
| --- | --- | --- | --- | --- |
| DRA-[n] + DRA-[n]\* |  |  |  |  |
| DRA-[n] + DRA-[n]\* |  |  |  |  |
| DRA-[n] + DRA-[n]\* |  |  |  |  |

\* Include the Tier where relevant

*[Insert/delete rows as needed.]*

**Conclusion**

*[Provide a brief conclusion on the acceptability of the scenario(s). Also clearly describe which RMMs are required for a safe use.]*

#### Maximum residue limits or equivalent

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

Table 3.86 Maximum residue limits or equivalent

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference**  | **Relevant commodities** | **Value** | **Estimated food concentration** **(mg/kg)** | **MRL exceedance (Yes/No)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Insert rows for additional reference values if necessary.]*

### Aggregated exposure and risk characterisation

*[Refer to the Guidance on the BPR: Volume III Human Health (Parts B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*.]*

### Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

*[Refer to the Guidance on the BPR: Volume III Human Health (Parts B+C) for the tiered approach to characterise the risk in case of exposure to several active substances or substances of concern within a product. Include the details of the risk characterisation in a table format, using the tables provided below. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*. The tables are copied from Appendix 4-7 of the Guidance and the examples provided should be considered as suggestions on how to fill in the tables.]*

**Tier 1 and tier 2**

Table 3.87 Tier 1 and tier 2

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario 1****Primary exposure** | **Active substance 1** | **Active substance 2** | **Active substance 3** | **Conclusions**  |
| ***Without PPE*** |
| *Tier 1* | *25% AEL* | *75% AEL* | *50% AEL* | *Acceptable* |
| *Tier 2* | *0.25* | *0.75* | *0.50* | *Not acceptable* |
| *HI = 1.5* |
| ***With gloves during application*** |
| *Tier 1* | *10% AEL* | *25% AEL* | *15% AEL* | *Acceptable* |
| *Tier 2* | *0.1* | *0.25* | *0.15* | *Acceptable* |
| *HI = 0.5* |
| **Scenario 2****Secondary exposure** | **Active substance 1** | **Active substance 2** | **Active substance 3** | **Conclusions**  |
| ***Acute*** |
| *Tier 1* | *5% AEL* | *10% AEL* | *7% AEL* | *Acceptable* |
| *Tier 2* | *0.05* | *0.1* | *0.07* | *Acceptable* |
| *HI = 0.12* |
| ***Chronic*** |
| *Tier 1* | *20% AEL* | *65% AEL* | *35% AEL* | *Acceptable* |
| *Tier 2* | *0.20* | *0.65* | *0.35* | *Not acceptable\** |
| *HI = 1.2* |

\* For secondary exposure, use of PPE cannot be recommended.

**Tier 3a**

Table 3.88 Tier 3a

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario 1** | **HQ Active substance 1** | **HQ Active substance 2** | **HQ Active substance 3** | **HI**  |
| *Liver* | *0.25* | *0.75* | *0.05* | *1.5* |
| *Thyroid* | *0.25* | *0.75* | *-* | *1* |
| *Kidney* | *0.25* | *-* | *0.05* | *0.75* |
| *Eye* | *0.25* | *-* | *-* | *0.25* |
| *Fertility* | *-* | *0.75* | *-* | *0.75* |
| **Scenario 2** | **HQ Active substance 1** | **HQ Active substance 2** | **HQ Active substance 3** | **HI**  |
| *Liver* | *0.2* | *0.65* | *0.35* | *1.2* |
| *Thyroid* | *0.2* | *0.65* | *-* | *0.85* |
| *Kidney* | *0.2* | *-* | *0.35* | *0.55* |
| *Eye* | *0.2* | *-* | *-* | *0.2* |
| *Fertility* | *-* | *0.65* | *-* | *0.65* |

*[According to this table, Tier 3a is not acceptable for scenario 1 and for scenario 2 (chronic) for liver toxicity.]*

**Tier 3b**

AEL can be refined by target organ.

Table 3.89 Tier 3b

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Active substance 1** | **Active substance 2** | **Active substance 3** |
| ***Liver (chronic)*** | *5 mg/kg/d* *(0.05 mg/kg/d)* | *2 mg/kg/d* *(0.02 mg/kg/d)* | *2 mg/kg/d* *(0.02 mg/kg/d)* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario 1** | **Organ HQ Active substance 1** | **Organ HQ Active substance 2** | **Organ HQ Active substance 3** | **HI**  |
| *Liver* | *0.25* | *0.375* | *0.05* | *1.125* |
| **Scenario 2** | **Organ HQ Active substance 1** | **Organ HQ Active substance 2** | **Organ HQ Active substance 3** | **HI**  |
| *Liver* | *0.2* | *0.325* | *0.35* | *0.875* |

*[After organ AEL refinement, the risk assessment is acceptable for scenario 2 (chronic).]*

### Overall conclusion on risk assessment for human health

Table 3.90 Overall conclusion on the risk assessment for human health from systemic and local exposure

| **Overall conclusion on the risk assessment for human health from systemic and local exposure**  |
| --- |
| **Use number1** | **Use description2** | **Conclusion3** | **Set of RMMs3** |
| *[1.1]* |  | *[acceptable, acceptable with the following risk mitigation measure, acceptable provided that [include the explanation, e.g. lower dose)], not acceptable]* |  |
| *[1.2]* |  |  |  |
|  |  |  |  |

1 Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.

