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

**ADDENDUM**

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION**

**MINOR CHANGE**

(submitted by the competent authority)



Liv DES+45

Product type: PT 2

Propan-2-ol

Case Number in R4BP: BC-EA025731-68

Competent Authority: Sweden

Date: 19 December 2023

Table of Contents

[1 Conclusion 6](#_Toc163726176)

[2 Information on the biocidal product 7](#_Toc163726177)

[2.1 Product type(s) and type(s) of formulation 7](#_Toc163726178)

[2.2 Uses 7](#_Toc163726179)

[2.3 Identity and composition 7](#_Toc163726180)

[2.4 Identity of the active substance(s) 7](#_Toc163726181)

[2.5 Information on the source(s) of the active substance(s) 7](#_Toc163726182)

[2.6 Candidate(s) for substitution 7](#_Toc163726183)

[2.7 Assessment of the endocrine-disrupting properties of the biocidal product 7](#_Toc163726184)

[2.8 Classification and labelling 7](#_Toc163726185)

[2.9 Letter of access 7](#_Toc163726186)

[2.10 Data submitted in relation to product authorisation 7](#_Toc163726187)

[2.11 Similar conditions of use across the Union 7](#_Toc163726188)

[3 Assessment of the biocidal product 7](#_Toc163726189)

[3.1 Packaging 7](#_Toc163726190)

[3.2 Physical, chemical, and technical properties 9](#_Toc163726191)

[3.3 Physical hazards and respective characteristics 9](#_Toc163726192)

[3.4 Methods for detection and identification 9](#_Toc163726193)

[3.5 Assessment of efficacy against target organisms 9](#_Toc163726194)

[3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected) 9](#_Toc163726195)

[3.5.2 Mode of action and effects on target organisms, including unacceptable suffering 9](#_Toc163726196)

[3.5.3 Efficacy data 9](#_Toc163726197)

[3.5.4 Efficacy assessment 9](#_Toc163726198)

[3.5.5 Conclusion on efficacy 9](#_Toc163726199)

[3.5.6 Occurrence of resistance and resistance management 9](#_Toc163726200)

[3.5.7 Known limitations 9](#_Toc163726201)

[3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products 9](#_Toc163726202)

[3.6 Risk assessment for human health 9](#_Toc163726203)

[3.6.1 Assessment of effects on human health 9](#_Toc163726204)

[3.6.2 Information on dermal absorption 9](#_Toc163726205)

[3.6.3 Available toxicological data relating to substance(s) of concern 9](#_Toc163726206)

[3.6.4 Other 9](#_Toc163726207)

[3.6.5 Available toxicological data relating to endocrine disruption 9](#_Toc163726208)

[3.6.6 Exposure assessment and risk characterisation for human health 9](#_Toc163726209)

[3.6.7 Monitoring data 9](#_Toc163726210)

[3.6.8 Dietary risk assessment 9](#_Toc163726211)

[3.6.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product 9](#_Toc163726212)

[3.6.10 Overall conclusion on risk assessment for human health 9](#_Toc163726213)

[3.7 Risk assessment for animal health 10](#_Toc163726214)

[3.7.1 Risk for companion animals 10](#_Toc163726215)

[3.7.2 Risk for livestock animals 10](#_Toc163726216)

[3.8 Risk assessment for the environment 10](#_Toc163726217)

[3.8.1 Available studies and endpoints applied in the environmental risk assessment 10](#_Toc163726218)

[3.8.2 Exposure calculation and risk characterisation 10](#_Toc163726219)

[3.8.3 Primary and secondary poisoning 10](#_Toc163726220)

[3.8.4 Mixture toxicity 10](#_Toc163726221)

[3.8.5 Aggregated exposure (combined for relevant emission sources) 10](#_Toc163726222)

[3.9 Assessment of a combination of biocidal products 10](#_Toc163726223)

[3.10 Comparative assessment 10](#_Toc163726224)

[4 Appendices 10](#_Toc163726225)

[4.1 Calculations for exposure assessment 10](#_Toc163726226)

[4.2 New information on the active substance(s) and substance(s) of concern 10](#_Toc163726227)

[4.3 List of studies for the biocidal product 10](#_Toc163726228)

[4.4 References 10](#_Toc163726229)

[4.5 Confidential information 10](#_Toc163726230)

**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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP | Sweden |  | dd.mm.yyyy | First authorisation |  |
| NA-MIC | Sweden |  | dd.mm.yyyy | Composition changeAmendment of packaging: addition of a new cap | Conf Annex 1.1-1.3 and 1.5PAR 3.1 |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

# Conclusion

**General**

**Composition**

**Conclusions of the assessments for each area**

Physical, chemical and technical properties

The changes in composition and packaging do not affect the conclusions in the first authorisation of the product.

Physical hazards and respective characteristics

The changes in composition and packaging do not affect the conclusions in the first authorisation of the product.

Methods for detection and identification

Efficacy against target organisms

Risk assessment for human health

Dietary risk assessment

Risk assessment for animal health

Risk assessment for the environment

**Post-authorisation conditions**

# Information on the biocidal product

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

## Uses

## Identity and composition

## Identity of the active substance(s)

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

## Candidate(s) for substitution

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

## Classification and labelling

## Letter of access

## Data submitted in relation to product authorisation

## Similar conditions of use across the Union

# Assessment of the biocidal product

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging**  | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 300 mL | HDPE | Flip-top cap (PP) | Professional and non-professional | Yes |
| Bottle | 1 L | HDPE | Flip-top cap (PP) | Professional and non-professional | Yes |
| Bottle | 1 L | HDPE | Snap top | Professional and non-professional | Yes |
| Bottle | 5 L | HDPE | Screw cap (PP) | Professional  | Yes |

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

## Physical hazards and respective characteristics

## Methods for detection and identification

## Assessment of efficacy against target organisms

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

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

### Efficacy data

### Efficacy assessment

### Conclusion on efficacy

### Occurrence of resistance and resistance management

### Known limitations

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

## Risk assessment for human health

### Assessment of effects on human health

### Information on dermal absorption

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

### Other

### Available toxicological data relating to endocrine disruption

### Exposure assessment and risk characterisation for human health

### Monitoring data

### Dietary risk assessment

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

### Overall conclusion on risk assessment for human health

## Risk assessment for animal health

### Risk for companion animals

### Risk for livestock animals

## Risk assessment for the environment

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

### Exposure calculation and risk characterisation

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

### Mixture toxicity

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

## Assessment of a combination of biocidal products

## Comparative assessment

# Appendices

## Calculations for exposure assessment

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

## List of studies for the biocidal product

## References

## Confidential information

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