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

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

(submitted by the evaluating Competent Authority)



KONSERVAN P40

Product type 18

Permethrin

Case Number in R4BP: BC-SH023802-41

Evaluating Competent Authority: France

Date: 02/08/2022

Table of Contents

[Table of Contents 2](#_Toc111202043)

[*1* CONCLUSION 4](#_Toc111202044)

[*2* ASSESSMENT REPORT 7](#_Toc111202045)

[2.1 Summary of the product assessment 7](#_Toc111202046)

[2.1.1 Administrative information 7](#_Toc111202047)

[**2.1.1.1** Identifier of the product / product family 7](#_Toc111202048)

[**2.1.1.2** Authorisation holder 7](#_Toc111202049)

[**2.1.1.3** Manufacturer(s) of the products of the family 7](#_Toc111202050)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 7](#_Toc111202051)

[2.1.2 Product (family) composition and formulation 8](#_Toc111202052)

[**2.1.2.1** Identity of the active substance 8](#_Toc111202053)

[**2.1.2.2** Candidate(s) for substitution 8](#_Toc111202054)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 9](#_Toc111202055)

[**2.1.2.4** Information on technical equivalence 9](#_Toc111202056)

[**2.1.2.5** Information on the substance(s) of concern 9](#_Toc111202057)

[**2.1.2.6** Endocrine disrupting properties 9](#_Toc111202058)

[**2.1.2.7** Type of formulation 9](#_Toc111202059)

[2.1.3 Hazard and precautionary statements 9](#_Toc111202060)

[2.1.4 Authorised use(s) 10](#_Toc111202061)

[**2.1.4.1** Use description 10](#_Toc111202062)

[2.1.5 General directions for use 11](#_Toc111202063)

[**2.1.5.1** Instructions for use 11](#_Toc111202064)

[**2.1.5.2** Risk mitigation measures 12](#_Toc111202065)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc111202066)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 12](#_Toc111202067)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc111202068)

[2.1.6 Other information 13](#_Toc111202069)

[2.1.7 Packaging of the biocidal product 13](#_Toc111202070)

[2.1.8 Documentation 13](#_Toc111202071)

[**2.1.8.1** Data submitted in relation to product application 13](#_Toc111202072)

[**2.1.8.2** Access to documentation 16](#_Toc111202073)

[2.2 Assessment of the biocidal product 16](#_Toc111202074)

[2.2.1 Intended use(s) as applied for by the applicant 16](#_Toc111202075)

[2.2.2 Physical, chemical and technical properties 17](#_Toc111202076)

[2.2.3 Physical hazards and respective characteristics 28](#_Toc111202077)

[2.2.4 Methods for detection and identification 30](#_Toc111202078)

[2.2.5 Efficacy against target organisms 37](#_Toc111202079)

[**2.2.5.1** Function and field of use 37](#_Toc111202080)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 38](#_Toc111202081)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 38](#_Toc111202082)

[**2.2.5.4** Mode of action, including time delay 39](#_Toc111202083)

[**2.2.5.5** Efficacy data 40](#_Toc111202084)

[**2.2.5.6** Occurrence of resistance and resistance management 56](#_Toc111202085)

[**2.2.5.7** Known limitations 57](#_Toc111202086)

[**2.2.5.8** Evaluation of the label claims 57](#_Toc111202087)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 57](#_Toc111202088)

[2.2.6 Risk assessment for human health 58](#_Toc111202089)

[**2.2.6.1** Assessment of effects on Human Health 58](#_Toc111202090)

[**2.2.6.2** Exposure assessment 63](#_Toc111202091)

[**2.2.6.3** Risk characterisation for human health 70](#_Toc111202092)

[2.2.7 Risk assessment for animal health 74](#_Toc111202093)

[2.2.8 Risk assessment for the environment 75](#_Toc111202094)

[**2.2.8.1** Effects assessment on the environment 75](#_Toc111202095)

[**2.2.8.2** Exposure assessment 82](#_Toc111202096)

[**2.2.8.3** Fate and distribution in exposed environmental compartments 85](#_Toc111202097)

[**2.2.8.4** Risk characterisation 113](#_Toc111202098)

[2.2.9 Measures to protect man, animals and the environment 130](#_Toc111202099)

[2.2.10 Assessment of a combination of biocidal products 130](#_Toc111202100)

[2.2.11 Comparative assessment 130](#_Toc111202101)

[*3* Annexes 131](#_Toc111202102)

[3.1 List of studies for the biocidal product (family) 131](#_Toc111202103)

[3.2 Output tables from exposure assessment tools 135](#_Toc111202104)

[3.3 New information on the active substance 135](#_Toc111202105)

[3.4 Residue behaviour 135](#_Toc111202106)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 136](#_Toc111202107)

[3.6 Confidential annex 142](#_Toc111202108)

[3.7 Biocidal Products Committee (BPC) Opinion on a request according to Article 38 of Regulation (EU) No 528/2012 on Questions on unresolved objections during the mutual recognition procedure of the PT 18 biocidal product Konservan P 40 containing permethrin 142](#_Toc111202109)

# CONCLUSION

The biocidal product KONSERVAN P40 is a permethrin-based PT18 biocidal product to be used by industrial users for “vector protection finishes of textiles against mosquitoes and ticks” and for “wool protection against clothes moths and carpet beetles”.

*In the course of mutual recognition process, one concerned member state disagreed with the proposed assessment performed by FR MS. this cMS referred objections to the coordination group set up pursuant to Article 35(1). As no agreement was reached in the coordination group, rMS referred the unresolved objection to the Commission pursuant to Article 36(1) of BPR. The Commission requested an opinion on that matter from ECHA in accordance with Article 36(1) and Article 38 of Regulation (EU) No 528/2012.*

*The following PAR and conclusion takes into account*

* *ECHA BPC opinion from the 17 June 2021 (ECHA/BPC/284/2021)*
* *Commission Implementing Decision (EU) 2021/2174 of 3 December 2021.*
* ***Physico-chemical properties***

KONSERVAN P 40 is an emulsifiable concentrate (EC). The product is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 365°C. In aqueous solution (1% dilution), it has a pH value of 5.5 at 23.1°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C and 2 years at 20°C, neither the active ingredient content nor the technical properties were changed except for emulsion characteristics which have not been tested.

The product KONSERVAN P 40 is not classified for the physico-chemical characteristics.

An analytical method for the determination of the active substance permethrin in the biocidal product is available and fully validated. Nevertheless, a new analytical method for the determination of active substance enantiomers in the product KONSERVAN P40 should be submitted in post-authorization along with the application for renewal of authorisation.

* ***Efficacy assessment***

In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18/19 (2012),

* For the use “vector protection finishes of textiles against mosquitoes and ticks”, the product KONSERVAN P40 shows sufficient efficacy against mosquitoes genus (*Aedes*, *Culex* and *Anopheles*) adults and ticks (*Ixodes ricinus* and *Hylomma marginatum*) nymphs and adults when used on textile washed up to 30 times at 60°C.
* For the use “wool protection”, the product KONSERVAN P40 shows sufficient efficacy in preventive treatment against clothes moths *Tineola bisselliella* (larvae and adults) and against carpet beetles *Anthrenus flavipes* (adults) on original treated textile (without washing). Efficacy has not been demonstrated for larvae of carpet beetles *Anthrenus flavipes*.
* ***Risk assessment for human health***

The use of Konservan P 40 in wool carpets **is acceptable** based on model calculations of exposure. **The conditions of Article 19(1)(b)(iii) are met for this use.**

Based on model calculation safe use of Konservan P 40 in clothing could not be identified, while the use in clothing **is supported** based on biomonitoring data with uncertainty analysis and Risk Mitigation Measure: “Do not use for manufacturing of clothing intended for the general public”.

* ***Risk for consumers via residues***

No exposure to residues in food is awaited based on the intended uses. Then, no assessment has been performed.

* ***Risk assessment for environment***

Concerning the industrial application step of the product KONSERVAN P40 for the claimed uses:

* Risks are unacceptable for the aquatic, sediment, terrestrial compartments, as well as for the treatment plant.
* The estimated concentrations in groundwater are above the threshold values ​​defined by Directive 98/83 /EC.

Industrial use of product KONSERVAN P40 is only possible with the following RMM “Application solutions must be collected and reused or disposed as a hazardous waste. They may not be released to soil, ground, surface water or any kind of sewer”. .

Regarding the use phase of treated textiles and wool (washing) with KONSERVAN P40, when they are washed:

* risks are unacceptable for the aquatic and sediment compartments.
* Risks are acceptable for terrestrial compartment and for treatment plant.
* the estimated concentrations in groundwater are below the threshold values ​​defined by Directive 98/83 / EC.

Several sub-scenarios have been considered for specific uses of treated clothes (military uniforms, forestry clothing) and risks are deemed unacceptable for the aquatic compartment.

Hence, according to Article 19(1)(b)(iv), use of KONSERVAN P40 is only possible for the treatment of non-washable wool. The following instruction must appear on the label : “for production of non-washable wool only”

* ***General conclusion***

**The conditions of Article 19(1) are met for the following use**:

|  |  |  |
| --- | --- | --- |
| **Target organism** | **Application rates** | **Use conditions** |
| *Tineola bisselliella* (moths) larvae and adults  *Anthrenus flavipes* (carpet beetles) adults | Amounts to be used to obtain protection against:  *Tineola bisselliella* (adults and larvae) + *Anthrenus flavipes* (adults): 0.06% product in the wool | Wool preventive protection against textile-attacking insects  Application: Wool textile fibers for use in the manufacturing of non-washable home textiles (carpets and rugs) or insulating material. |

under the following conditions

* the following RMM “Application solutions must be collected and reused or disposed as a hazardous waste. They may not be released to soil, ground, surface water or any kind of sewer”.
* The product can be used only for the treatment of wool that will not be washed. The following instruction must appear on the label: “for production of non-washable wool only”

**The conditions of Article 19(1) are not met for the use for vector protection finishes of textiles,** considering risk for the general public wearing treated clothes and considering environmental risk when washing textiles. **Such use may only be authorized in some member states according to article 19(5).**

In France, only uses for which conditions of article 19(1) are met will be authorized.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| KONSERVAN P40 |  |
| BEMATIN Per 40 |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | THOR GmbH |
| **Address** | Landwehrstrasse 1  D-67346  Speyer  Rheinland-Pfalz  Germany |
| **Authorisation number** | FR-2022-0065 | |
| **Date of the authorisation** | 11/08/2022 | |
| **Expiry date of the authorisation** | 10/08/2032 | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Thor France SARL |
| **Address of manufacturer** | 325, rue des Balmes CS  50041 SALAISE SUR SANNE  France |
| **Location of manufacturing sites** | 325, rue des Balmes  CS 50041 SALAISE SUR SANNE  France |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Lanxess Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz  1 50569 Köln  Germany |
| **Location of manufacturing sites** | Bayer Vapi Private Limited Plot # 306/3 II Phase,  GIDC Vapi – 396 195 Gujarat  India |

### Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | 3-phénoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-  dichlorovinyl)-2,2- iméthylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 930 g/kg |
| **Structural formula** | Résultat de recherche d'images pour "PERMETHRINE" |

#### Candidate(s) for substitution

At the time of PAR validation, permethrin is only classified as toxic and is therefore not subject to substitution. However, the persistence and bioaccumulation issues have been brought up for discussion at the ECHA PBT EG, and are currently under further evaluation by eCA IE. If found persistent and bioaccumulative, it will fulfil the three PBT criteria and should then be considered as a candidate for substitution or exclusion as identified in the provisions of Article 10 and 5 of Regulation (EU) No 528/2012.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | (1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-diméthylcyclopropanecarboxylate de 3-phénoxybenzyle | Substance active | 52645-53-1 | 258-067-9 | 40 (pure)  43\* (technical) |

*\* Based on a minimum purity of 93%*

#### Information on technical equivalence

*Not relevant*

#### Information on the substance(s) of concern

Please see the confidential annex for further details.

#### Endocrine disrupting properties

According to our assessment, none of the co-formulants contained in KONSERVAN P40 are regulatory identified as endocrine disruptors.

However, one co-formulant shows indications of endocrine activity (refer to confidential annex).

Based on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| Emulsifiable Concentrate (EC) |

### Hazard and precautionary statements[[1]](#footnote-2)

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Acute oral toxicity, cat 4  Skin Sens 1  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H302 Harmful if swallowed  H317: May produce an allergic reaction  H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H302 Harmful if swallowed  H317: May produce an allergic reaction  H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P261: Avoid breathing dust/fume/ gas/mist/vapours/spray  P264 : Wash hands thoroughly after handling.  P270 : Do not eat, drink or smoke when using this product.  P272: Contaminated work clothing should not be allowed out of the workplace.  P273 : Avoid release to the Environment  P280: Wear protective gloves/ protective clothing/eye protection/face protection  P301 + P312 : IF SWALLOWED: Call a POISON CENTER/ if you feel unwell.  P302+P352: IF ON SKIN: Wash with plenty of water/…  P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  ~~P321: Specific treatment (see … on this label)~~.  P362+P364: Take off contaminated clothing and wash it before reuse.  P330 : Rinse mouth.  P391 : Collect spillage  P501 : Dispose of contents/container to hazardous waste |
|  | |
| Note | **For treated textiles: “**Contains Permethrin. May produce an allergic reaction.” |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Wool protection for non-wet washable wool

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Wool preventive protection against textile-attacking insects |
| **Target organism (including development stage)** | *Tineola bisselliella* (moths) larvae and adults  *Anthrenus flavipes* (carpet beetles) adults |
| **Field of use** | Indoor application of the biocidal product with insecticide active component for preventive treatment against keratin feeding textile pests. Application: Wool textile fibers for use in the manufacturing of non-washable home textiles (carpets and rugs) or insulating material. |
| **Application method(s)** | The requested amount of the biocidal product is added to the dyeing bath. |
| **Application rate(s) and frequency** | Amounts to be used to obtain protection against:  *Tineola bisselliella* (adults and larvae) + *Anthrenus flavipes* (adults): 0.06% product in the wool |
| **Category(ies) of users** | Industrial users |
|  |  |
| **Pack sizes and packaging material** | Jerry can, Plastic: HDPE , 20 kg  Jerry can, Plastic: HDPE , 25 kg  Jerry can, Plastic: HDPE , 30 kg  IBC (intermediate bulk container), Plastic: HDPE , 1000 kg |

##### Use-specific instructions for use

|  |
| --- |
| - For production of non-washable wool only |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product on wet washable wool. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect follow all the instructions provided * Respect the recommended application doses. * Inform the authorization holder if the treatment is ineffective. * The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. |

#### Risk mitigation measures

|  |
| --- |
| * For industrials, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coverall during the coupling and decoupling of transfer lines as well as during handling (cutting, sewing) of treated wool. * Avoid direct and indirect contact with food and feed. * Application solutions must be collected and reused or disposed as a hazardous waste. They must not be released to soil, ground, surface water or any kind of sewer. * The product may only be loaded with an automatic dosing system. * The textile treatment process (application and post-application) has to be an automated process, without direct contact by the workers. * Avoid contact to freshly treated textiles. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * Pyrethroids and pyrethrins may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Shelf life of the product: 12 months  Storage over 10°C |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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)** |
| Container | 20 L | HDPE | Screw closure | Industrial | Yes |
| Barrel | 25 L | HDPE | Screw closure | Industrial | Yes |
| Barrel | 30 L | HDPE | Screw closure | Industrial | Yes |
| IBC\* | 1000 L | HDPE |  | Industrial | Yes |
| IBC | 1054 L | HDPE |  | Industrial | Yes |