2 Title of the specific use, as indicated in the SPC

3 For the wording of the RMMs, refer to the “Frequently used sentences in the SPC and translations” available at <https://echa.europa.eu/support/dossier-submission-tools/spc-editor>. The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2

*[If further explanation is necessary, provide an overall conclusion on risk assessment for human health.]*

## Risk assessment for animal health

*[Dietary risk assessment for livestock animals is to be reported in the relevant chapter of dietary risk assessment.*

*Using the same relevant principles as described in the section dealing with effects on humans, include relevant information and considerations on the risks posed to animals from the BPF in terms of immediate or delayed unacceptable effects itself, or as a result of its residues, directly or through drinking water, feed, air, or through other indirect effects. If no exposure to animals is envisaged, a justification should be provided.]*

### Risk for companion animals

*[Assess the risk for companion animals. If not relevant, do not delete this section, but indicate it is not relevant.]*

### Risk for livestock animals

*[Assess the risk for livestock animals. If not relevant, do not delete this section, but indicate it is not relevant.]*

## Risk assessment for the environment

*[Refer to the Guidance on the BPR: Volume IV Environment (Part A) as well as (Parts B+C) when compiling this section. The guidance is available on the ECHA website at* [*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation*](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation)*.]*

Information on the choice of the worst case composition for environmental risk assessment (e.g. representative test product(s)) and the justification for why the chosen test product(s) [is / are] considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test product(s) chosen, the corresponding justification and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

### Available studies and endpoints applied in the environmental risk assessment

#### Endpoints for the active substance(s), metabolite(s), and transformation product(s)

*[When no new endpoints for the active substance(s)/metabolite(s)/transformation product(s) have been submitted, include:]*

No new endpoint studies have been submitted since the approval of the active substance. The risk assessment is entirely based on the list of endpoints as published in the assessment report (Assessment report for [name of the active substance] [product type(s)], [day/month/year]) for which [Member State abbreviation] was the rapporteur member state. The assessment report is available on the ECHA website.

*[In case of more than one active substance repeat the text for each active substance.]*

*[When new endpoints for the active substance(s)/metabolite(s)/transformation product(s) have been submitted, include:]*

The risk assessment is based on the list of endpoints as published in the assessment report (Assessment report for [name of the active substance] [product type(s)], [day/month/year]) for which [Member State abbreviation] was the rapporteur member state. The assessment report is available on the ECHA website. New studies for the active substance*/metabolite/transformation product* have been submitted along with this product application. These are *[some examples are provided below and should be considered as suggestions on how to list the studies]*:

* *[Degradation in soils]*;
* *[Chronic toxicity in aquatic invertebrates.]*

The new endpoints have been evaluated by the Competent Authority. The following endpoints have been added to the List of Endpoints *[some examples are provided below and should be considered as suggestions on how to list the added endpoints]*:

* *[Half-life for degradation in soils]*;
* *[EC10/NOEC from a chronic toxicity in aquatic invertebrates.]*

*[In case of more than one active substance repeat the text for each active substance.]*

*[The text and tables underneath are always added to the PAR. There is a table for the active substance(s) and a separate table for the metabolite(s)/transformation product(s). Start with a brief summary of the active substance’s/metabolite’s/transformation product’s fate and behaviour including metabolic pathway. An example is provided.]*

*[Example text:]* *[The active substance is volatile, but will not evaporate from water due to its high water solubility and consequent low Henry’s law constant. The active substance cannot be classified as readily biodegradable, but nevertheless degrades quickly into YYY and subsequently into ZZZ. All these metabolites trigger the BPR criteria for major metabolites and are therefore considered in the environmental risk assessment. Although the active substance binds strongly to organic material, the metabolites are highly mobile in soils and will not accumulate in sediment.]*

The endpoints applied in the environmental risk assessment are summarised in the tables below.

Table 3.91 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

|  |
| --- |
| **Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment** |
|  | **Value** | **Unit** | **Remarks** |
| **Active substance 1** | **Active substance 2** |
| **Fate and behaviour in the environment** |
| Molecular weight |  |  | g/mol |  |
| Melting point |  |  | °C |  |
| Vapour pressure (at X°C) |  |  | Pa |  |
| Water solubility (at X°C) |  |  | mg/l |  |
| Log Octanol/water partition coefficient (Kow) |  |  | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) |  |  | L/kg | *[e.g. experimental value / no studies on adsorption and desorption are available. Koc was therefore derived from the kow by applying the QSAR for XX.]* |
| Henry’s Law Constant (at X C)*[if measured data available]* |  |  | Pa/m3/mol | *[e.g. experimental value / calculated from molecular weight, vapour pressure, and water solubility]* |
| Characterisation of biodegradability | *[e.g. ready biodegradable, not biodegradable]* |  | - |  |
| Rate constant for STP |  |  | h-1 | *[e.g. no experimental value is available. Default endpoint for readily biodegradable was used.]* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for biodegradation in surface water |  |  | d or hr (at 12ºC) | *idem* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for hydrolysis in surface water |  |  | d or hr (at 12ºC /pH)  | *idem* |
| DT50 for degradation in soil |  |  | d or hr (at 12ºC) | *idem* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for degradation in air |  |  | d or hr | *idem* |
| DT50 for degradation in the sewer system |  |  | d or hr (at 12ºC) | *[e.g. no experimental data is available. Degradation in the sewer was therefore not considered.]* |
| DT50 for degradation in manure |  |  | d or hr (at 12ºC) | *idem* |
| **Predicted no effect concentrations (PNEC) *[highlight in bold PNEC values derived from new endpoints]*** |
| Sewage treatment plant |  |  | mg/L | *[e.g. based on a EC50 for respiration inhibition and an assessment factor of XX]* |
| Surface water |  |  | mg/L | *[e.g. based on three acute studies and an assessment factor of 1000. Daphnia are most sensitive.]* |
| Marine water |  |  | mg/L | *[e.g. no studies with marine organisms are available. PNEC was derived from the PNEC for surface water by applying an additional assessment factor of 10.]* |
| Sediment |  |  | mg/kg wwt | *[e.g. no data is available. PNEC was calculated from the PNEC for surface water]* |
| Marine sediment |  |  | mg/kg wwt | *idem* |
| Soil |  |  | mg/kg wwt | *[e.g. acute and chronic endpoints are available. Earthworms were most sensitive. An assessment factor of XX was applied.]* |
| Bird |  |  |  | *[e.g. no endpoint is available.]* |
| Mammals |  |  |  | idem |

Table 3.92 Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment

| **Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment** |
| --- |
|  | **Value** | **Unit** | **Remarks** |
| **Metabolite 1** | **Transformation product 1** |
| **Fate and behaviour in the environment** |
| Molecular weight |  |  | g/mol |  |
| Melting point |  |  | °C |  |
| Vapour pressure (at X°C) |  |  | Pa |  |
| Water solubility (at X°C) |  |  | mg/l |  |
| Log Octanol/water partition coefficient (Kow) |  |  | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) |  |  | L/kg | *[e.g. experimental value / no studies on adsorption and desorption are available. Koc was therefore derived from the kow by applying the QSAR for XX.]* |
| Henry’s Law Constant (at X C)*[if measured data available]* |  |  | Pa/m3/mol | *[e.g. experimental value / calculated from molecular weight, vapour pressure, and water solubility]* |
| Characterisation of biodegradability | *[e.g. ready biodegradable, not biodegradable]* |  | - |  |
| Rate constant for STP |  |  | h-1 | *[e.g. no experimental value is available. Default endpoint for readily biodegradable was used.]* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for biodegradation in surface water |  |  | d or hr (at 12ºC) | *idem* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for hydrolysis in surface water |  |  | d or hr (at 12ºC /pH)  | *idem* |
| DT50 for degradation in soil |  |  | d or hr (at 12ºC) | *idem* |
| Transformation fraction and maximum radioactivity | - |  | -% |  |
| DT50 for degradation in air |  |  | d or hr | *idem* |
| DT50 for degradation in the sewer system |  |  | d or hr (at 12ºC) | *[e.g. no experimental data is available. Degradation in the sewer was therefore not considered.]* |
| DT50 for degradation in manure |  |  | d or hr (at 12ºC) | *idem* |
| **Predicted no effect concentrations (PNEC) *[highlight in bold PNEC values derived from new endpoints]*** |
| Sewage treatment plant |  |  | mg/L | *[e.g. based on a EC50 for respiration inhibition and an assessment factor of XX]* |
| Surface water |  |  | mg/L | *[e.g. based on three acute studies and an assessment factor of 1000. Daphnia are most sensitive.]* |
| Marine water |  |  | mg/L | *[e.g. no studies with marine organisms are available. PNEC was derived from the PNEC for surface water by applying an additional assessment factor of 10.]* |
| Sediment |  |  | mg/kg wwt | *[e.g. no data is available. PNEC was calculated from the PNEC for surface water.]* |
| Marine sediment |  |  | mg/kg wwt | *idem* |
| Soil |  |  | mg/kg wwt | *[e.g. acute and chronic endpoints are available. Earthworms were most sensitive. An assessment factor of XX was applied.]* |
| Bird |  |  |  | *[e.g. no endpoint is available]* |
| Mammals |  |  |  | *idem* |

*[If no PNECs are available for sediment, include:]*

No PNECs are available for sediment and were therefore derived from the PNEC for surface water. Considering that both the predicted environmental concentration (PEC) in sediment and the PNEC for this compartment are calculated by equilibrium partitioning and because of the active substance’s hydrophobicity no additional assessment factors are required, the risk ratios (PEC: PNEC) in sediment are always equal to those for water, except for substances with a log Kow ≥ 5, for which an additional safety factor of 10 is applied to the PNECsediment. The risk evaluation for sediments is therefore covered by the risk ratios for surface water. No PECs and PEC:PNEC ratios were consequently calculated for sediment.

*[If no PNECs are available for the marine ecosystem, include, where required:]*

No PNECs are available for the marine ecosystem. Because an additional dilution factor of ten is applied to both PEC and PNEC, the risk ratios for the marine compartment are always equal to those for fresh water and fresh water sediment. Considering that the risk assessment for marine water is covered by the assessment for fresh water, PECs and PEC:PNECs ratios were not calculated for the marine ecosystem.

*[If no PNECs are available for soil, include:]*

No PNECs are available for soil and were therefore derived from the PNEC for surface water.

#### Endpoints for the products

*[If no endpoint has been submitted, include:]*

There are no new additional data available for the products. The exposure assessment and classification and labelling is based on the agreed endpoints for the active substance(s) and available information for the non-active substance(s).

*[In case endpoint(s) (has / have) been submitted, include:]*

Studies have been submitted for the exposure assessment of the products such as:

* *Leaching of active substances from preserved wood/paint/plastic;*
* *Deposition of insecticides on floors.*

*[For e.g. leaching behaviour, provide a summary of the leaching behaviour of the active substance(s) from treated commodities, if leaching tests are relevant for the PT and available.]*

There are new ecotoxicological data available for the products. The summary of these data is provided in Table XX *[use a separate table for each type of study submitted]*.

*[Provide a brief summary of the submitted studies including the endpoints that are used in the risk assessment. Information on the substance(s) of concern needs to be provided under section 3.8.1.3.]*

Table 3.93 Summary table of [further ecotoxicological studies] [[9]](#footnote-10)

|  |
| --- |
|  **Summary table of *[further ecotoxicological studies]***  |
| **Method, Guideline, GLP status, Reliability** | Species/Inoculum | Endpoint | Exposure | Results | Remarks | Refe-rence1 |
| Design | Duration | EC0 | EC50 | EC100 |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

1 Include the reference to IUCLID.

*[Insert/delete rows according to the number of studies.]*

Table 3.94 Conclusion used in Risk Assessment – [further ecotoxicological studies]

|  |
| --- |
| **Conclusion used in Risk Assessment – *[further ecotoxicological studies]*** |
| Value/conclusion |  |
| Justification for the value/conclusion |  |

The submitted studies have been evaluated by the Competent Authority.