\*IBC= intermediate bulk container

### Documentation

#### Data submitted in relation to product application

**List of physico-chemical Tests:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed** | **Owner (PUB / ORG)** |
| Wannenwetsch | 2016 | Determination of colour, physical state and odour of KONSERVAN P 40  Report No 1512-K4002-20-UWA-0454-1 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2016 | Determination of the pH value of an aqueous 1% solution of KONSERVAN P 40  Report No 1512-K 4002-2-UWA-0455-2 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2016 | Determination of the density of KONSERVAN P 40  Report No 1512-K 4002-6-UWA-0456-3 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2016 | Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54°C over 14 days and sample specific validation  Report No 1512-K4002-13.1-UWA-0466-7 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2016 | Determination of the surface tension and the critical micelle concentration of an aqueous solution of KONSERVAN P 40  Report No 1512-K 4002-3-UWA-0458-5 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2016 | Determination of the viscosity of KONSERVAN P 40  Report No 1512-K 4002-5-UWA-0457-4 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Simonides | 2016 | Determination of the explosive properties of KONSERVAN P 40  Report No MSI2016-01 | Yes | Thor GmbH |
| Smeykal | 2016 | Determination of physico-chemical properties Flash Point  Report No CSL-16-0059.01 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Smeykal | 2016 | Determination of physico-chemical properties Thermal Stability (OECD 113) Self-Reactive Substances (UN Class 4, division 4.1)  Report No CSL-16-0059.02 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Simonides | 2016 | Determination of the oxidising properties of KONSERVAN P 40  Report No MSl2016-02 | Yes | Thor GmbH |
| Bäßler | 2016 | EVALUATION OF THE CORROSIVE EFFECT OF BIOCIDE PRODUCT  Report No 16001095 (6.1/15272) | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Smeykal | 2016 | Determination of physico-chemical properties Auto-Ignition Temperature  Report No CSL-16-0059.03 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Möller M | 2017 | Colorimetric Method for Determination of the Stability of Dilute Emulsions  Study CSL-17-0525.01 | Yes | Thor SARL |
| Wannenwetsch | 2016 | Determination of the foaming of KONSERVAN P 40  Report No 1512-K 4002-15-UWA-0459-6 | Yes | CHT R. Beitlich GmbH / Thor SARL |
| Wannenwetsch | 2018 | Emulsion characteristics of KONSERVAN P 40 before and after storage at room temperature for 24 months, Study AP 30565 | Yes | CHT R. Beitlich GmbH / Thor SARL |

**EFFICACY**

For the use “vector protection finishes of textiles” against mosquitoes and ticks, the following tests were submitted:

* Two laboratory tests with the product KONSERVAN P40 (BEMATIN PER 40) on mosquitoes’ species *Anopheles gambiae*, *Aedes aegypti* and *Culex quinquefasciatus* according to tubes[[2]](#footnote-3) and cones[[3]](#footnote-4) tests WHO methods;
* Four laboratory tests with the product KONSERVAN P40 (BEMATIN PER 40) on *Ixodes ricinus* according to cones test WHO method and the technical guideline TL 8305-0331 of the German Armed Forces[[4]](#footnote-5);
* One laboratory test with the product KONSERVAN P40 (BEMATIN PER 40) on *Hyalomma marginatum* according to cones test WHO method;
* One choice test with the product KONSERVAN P40 (BEMATIN PER 40) on *Ixodes ricinus* and *Hyalomma marginatum* according to OPPTS 810.3700 method[[5]](#footnote-6);
* One simulated test (arm-in-cage) in temperate conditions with the product KONSERVAN P40 (BEMATIN PER 40) on *Anopheles gambiae*, *Aedes aegypti* and *Culex quinquefasciatus* according to WHO method[[6]](#footnote-7);
* One simulated test (arm-in-cage) in tropical conditions with the product KONSERVAN P40 (BEMATIN PER 40) on *Anopheles gambiae*, *Aedes aegypti* and *Culex quinquefasciatus* according to WHO method8;

For use wool protection against moths and carpet beetles, the following test was submitted:

* One Simulated-use test with the product KONSERVAN P40 (BEMATIN PER 40) on *Tineola bisselliella* and *Anthrenus flavipes* according to internal method[[7]](#footnote-8).

Other supportive studies have been submitted by the applicant and they are summarised in appendix 3.5.

#### Access to documentation

A letter of access from LANXESS Deutschland GmbH grants the access to the complete BPD 98/8/EC dossier submitted to the European Commission for the listing of permethrin.

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

Table 3. Intended use # 1 – Vector protection finishes of textiles

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide vector protection finishes of textiles.  Indoor and outdoor use of the treated article.  The product is intended to stay on the surface of the treated article (textile). No significant release to the surface water or soil caused by use of the treated article expected. |
| Target organism (including development stage) | * Ixodidae (Nymphs and Adults) - *Ixodes ricinus* * Culicidae (Adults) - *Aedes mosquitoes* * Culicidae (Adults) - *Anopheles mosquitoes* * Ixodidae (Nymphs and Adults) - *Hyalomma marginatum* * Culicidae (Adults) - *Culex quinquefasciatus* |
| Field of use | Indoor |
| Application method(s) | Open system: immersion |
| Application rate(s) and frequency | Final concentration on the textile 1,300 mg Permethrin/m² (= 1300 ppm) (the necessary concentration of the product in the bath is dependent on the textile used), for forest worker clothing: 200 ppm Permethrin.  Automatically adding the product to the bath for the padding process: once a day handling 75 mg product; 10 minutes/task.  Dependent on the fabric weight and liquor pick-up, for military use e.g. 29.3 g/L can be assumed |
| Category(ies) of user(s) | Industrial |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE , 25 kg  IBC (intermediate bulk container), Plastic: HDPE , 1000 kg  IBC (intermediate bulk container), Plastic: HDPE , 1054 kg  Jerry can, Plastic: HDPE , 20 kg  Jerry can, Plastic: HDPE , 30 kg |

Table 4. Intended use # 2 – Wool protection

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Wool protection against textile - attacking insects (including fur and fabric attacking insects) |
| Target organism (including development stage) | * Tineidae (Larvae and adults) - *Tineola bisselliella* * *Anthrenus flavipes* (Larvae and adults) - Carpet beetle |
| Field of use | Indoor |
| Application method(s) | exhaust process  The biocidal product may be applied according to the exhaust method on wool flock, yarns or woven material.  The requested amount of the biocidal product is added to the dyeing bath with the other auxiliaries. This method ensures an even distribution of the product on the fibre.  If wool is to be treated separately, it is then recommended to apply the biocidal product at 70°C, at a pH of 4.0 to 5.0 with acetic acid or formic acid during 30-40 min.  The biocidal product may also be applied prior to or during spinning. To ensure full effect the yarns must be steamed for 10 min at 105°C.  The application takes places during the dyeing process in most of the cases - or in some special cases (white or natural coloured wool) in an extra application step at 70°C. - After moth proof finishing a softener will be applied. The following steps will be mechanical ones - depending on the material - yarns go to weaving or knitting, woven or knitted fabrics to cutting and sewing. |
| Application rate(s) and frequency | 0.09% biocidal product (0.0036 % Permethrin) on all the mentioned materials / textiles -  The application rate is from 0.03% up to 0.09% on pure wool - depending on the needed protection level and 0.05% to 0.13% on wool/PA blends - also depending on the needed  protection level.  Up to 0.09 % (w/w) on all the mentioned materials / textiles.  The application amount is up to 0.09 % related to the weight of the textile.  Amounts to be used to obtain protection against:   * *Tineola bisselliella*: 0.03% * *Tineola bisselliella* + *Anthrenus flavipes*: 0.06% |
| Category(ies) of user(s) | Industrial |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE , 20 kg  IBC (intermediate bulk container), Plastic: HDPE , 1000 kg  Jerry can, Plastic: HDPE , 25 kg  Jerry can, Plastic: HDPE , 30 kg |

### Physical, chemical and technical properties

Type of formulation: Emulsifiable Concentrate (EC)

The biocidal product does not contain hydrocarbons or H304 co-formulants content ≥10%.

The concentration ranges are:

* Use #1: from 0.98% to 7.32% (w/v)
* Use #2: from 0.03 to 0.09% (w/v)

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | 40.86% | Liquid | Wannenwetsch (2016) Determination of colour, physical state and odour of KONSERVAN P 40 | Acceptable |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 | Clear yellow |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | Slight sweetish odour |
| Acidity / alkalinity | CIPAC MT 75 | 40.86% | 1% (w/v) dilution  Average on 3 measures:  pH = 5.5 at 23.1°C  Determination of acidity or alkalinity not necessary | Wannenwetsch (2016) Determination of the pH value of an aqueous 1% solution of KONSERVAN P 40 | Acceptable |
| Relative density / bulk density | OECD Guideline No 109 | 40.86% |  | Wannenwetsch (2016) Determination of the density of KONSERVAN P 40 | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Method for AS content fully validated | 40.86% | Test item stored in HDPE with PP screw cap for 14 days at 54°C  Packaging:  No signs of corrosion  Product aspect:  No visual changes  pH 1% dilution  Before storage: 5.4 at 23.6°C  After storage: 5.3 at 23.6°C  AS content  Before storage: 41.9%  After storage: 42.0%  Variation: 0.11%  The product is considered stable after storage at 54°C for 14 days in HDPE. | Wannenwetsch (2016) Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54°C over 14 days and sample specific validation | Acceptable |
| Storage stability test – **long term storage at ambient temperature** | HPLC/UV method validated in study 1512-K 4002-13.1-UWA-0466-7 | Batch number: RP-6000265-1805 | |  |  |  | | --- | --- | --- | |  | **Initial** | **After 2 years in HDPE** | | Content of a.s. |  |  | | Trans permethrin | 30.8% | 30.8 % (-0.15%) | | Cis permethrin | 11.1% | 11.0 % (-0.65%) | | Sum cis-trans | 41.9% | 41.8 % (-0.28%) | | pH (1% dilution) | 5.4 at 24°C | 5.1 at 24°C | | Examination of container | No visual changes and no corrosion | | | Emulsion characteristics |  | | | At 0.03% | **Initial:** Homogeneous emulsion, 5mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1cm of froth, no sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 0.6cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | | At 0.98% | **Initial:** Homogeneous emulsion, 3mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1.4cm of froth, a minute amount of sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 1.1cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | | At 7.32% | **Initial:** Homogeneous emulsion, 3mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1.1cm of froth, no sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 1.3cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | | Wannenwetsch (2018)  Study 1512K4002-13.0-UWA-0467-8  Wannenwetsch (2018), Study AP30565 | **Acceptable**  **The product is considered stable after 24 months storage but the applicant want to set the shelf life at 12 months.** |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not provided |  | **The low temperature storage was not provided.**  **The label should be indicating the following mention: “protect from frost”.**  **Nevertheless, the applicant want to indicate the mention: “Storage over 10°C”.No other data is required.** |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement |  | *Considering the assessment report for Permethrin PT 18, the active substance is regarded to be photolytically stable. With regards to the biocidal product containing solvents and emulsifiers, the active substance is dissolved and not directly exposed to light as it was in the photolysis study. Therefore no relevance for investigating the effects of light to the biocidal product can be identified. The endpoint is waived according to BPR Annex IV Nr. 1.1 testing does not appear to be scientifically necessary based on existing data.*  *As the active substance is not photolytically instable according to the assessment report, we still see no reason why our argumentation is not acceptable. However, beginning from T 6 the longterm storage stability samples are stored under influence of light.* |  | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | No significant change in content of the active substance after storage at 54°C for 14 days. | Wannenwetsch (2016) Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54°C over 14 days and sample specific validation | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | No significant change in content of the active substance after accelerated storage in HDPE.  The storage container showed no signs of corrosion for up to 14 days. | Wannenwetsch (2016) Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54°C over 14 days and sample specific validation | Acceptable |
| Wettability |  |  | Not required for an EC formulation. |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required for an EC formulation. |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not required for an EC formulation. |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 173 | Konservan P40  Batch IF18311-1801 | Emulsion stability at a concentration of 0.03%: 129%  Emulsion stability at a concentration of 7.3%: 104%   |  |  | | --- | --- | | Emulsion characteristics |  | | At 0.03% | **Initial:** Homogeneous emulsion, 5mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1cm of froth, no sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 0.6cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | At 0.98% | **Initial:** Homogeneous emulsion, 3mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1.4cm of froth, a minute amount of sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 1.1cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | At 7.32% | **Initial:** Homogeneous emulsion, 3mm of froth, little sediment, no oil or cream  **After 30minutes, 2h and 24h of inverted 10times:**  Homogeneous emulsion, less than 1.1cm of froth, no sediment, no oil or cream  **Re-emulsification after 24hstanding:**  Homogeneous emulsion, less than 1.3cm of froth, no sediment, no oil or cream after 30 seconds and 30minutes. | | Möller M., 2017  Study CSL-17-0525.01  Wannenwetsch (2018), Study AP30565 | The colorimetric method CIPAC MT173 is suitable for the concentration between 0.1% and 2%. Moreover, the emulsion stability is outside the acceptable limits at 0.03% (>105%). |
| Disintegration time |  |  | Not required for an EC formulation. |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required for an EC formulation. |  |  |
| Persistent foaming | CIPAC MT 47.2 | 40.86% | 0.98% emulsion:  0s: 24 ml  10s: 20 ml  1min: 16 ml  3min: 14 ml  12min: 6 ml  7.32% emulsion:  0s: 44 ml  10s: 26 ml  1min: 16 ml  3min: 10 ml  12min: 8 ml  Foam volume < 60 ml after 1 min | Wannenwetsch (2016) Determination of the foaming of KONSERVAN P 40 | Acceptable  The tests are not performed at the minimum concentration of uses (0.03% w/v). Nevertheless, as the volume of foam is <30mL different concentrations (0.98% and 7.32%), no other data is required. |
| Flowability/Pourability/Dustability |  |  | Not required for an EC formulation. |  |  |
| Burning rate — smoke generators |  |  | Not required for an EC formulation. |  |  |
| Burning completeness — smoke generators |  |  | Not required for an EC formulation. |  |  |
| Composition of smoke — smoke generators |  |  | Not required for an EC formulation. |  |  |
| Spraying pattern — aerosols |  |  | Not required for an EC formulation. |  |  |
| Physical compatibility |  |  | Not required as the product is not intended to be used in mixture. |  |  |
| Chemical compatibility |  |  | Not required as the product is not intended to be used in mixture. |  |  |
| Degree of dissolution and dilution stability |  |  | Not required for an EC formulation. |  |  |
| Surface tension | OECD Guideline No 115 | 40.86% | 7.33% emulsion:  38.0 mN/m at 20°C  Product is surface active  CMC: 3.25% at 20°C | Wannenwetsch (2016) Determination of the surface tension and the critical micelle concentration of an aqueous solution of KONSERVAN P 40 | Acceptable |
| Viscosity | OECD Guideline No 114 | 40.86% | |  |  |  | | --- | --- | --- | | Temperature | 20°C | 40°C | | Shear rate | 4-30 rpm | 10-60 rpm | | Dynamic viscosity | 193.9 mPa.s | 68.5 mPa.s | | Kinematic viscosity | 178.2 m²/s | 62.9 m²/s |   Newtonian liquid | Wannenwetsch (2016) Determination of the viscosity of KONSERVAN P 40 | Acceptable |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| KONSERVAN P 40 is an Emulsifiable Concentrate (EC). The appearance of the product is a clear yellow liquid, with a slight sweetish odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 365°C. In aqueous solution (1% dilution), it has a pH value of 5.5 at 23.1°C.  There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C and 2years at 20°C, neither the active ingredient content nor the technical properties were changed.  No low temperature storage was provided. Consequently, the product should be stored away from frost. The applicant proposes the RMM “store above 10°C”, which is accepted by rMS.  Instructions for SPC:  Shelf-life: 12 months  Store above 10°C |

### Physical hazards and respective characteristics

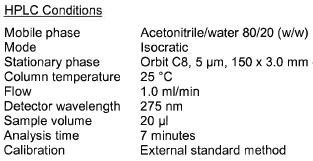
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |  |
| --- | --- | --- | --- | --- | --- |
| Explosives | Expert statement | 40.0% (nominal) | No explosive properties are expected based on the molecular structures of the active substance and the inert ingredients. | Simonides, M. (2016) Determination of the explosive properties of KONSERVAN P 40 | Acceptable, extrapolated to CLP regulation |
| Flammable gases |  |  | Not required for an EC formulation. |  |  |
| Flammable aerosols |  |  | Not required for an EC formulation. |  |  |
| Oxidising gases |  |  | Not required for an EC formulation. |  |  |
| Gases under pressure |  |  | Not required for an EC formulation. |  |  |
| Flammable liquids | EC A.9 | 40.86% | Flash point: 109.5°C  Not flammable | Smeykal (2016) Determination of physico-chemical properties Flash Point | Acceptable, extrapolated to CLP regulation |
| Flammable solids |  |  | Not required for an EC formulation. |  |  |
| Self-reactive substances and mixtures | OECD 113  Thermal stability (DSC) | 40.86% | The test item showed a very small exothermic effect in the temperature range 120-160°C and a second one in the temperature range 250-380°C with a maximum overall energy of 130 J/g.  Not classified as self-reactive substance because decomposition energy of the exothermic effect < 300 J/g | Smeykal (2016) Determination of physico-chemical properties Thermal Stability (OECD 113) Self-Reactive Substances (UN Class 4, division 4.1) | Acceptable, extrapolated to CLP regulation |
| Pyrophoric liquids |  |  | Not required for an EC formulation. |  |  |
| Pyrophoric solids |  |  | Not required for an EC formulation. |  |  |
| Self-heating substances and mixtures |  |  | Not required for an EC formulation. |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required for an EC formulation. |  |  |
| Oxidising liquids | Expert statement | 40.0% (nominal) | No oxidising properties are expected based on the molecular structures of the active substance and the inert ingredients. | Simonides, M. (2016) Determination of the oxidising properties of KONSERVAN P 40 | Acceptable, extrapolated to CLP regulation |
| Oxidising solids |  |  | Not required for an EC formulation. |  |  |
| Organic peroxides |  |  | Not required for an EC formulation. |  |  |
| Corrosive to metals | UN-MTC | 40.86% | Plates made of steel and aluminium material were exposed for 28 days at 55°C to the test item.  Not corrosive | Bäßler (2016) EVALUATION OF THE CORROSIVE EFFECT OF BIOCIDE PRODUCT | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) | EC A.15 | 40.86% | Auto-ignition temperature: 365°C | Smeykal (2016) Determination of physico-chemical properties Auto-Ignition Temperature | Acceptable  The test is not performed according to CLP regulation, nevertheless, as the product is not classified, no other data is required. |
| Relative self-ignition temperature for solids |  |  | Not required for an EC formulation. |  |  |
| Dust explosion hazard |  |  | Not required for an EC formulation. |  |  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product KONSERVAN P 40 is not classified regarding its physico-chemical characteristics. |

### Methods for detection and identification

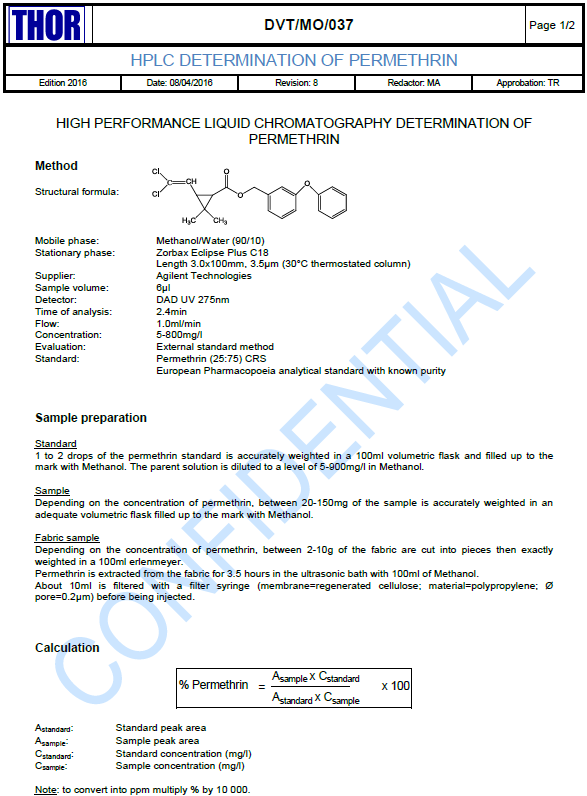
**Principle of the method:**

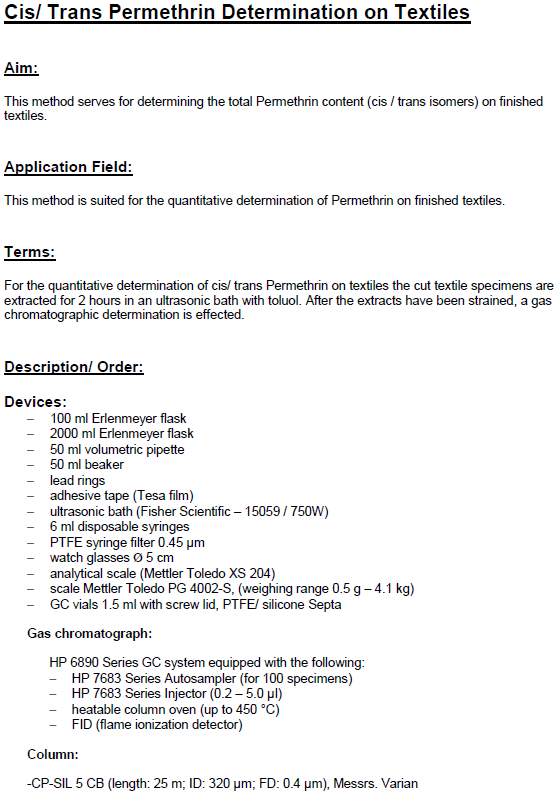
Considering analysis via HPLC, the isomers of the active ingredient (trans and cis Permethrin) in the sample were separated and detected using a DAD detector. The concentrations of the isomers of the active ingredient in the samples were determined by measuring the peak areas of the components and comparing them to the peak areas of the analytical standard of known concentrations.

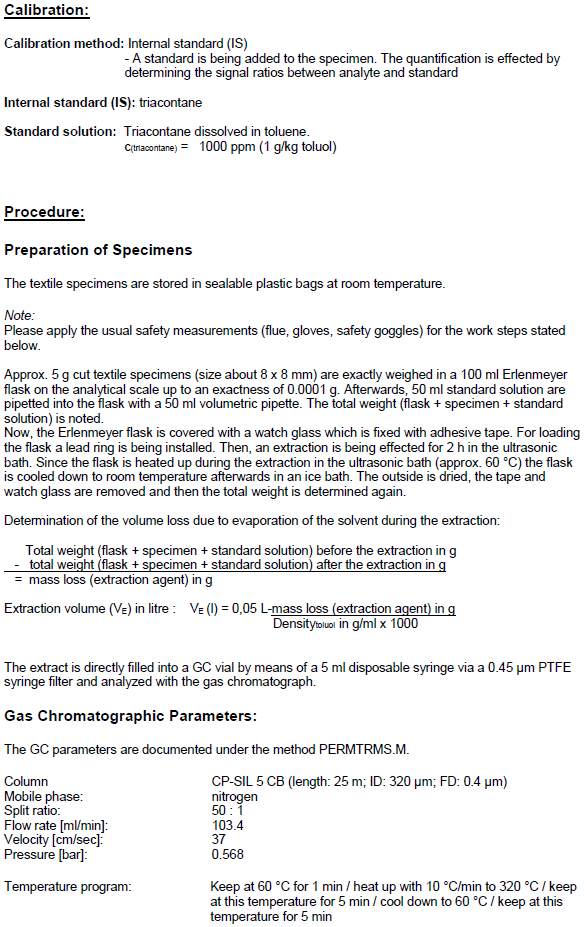


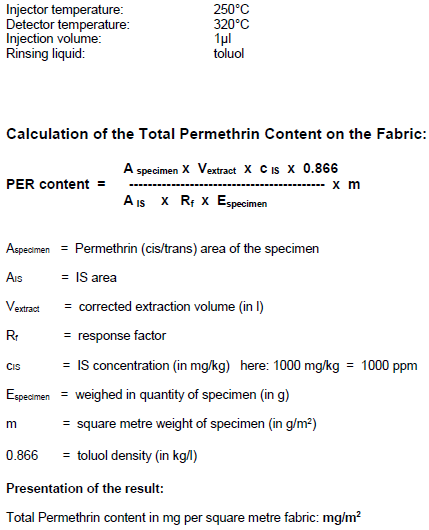
|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Active substance permethrin*  *Trans & cis* | HPLC-DAD (275 nm) | Trans: 31%  Cis: 11%  (n=7) | Trans:  From 10 to 70 mg/L  n=4  R²=1.000  Cis:  From 4 to 25 mg/L  n=4  R²=0.999 | Cis & trans: Blank, reference and matrix chromatograms do not show any interfering peaks at the retention time of the test items. | Trans: 99.6 – 100.3  Cis: 99.5 – 100.3 | Trans: 100.0  (n=7)  Cis: 99.8  (n=7) | Trans: 0.26  Cis: 0.28 | Not applicable, content method | Wannenwetsch (2016) Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54 °C over 14 days and sample specific validation |

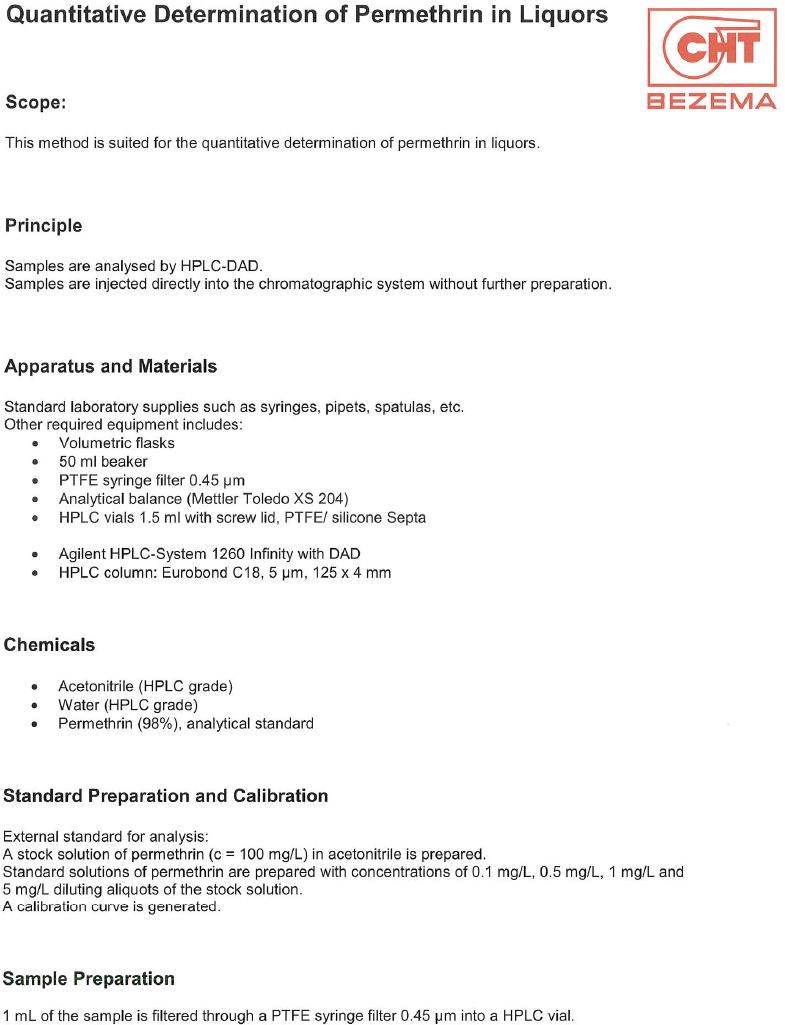
**Analytical methods principles for the determination of permethrin in textiles and in washing liquors submitted by applicant are described below. There is no validation data for these methods, nevertheless, as there is no EU requirement, no other data is required.**

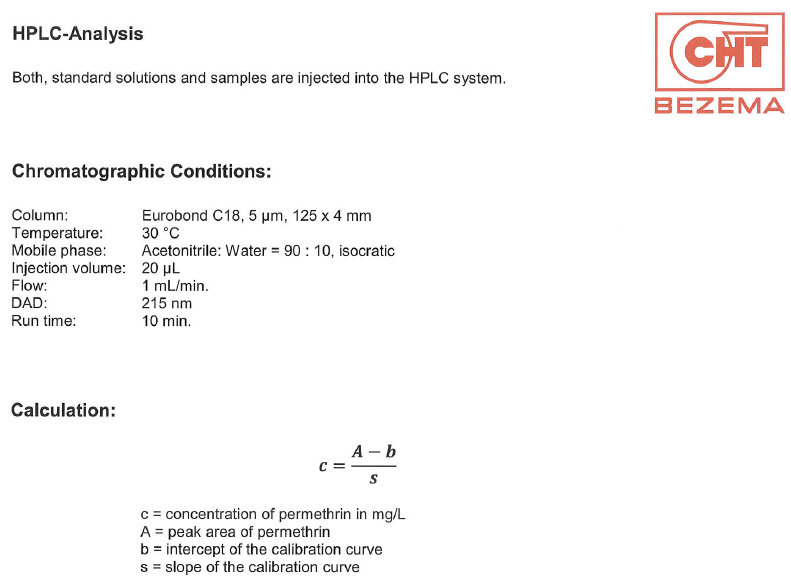












|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| An analytical method for the determination of the active substance permethrin in the biocidal product is available and fully validated.  **An analytical method for the determination of active substance enantiomers in the product KONSERVAN P40 should be submitted in post-authorization.**  Validated analytical methods are available in soil, water and air. A letter of access from LANXESS Deutschland GmbH is available.  Other analytical methods are not required for the intended uses. |

### Efficacy against target organisms

#### Function and field of use

Main Group 3: Pest control

Product type 18: Insecticides

KONSERVAN P40 is a biocidal insecticide product. It is an emulsifiable concentrate containing 40 % w/w Permethrin as active substance. The product is intended for application on fabrics (e.g. cotton, synthetic materials) to protect humans wearing the textile from being bitten by ticks and mosquitoes. The treated fabric is used for textile production in areas where a vector protection finish of clothes is necessary (tropical uniforms for armed forces, clothes for forest workers, hunting or trekking clothes…).

Additionally, according to the applicant, the product is used for treatment of wool to control keratin feeding textile pests. The wool and the other keratin fibers are used for apparels, home textiles, carpets, insulating materials).

For both uses, the application is done by industrial workers only.

#### Organisms to be controlled and products, organisms or objects to be protected

Vector protection finishes of textiles: Mosquitoes (*Aedes aegypti*, *Anopheles gambiae* and *Culex quinquefasciatus*) and ticks (*Ixodes ricinus* and *Hyalomma marginatum*).

Wool protection: Clothes moths *Tineola bisselliella* and carpet beetles *Anthrenus flavipes*.

The product is intended to protect humans from mosquito and tick biting, as they can act as potential vectors of diseases. The product is also intended to be used to impregnate textile to protect the textile from damage by textile attacking insects.

#### Effects on target organisms, including unacceptable suffering

After the exposure to sufficient doses of permethrin, mosquitoes show certain behavioral changes including staggering, decreased flight activity or laying on the back or on the side. Target organisms show convulsions which in the end lead to paralysis of the animal. This is the so-called knock-down effect which normally occurs within minutes after getting into contact with Permethrin.

Ticks are considered to be more susceptible to permethrin than mosquitoes (Faulde et al., 2003)[[8]](#footnote-9). This could be shown in the experimental data on the effectiveness of the product which are presented below. Knock-down rates were highest for ticks compared to mosquitoes.

For the use regarding wool protection, the target organisms ingest a small amount of the permethrin contained in treated keratin fibers, which, once ingested, results in death.

The so-called “hot feet” effect (see below, section mode of action) does play an important role in permethrin-induced effects on target organisms. The insect gets hot feet upon contact with permethrin-treated surfaces and is repelled. Thus, permethrin also has repellent properties, justifying efficacy tests according to both PT18 and PT19 protocols.

Additionally, higher permethrin concentrations induce the hot feet effect in insects as they tend to avoid landing on a treated textile. Therefore, uptake of permethrin is reduced at such high concentrations (> 1300 mg permethrin/m² textile) because the insects are repelled by permethrin. Thus, lower knock- down and mortality rates are observed in such tests. Additionally, this hot feet effect is species- dependent.

#### Mode of action, including time delay

Permethrin is a type 1 pyrethroid substance. Pyrethroids in general show a high potency and selectivity towards insects, especially in comparison to mammals. It is taken up by insects and arthropods via the whole body surface from where it spreads in the body.

Permethrin is a neurotoxic insecticide that affects the voltage-gated sodium channels (type I axonic poison) within the nervous system of insects upon contact with the substance.

Permethrin binds to the sodium channel triggering continuous stimulation (“hyperexcitation”) of the respective nerve. Therefore, it affects both the peripheral and central nervous system.