#### Substance(s) of concern

*[If the BPF contains substances of concern, include:]*

According to the criteria as set in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)), the following substance(s) need(s) to be considered as substance(s) of concern regarding the environment:

Table 3.95 Substance(s) of concern

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta-SPC** | **Substance of concern** | **Criterion for the identification as a substance of concern** | **Type of risk assessment performed** |
| *[Meta-SPC X]* | *[No substance of concern identified]* | *[Not relevant]* | *[Not relevant]* |
| *[Meta-SPC Y]*  | *[Chemical name of the substance of concern (max. conc. XX%)]* | *[i.e. BPR, Art. 3 (f) or “other grounds for concern” as in Guidance Vol IV Environment Parts B+C]* | *[e.g. qualitative assessment]* |

The substance(s) of concern [is /are] assessed based on the endpoints presented in the table below.

Table 3.96 Endpoints and PNEC values for the substance(s) of concern applied in the environmental risk assessment

| **Endpoints and PNEC values for the substance(s) of concern applied in the environmental risk assessment** |
| --- |
|  | **Value** | **Unit** | **Remarks** | **Source of data** |
| **Substance of concern 1** | **Substance of concern 2** |
| **Fate and behaviour in the environment** |  |
| Molecular weight |  |  | g/mol |  |  |
| Melting point |  |  | °C |  |  |
| Vapour pressure (at X°C) |  |  | Pa |  |  |
| Water solubility (at X°C) |  |  | mg/l |  |  |
| Log Octanol/water partition coefficient (Kow) |  |  | Log 10 |  |  |
| Organic carbon/water partition coefficient (Koc) |  |  | L/kg | *[e.g. experimental value / no studies on adsorption and desorption are available. Koc was therefore derived from the kow by applying the QSAR for XX.]* |  |
| Henry’s Law Constant (at X C)*[if measured data available]* |  |  | Pa/m3/mol | *[e.g. experimental value / calculated from molecular weight, vapour pressure, and water solubility]* |  |
| Characterisation of biodegradability | *[e.g. ready biodegradable, not biodegradable]* |  | - |  |  |
| Rate constant for STP |  |  | h-1 | *[e.g. no experimental value is available. Default endpoint for readily biodegradable was used.]* |  |
| Transformation fraction and maximum radioactivity | - |  | -% |  |  |
| DT50 for biodegradation in surface water |  |  | d or hr (at 12ºC) | *idem* |  |
| Transformation fraction and maximum radioactivity | - |  | -% |  |  |
| DT50 for hydrolysis in surface water |  |  | d or hr (at 12ºC /pH)  | *idem* |  |
| DT50 for degradation in soil |  |  | d or hr (at 12ºC) | *idem* |  |
| Transformation fraction and maximum radioactivity | - |  | -% |  |  |
| DT50 for degradation in air |  |  | d or hr | *idem* |  |
| DT50 for degradation in the sewer system |  |  | d or hr (at 12ºC) | *[e.g. no experimental data is available. Degradation in the sewer was therefore not considered.]* |  |
| DT50 for degradation in manure |  |  | d or hr (at 12ºC) | *idem* |  |
| **Predicted no effect concentrations (PNEC) *(highlight in bold PNEC values derived from new endpoints)*** |
| Sewage treatment plant |  |  | mg/L | *[e.g. based on a EC50 for respiration inhibition and an assessment factor of XX]* |  |
| Surface water |  |  | mg/L | *[e.g. based on three acute studies and an assessment factor of 1000. Daphnia are most sensitive.]* |  |
| Marine water |  |  | mg/L | *[e.g. no studies with marine organisms are available. PNEC was derived from the PNEC for surface water by applying an additional assessment factor of 10.]* |  |
| Sediment |  |  | mg/kg wwt | *[e.g. no data is available. PNEC was calculated from the PNEC for surface water.]* |  |
| Marine sediment |  |  | mg/kg wwt | *idem* |  |
| Soil |  |  | mg/kg wwt | *[e.g. acute and chronic endpoints are available. Earthworms were most sensitive. An assessment factor of XX was applied.]* |  |
| Bird |  |  |  | *[e.g. no endpoint is available]* |  |
| Mammals |  |  |  | *idem* |  |

*[If the BPF does not contain substances of concern, include:]*

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substance(s) was (were) addressed in the environmental risk assessment.

#### Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

### Emission estimation

#### General information

Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario documents (ESDs, release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment), the Technical Agreement on Biocides (TAB) and the model SimpleTreat (concentrations for micro-organisms in the sewage treatment plant (STP) the STP’s effluent) by using the default values for parameters, unless otherwise noted. Distribution in the STP has been calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance with the TAB. Distribution in the STP and the environment is calculated based on the physical-chemical properties as listed in section 3.2.

Release of active substance(s) during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substance(s) [is / are] added are disposed as solid waste and usually incinerated.

*[Adapt the aforementioned text accordingly when distribution in the STP is based on experimental data, e.g. an OECD 303 simulation study of field data for municipal STPs.]*

*[When emission to groundwater is assessed using equilibrium partitioning, include:]*

Emission to groundwater was assessed based on the substance’s mobility in soils (Koc) as described in the guidance. No higher tier modelling was deemed necessary.

*[When emission to groundwater is modelled, include:]*

Emission to groundwater was modelled using the latest version of FOCUS PEARL (version x.x.x) based on the substance’s physical-chemical parameters. Details on the assessment are presented in section 3.8.3 of the PAR.

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Compartments highlighted in bold are directly exposed.

Emission was calculated for each intended use based on the worst case composition that results in the highest emission to the environment which depends on the highest concentration (which must be at the same time efficacious), application rate and frequency.

The risk assessment approach is summarised below.

Table 3.97 Environmental risk assessment

| **Environmental risk assessment** |
| --- |
| **Use number1** | **Scenario assessed**  | **ESD applied2** | **Maximum in-use concentration of the active substance(s)3** | **Maximum in-use concentration of substance(s) of concern4** |  | **Receiving compartments5** |
| *[1.1]* | *[Scenario [n] - Disinfection of rooms, furniture and objects]* | *[Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001]*  | *[AS1:]* *[AS2:]* | *[SoC1:]* |  | *[****STP****]**[Freshwater]* |
| *[1.2]* | *[Scenario [n] - Disinfection of instruments]* | *[SoC2:]* |  |  |
| *[1.3]* |  | *[Not assessed, emission is covered by use 1.1.]* |  |  |  |  |
| *[2.1]* |  | *[No ESD is available for this use. A scenario was proposed by the applicant.]* |  |  |  |  |
| *[2.2]* | *[SCENARIO6]* |  |  |  |  |  |
|  |  |  |  |  |  |  |

1 Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.