Permethrin acts on the nervous system in several ways, e.g. by slowing action potential decay and inducing repetitive discharges in motor and sensory axons. This is due to the fact that Permethrin slows the kinetics of opening and closing of Na channels.

Permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lambda-cyhalothrin) and is known as the “hot-foot effect” and may be relevant for some arthropods. The repellent effect is dose-related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

#### Efficacy data

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisa ged** | **Test substance** | **Test**  **Organism (s)** | **Test method** | **Test system / concentrat ions applied / exposure time** | **Test results: effects** | **R.I** | **Reference** |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without Bematin Per 40 | *Ixodes ricinus*  5 nymphs/  replication | WHO Tube test  Test conditions :  Temperature 23 +/-0.5°C  RH 41.9+/-1.5%  Post monitoring:  Temperature 20 °C  RH 90% | One piece of fabric (12x12.6 cm) is inserted into a standard WHO plastic tube and attached to the inner wall. 5 ticks were transferred simultaneously into the tube using a soft brush. The test individuals were observed through the open end of the tube and the time from placement of the ticks until knock-down was documented.  The exposure time is 27.1 min.  Post monitoring: ticks are kept in insecticide free air. The mortality is determined after 24 h.  10 replications/ sample  3 samples of fabric were tested:   1. Untreated fabric 2. Binding agent 3. BEMATIN PER 40 (permethrin content **1300 mg/m²** )+ binding agent | |  |  |  |  | | --- | --- | --- | --- | | sample | alive | Moribund | Died | |  | | (a) | 98 | 0 | 2 | | (b) | 96 | 2 | 2 | | (c) | 0 | 46 | 54 |   KD of samples (a) and (b) > 27.1  KD (mean) of sample (b) = 8 min and 52 sec  Mortality of samples (a) & (b) = 2 %  Mortality of sample (c) = 54 %  The moribund ticks are not considered as died. Therefore, mortality is less than 95 % as required in TNsG PT18 (2012) for this use.  This study was considered as a key data | 3 | Dautel, 2016 CHT\_IR\_0116\_01 |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without BEMATIN PER 40 (Konservan P 40) | *Tineola bisselliella*  (clothes moths), *Anthrenus flavipes* (carpet beetles)  20 insects per vials plastic/test box | Simulated-use test (preventive treatment)  Test conditions:  Temperature 24-25 °C  RH 45-47%  Exposure time: 21 days | The adult clothes moths and adult carpet beetles are exposed to the treated cloths by keeping them caged in a plastic vial with wire gauze cover and a piece of treated fabric (**0.061 %** BEMATIN PER 40) on the bottom. The larvae of the moths and the larvae of the carpet beetles are placed on treated fabric in larvae test boxes. The vials with the adult clothes moths and the vials with the adult carpet beetles, as well as the test boxes with the moth larvae and the test boxes with the carpet beetle larvae are then positioned on the shelf of each single cabinet (0.5 m3). 20 insects per plastic vial / test box are used.  The larvae of clothes moths and the larvae of the carpet beetles are placed on pieces of cut out treated fabric (in the larvae test boxes), each 6 x 6 cm in size. The test boxes with the clothes moth larvae and the test boxes with the carpet beetle larvae are positioned on the shelf of each single cabinet.  As controlling measurement clothes moth adults, clothes moth larvae, carpet beetle larvae and  carpet beetle adults are exposed to untreated clothes in clean cabinets.  5 replications | |  |  |  | | --- | --- | --- | | Test days | Untreated fabric | Treated fabric | | 7 | L 13  A 17 | L 100  A 100 | | 14 | L 15  A 38\* | L 100  A 100 | | 21 | L 38  A 100\* | L 100  A 100 | | Damage wool \*\*D14 | L Yes  A No | L No  A No | | Damage wool D21 | L Yes  A No | L No  A No |   Mortality (%) against clothes moths *Tineola bisselliella*  L= larvae, A= adult  \* clothes moths have a natural life span of around 14  days, which explains the high mortality of adults\*\* visible damage after 14 and 21 days of exposure  Mortality (%) against carpet beetles *Anthrenus flavipes*   |  |  |  | | --- | --- | --- | | Test days | Untreated fabric | Treated fabric | | 7 | L 4  A 6 | L 16  A 78 | | 14 | L 5  A 38 | L 20  A 91 | | 21 | L 7  A 100\*\*\* | L 31  A 100 | | Damage wool D14 | L Yes  A No | L No  A No | | Damage wool D21 | L Yes  A No | L No  A No |   \*\*\*adults carpet beetles have a natural life span of  around 30 days, which explains the high mortality of adults  The product shows complete mortality against adults and larvae of clothes moths *Tineola bisselliella* at the dose 0.061 % in preventive treatment  Regarding carpet beetles *Anthrenus flavipes* complete mortality was achieve against adults and only 31 % on larvae at the dose 0.061 %  This study was considered as a key data | 2 | Linn (2016) BIO151b-16 |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without BEMATIN PER40 | *Ixodes ricinus*  5 nymphs/  replication | WHO Tube test  Test conditions:  Temperature 23 +/-0.5°C  RH 44+/-1.5%  Post monitoring:  Temperature 20 °C  RH 90% | One piece of fabric (12x12.6 cm) is inserted into a standard WHO plastic tube and attached to the inner wall. 5 ticks were transferred simultaneously into the tube using a soft brush. The test individuals were observed through the open end of the tube and the time from placement of the ticks until knock-down was documented.  The exposure time is 27.1 min.  Post monitoring: Mosquitoes are kept in insecticide free air. The mortality is determined after 24 h.  2 replications/ sample  2 samples of fabric were tested:  (a) Untreated and unlaundered fabric  (c) treated with BEMATIN PER 40 (permethrin content **1300 mg/m²**)+ binding agent, laundered 30 times at 60°C, | |  |  |  |  | | --- | --- | --- | --- | | sample | alive | Moribund | Died | | (a) | 98 | 0 | 2 | | (c) | 2 | 46 | 52 |   KD of samples (a) > 27.1  KD (mean) of sample (c) = 16 min and 5 sec  Mortality of sample (a) = 2 %  Mortality of sample (c) = 52 %  The moribund ticks are not considered as died. Therefore, mortality is less than 95 % as required in TNsG PT18 (2012) for this use  This study was considered as a key data | 3 | Dautel, 2017 CHT\_IR\_0117\_01 |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Aedes aegypti*  *Culex quinquefasciatus*  *Anopheles gambiae*  (10 female adults / replication) | WHO Tube test  Test conditions :  Temperature 27 +/-2°C  RH 60-80%  Post monitoring:  Temperature 27+/-2 °C  RH 80+/-10% | A test sample is inserted into a standard WHO plastic tube and fastened in position with two spring-wire clips, in a way that it lines with the inner wall of the tube.  5 mosquitoes are collected into a transfer tube with an aspirator, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 3 min.  Post monitoring: Mosquitoes are kept in insecticide free air. 30 min and one hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  10 replications/ sample  3 samples of fabric were tested:  S1: Untreated fabric  S2: treated with BEMATIN PER 40 (permethrin content **1300 mg/m²**)+ binding agent  (S3): treated with BEMATIN PER 40 (permethrin content **730 mg/m²**)+ binding agent (washed 30 times at 60°C) | Mortality (%) against *Aedes aegypti*   |  |  |  |  | | --- | --- | --- | --- | | sample | Kd (%) at 30 min | Kd (%) at 60 min | Mortality (%) | | S1 (control) | ND\* | 0 | 2 | | S2 | 100 | 100 | 100 | | S3 | 76 | 100 | 100 |   Mortality (%) against *Culex quinquefasciatus*   |  |  |  |  | | --- | --- | --- | --- | | sample | Kd (%) at 30 min | Kd (%) at 60 min | Mortality (%) | | S1 (control) | ND | 0 | 4 | | S2 | 100 | 100 | 100 | | S3 | 48 | 100 | 100 |   Mortality (%) against *Anopheles gambiae*  \*ND: not defined   |  |  |  |  | | --- | --- | --- | --- | | sample | Kd (%) at 30 min | Kd (%) at 60 min | Mortality (%) | | S1 (control) | ND | 0 | 2 | | S2 | 100 | 100 | 100 | | S3 | 40 | 100 | 100 |   The textile treated with Permethrin showed a sufficient efficacy against *Aedes aegypti*, *Culex quinquefasciatus* and *Anopheles gambiae*,(> 90%) at the dose 1300 mg/m² according to the criteria of TNsG PT 18 (2012)  The efficacy remained the same after 30 washes at 60°C on sample treated at the dose 730 mg/m²  This study was considered as a key data | 1 | Serrano  , (2017) 2204/0317 |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | Mosquitoes  *Culex quinquefasciatus*  *Aedes aegypti*  *Anopheles gambiae*  Ticks  *Ixodes ricinus*  *Hyalomma marginatum*  (5 female adults / replication) | WHO cone test  Test conditions:  Temperature 26 +/-1°C  RH 60-80%  Post monitoring:  Temperature 29-31 °C  RH 70-80% | A test sample is inserted into a standard WHO plastic tube and fastened in position with two spring-wire clips, in a way that it lines with the inner wall of the tube.  5 mosquitoes are collected into a transfer tube with an aspirator, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 3 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  10 replications/ sample  8 samples of fabric were tested with 2 references:  **M 4032 BIO**  S1: Untreated fabric  S2: treated with formulation without KONSERVAN P40  S3: treated with all additives and KONSERVAN P40 (permethrin content **1555** mg/m²)  S4: treated KONSERVAN P40 | **M 4032 BIO**  Mortality (%) against *Aedes aegypti*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 2 | | S2 (without KONSERVAN P40) | 0 | 4 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   Mortality (%) against *Culex quinquefasciatus*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 0 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   Mortality (%) against *Anopheles gambiae*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 1 | | S2 (without KONSERVAN P40) | 0 | 2 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 | | 1 | Serrano  , (2016) 2085/0516 |
|  |  |  |  |  | **M 4380 BIO**  S2: treated with formulation without KONSERVAN P40  S3: treated with all additives and KONSERVAN P40 (permethrin content **1555 mg/m²** )  S4: treated with KONSERVAN P40 (permethrin content **1555 mg/m²** ) | Mortality (%) against *Ixodes ricinus*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 0 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   Mortality (%) against *Hyalomma marginatum*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 0 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   **M 4032 BIO**  Mortality (%) against *Aedes aegypti*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 2 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 | |  |  |
|  |  |  |  |  |  | Mortality (%) against *Culex quinquefasciatus*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 1 | | S2 (without KONSERVAN P40) | 0 | 1 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   Mortality (%) against *Anopheles gambiae*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 2 | | S2 (without KONSERVAN P40) | 0 | 12 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   Mortality (%) against *Ixodes ricinus*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 0 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   The textile treated with Permethrin showed a sufficient efficacy against *Aedes aegypti*, *Culex quinquefasciatus* and *Anopheles gambiae*,(> 80%) according to the criteria of TNsG PT 18  This study was considered as a key data |  |  |
|  |  |  |  |  |  | Mortality (%) against *Hyalomma marginatum*   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 0 | | S2 (without KONSERVAN P40) | 0 | 0 | | S3 (with KONSERVAN P40) | 100 | 100 | | S4 (with KONSERVAN P40) | 100 | 100 |   The textile treated with Permethrin showed a sufficient efficacy against mosquitoes *Aedes aegypti*, *Culex quinquefasciatus* and *Anopheles gambiae*,(> 90%) and tickes Ixodes ricinus and Hyalomma marginatum (≥ 95 %) at the dose 1555 mg/m² according to the criteria of TNsG PT 18.  This study was considered as a key data |  |  |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Aedes aegypti*  *Culex quinquefasciatus*  *Anopheles gambiae*  200 mosquitoes/  replication (1 volunteer) | arm-in-cage trial (according to WHO\_HTM\_NTD\_WHOPES\_2009.4)  Test conditions:  *Aedes aegypti* and *Culex quinquefasciatus*  Temperature 25 +/-2°C  RH 65+/-5%  *Anopheles gambiae*  Temperature 32 +/-2°C  RH 75+/-5% | The fabrics were set around the forearms of the volunteers in order to cover all the skin from wrist to  elbow.  One of the forearms, covered by the untreated fabric, was used as a control to demonstrate the attractiveness of arthropods to the volunteer's skin.  The other forearm of the same volunteer was covered by a treated fabric. The subject was positioned standing in front of the cage.  The control arm was inserted into the cage for 5 minutes. The trial was validated only if there are at least 5 bites in less than 1 minute of exposure (as soon as this is done, the untreated forearm is set out of the cage to avoid useless bites).  After validation of the untreated control, the forearm with the treated fabric was inserted into the cage for 5 minutes. The number of bites was recorded.  10 volunteers/sample  3 samples of fabric were tested:  S1: Untreated fabric  S2: treated with BEMATIN PER 40 (content **1300 mg/m²**)+ binding agent  S3: treated with BEMATIN PER 40 (permethrin content **730 mg/m²** )+ binding agent (washed 30 times at 60°C) | *Aedes aegypti*   |  |  |  | | --- | --- | --- | | sample | Mean of landing | Number of bites through | | S1 (control) | > 5\* | > 5 | | S2 treated (unwashed) | 1.6 | 0 | | S3 treated (washed) | 4 | 0 |   *Culex quinquefasciatus*   |  |  |  | | --- | --- | --- | | sample | Mean of landing | Number of bites through | | S1 (control) | > 5 | > 5 | | S2 treated (unwashed) | 2.1 | 0 | | S3 treated (washed) | 2.8 | 0 |   *Anopheles gambiae*   |  |  |  | | --- | --- | --- | | sample | Mean of landing | Number of bites through | | S1 (control) | > 5 | > 5 | | S2 treated (unwashed) | 2 | 0 | | S3 treated (washed) | 4.1 | 0 |   \* The trial was stopped  The treated fabrics have proved a complete protection against bites and a repellent effect with less mosquitoes landing (< 5) on the arms of volunteers  Therefore, the treated fabric has proved a complete protection against the bites of mosquitoes at the dose 1300 mg/m²  The efficacy remained the same after 30 washes at 60°C on sample treated at the dose 730 mg/m²  This study was considered as a key data | 2 | Serrano  , (2017) 2204b/0317 |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Aedes aegypti*  *Culex quinquefasciatus*  *Anopheles gambiae*  200 mosquitoes/  replication (1 volunteer) | arm-in-cage trial (according to WHO\_HTM\_NTD\_WHOPES\_2009.4)  tropical conditions  Test conditions (tropical condition):    Temperature 32 +/-2°C  RH 75+/-5% | The fabrics were set around the forearms of the volunteers in order to cover all the skin from wrist to  elbow.  One of the forearms, covered by the untreated fabric, was used as a control to demonstrate the attractiveness of arthropods to the volunteer's skin.  The other forearm of the same volunteer was covered by a treated fabric. The subject was positioned standing in front of the cage.  The control arm was inserted into the cage for 5 minutes. The trial was validated only if there are at least 5 bites in less than 1 minute of exposure (as soon as this is done, the untreated forearm is set out of the cage to avoid useless bites).  After validation of the untreated control, the forearm with the treated fabric was inserted into the cage for 5 minutes. The number of bites was recorded.  10 volunteers/sample  3 samples of fabric were tested:  1- Untreated fabric  2- treated (permethrin content **1236 mg/m²**),original (unwashed)  3- Treated (permethrin content **493 mg/m²**), washed 30 X60°C | |  |  |  | | --- | --- | --- | | Target species | Sample | Protection (%) | | *Aedes aegypti* | untreated | 0 | | Treated, original | 100 | | Treated, washed 30X60°C | 100 | | *Culex quinquefasciatus* | untreated | 0 | | Treated, original | 100 | | Treated, washed 30X60°C | 100 | | *Anophes gambiae* | untreated | 0 | | Treated, original | 100 | | Treated, washed  30X60°C | 100 |   The treated fabric has proved a complete protection against the bites of mosquitoes at the dose 1236 mg/m²  The efficacy remained the same after 30 washes at 60°C on sample treated at the dose 493 mg/m²  This study was considered as a key data | 2 | Serrano  , (2017) 2178a/0117 |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Ixodes ricinus*  30 nymphs/  sample | Laboratory test  Test conditions : 23+/-0.5°C  RH 60.4+/-3.27% | A drum (brass filled with warm water 38°C) and wrapped in a treated or no treated fabric (control).  The *I. ricinus* nymphs were placed on a horizontal glass rod (diameter 2mm) pointing perpendicularly to the drum and positioned such that the tip of the rod was close to the marked landing line on the fabric.  A small point marked a distance of 1 cm to the tip of the glass rod. The distance between the glass of 1 cm to the tip of the glass rod.  The tick is attracted by the warmth of the drum and changes to the moving surface of the drum. When the attachment site is covered by repellent, the repellent effect can be detected either by (i) a reduced number of ticks approaching the drum, (ii) a reduced number of ticks transferring to the drum.  3 samples of fabric were tested:  A: untreated, original fabric, (unwashed)  W:treated with BEMATIN PER 40 (permethrin content **570 mg/m²** ), washed 30 times at 60°C)  X: treated with BEMATIN PER 40 (permethrin content **570 mg/m²** ) + binding agent ( unwashed) | |  |  |  |  |  | | --- | --- | --- | --- | --- | | sample | Non-repelled | repelled | Absolute repellency (%) | Relative repellency (%) | | A | 27 | 3 | 10 | 0 | | X | 13 | 17 | 56.7 | 51.85 | | W | 16 | 14 | 46.7 | 40.74 |   The samples treated with the product show repellency < 90 %. Therefore the results don’t fulfill requirement of TNsG PT 18 (2012)  This study was considered as a key data | 3 | Dautel, 2017 CHT\_IR\_0207\_01 |
|  |  |  |  |  | It is thus possible to discern between contact repellents and substances acting on short distance.  In the course of a test, the occurrence of certain tick behaviors was recorded using the software package "The Observer XT 12". The following behavioral steps were recorded:  - whether a tick traversed the 1 cm-mark and went to the tip of the rod  - whether a tick would transfer from the tip to the drum  - whether a tick dropped off any stage of the test, particularly in the course of changing to the drum or when staying on the treated surface,  - whether the tick would leave the fabric upwards, downwards, stay put or drop off of it.  - When the tick changed to the drum, the drum was stopped in order to better observe tick behavior.  The maximum time for any tick run was 5 min. If a tick at any step did not continue walking after that time, the run was terminated and the tick was removed.  10 mice/sample |  |  |  |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Ixodes ricinus*  *Hyalomma marginatum*  5 Females adults and 5 nymphs/  replication (1 mice) | Choice test according to OPPTS 810:3700 (2010) method  Test conditions: 25+/-2°C  RH 65+/-5% | The fabrics were set around the mouse in order to cover all the skin available to the ticks.  The mouse was positioned in a net cage (10 cm long, 3 cm diameter) avoiding the movements and allowing the bites but with a protection on the head and eyes of the mouse.  Each mouse was covered by the treated fabric and exposed to the ticks and the experimenter recorded the number of ticks going onto the mouse in comparison with the same trial but with the mice covered by untreated fabric.  With an artist's paintbrush, the experimenter placed a tick, one at a time, near the back part of the cage containing the mouse covered by the treated fabric, at a release point marked 3 cm from the body of the mouse. The tick was oriented gently with a paint brush toward the treated area. After its first movement up the mouse toward the margin for the treated area, each tick was allowed 3 minutes to move across the boundary onto the treated area. A tick that walked these 3 cm and went on the mouse into the treated area or that crawls into the treated area but immediately turns back or falls off was reported as "repelled".3 samples of fabric were tested: | \*A= adult, N= nymphs   |  |  |  | | --- | --- | --- | | Target species | Sample | Protection (%) | | *Ixodes ricinus* | untreated | 0 | | Treated, original | A + N\*100 | | Treated, washed 30X60°C | A 96  N 100 | | *Hyalomma marginatum* | untreated | 0 | | Treated, original | A+N 100 | | Treated, washed 30X60°C | A 94  N 100 |   The treated fabric has proved a complete protection against the bites of ticks at the dose 1236 mg/m²  The efficacy remained the same after 30 washes at 60°C on sample treated at the dose 493 mg/m²  This study was considered as a key data | 2 | Serrano  , (2017) 2178b/0117 |
|  |  |  |  |  | 1-Untreated fabric  2- treated (permethrin content **1236 mg/m²**),  3- Treated (permethrin content **493 mg/m²**),  original (unwashed) washed 30 X60°C |  |  |  |

**For use “vector protection finishes of textiles against mosquitoes and ticks” (use 1)**

* Regarding the claim against mosquitoes, laboratory tests (tubes and cones tests according to WHO methods) and simulated use tests (arm-in-cage tests according to WHO method) were submitted to support this claim. The results of key data fulfill the criteria of TNsG PT 18/19[[9]](#footnote-10) and show the efficacy of the product when applied on textiles (65 % cotton/35 % polyester) at the dose interval 1236-1555 mg/m² on original samples and 493-730 mg/m² on samples washed 30 times at 60°C against mosquito’s genus *Aedes*, *Culex* and *Anopheles*.
* Regarding the use against ticks, laboratory test (cones tests according to WHO method) and choice test (according to OPPTS 810.3700 method) were submitted to support this claim.

The results of key data fulfill the criteria of TNsG PT 18/19 and show the efficacy of the product when applied on textiles (military textile) at the dose interval 1236-1555 on original samples and 493 mg/m² on samples washed 30 times at 60°C against ticks species *Ixodes ricinus* and *Hyalomma marginatum*.

It has to be noted that three tests (two tests from Dautel 2016 and 2017 according to the technical guideline TL 8305-0331 of the German Armed Forces, and one test from Dautel, 2017 using the Moving Object) for the claim against ticks were not acceptable, as mortality or repellency assessed in these tests were < 90 % (for more details, see experiment data table). Nevertheless, the two other tests submitted have been considered sufficient to prove the efficacy of the product against ticks.

**For use “wool protection clothes moths and carpet beetle” (use 2)**

* One laboratory test was submitted (Linn, 2017) against clothes moths *Tineola bisselliella* and carpet beetles *Anthrenus flavipes*. The results show complete efficacy against adults and larvae of clothes moths *Tineola bisselliella*. However, for the claim against carpet beetles *Anthrenus flavipes*, if 100 % of mortality against adults were achieved, only 31 % of mortality is obtained against larvae. Regarding the high mortality for controls, the applicant justified this phenomenon by the short life cycle of clothes moths and carpet beetles.
* According to the criteria of TNsG PT18, at the end of an exposure period, more that 90 % of the adults and larvae should be killed (unless claimed differently). Therefore, based on the results obtained, the efficacy was demonstrated against adults and larvae of cloths months *Tineola bisselliella* and only against adults of carpet beetles *Anthrenus flavipes*, as mortality against larvae was less than 90%.

Therefore, the product KONSERVAN P40 is efficient against clothes moths *Tineola bisselliella* (larvae and adults) and against carpet beetles *Anthrenus flavipes* (adults) in preventive treatment on original textile (without washing).

The effectiveness of the product on washed textile has not been demonstrated therefore it is not guaranteed on a washed textile for this claim.

Additional data were submitted and considered as a supportive data. The supportive data are presented in the annex 3.5.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In accordance with the submitted tests and the requirements of the TNsG on product evaluation for PT18/19 (2012),   * For the use “vector protection finishes of textiles against mosquitoes and ticks”, the product KONSERVAN P40 shows sufficient efficacy against mosquitoes genus (*Aedes*, *Culex* and *Anopheles*) and ticks (*Ixodes ricinus* and *Hylomma marginatum*) when used on textile washed up to 30 times at 60°C. * For the use “wool protection clothes moths and carpet beetle”, the product KONSERVAN P40 shows sufficient efficacy in preventive treatment against clothes moths *Tineola bisselliella* (larvae and adults) and against carpet beetles *Anthrenus flavipes* (adults) on original treated textile (without washing). Efficacy has not been demonstrated for larvae of carpet beetles *Anthrenus flavipes.* |

#### Occurrence of resistance and resistance management

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (*Atkinson et al.,* 1991)[[10]](#footnote-11), house fly (Meyer et al.,1987)[[11]](#footnote-12)), stable fly (Pitzer et al.,2010)[[12]](#footnote-13), *Culex* mosquitos (*Wan* *Norafikah et al*., 2013)[[13]](#footnote-14), *Aedes* mosquitos (*Saavedra-Rodriguez et al.*, 2008)[[14]](#footnote-15), *Anopheles* mosquitos (Corbel et al., 2004)[[15]](#footnote-16) when permethrin has been used as a general insecticide (PT18 use). In general, pyrethroid resistance has been attributed to reduce neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms (see Assessment Report permethrin, PT18, January 2014).

In a study performed in Thailand, some populations of *Aedes aegypti* and *Culex quinquefasciatus* have been found to be resistant against permethrin. Permethrin had been introduced to the relevant region ten years before the study was conducted. Permethrin is among the main insecticides used in controlling vector-borne diseases throughout Thailand. If certain populations of mosquitoes are resistant to DDT, they might become resistant to permethrin as well, as cross-resistance has been observed (Somboon et al., 2003)[[16]](#footnote-17).

*Culex quinquefasciatus* is a model organism for studying resistance due to its inherent ability to resists insecticides. Permethrin induces both killing and avoidance responses in *Culex* mosquitoes. Studies on the resistance of *C. quinquefasciatus* have been conducted for example in the US, India, Malaysia and Thailand. All these studies showed various levels of resistance against permethrin in these populations (Wan-Norafikah et al., 2013).

Additionally, the reason for developing resistance against permethrin is species-dependent. In general it can be said that resistance develops due to uncontrolled use of the insecticide. It has been documented that resistance is occurring due to reduced neural sensitivity due to a specific mutation, enhanced metabolic detoxification of permethrin, and reduced penetration ratio. Other mechanisms are likely to exist but have not been described so far. Additionally, permethrin has been described to be less effective at higher temperatures, especially above 30 °C (Somboon et al., 2003; Wan-Norafikah et al., 2013).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

For use “vector protection finishes of textiles against mosquitoes and ticks”, experimental data demonstrate the efficacy of the product KONSERVAN P40 up to 30 washes at 60°C.

The effectiveness of the product has not been verified when the number of washings exceeds 30 times or temperature of washing is above 60°C.

For use “wool protection clothes moths and carpet beetle”, the effectiveness of the product on a textile which has undergone washing and cleaning tests has not been verified therefore it is not guaranteed on a washed textile.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product KONSERVAN P40 has shown a sufficient efficacy, for the following uses claimed:

* For the use “vector protection finishes of textiles against mosquito’s genus *Culex*, *Aedes* and *Anopheles* and ticks species *Ixodes ricinus* and *Hyalomma marginatum”* on textile treated with 1300 mg permethrin/m² and washed up to 30 times at 60°C.
* For the use“wool protection clothes moths *Tineola bisselliella* (larvae and adults) and carpet beetle *Anthrenus flavipes* (adults)” on original textile (without washing) at the application rate of product is 0.06 % w/w, for preventive treatment. Nevertheless, the control of keratin feeding textile pests is not validated.

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

None

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No data on skin corrosion and irritation has been provided. Consequently, a classification by calculation has been performed. None of the formulants or active substance are classified for skin corrosion and irritation. Therefore, KONSERVAN P40 does not require a classification for this endpoint.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The product is not a skin irritant |
| Justification for the value/conclusion | None of the formulants or active substance are classified for skin corrosion and irritation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Eye irritation***

No data on eye irritation has been provided. Consequently, a classification by calculation has been performed. None of the formulants or active substance are classified for eye irritation. Therefore, KONSERVAN P40 does not require a classification for this endpoint.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The product is not an eye irritant |
| Justification for the value/conclusion | None of the formulants or active substance are classified for eye irritation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Respiratory tract irritation***

No *in vivo/in vitro* respiratory tract irritation test has been performed with KONSERVAN P40 product and no human data are available.

The respiratory tract irritation potential of the biocidal product is therefore assessed by calculation, according to the CLP calculation rules. None of the components are toxicologically relevant for respiratory tract irritation, therefore, no classification is required for the product.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | The product is not an irritant to respiratory tract. |
| Justification for the value/conclusion | None of the formulants or active substance are classified for Respiratory tract irritation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Skin sensitization***

No skin sensitization study performed with KONSERVAN P40 has been submitted.

The classification of the product has been set according to the classification rules of the CLP regulation 1272/2008.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | The product KONSERVAN P40 is a skin sensitizer |
| Justification for the value/conclusion | The content of permethrin in KONSERVAN P40 is of 40% leading to a classification Skin Sens 1 – H317 of the product. |
| Classification of the product according to CLP | Classified according to Regulation (EC) No 1272/2008 (CLP).  **For treated textiles, the following mention is needed: “**Contains Permethrin. May produce an allergic reaction.” |

A LLNA study performed with an extraction of the solution of KONSERVAN P40 used to treat a textile has been submitted in order to assess the skin sensitization potential of treated textiles.

| **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** |
| Local Lymph Node Assay (LLNA) OECD 429  Reliability 2 | Mice CBA/Ca  5 Females/ dose | Extract of treated solution (KONSERVAN P40) in  Ethanol/ water (50/50)  Topical exposure | The SI values for the treated group were in range from 0.85 to 3.10 with mean value of 1.78.  All animals survived throughout the test period without showing any clinical signs. | Only one concentration had been tested (whereas three concentrations are required according to guideline OECD 429). The applied quantity of permethrin on tested treated textile is of 1471 mg/m2 which is higher that the application dose of 1300 mg/m2 claimed by the applicant for KONSERVAN P40. | STUR-00318-BIO  Studt code : 600333410 |

Conclusion

A SI < 1.78 is observed when the extract of the treated solution is tested in a LLNA assay.

The LLNA test was done with the binding agent TOPICOAT MOP NEU (acrylate/polyurethane dispersion). Since KONSERVAN P40 is not intended to be used with a binding agent for non-washable wool, no conclusion could be drawn to assess the skin sensitization potential of treated textiles. Therefore the sentence “Contains Permethrin. May produce an allergic reaction” is applied for treated textiles.

***Respiratory sensitization (ADS)***

No *in vivo*/*in vitro* respiratory sensitization test has been performed with KONSERVAN P40 and no human data are available.

The respiratory sensitization potential of the biocidal product is therefore assessed by calculation, according to the CLP calculation rules.

The biocidal product doesn’t contain any substance classified for respiratory sensitization therefore, no classification is required.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | The product is not a respiratory sensitizer. |
| Justification for the value/conclusion | None of the formulants or active substance are classified for Respiratory sensitisation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

No acute oral toxicity study has been provided. Consequently, the acute oral toxicity of the biocidal product is assessed by calculation, according to the CLP calculation rules.

The active substance (permethrin) is classified for acute oral toxicity ( LD50 of 480 mg/ kg bw according to the CAR of the active substance). The others formulants are not classified for acute oral toxicity. According to the CLP calculation rules, KONSERVAN P40 should be classified for Acute oral toxicity, Cat 4 – H302 Harmful if swallowed.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Classification by calculation |
| Justification for the selected value | The active substance (permethrin) is classified for acute oral toxicity ( LD50 of 480 mg/ kg bw according to the CAR of the active substance). |
| Classification of the product according to CLP | Acute oral toxicity, Cat 4 – H302 Harmful if swallowed. |

*Acute toxicity by inhalation*

No acute inhalation toxicity study has been provided. Consequently, the acute inhalation toxicity of the biocidal product is assessed by calculation, according to the CLP calculation rules.

The active substance (permethrin) is classified for acute inhalation toxicity (LC50 of 2.3 mg/L according to the CAR of the active substance). The others formulants are not classified for acute inhalation toxicity. According to the CLP calculation rules, KONSERVAN P40 should not be classified for acute inhalation toxicity.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Classification by calculation |
| Justification for the selected value | The active substance (permethrin) is classified for acute inhalation toxicity (LC50 of 2.3 mg/L according to the CAR of the active substance). The others formulants are not classified for acute inhalation toxicity. |
| Classification of the product according to CLP and DSD | No classification required |

*Acute toxicity by dermal route*

No acute dermal toxicity study has been provided. Consequently, the acute dermal toxicity of the biocidal product is assessed by calculation, according to the CLP calculation rules.

None of the formulants are classified for acute dermal toxicity. According to the CLP calculation rules, KONSERVAN P40 should not be classified for acute dermal toxicity.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Classification by calculation |
| Justification for the selected value | None of the formulants are classified for acute dermal toxicity. |
| Classification of the product according to CLP | No classification required |

***Information on dermal absorption***

No dermal absorption study has been carried out on the biocidal product.