2 Refer to the ESD or TAB-agreement that is applied in the risk assessment. Indicate if the assessment is covered by another use.

3 For the respective use indicated the maximum concentration for all active substances.

4 Maximum concentration of the substance(s) of concern if relevant for the use.

5 Only relevant receiving compartments based on the exposure pathway are listed and the compartment receiving the direct emissions is highlighted in bold. Include sediment and groundwater if applicable.

6 The applied scenario is based on tonnage data which are confidential. The risk assessment is consequently included in the confidential annex of the PAR.

*[If remarks are necessary, add footnotes right below the table.]*

#### Emission estimation for the scenario(s)

**Scenario 1 - [description/name]**

*[Include a section for each scenario per PT per life cycle step.]*

*[Indicate all the values which have been used in the emission scenario. Clearly indicate in the remarks field whether the value is a “default” or “set” value. Export files from EUSES should be included in Appendix 4.1.2.]*

Table 3.98 Input parameters for calculating the local emission

| **Input parameters for calculating the local emission** |
| --- |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario: *[Disinfection of rooms, furniture and objects]* |
| Concentration of active substance in the product |  | g/l |  |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* |  | L/m² |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Insert/delete rows according to the number of relevant set values or other necessary input parameters depending on the scenario chosen.]*

Calculations for Scenario [*description*]

*[Include the detailed calculations in Appendix 4.1.2. Leaching rate determination for PT8 scenarios should be included here.]*

Table 3.99 Resulting local emission to relevant environmental compartments

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP |  |  |
| Freshwater1 |  |  |
|  |  |  |
| Seawater1 |  |  |
|  |  |  |
| Air |  |  |
| Soil2 |  |  |
|  |  |  |

1 Including sediment

2 Including groundwater

*[Insert/delete additional compartments, if relevant.]*

*[Include text here, if relevant.]*

### Exposure calculation and risk characterisation

*[Active substance(s) and metabolite(s) (when applicable) should be taken into account in the exposure calculation and risk characterisation.* *It is suggested to present all values (PECs as well as PEC:PNEC ratios) in the scientific notation (two digits), e.g. 1.23E+01.]*

Table 3.100 Summary table of PNEC, PEC and PEC:PNEC values

|  |
| --- |
| **Summary table of PNEC, PEC and PEC:PNEC values** |
|  | **Active Substance 1** | **Active Substance 2** | **Metabolite 1** | **Transformation product 1** |
| **PNEC values** |
| PNECstp(mg/L) |  |  |  |  |
| PNECwater (mg/L) |  |  |  |  |
| PNECsed (mg/kg wwt) |  |  |  |  |
| PNECsoil (mg/kg wwt) |  |  |  |  |
| **SCENARIO 1**  |
| **PEC values** |
| PECair |  |  |  |  |
| PECstp(mg/L) |  |  |  |  |
| PECwater (mg/L)  |  |  |  |  |
| PECsed (mg/kg wwt)  |  |  |  |  |
| PECsoil (mg/kg wwt) |  |  |  |  |
| PECgw(g/L) |  |  |  |  |
| **PEC/PNEC values** |
| PEC/PNECstp |  |  |  |  |
| PEC/PNECwater |  |  |  |  |
| PEC/PNECsed |  |  |  |  |
| PEC/PNECsoil |  |  |  |  |
| **SCENARIO [n]**  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows/columns as needed. In case both direct and indirect emissions are identified for a given compartment, present both routes in separate rows.]*

Atmosphere

*[Include a short conclusion of the assessment of the air compartment. An example is provided in case emission to air is acceptable. If not, additional arguments may be necessary, e.g. although emission to air may result in unacceptable risks, emission to air is unlikely considering that the active substance is not volatile/has a low Henry’s law constant and will therefore not evaporate from the sanitising solution and the STP/the product is not sprayed/possible deposition to soils will not result in unacceptable risks, etc.]*

Conclusion: *[Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimise the risk for stratospheric ozone depletion. There are no indications that the active substance(s) contribute(s) to depletion of the ozone layer as the compounds are not listed as ‘controlled substances’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPWIN calculates for the active substance(s) a half-life of XXX hours in air (OH timeframe 24 hrs/day, 0.5×106 OH radicals/cm³). The calculated half live is below the trigger of 2 days, which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.]*

Sewage treatment plant (STP)

Conclusion: *[Include a short text summarising the conclusion of the risk assessment. If emission results in unacceptable risks, add refinements and/or propose risk mitigation measures, and demonstrate (qualitatively or quantitatively) that these reduce risks to acceptable levels.]*

Aquatic compartment

*[The marine environment is not included in the summary table under section 3.8.3 considering that the risk assessment for freshwater covers that of the marine environment. Add additional rows for the marine environment, in case of direct release to the marine environment (e.g. biocides applied for oil exploitation (PT11/12), anti-foulings (PT21) or wood preservatives use class 5 (PT8 – UC 5)), and/or when the PNEC for the marine environment has been based on endpoints for marine organisms. The rows for sediment may be deleted when the PNEC for this compartment is derived from PNECwater without an additional assessment factor for hydrophobic substances.*

*Also note that some intended uses may have both direct and indirect emission to surface water (e.g. PT8 with release to the sewer and directly to surface water). Present both routes, preferably by adding separate rows for direct and indirect emission to the summary table under section 3.8.3.]*

Conclusion: *[Include a short text summarising the conclusion of the risk assessment. If emission results in unacceptable risks, add refinements and/or propose risk mitigation measures, and demonstrate (qualitatively or quantitatively) that these reduce risks to acceptable levels.]*

Terrestrial compartment

*[Note that some intended uses may have both direct and indirect emission to soil (e.g. PT11 with release to the sewer and directly to soils). Present both routes, preferably by adding separate rows for direct and indirect emission to the table above.]*

Conclusion: *[Include a short text summarising the conclusion of the risk assessment. If emission results in unacceptable risks, add refinements and/or propose risk mitigation measures, and demonstrate (qualitatively or quantitatively) that these reduce risks to acceptable levels.]*

Groundwater

*[Assess according to BPR Annex VI point 68 if the foreseeable concentration (PEC) of the active substance(s) or any other substance(s) of concern, or of relevant metabolite(s) or breakdown or reaction product(s) in groundwater, exceeds the lower of the following concentrations:*

* *the maximum permissible concentration laid down by Directive 98/83/EC, or*
* *the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological (please refer to section 14.2.4 of the CAR),*

*unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.]*

FOCUS PEARL calculations

*[Remove this section if emission to groundwater has been assessed qualitatively or by using equilibrium partitioning. Only relevant when additional FOCUS PEARL calculations are required.]*

Emission to groundwater has been assessed using the latest version of FOCUS PEARL (version x.x.x) by applying the active substance’s physical-chemical parameters as presented in section 3.2. The tables with input parameters and output from FOCUS PEARL are included in Appendix 4.1.2. The required organic matter-water partitioning coefficient (Kom) was derived by Koc/1.724. The Freundlich constant (1/n) was set equal to 1, i.e. no concentration-dependent sorption to soils.

*[For emission via distribution of sewage sludge, include:]*

The dose (kg/ha) was derived from PECsoil by applying the agreed mixing depth for grassland and arable land, and a soil density of 1700 kg/m³. Sewage sludge is mixed with the soil’s top layer (incorporation) for which the mixing depth is set to the agreed values for grassland and arable land. The application scheme (timelines and crops) is the one agreed for grassland and arable land. Irrigation, tillage, and crop uptake were not considered.

*[For emission via distribution of manure, include:]*

The dose (kg/ha) was derived from the concentration in soils after the first manure application (PECsoil) by applying the agreed mixing depth for grassland and arable land, and a soil density of 1700 kg/m³. Manure is mixed with the soil’s top layer (incorporation) for which the mixing depth is set to the agreed values for grassland and arable land. The application scheme (application schedule and crops) is the one agreed for grassland and arable land. Irrigation, tillage, and crop uptake were not considered.

*[For emission due to leaching, include:]*

The dose (kg/ha) was derived from the leaching rate (mg/m²/d) multiplied by 16 houses of 125 m² each, and 365 days. The dose was divided over ten equal proportions and applied on the top of the soil surface according to the application scheme (application schedule and crops) agreed.

*[Always use this table for the FOCUS PEARL calculations. Note that, when the Freundlich constant is equal to one, the concentration is linear with the dosage. It is therefore not necessary to calculate all scenarios.]*

The dosage for each scenario is summarised below.

Table 3.101 Dosage applied to calculate emission to groundwater

| **Dosage applied to calculate emission to groundwater** |
| --- |
|  | **Grassland** | **Arable land** |
| kg/ha/y | kg/ha/y |
| Scenario 1 |  |  |
| Scenario [n] |  |  |

Conclusion: *[Include a short text summarising the conclusion of the risk assessment. If emission results in unacceptable risks, add refinements and/or propose risk mitigation measures, and demonstrate (qualitatively or quantitatively) that these reduce risks to acceptable levels.]*

### Primary and secondary poiso**n**ing

#### Primary poisoning

*[Explain why primary poisoning is not applicable for the BPF, e.g. products are applied indoors where non-target organisms usually not reside. An example is provided. If primary poisoning is likely, add the risk assessment for primary poisoning here].*

*[The products are applied as disinfectants indoors. Considering that non-target organisms do not normally reside in industrial/institutional/public areas, primary poisoning is unlikely. The risks related to primary poisoning are therefore acceptable.]*

#### Se**c**ondary poisoning

*[If secondary poisoning is not relevant, include:]*

As the log Kow for all active substances is <3 and the active substances are not highly adsorptive (Koc <20000 L/kg in sediment and/or 50000 L/kg in soils), bioconcentration is not expected according to the trigger values presented in the guidance. Experimentally-derived bioconcentration factors (BCFs) demonstrated that the active substance does not fulfil the criteria for bioaccumulation (BCF <2000). The risk for bioconcentration in the proposed use is therefore considered not relevant. The standards for bioconcentration are met and no further assessment of secondary poisoning is deemed necessary.

*[Where applicable, take into account exposure to bees, once the specific guidance is available. Until the guidance is not available, include the following text:]*

Considering that the active substance(s) [has / have] neither a non-systemic mode of action nor [does it / do they] accumulate in plants, exposure to bees via contaminated pollen is negligible. It cannot be conclusively expected that the BPF is harmful to bees and other pollinators.

*[If secondary poisoning is relevant, include the following table and text. Secondary poisoning is always required for outdoor PT18 applications.]*

Table 3.102 Summary table of estimated theoretical exposition (ETE)

|  |
| --- |
| **Summary table of estimated theoretical exposition (ETE)** |
|  | **ETE** | **ETE** |
| [mg/kg\*d-1] | [mg/kg\*d-1] |
| Scenario 1 |  |  |
| Scenario [n] |  |  |

*[Insert/delete columns according to the number of species for which ETE was calculated. Adapt the number of scenarios as necessary.]*

As the log Kow is >3 (see section 2.2.8.1) and/or the active substance(s) [is / are] highly adsorptive, the potential for bioaccumulation is considered high. Distribution of the active substance(s) into the food chain is therefore realistic. The predicted environmental concentration in fish-eating (aquatic) and worm-eating (terrestrial) birds and mammals (PECoral, predator) was calculated according to the guidance. The PEC for predators (PECoral, predator) for the aquatic environment was based on a BCF of XXX L/kg wet fish and the default biomagnification factor (BMF = 1) for compounds with a log Kow <4.5. The PEC for worm-eating birds and mammals was based on a BCF of XXX L/kg wwt and the equilibrium partitioning-derived concentration in porewater.