The applicant proposed to use the dermal absorption value set in the CAR of the active substance. Nevertheless, this bridging is not considered acceptable. Indeed, the dermal absorption value set in the CAR of permethrin is based on a study carried out with the active substance alone. Therefore, the impact of the different formulants present in the product is not taken into account.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value | 25% and 50% |
| Justification for the selected value | 25% : Default value according to the guidance on dermal absorption (EFSA Journal 2012; 10(4):2665), the content of a.s in the product being higher than 5% for the concentrate.  A value of 50 % is retained for the product in textiles based on ECHA opinion 17/06/2021. |

***Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)***

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, KONSERVAN P40 does not contain any substance of concern.

***Available toxicological data relating to a mixture***

No toxicological data for the mixture is available.

#### Exposure assessment

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | Negligible | n.a | n.a | n.a | Yes | Negligible | n.a |
| Dermal | Yes | n.a | n.a | n.a | Yes | Yes | n.a |
| Oral | No | No | n.a | n.a | n.a | Yes | n.a |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Coupling/ decoupling transfer lines | **Primary exposure**  Biocidal product is applied into textiles by dipping/ padding or knife-coating methods.  Dermal exposure can occurs *via* the coupling and decoupling of transfer lines.  Cleaning is automated, and thus, workers exposure is considered negligible. | Professionals |
| 2. | Cutting and sewing textiles | **Secondary exposure**  Dermal and inhalation exposure can occur during the processing of the bulk good in garment factories. Inhalation exposure : textile workers may be exposed to airborne particulates (generated by cutting and sewing of the fabric)  Dermal exposure: textile workers may be exposed during the handling and processing of textiles. | Professionals |
| 3. | Wearing treated garment | **Secondary exposure**  Treated garment is intended to be worn by military, forest workers or during trekking.  A worst-case scenario is represented by the wearing of treated clothes by adults and children.  Exposure via inhalation route is considered negligible (because of its low vapour pressure). | Adults and children |
| 4. | Crawling on treated carpet | **Secondary exposure**  Infant can be exposed while crawling on treated carpets. | Children (infant) |

***Industrial exposure - primary exposure***

*Scenario [1] Coupling/decoupling transfer lines*

| **Description of Scenario [1]** | | | | |
| --- | --- | --- | --- | --- |
| Biocidal product is applied into textiles by dipping/ padding or knife-coating methods.  Dermal exposure can occur *via* the coupling and decoupling of transfer lines (resulting from accidental touching of contaminated surfaces).  Cleaning is automated, and thus, workers exposure is considered negligible.  No specific model exists for the loading scenario, however, the use of RISKOFDERM is suggested by the HEEG opinion 1.  The potential hand exposure has been calculated using RISKOFDERM.  The 75th percentile distribution of exposure is adopted. The assumed use rate is 100L/min, meaning that 1 m3 of biocidal product can be emptied within 10 minutes. This represents a worst-case flow rate.  The total duration of this task is assumed to be 10 min/day in accordance with the Guidance for Human Health Risk Assessment (Vol3, Part B, Chapter 3). | | | | |
|  | **Parameters** | **Value** | **Unit** | **Reference** |
|  | Dermal exposure | | | |
| Tier 1 | AS content (technical) on textile | 43 | % | Applicant’s data |
| Potential hand exposure | 75 | mg product/ shift | RISKOFDERM |
| Body weight | 60 | kg | HEAD Hoc Recommendation N°14 |
| Active substance dermal absorption | 25 | % | Default value (EFSA, 2012) |
| No PPE, clothing penetration | 100 | % | - |
| Tier 2 | PPE, gloves penetration factor | 10 | % | HEEG opinion 9 |

***Calculations for Scenario [1]***

| **Summary table: estimated exposure from industrial uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/ kg bw/d)** |
| Coupling/ decoupling transfer lines | Tier 1/no PPE | Negligible | 1.34 x 10-1 | - | 1.34 x 10-1 |
| Tier 2/ gloves : 90% of protection | Negligible | 1.34 x 10-2 | - | 1.34 x 10-2 |

***Further information and considerations on scenario [1]***

*Not relevant*

***Secondary exposure***

*Scenario [2] Cutting and sewing textiles*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [2]** | | | | |
| Dermal and inhalation exposure can occur during the processing of the bulk good in garment factories.  Inhalation exposure :  Textile workers may be exposed to airborne particulates (generated by cutting and sewing of the fabric). The textile dust, generated by cutting and sewing of the fabric, is considered a carrier of permethrin and thus, inhalation exposure to the a.s needs to be estimated. No appropriate model exists to estimate the inhalation exposure of a professional working in textile processing industries.  Therefore, maximum exposure limit (MEL)from UK has been taken into account, *i.e* a value of **10 mg/m3 for wool dust**.  Dermal exposure and migration rates :  Textile workers may be exposed during the handling and processing of treated textiles.  No experimental data on migration of permethrin out of the textile is available. values have been discussed and agreed in the BPC Opinion on 17/06/2021 | | | | |
|  | **Parameters** | **Value** | **Unit** | **Reference** |
| Tier 1 | Inhalation rate | 1.25 | m3/h | HEEG 17 |
| Exposure duration | 8 | h |  |
| Dust concentration | 10 | mg/m3 | UK value for wool dust |
| AS content on textile | 1.3 | g/m2 |  |
| Textile’s area density | 170 | g/m2 | efficacy studies |
| Inhalation absorption | 100 | % |  |
| Body weight | 60 | kg | HEADHoc Recommendation N°14 |
| Migration rate | 1 | % | ECHA opinion 17/06/2021 |
| Exposed body area (palms and back of both hands and lower arms) | 1.9488 | m2 | HEADHoc Recommendation N°14 |
| Dermal absorption | 50 | % | ECHA opinion 17/06/2021 |

**Calculations for Scenario [2]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake**  **(mg/ kg bw/ d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | 1.27 x 10-2 | 1.06 x 10-1 | - | 1.18 x 10-1 |
| Scenario [2] | Tier2 / PPE: gloves |  |  |  | 2.23 x 10-2 |

**Further information and considerations on scenario [2]**

*Not relevant*

*Combined scenarios*

*Not relevant*

***Professional exposure***

*Only industrial application is claimed.*

***Non-professional exposure***

*Not relevant the product is only for professional use.*

***Exposure of the general public - secondary exposure***

*Scenario [3] Wearing treated garment*

| **Description of Scenario [3]** | | | | |
| --- | --- | --- | --- | --- |
| Treated garment is intended to be worn by military, forest workers or during trekking.  A worst-case scenario is represented by the wearing of treated clothes by adults and children.  It is considered that trunk, arms and legs are covered.  As the age to which children can use treated clothes for trekking is unknown, it is considered that children about 2 to 5 years old represent a worst case. Calculations have also been made for toddlers and infants (see ECHA opinion 17/06/2021 in Annex).  The migration rate used comes from ECHA opinion on 17/06/2021 (see Annex 3.7). | | | | |
|  | **Parameters** | **Value** | **Unit** | **Reference** |
| Tier 1 | AS content on textile | 1300 | mg/m² | Applicant data |
| Migration rate | 1 | % | ECHA opinion on 17/06/2021 |
| Dermal absorption | 50 | % | Efsa Default value (2012) |
| Adult Body weight | 60 | kg | HEADHoc Recommendation N°14 |
| Adult skin area in contact with treated clothes (trunk, arms and legs) | 1.354 | m² |
| Children (2-5 years) body weight | 15.6 | kg |
| Children (2-5 years) skin area in contact with treated clothes (trunk, arms and legs) | 0.5516 | m² |

**Calculations for Scenario [3]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] adults | Tier 1/no PPE | Negligible | 1.47x 10-1 | - | 1.47x 10-1 |
| Scenario [3] children | Tier 1/no PPE | Negligible | 2.30 x 10-1 | - | 2.30 x 10-1 |

**Further information and considerations on scenario [3]**

*Not relevant*

*Scenario [4] infant crawling on treated carpet*

| **Description of Scenario [4]** | | | | |
| --- | --- | --- | --- | --- |
| The infant can be dermally and orally exposed will playing on a treated carpet.  The rubbing off model from ConsExpo is used with the revised TC value from Headhoc recommendation 12.  The recommendation 12 proposes a TC value of 0.2 m²/h for an infant >6 to 12 months.  The same dislodgeable faction 0.1% as for treated clothing is used based on the BFR report.  It is assumed that the carpet contains 2.5 kg wool/m² (value from the CAR on permethrin), therefore an application dose of **645 mg/m²** can be calculated. | | | | |
|  | **Parameters** | **Value** | **Unit** | **Reference** |
| Tier 1 | AS content on textile | 645 | mg/m² | Applicant data |
| Migration rate | 0.5 | % | ECHA opinion on 17/06/2021 |
| Dermal absorption | 50 | % | ECHA opinion on 17/06/2021 |
| Infant body weight | 8 | kg | HEADHoc Recommendation N°14 |
| Transfer coefficient from treated carpet to skin | 0.2 | m²/h | HEADHoc Recommendation N°12 |
| Transfer from skin to mouth | 10% | - | Consexpo |
| Oral absorption | 100% | - | Permethrin CAR |

**Calculations for Scenario [4]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] infant | Tier 1/no PPE | Negligible | 4.43 x 10-2 | 1.61 x 10-3 | 4.43 x 10-2 |

**Further information and considerations on scenario [4]**

*Not relevant*

*Combined scenarios*

*Not relevant*

***Monitoring data***

*Not relevant*

***Dietary exposure***

No exposure to residues in food is awaited based on the intended uses. Then, no assessment has been performed.

*Information of non-biocidal use of the active substance*

Residue definitions

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Residue definition -** |
| 1. | Plant protection product | Not approved | Permethrin (sum of isomers) -MRL (Reg. (EU) 2017/623) |
| 2. | Veterinary use | Antiparasitic agent on bovine | Permethrin (sum of isomers) -MRL (Reg (EU) 37/2010 |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

*Not relevant*

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

*Not relevant*

***Exposure associated with production, formulation and disposal of the biocidal product***

*Not relevant*

***Aggregated exposure***

*Not relevant*

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| 1. Coupling/ decoupling transfer lines | **Professionals** | Tier 1/ No PPE | 1.34 x 10-1 |
| Tier 2/ Gloves | 1.34 x 10-2 |
| 2. Cutting and sewing textiles | **Professionals** | Tier 1/ No PPE | 1.18 x 10-1 |
| 3. Wearing treated garment | **Adults** | Tier 1/ No PPE | 1.47 x 10-1 |
| 3. Wearing treated garment | **child (2-5y)** | Tier 1/ No PPE | 2.30 x 10-1 |
| 4. Crawling on treated carpet | **Infant** | Tier 1/ No PPE | 4.43 x 10-2 |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value**  **(mg/kg bw/d)** |
| AELshort-term | 2-year rat toxicity study | NOAEL = 50 mg/kg bw/d | 100 | No | 0.5 |
| AELmedium-term/long-term | 1-year dog chronic toxicity study | NOAEL = 5 mg/kg bw/d | 100 | No | 0.05 |
| ARfD | 2-year rat toxicity study | NOAEL = 50 mg/kg bw/d | 100 | No | 0.5 |
| ADI | 1-year dog study | NOAEL = 5 mg/kg bw/d | 100 | No | 0.05 |

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| MRL | EU Reg. 396/2005 (PPP) | All commodities | Cf: Reg. (EU) 2017/623 |
| EU Reg. 470/2009 (VMP) | Food of animal origin (bovine) | Cf: Reg (EU) 37/2010 |

PPP: plant protection product

VMP: veterinary medicinal product

Since no residue in food is awaited regarding the intended uses, the existing MRLs are no expected to be exceeded.

***Risk for industrial users***

**Systemic effects**

* ***Scenario [1] Coupling / decoupling transfer lines***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 1  (Coupling/ decoupling transfer lines) | Tier 1/ No PPE | 0.05 | 1.34 x 10-1 | 269 | No |
| Tier 2/ Gloves | 0.05 | 1.34 x 10-2 | 27 | Yes |

**Local effects**

According to the guidance on the BPR for human health[[17]](#footnote-18), a qualitative local risk assessment is performed, since KONSERVAN is classified H317:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Medium high | Skin Sens. 1, H317 | - | 18 | Industrial users | Loading of the concentrate product | Dermal | More than few minutes but equal to or less than few hours per day | Sources for contamination being from:  - splashes;  - hand | **RMM Technics**  - Very high level of containment required, except for short term exposures e.g. taking samples;  - Design closed system to allow for easy maintenance;  - If possible keep equipment under negative pressure;  - Regular cleaning of equipment and work area.  **RMM Organisation**  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene  **PPE**  - All skin and mucous membranes with potential  exposure protected with appropriate PPE | Exposure must be limited during application of the product by means of appropriate PPE and RMM **(see conclusion below).** |

**Conclusion**

The risk is acceptable for industrial users when PPE (gloves with 90% of protection, coverall) are worn. The following RMMs are proposed to exclude post-application exposure:

* The product may only be loaded with an automatic dosing system.
* The textile treatment process (application and post-application) has to be an automated process, without direct contact by the workers.
* Avoid contact to freshly treated textiles.
* ***Scenario [2] Cutting and sewing textiles***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 2  (Cutting and sewing textiles) | Tier 1/no PPE | 0.05 | 0.118 | 237 | no |
| Scenario 2  (Cutting and sewing textiles) | Tier 2/gloves | 0.05 | 0.0233 | 46 | yes |

**Local effects**

Treated textiles are not classified, therefore no qualitative risk assessment is needed.

**Conclusion**

The risk is acceptable for professional cutting and sewing treated textiles*.*

***Risk for non-professional users***

*Not applicable*

***Risk for the general public***

* ***Scenario [3] Wearing treated garment***

**Assessment based on model estimation**

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 3 - Adults  (Wearing treated garment) | Tier 1/no PPE | 0.05 | 1.47 x 10-1 | 293 | No |
| Scenario 3 - children  (Wearing treated garment) | Tier 1/no PPE | 0.05 | 2.30 x 10-1 | 460 | No |

**Local effects**

Treated textiles are not classified, therefore no qualitative risk assessment is needed.

**Conclusion based on model estimations**

Based on calculation models, the risk is not acceptable for adults and children wearing treated tissues.

**Assessment based on biomonitoring studies**

In the BPC opinion on questions on unresolved objections during the mutual recognition procedure of the PT 18 biocidal product Konservan P 40 containing permethrin (17/06/2021), the assessment of the risk for people waring treated garment has been refined for some specific part of the population, i.e. for adults wearing treated clothing in the frame of profession in army and forestry.

Details of the assessment are given in the opinion in Annex. It is concluded that

“Biomonitoring data is considered to allow a realistic and more reliable risk assessment than modelling estimations with default values for the risk characterisation of the product Konservan P 40 in treated clothing.

Therefore, **the approval of Konservan P 40 for the use in clothing is supported** based on biomonitoring data with uncertainty analysis and Risk Mitigation Measure: Do not use for manufacturing of clothing intended for the general public.”

* ***Scenario [4] infant crawling on treated carpet***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 4 - infant crawling | Tier 1/no PPE | 0.05 | 4.43 x 10-1 | 89 | No |

**Local effects**

Treated textiles are not classified, therefore no qualitative risk assessment is needed.

**Conclusion**

The risk is acceptable for infant crawling on treated carpets.

**Conclusion for ECHA BPC opinion 17/06/2021 on the risk for general public (scénario [3] and 4)**

“ • The use of Konservan P 40 in wool carpets **is acceptable** based on model calculations of exposure. **The conditions of Article 19(1)(b)(iii) are met for this use.**

• Based on model calculation safe use of Konservan P 40 in clothing could not be identified, while the use in clothing **is supported** based on biomonitoring data with uncertainty analysis and Risk Mitigation Measure: Do not use for manufacturing of clothing intended for the general public. **The conditions of Article 19(1)(b)(iii) are met for this use.”**

***Risk for consumers via residues in food***

No exposure to residues in food is awaited based on the intended uses. Then, no assessment has been performed.

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

*Not relevant*

### Risk assessment for animal health

For dogs, a NOAEL of 10 mg/kg bw/day has been established in a 6-month dog study based particularly on increased liver weight at 50 and 250 mg/kg/day (CAR Permethrin, 2014). It could be considered that the risk assessment is covered by infants crawling on treated carpets considering a safety factor of 100.