Table 3.103 Summary table of secondary poisoning

|  |
| --- |
| **Summary table of secondary poisoning** |
| **Scenario** | **Concentration in compartment** | **PECoral predator** | **PEC/PNECbirds** | **PEC/PNECmammals** |
| Aquatic environment |
|  |  |  |  |  |
|  |  |  |  |  |
| Terrestrial environment |
|  |  |  |  |  |
|  |  |  |  |  |

*[Insert/delete rows as needed.]*

Conclusion: *[Include a short text summarising the conclusion of the risk assessment. If emission results in unacceptable risks, add refinements and/or propose risk mitigation measures, and demonstrate (qualitatively or quantitatively) that these reduce risks to acceptable levels]*

### Mixture toxicity

*[Include an assessment if mixture toxicity is relevant (according to the Guidance on the BPR: Volume IV Environment (Part B; Part II)) and an overview on the results if a mixture toxicity assessment was conducted, and which tier level.]*

#### Screening step

Screening Step 1: Identification of the concerned environmental compartments

*[Indicate whether a significant exposure of environment is likely and, if so, which environmental compartments are likely to be at risk.]*

Screening Step 2: Identification of relevant substances

*The following substances are regarded as relevant for mixture assessment:*

*1) Active substance(s).*

*2) Substance(s) of concern*

*[Indicate how many relevant substances are present in the BPF.]*

For information on the endpoints to be used for mixture assessment refer to table “Endpoints and PNEC values for the substance(s) of concern applied in the environmental risk assessment” in section 3.8.1.3 of the PAR.

Screening Step 3: Screen on synergistic interactions

*[Indicate whether synergistic effects are likely to occur.]*

Table 3.104 Screening step

|  |
| --- |
| **Screening step** |
| 1 | Significant exposure of environmental compartments? (Y/N) |
| 2 | Number of relevant substances >1? (Y/N) |
| 3 | Indication for synergistic effects for the product or its constituents in the literature? (Y/N) |

*[Report the conclusions and proceed with the assessment, if questions 2 and/or 3 are answered with yes.]*

#### Tiered approach

*[Indicate which tier has to be followed according to the data available for the substances identified as relevant in Screening Step 2 (see above).]*

Tier 1. PEC/PNEC summation

Table 3.105 Tier 1

|  |
| --- |
| **Tier 1** |
| RQ product | Acceptable risk for the environment? (Y/N) | Remarks |
|  |  |  |

*[If yes, report the conclusions; if not, proceed with the following Tier.]*

Tier 2: Modified Toxic Unit Summation (TUS)

Table 3.106 Tier 2

|  |
| --- |
| **Tier 2** |
| RQ product | Acceptable risk for the environment? (Y/N) | Remarks |
|  |  |  |

*[If yes, report the conclusions; if not, proceed with the following Tier.]*

Tier 3: Standard Toxic Unit Summation (TUS)

Table 3.107 Tier 3

|  |
| --- |
| **Tier 3** |
| RQ product | Acceptable risk for the environment? (Y/N) | Remarks |
|  |  |  |

*[If yes, report the conclusions; if not, proceed with the following Tier.]*

Tier 4: Experimental testing

Table 3.108 Tier 4

|  |
| --- |
| **Tier 4** |
| RQ product | Acceptable risk for the environment? (Y/N) | Remarks |
|  |  |  |

Conclusion: *[Include a short text summarising the conclusion of the mixture toxicity assessment.]*

### Aggregated exposure (combined for relevant emission sources)

*[Include an assessment if aggregated exposure is relevant based on the decision scheme included in the Guidance on BPR: Vol IV Environment (Parts B+C). Also include an overview on the results in the table below, if an aggregated exposure was conducted.]*

Table 3.109 Summary table of calculated ΣPEC/PNEC values

|  |
| --- |
| **Summary table of calculated ΣPEC/PNEC values** |
| **Active substance** | **ΣPEC/PNECSTP** | **ΣPEC/PNECwater** | **ΣPEC/PNECsed** | **ΣPEC/PNECseawater** | **ΣPEC/PNECseased** | **ΣPEC/PNECsoil** | **ΣPECGW** | **ΣPECair** |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |

*[Insert additional compartments if additional environmental compartments are relevant.]*

Conclusion: *[Include a short text summarising the conclusion of the risk assessment based on aggregated exposure. Discuss also the realism and effectivity of mitigation measures.]*

*[This part of the PAR will be further elaborated as soon as the guidance on aggregated exposure is available.]*

### Ove**r**all conclusion on the risk assessment for the environment

Table 3.110 Overall conclusion on the risk assessment for the environment

| **Overall conclusion on the risk assessment for the environment**  |
| --- |
| **Use number1** | **Use description2** | **Conclusion3** | **Set of RMMs3** |
| *[1.1]* |  | *[acceptable, acceptable with the following risk mitigation measure(s), acceptable provided that [include the explanation, e.g. lower dose], not acceptable]* |  |
| *[1.2]* |  |  |  |
|  |  |  |  |

1 Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.

2 Title of the specific use, as indicated in the SPC

3 The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2.

*[If further explanation is necessary, provide an overall conclusion on risk assessment for the environment.]*

## Assessment of a combination of biocidal products

*[For biocidal products that are intended to be authorised for the use with other biocidal products**, refer to the Guidance on the BPR: Volume III Human Health (Part A) to characterise the risk in case of exposure to several products.]*

## Comparative assessment

*[If not relevant, do not delete this section, but indicate why comparative assessment is not required.]*

*[Include a reference to the comparative assessment report to be forwarded to ECHA and the other MSs, in accordance with Art. 23(2) of the BPR].*

### Screening phase

* Description of the assessment of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.
* Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.
* Conclusion of the screening phase: Stop comparative assessment / Tier IA / Tier IB / Tier II

### Tier IA

* Description of biocidal products included in the comparison
* Main outcome of the comparison for:
	+ Risk for human health, animal health, and the environment
	+ Significant economic or practical disadvantages
* Conclusion of Tier IA: Tier IB / Tier II

### Tier **I**B

* Main outcome of the comparison for:
	+ Risk for human health, animal health, and the environment
	+ Significant economic or practical disadvantages
* Conclusion of Tier IB: End of comparative assessment / Tier II

### Tier II

* Description of non-chemical alternatives included in the comparison
* Main outcome of the comparison for:
	+ Risk for human health, animal health, and the environment
	+ Efficacy
	+ Significant economic or practical disadvantages
* Conclusion of Tier II: stop comparative assessment / End of comparative assessment

### Overall **c**onclusion

Final recommendation in terms of restriction(s) or prohibition of the biocidal products subject to comparative assessment.

*[See the latest version of the SPC in the relevant Member State to see all the authorised uses and RMMs authorised for the products].*

# Appendices

## Calculations for exposure assessment

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

### Human health

Task/scenario: *[indicate the name and number of the task/scenario; repeat the section as many times as needed.]*

*[Provide the calculation(s) for the scenario, including the output table from exposure assessment tools, where relevant.]*

### Dietary assessment

*[Provide the calculations for dietary risk assessment (for example, among others, calculation excel sheet from livestock calculator and PRIMo excel sheet).]*

### Environment

Scenario: *[indicate the description of the scenario; repeat the section as many times as needed.]*

*[Provide the calculation(s) for the scenario, including the output table from exposure assessment tools, where relevant.]*

**Tables with input parameters and output from FOCUS PEARL for groundwater**

Table 4.1 Summary of PECgw simulations with FOCUS PEARL [vs…]

|  |
| --- |
| Summary of PECgw simulations with FOCUS PEARL [vs…] |
| Input parameters related to active substance |
| Molecular weight (g/mol) |  |
| Vapour pressure at 20°C (Pa) |  |
| Water solubility at 20°C (mg/L) |  |
| Log10 Octanol/water partition coefficient (-) |  |
| Organic carbon/water partition coefficient (L/kg) |  |
| DT50 in soil at 12°C (d) |  |
| Coefficient for uptake by plant (-) |  |
| 1/n |  |
| Molar activation energy (kJ/mol) |  |
| Scenario 1 |
| Input parameters related to scenario |
| Local emission of active substance (kg/d) |  |
| Number of houses estimated per hectare |  |
| Local emission of active substance (kg/ha/month) |  |
| Application date |  |
| Application type |  |
| Crop |  |
| Scenario [n] |
| Input parameters related to scenario |
| Local emission of active substance (kg/d) |  |
| Number of houses estimated per hectare |  |
| Local emission of active substance (kg/ha/month) |  |
| Application date |  |
| Application type |  |
| Crop |  |

Table 4.2 PECgroundwater - Output (FOCUS PEARL [vs…]) in µg/L

|  |
| --- |
| PECgroundwater - Output (FOCUS PEARL [vs…]) in µg/L |
| Scenario 1 |  |  |
| Location | Grassland (crop) | Arable land (crop) |
| Chateaudun |  |  |
| Hamburg |  |  |
| Jokioinen |  |  |
| Kremsmunster |  |  |
| Okehampton |  |  |
| Piacenza |  |  |
| Porto |  |  |
| Sevilla |  |  |
| Thiva |  |  |
| Scenario [n] |  |  |
| Location | Grassland (crop) | Arable land (crop) |
| Chateaudun |  |  |
| Hamburg |  |  |
| Jokioinen |  |  |
| Kremsmunster |  |  |
| Okehampton |  |  |
| Piacenza |  |  |
| Porto |  |  |
| Sevilla |  |  |
| Thiva |  |  |

## New information on the active substance(s) and substance(s) of concern

[No new information on the active substance(s) is available] / [The following new information on the active substance(s)is available. *[Indicate the new information.]*]

[No new information on the substance(s) of concern is available] / [The following new information on the substance(s) of concernis available. *[Indicate the new information.]*]

## List of studies for the biocidal product family

*[List the studies by Reference No (Annex III requirement)/IUCLID Section Number and within a section alphabetically by author.]*

Table 4.3 List of studies for the biocidal product family

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author (s)** | **Year****Report date** | **Reference No. *(Annex III requirement)*****/****IUCLID Section No.** | **IUCLID Document name** | **Title.****Report No.** | **Type of publication**  | **Source (where different from company)****Study sponsor** | **GLP** **(Yes/No)** | **Data Protection Claimed****(Yes/No)** |
| YYY | YYY | YYY | YYY | YYY | YYY | YYY | YYY | YYY |
| YYY | YYY | YYY | YYY | YYY | YYY | YYY | YYY | YYY |

*[Insert/delete rows as needed.]*

## References

### References other than list of studies for the BPF

* Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year
* Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year

### Guidance documents

* [Title of the guidance document], year
* [Title of the guidance document], year

### Legal texts

* Regulation (EU) No XXX/year of the European Parliament and of the Council of day Month year concerning (topic)

## Confidential information

Please refer to the separate document Confidential Annex of the PAR.

1. Use “can/cannot” for national authorisation and “may/may not” for Union authorisation. [↑](#footnote-ref-2)
2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [↑](#footnote-ref-3)
3. This sentence should be included only if there are significant indications. 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-4)
4. The document is available in CIRCABC at <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>. [↑](#footnote-ref-5)
5. A source is defined by the following information: the applicant; the manufacturer; the manufacture location/plant location; the manufacturing process (“Guidance on applications for technical equivalence”; <https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>) [↑](#footnote-ref-6)
6. This sentence should be included only if there are significant indications. 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-7)
7. Section 3 of the CA note of Q&A concerning the content of some SPC sections. The document is available at <https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b>. [↑](#footnote-ref-8)
8. The document is available at <https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure>. [↑](#footnote-ref-9)
9. Nomenclature according to BPR Annex III [↑](#footnote-ref-10)