It is known that cats are more sensitive to pyrethroids, but there is currently no agreed guidance for a quantitative risk assessment for animals and no appropriate value to perform such risk assessment. Awaiting harmonized guidance, risk assessment could not be performed.

### Risk assessment for the environment

|  |
| --- |
| Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes.** |

Permethrin is used as an active substance (AS) with an insecticidal action (product type (PT) 18). The following environmental exposure and risk assessment was conducted for the biocidal product (BP) KONSERVAN® P 40 used for vector protection finishes of textiles and wool protection.

No additional studies regarding ecotoxicity and environmental fate for the biocidal product have been performed. However, a washing test with the treated textile has been performed.

#### Effects assessment on the environment

An overview for the PNECs for the active substance Permethrin is given in the table below:

|  |  |
| --- | --- |
| **Compartment** | **PNEC (permethrin)** |
| STP microorganisms | 4.95 µg/l |
| Surface water | 0.00047 µg/l |
| Sediment | 0.217 µg/kg wwt |
| Soil | 87.6 µg/kg wwt |

|  |  |
| --- | --- |
| **Compartment** | **PNEC (DCVA)** |
| STP microorganisms | Not available |
| Surface water | 15 µg/l |
| Sediment | 12 µg/kg wwt |
| Soil | 4600 µg/kg wwt |

|  |  |
| --- | --- |
| **Compartment** | **PNEC (PBA)** |
| STP microorganisms | Not available |
| Surface water | >10 µg/l |
| Sediment | 9 µg/kg wwt |
| Soil | 1440 µg/kg wwt |

In the Assessment Report for Permethrin PT 18 the following information is given (p. 41):

“The log Kow of Permethrin was calculated as 4.67: 99% technical a.s. 25:75 indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. The Bioconcentration factors recorded in a 28 day bioconcentration study with permethrin in Bluegill sunfish measured 500-570 L/kg. Data obtained during the subsequent depuration phase indicate removal of residues from whole fish, with time to 50% depuration of 4.7 days.

PECoral,predator/PNECoral ratios determined for fish-eating mammals and birds (2 x 10-6 and

1.4 x 10-5 respectively) and for earthworm eating mammals and birds (8.3 x 10-6 and 6 x 10-5, respectively) indicate that there is no risk of secondary poisoning following the appropriate use of Permethrin. The calculated PECoral,predator/PNECoral ratios showed no risk of metabolite poisoning for aquatic or terrestrial organisms.

The rapid rate of depuration demonstrates that, in practice, any Permethrin taken up by aquatic or terrestrial organism will be rapidly eliminated once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning.”

The risk assessment below was calculated using a PNECmicroorganisms of 0.00495 mg/L. This PNEC was agreed on during the evaluation of the active substance. Due to the low water solubility and the fact that no toxicity on microorganisms could be observed in the submitted studies, water solubility was chosen as PNECmicroorganisms. Yet, we question this approach. According to the official published list of endpoints permethrin showed no effect on microorganisms in concentrations above 0.42 mg/L which is about 100x higher than the water solubility. In our understanding permethrin cannot show a negative effect on microorganisms present in the STP at water solubility. The permethrin concentration in the water can thus never reach levels where negative effects on microorganisms are found because permethrin is only bioavailable up to 0.00495 mg/L, a concentration where it does not harm microorganisms.

|  |
| --- |
| **Infobox 1 - FR CA position**  We are in agreement with the PNEC values proposed. |

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 2 - FR CA position**  No new data is available.   |  |  | | --- | --- | | **Classification of the Active Substance Permethrin** | | | Value/conclusion | Very toxic to aquatic life  Very toxic to aquatic life with long-lasting effects | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest acute ecotoxicity endpoint (48h): EC50 1.27E-03 mg/L and the lowest chronic ecotoxicity endpoint (21d): NOEC4.7E-06 mg/L. | | Classification of the product according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR:  Aquatic Acute 1; H400; M = 100  Aquatic Chronic 1, H410, M = 10000 |  |  |  | | --- | --- | | **Classification of the Product Konservan P40** | | | Value/conclusion | Aquatic Acute Cat 1; H400  Aquatic Chronic Cat 1; H410 | |

No additional ecotoxicological data is available on the biocidal product.

***Further Ecotoxicological studies***

|  |
| --- |
| **Infobox 3 - FR CA position**  No new data is available. |

No additional ecotoxicological data is available on the biocidal product.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

|  |
| --- |
| **Infobox 4 - FR CA position**  No new data is available. |

No additional ecotoxicological data is available on the biocidal product.

***Supervised trials to assess risks to non-target organisms under field conditions***

|  |
| --- |
| **Infobox 5 - FR CA position**  No new data is available. |

No additional ecotoxicological data is available on the biocidal product.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

|  |
| --- |
| **Infobox 6 - FR CA position**  No new data is available. |

No additional ecotoxicological data is available on the biocidal product.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

|  |
| --- |
| **Infobox 7 - FR CA position**  No new data is available. |

No additional ecotoxicological data is available on the biocidal product.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

|  |
| --- |
| **Infobox 8 - FR CA position**  See infobox 18. |

***Further studies on fate and behaviour in the environment (ADS)***

|  |
| --- |
| **Infobox 9 - FR CA position**  No new data is available. |

No additional data on fate and behaviour is available on the biocidal product.

***Leaching behaviour (ADS)***

A new washing test was conducted by Thor SARL in January 2017.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 10 - FR CA position**  A washing test was used by the applicant in order to evaluate the emission of permethrin during the service life of article treated with KONSERVAN P40. Data used in the environmental assessment are presented below:   |  |  |  | | --- | --- | --- | | **Data used to determine the release of permethrin during the service life** | | | | Sampling time | Permethrin quantity extracted from the washed textile (mg/m2) | Percentage of permethrin release | | Before washing | 1236 | - | | After 1 washing | 1041 | 15.7% | | After 10 washings | 717 | 41.9% | | After 20 washings | 599 | 51.5% | | After 30 washings | 493 | 60.1% |   The value of 60.1% release after 30 washings is used in the risk assessment of treated article service life as representative of emission during 1 year.  It should be noted that these proposed values are not completely reliable. Indeed, the provided report is incomplete; no information is available concerning test conditions, replicates, measurement techniques and detection limits in order to evaluate the quality of the study. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 11 - FR CA position**  A test of residual permethrin quantity in liquors after treatment with sodium sulfate (flocculation) was proposed by the applicant in order to evaluate the emission of permethrin to wastewater of factories using KONSERVAN P40. The composition of the analysis solution is presented below.   |  |  | | --- | --- | | **The base formulation of liquor tested** | | | Product | Quantity (g/L) | | KOLLASOL CDO | 1 | | LAVOTAN SE | 3 | | NEUTRACID NVM 200 | 2 | | ARRISTAN PEB | 80 | | KONSERVAN P40 | 36 | | ARRISTAN PIC | 20 |   According to the provided study, this formulation was mixed with sodium sulfate in the ratio 10:1. This mixture was left for 12 hours, and then filtered.  The quantification of permethrin in the liquor tested and in the filtrate (post flocculation) is shown below.   |  |  | | --- | --- | | **Quantification of permethrin** | | | Compartment measured | Quantity (g/L) | | Liquor tested (before flocculation) | 14.4 | | Filtrate solution (post flocculation) | 0.2 |   Finally, the proposed conclusion is that 98.6% of the permethrin were removed with the flocculation treatment.  As in the previous test presented above (see infobox 10), the provided report is incomplete: no data is available on products presented in the liquor tested (except for the KONSERVAN P40). No information is available concerning test conditions, replicates, measurement techniques and detection limits in order to evaluate the quality of the study.  In this context, the environmental risk assessment cannot be only based on these data. So, scenarios and default values from ESD PT9 & 18 and /or ESD PT19[[18]](#footnote-19) are provided in the following assessment to compare and contrast the different approaches.  Furthermore, data from the document “Best Available Techniques for the Textiles Industry” [[19]](#footnote-20) are compared with the applicant study.  The following table adapted from the Reference Document on Best Available Techniques for the Textiles Industry compares the effluent before and after different flocculation treatments implementing in different mills for synthetic pyrethroids.   |  |  |  | | --- | --- | --- | | **Performance of effluent treatment plants** | | | | Mills | Treatment type | Removal rate (%) of synthetic pyrethroids | | 1 | Continuous flocculation with iron | 94 | | 2 | Continuous flocculation with acid | 40 | | 3 | Batchwise flocculation with iron | 71 | | 4 | Continuous flocculation | 94 | | 5 | Continuous flocculation with iron | 74 | | 6 | Hot batchwise flocculation | 89 |   According to these results, flocculation treatments present a wide range of removal rate of synthetic pyrethroids. In fact, a continuous flocculation treatment can remove 40% of pyrethroids whereas continuous flocculation with iron can reach 94%. Moreover, for the same treatment the removal rates of synthetic pyrethroids vary widely from mill to mill. In fact, for continuous flocculation with iron, the removal rate of synthetic pyrethroids is 94 % in mill 1 and only 74% in mill 5. Such difference of 20% in treatment efficiency is significant and must be taken into consideration in a proposal of removal rate of synthetic substances. |

***Testing for distribution and dissipation in soil (ADS)***

|  |
| --- |
| **Infobox 12 - FR CA position**  No new data is available. |

No additional data on fate and behaviour is available on the biocidal product.

***Testing for distribution and dissipation in water and sediment (ADS)***

|  |
| --- |
| **Infobox 13 - FR CA position**  No new data is available. |

No additional data on fate and behaviour is available on the biocidal product.

***Testing for distribution and dissipation in air (ADS)***

|  |
| --- |
| **Infobox 14 - FR CA position**  No new data is available. |

No additional data on fate and behaviour is available on the biocidal product.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

|  |
| --- |
| **Infobox 15 - FR CA position**  No new data is available. |

The biocidal product will only be used indoors.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

|  |
| --- |
| **Infobox 16 - FR CA position**  No new data is available. |

The biocidal product will only be used indoors.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | **Use 1: Vector protection finishes of textiles**  Military uniforms  Scenario 1: Use/application step  Scenario 2: Service life step  Forestry clothing  Scenario 1: Use/application step  Scenario 2: Service life step  **Use 2: Wool protection**  Scenario 1: Use/application step  Scenario 2: Service life step |
| ESD(s) used | Emission Scenario Document for Biocides used as preservatives in the textile processing industry (Product Type 9 & 18), May 2001 |
| Approach | **Use 1: Vector protection finishes of textiles**  Military uniforms  Scenario 1: Average consumption based (Tier 1)  Tonnage based (Tier 2)  Scenario 2: Average consumption based  Forestry clothing  Scenario 1: Average consumption based  Scenario 2: Average consumption based  **Use 2: Wool protection**  Scenario 1: Average consumption based  Scenario 2: Tonnage based |
| Distribution in the environment | Calculations based on Guidance on BPR Volume IV Environment –Part B Risk Assessment (active substance) (April 2015) |
| Groundwater simulation | Guidance on the Biocidal Products Regulation  Volume IV Environment –Part B Risk Assessment (active substances) (Version 1.0, April 2015) |
| Confidential Annexes | *NO* |
| Life cycle steps assessed | **Use 1: Vector protection finishes of textiles**  Military uniforms  Production: No  Formulation: No  Use: Yes, formulation of the biocidal product into the textile (Scenario 1)  Service life: Yes, washing of treated article (Scenario 2)  Forestry clothing  Production: No  Formulation: No  Use: Yes, formulation of the biocidal product into the textile (Scenario 1)  Service life: Yes, washing of treated article (Scenario 2)  **Use 2: Wool protection**  Production: No  Formulation: No  Use: Yes, formulation of the biocidal product into the textile (Scenario 1)  Service life: Yes, washing of several treated articles (Scenario 2) |
| Remarks |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 17 - FR CA position**  **General information**   |  |  | | --- | --- | | Assessed PT | PT 18 | | Assessed scenarios | KONSERVAN P40 is a biocidal product containing 43% (technical content) of Permethrin as active substance. Due to a misunderstanding with the applicant, the calculations below were carried out with a concentration of 40% of permethrin in the product. However, since all uses already present unacceptable risks (see the Overall conclusion on the risk assessment for the environment, Infobox 35), the calculations have not been updated.  Two intended uses are claimed for the biocidal product KONSERVAN P40.   * The use 1 is a vector protection finishes of textiles. The objective pursued is to protect the wearer of the treated textiles from being bitten by insects and ticks. Typical treated articles are tropical uniforms (armed forces), workwear (forest workers), hunting clothes, trekking clothing. * The use 2 is a wool protection against textile-attacking insects. The aim is to control keratin feeding textile pests. Typical treated articles are wool textile fibres for use in the manufacturing of non-washable home textiles (sofa\*, carpets, rugs) or insulating material.   During the industrial application, KONSERVAN P40 is manipulated by industry professionals. The biocidal product is added into a bath for a padding process to stay on the surface of the treated textile (for the use 1) or is added to the dyeing bath with other auxiliaries (for the use 2).  For the emission calculations, the release of permethrin from the KONSERVAN P40 has been determined during the application step and the service life of the treated articles.  For the use 1, two types of clothing are considered in the environmental assessment as proposed by the applicant.   * The military uniform presents a quantity of permethrin of 1300 mg/m2 of treated textile. The treated fabric is a cotton polyester mix with a surface weight of 160 g/m2. * The forestry clothing presents a permethrin content of 200 mg/m2 of treated textile. The surface weight of the textile used for forestry clothing is about 220 g/m2. | | ESD(s) used | The environmental risk assessment has been performed considering equations and default values from “Emission scenario document for biocides used as preservatives in the textile processing industry (Product type 9 & 18)” (May, 2001) and from Emission Scenario Document for Product Type 19 - Repellents and attractants (May, 2015). Information from the OECD ESD on textile finishing industry (ENV/JM/MONO(2004)12) and the Prevention, Integrated Pollution. "Control (IPPC) Reference Document on Best Available Techniques for the Textiles Industry." European Commission (2003) were also used to support the assessment. | | Approach | Tonnage and average consumption approaches | | Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015 | | Confidential Annexes | No | | Life cycle steps assessed | Releases to the environment can take place from the following steps:   * Application step   During the application, a part of permethrin unfixed to the treated articles is released toward the wastewater treatment plant of the textile factory. Furthermore, a partial elimination of permethrin from wastewater by flocculation reactions with sodium sulfate is contemplated in the proposed assessments.   * Service life step   Indirect release to the environment via sewage treatment plant occurs by the washing of the treated textile articles.  To conclude, 6 scenarios are proposed for the environmental risk assessment:   * Scenario 1: For the vector protection finishes of textiles (use 1), during the application step on military uniforms (consumption approach and tonnage approach). * Scenario 2: For the vector protection finishes of textiles (use 1), during the service life of military uniforms (tonnage approach and average consumption approach). * Scenario 3: For the vector protection finishes of textiles (use 1), during the application step on forestry clothing (consumption approach). * Scenario 4: For the vector protection finishes of textiles (use 1), during the service life of forestry clothing (average consumption approach). * Scenario 5: For the wool protection (use 2), during the application step on treated articles (consumption approach). * Scenario 6: For the wool protection (use 2), during the service life of treated articles (worst case tonnage approach and refined tonnage approach). | | Remarks |  | |

The use of the product on sofas has been dropped by the applicant in the frame of the European peer review.

#### Fate and distribution in exposed environmental compartments

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Use 1 Military Scenario 1 Tier 1 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 1 Military Scenario 1 Tier 2 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 1 Military Scenario 2 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 1 Forestry Scenario 1 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 1 Forestry Scenario 2 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 2 Scenario 1 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |
| Use 2 Scenario 2 | Yes | Yes | Not relevant | Not relevant | Yes | Not relevant | Yes | Yes |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment (Permethrin)** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 391.29 | g/mol |  |
| Vapour pressure (at 20°C) | 2.155 x 10-6 | Pa |  |
| Water solubility (at 20°C) | <0.0049  5 | mg/l |  |
| Log Octanol/water partition coefficient | 4.67 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 70003.4 | l/kg |  |
| Henry’s Law Constant (at 25°C) | >0.045 | Pa/m3/mol |  |
| Biodegradability | Not readily biodegradable |  |  |
| Aquatic first order degradation constant | 0.0007291 | h-1 |  |
| DT50 for biodegradation in water- sediment systems | 39.7 | d (at 12ºC) |  |
| DT50 for degradation in soil | 106 | d (at 12ºC) |  |
| DT50 for degradation in air | 0.0701 | d |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment (Metabolite DCVA)** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 209.07 | g/mol |  |
| Vapour pressure (at 20°C) | 0.260 | Pa | Source: Lanxess |
| Water solubility (at 20°C) | 127.6 | mg/l | Source: Lanxess |
| Organic carbon/water partition coefficient (Koc) | 188.53 | l/kg | Source: Lanxess |
| DT50 for biodegradation in water- sediment systems | 49.8 | d (at 12ºC) | Source: Lanxess |
| DT50 for degradation in soil | 175 | d (at 12ºC) | Source: Lanxess |
| Maximum percentage in water | 62.6 | % | Source: Lanxess |
| Maximum percentage in sediment | 21.7 | % | Source: Lanxess |
| Maximum percentage in soil | 11.3 | % | Source: Lanxess |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment (Metabolite PBA)** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 214.22 | g/mol |  |
| Vapour pressure (at 20°C) | 0.000421 | Pa | Source: Lanxess |
| Water solubility (at 20°C) | 16.91 | mg/l | Source: Lanxess |
| Organic carbon/water partition coefficient (Koc) | 37.55 | l/kg | Source: Lanxess |
| DT50 for biodegradation in water- sediment systems | 61.8 | d (at 12ºC) | Source: Lanxess |
| DT50 for degradation in soil | 2.5 | d (at 12ºC) | Source: Lanxess |
| Maximum percentage in water | 28.8 | % | Source: Lanxess |
| Maximum percentage in sediment | 16.4 | % | Source: Lanxess |
| Maximum percentage in soil | 15 | % | Source: Lanxess |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP (Permethrin)** | | | |
| Compartment | Percentage [%] | | Remarks |
| Use 1: Military uniforms Scenario 1  Use 1: Forestry clothing Scenario 1+2  Use 2: Scenario 1+2 | Use 1  Military uniforms Scenario 2 |
| Air | 0.009689 | 0.01075 |  |
| Water | 10.4 | 10.38 |  |
| Sludge | 28.95 | 28.9 |  |
| Degraded in STP | 0.04576 | 0.1141 |  |

The distribution in the STP was calculated using Simple Treat 4.0 by RIVM (Output tables are presented in Annex 2.2).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 18 - FR CA position**   | **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | --- | --- | --- | --- | --- | --- | --- | |  | STP | Freshwater | Freshwater sediment | Air | Soil | Groundwater | | Scenario1 | ++ | + | + | - | + | + | | Scenario 2 | ++ | + | + | - | + | + | | Scenario 3 | ++ | + | + | - | + | + | | Scenario 4 | ++ | + | + | - | + | + | | Scenario 5 | ++ | + | + | - | + | + | | Scenario 6 | ++ | + | + | - | + | + |   **Active substance: Permethrin**   |  |  |  | | --- | --- | --- | | **Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)** | | | | Input | Value | Unit | | **Permethrin** | | | | CAS number | 52645-53-1 | - | | Molecular weight | 391.29 | g.mol-1 | | Vapour pressure (at 20°C) | 2.16E-06 | Pa | | Water solubility (at 20°C) | 4.95E-03 | mg.L-1 | | Partition coefficient (log POW) (pH 7) | 4.67 | Log 10 | | Biodegradability | Not Ready biodegradable |  | | Degradation in soil (DT50) (at 12°C) | 106 | days | | Adsorption / desorption Koc | 26930 | L.kg-1 | | BCF fish | 570 | L.kg-1 | | BMF fish | 1 | - | | BCF earthworms | 15108 | L.kg-1 | | **Metabolites** | | | | **DCVA** | | | | Molecular weight | 209.07 | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 175 | days | | Max. % occurrence water | 62.6 | % | | Max. % occurrence soil | 11.3 | % | | Koc | 188.53 | L.kg-1 | | **PBA** | | | | Molecular weight | 214.22 | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 2.5 | days | | Max. % occurrence water | 28.8 | % | | Max. % occurrence soil | 15 | % | | Koc | 37.55 | L.kg-1 |  |  |  | | --- | --- | | **Calculated fate and distribution of Permethrin in the STP (EUSES model 2.1)** | | | Compartment | Percentage [%] | |  | | Air | 0 | | Water | 27.6 | | Sludge | 72.4 | | Degraded in STP | 0 |   **Calculation method of metabolites emissions**  To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. Following the releases to STP, concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water were further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic compartment. |

***Emission estimation***

The following sections address the relevant environmental exposure routes for the biocidal products KONSERVAN® P 40.

The officially adopted emission scenario document EUBEES “Emission scenario document for biocides used as preservatives in textile processing industry. (Product type 9 & 18)” (May 2011) and Guidance on BPR Volume IV Environment –Part B Risk Assessment (active substance) (April 2015) were used, along with information from the applicant.

The biocidal product is used for vector protection finishes of textiles as well as wool protection.

Considering vector protection (Use 1), the treated article is used indoors and outdoors. The textile fabric is treated with the biocidal product on the outer face. The application on the fabric is by padding or foam coating. The treated fabric leaving the coating plant is dried and wrapped/rolled. The rolled fabric enters a washing process and is dried and wrapped/rolled again. In the end the textile fabric is distributed for tailoring to different sites and processed to textile clothes. The treated article (clothes) is washed during service life.

Wool protection (Use 2) is intended to be used for apparel, home textiles, carpets and insulation materials. The effect mechanism is killing the insects and/or their larvae to avoid laying eggs (by adult insect) or damaging the wool (by their larvae). Permethrin reduces the number of laid eggs, preventing the hatching of new larvae out of the eggs. Since this is a long-term process, wool protection works with relatively low concentrations. Application method is the exhaust process. According to the Bezema 20% of the treated wool articles are washable.

Emissions of Permethrin to waste water entering the municipal sewage treatment plant (STP) and further into the freshwater compartment occur in all life-cycle steps (Use and Service life) assessed here. This is the primary exposure path. The biocidal product is not applied directly to soil. The only exposure path to soil and groundwater could be by application of sewage sludge to soil and leaching to groundwater. Volatilization of the active is expected to be minimal due to low vapour pressure (2.155 x 10-6 Pa), low Henry´s Law constant (>4.5 x 10-2 Pa x m³ x mol-2) and high adsorption potential (Koc = 70003.4 L/kg).

Predicted Environmental Concentrations in the waste water were calculated using equations as implemented in the ESD calculation spreadsheet ([http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-](http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents) [scenario-documents](http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents)) and further case-specific adaptions.

The fate of Permethrin in the Sewage Treatment Plant were calculated using SimpleTreat 4.0.

Predicted Environmental Concentrations in freshwater, sediment, soil and groundwater were calculated according to the equations as stated in the Guidance on BPR Volume IV Environment.

**Production / formulation of the active substance and biocidal products**

The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the AS was not required, unless the AS was totally new to the EU market and manufactured in the EU. This is not the case for permethrin which is an existing biocidal AS within the EU.

**Use 1: Vector protection finishes of textiles/Military uniforms**

**Scenario 1: Use/Application step Tier 1**

In a first approach an emission estimation using the equations of the ESD calculation spreadsheet along with several standard default values as stated in the Guidance Documents was conducted.

The standard default of 7 t/d of treated fabric for ennobling was assumed as a worst case. The treated fabric is a cotton polyester mix with a surface weight of 160 g/m². The applied quantity of Permethrin in the textile fabric is 1300 ppm. The fixation rate of 0.842 was calculated based on the results of the washing test (Thor SARL, 2017) and corresponds to the fixation of Permethrin after one washing cycle.

The dilution factor was calculated using information on the receiving water as well as the industrial sewage treatment plant of the application site in Spain, which is considered as worst-case. The calculations are based on the flow rate of the receiving water Rio Saja (12.1 m3/s) and data on the quantity of the treated water volume per month in the industrial sewage treatment plant of the application site in Spain. There are exclusively two application sites within the EU, and the receiving water associated with the second application site in Germany is the Rhine with a much higher flow rate of 2300 m3/s. The calculated annual mean dilution factor is 543.6 for the Spanish application site. However, as a worst-case, a dilution factor of 500 was applied. Further elimination of Permethrin from the waste water at the application site was achieved by flocculation reactions with sodium sulphate as a risk mitigation measure. As shown in the PEC/PNEC tables the Risk Characterisation Ratios exceed the trigger value of 1 for the environmental compartments sewage treatment plant, surface water and sediment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Application of the biocidal product KONSERVAN® P 40- Tier 1 (Use 1) Average consumption based approach | | | |
| Quantity of fibres treated per day | 7 | t/day |  |
| Quantity of active substance applied per ton of fibres/fabrics for one treatment step | 8.125 | kg/t |  |
| Fixation rate | 0.842 |  | Source: Thor SARL (2017) |
| Elimination rate by site sewage treatment (flocculation) | 0.986 |  | Source: CHT (2017) |
| Dilution factor | 500 |  | Source: CHT (2016) |

Calculations of the PEC are presented in Annex 2.2 for the Scenario 1: Use/Application step Tier 1(average consumption based approach), Use 1: Vector protection finishes/Military uniforms

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 19 - FR CA position**  **Emission calculation**  The fixation rate of biocide product estimated by the applicant (Ffix = 0.842) represents the quantity of permethrin remaining on textile after one washing (knowing that 15.7% of permethrin is released during the first wash) (see data infobox 10). According to FR CA, there is no direct relation between the quantity of permethrin on textile after washing and the quantity of permethrin fixed to the textile after the bath with KONSERVAN P40 during the application phase. Moreover, as explained in infobox 10, the accuracy of the provided data is not sufficient to validate the proposed value. So, the default value of fixation rate set at 0.7 is adopted in the following scenario.  To reduce permethrin emissions in waste water after the application step of KONSERVAN P40, a flocculation treatment of residual liquors with sodium sulfate is suggested by the applicant. Despite the result provided by the applicant showing 98.6% of permethrin removed with the flocculation reaction, the robustness of data is not demonstrated in the provided report (see comment infobox 11). So, all permethrin emissions for the application step (in use 1 and 2) are calculated with and without flocculation treatment.  The proposal of new dilution factor of 500 based on the case of an application site in Spain cannot be spread to all the industrial sewage treatment plants. Today, only two plants in Europe ensure the application of the KONSERVAN P40. But there is no guarantee that such a high level of dilution would be possible in all planned factory using the product KONSERVAN P40.  Consequently, scenarios from ESD PT9&18, or from ESD PT 19 are used as a starting point to calculate environmental emissions.  **Scenario 1: For the vector protection finishes of textiles (use 1), during the application step on military uniforms (consumption approach)**  The table below presents the input parameters for the calculation of emissions to STP after application of KONSERVAN P40 on military uniforms in accordance with the characteristics of the product and the ESD for PT9&18.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario1** | | | | | | | **Parameter** | **Symbol** | **Value** | | **Unit** | **Remarks** | | **Scenario 1- Consumption app.: Emission during application step on military uniforms** | | | | | | | INPUTS SCENARIO 1 | | | | | | | Type of fibres/Fabric | Cotton | - | - | | Default value - ESD PT9 & 18 | | Quantity of fibres treated per day | Q fibres | 7 | [t/day] | | Default value - ESD PT9 & 18 | | Quantity of active substance | Qx-active | 8.125 | [kg/t] | | 1300 mg permethrin/m2 for cotton polyester mix (160 g/m2) | | Fixation rate | Ffix | 0.7 | - | | Default value - ESD PT9 & 18 | | Elimination rate by site sewage treatment (flocculation) | Fflo | 0.986 | - | | Input Applicant  See **Infobox 11 - FR CA position** | | OUTPUT SCENARIO 1 | | | | | | | Total local emission of active substance (without flocculation) | Elocal,tot,water | 17.1 | [kg.d-1] | | - | | Total local emission of active substance (with flocculation) | Elocal,tot,water | 2.39E-01 | [kg.d-1] | | - |   **Scenario 1: For the vector protection finishes of textiles (use 1), during the application step on military uniforms (Tonnage approach)**  The tonnage approach is presented in the confidential PAR. |

**Use 1: Vector protection finishes of textiles/Military uniforms Scenario 2: Service Life step**

Emissions during the service life of the biocidal product KONSERVAN®P 40 were calculated using a case-specific approach. Since the product is intended to stay on the surface of the treated textile, no significant direct release to the environment is expected during service life of the military uniforms. Indirect release to the environment via sewage treatment plant occurs by the washing of the military uniforms.

Vector protection of military uniforms is needed if worn in the subtropics or tropics due to the risk of vector-borne diseases, especially malaria.

According to data of the German Military, there is no deployment of militaries in the tropics or subtropics, which are also part of the European Union [https://www.bundeswehr.de]. Therefore emissions from treated uniforms worn in German military operations abroad are not covered by the BPR and therefore are not included in the calculations.

The French Army is also stationed in French oversea territories of the tropics, which belong to the European Union. These are the Antilles, French Guyana, French Polynesia, New Caledonia and Réunion. Data on the militaries at each French oversea territory are taken from the French Ministry of Defense [http://www.defense.gouv.fr]. Between 900 and 2100 militaries are stationed at one of the oversea territories. At each territory the militaries are distributed on several locations. Considering the Antilles, French Polynesia and Réunion the locations within one territory are distributed on different isles with a distance between 250 and 3300 km to each other. The locations in New Caledonia and French Guyana are widely distributed over the respective isles. The distribution as well as the distance between the locations is illustrated in the maps below (created with Google Maps).The distribution of militaries at the French oversea territories is given in the table below. Given these data, the assumption that 1000 militaries are localized together is considered a really worst case situation.

A general estimation on the military personnel wearing a uniform is about one third. Therefore about 350 uniforms are simultaneously in use at one location as worst case. Since efficacy is proved for 30 washing cycles in the service life of one year (as defined in the ESD), it is assumed that every military uniform is washed 30 times per year.

Therefore, in average less than 30 military uniforms are washed per day. In order to consider the worst case, calculations were conducted with 50 uniforms washed per day and location.

The proven efficacy for 30 washing cycles corresponds to a release of 60.1% of the quantity of Permethrin (Thor SARL, 2017). The total quantity of Permethrin per uniform was calculated by the application rate of Permethrin (1300 ppm), the weight of one uniform (2 kg) and the percentage of treated surface of the uniforms. The rate of treated surface was estimated to be 0.75 since the shirts of the uniform are exclusively treated at the sleeves, shoulders and pockets.

The Simple Treat calculation (version 4.0) for the elimination in the sewage treatment plant was performed considering the climatic conditions of the French oversea territories of interest. Therefore the average temperature of tropic regions, which accounts 25°C (298.15 K), was used instead of the average temperature of the European Union. The mean value applied was confirmed by further research on annual average temperatures of the specific locations, which account about 26 °C (299.15 K).

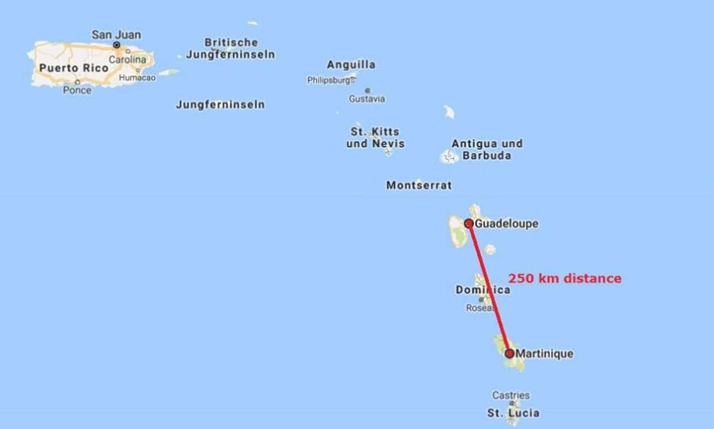
However, as a worst-case an average temperature of 25°C (298.15 K) was applied for further calculations.

Further, a dilution factor of 500 was applied for the PEC calculations. This deviation from the default value is justified by divergent climatic as well as hydrologic conditions of the French oversea territories of interest. According to our research results, annual precipitation of the regions of interest accounts 2250 mm. For a comparison with Europe, data from the Focus groundwater scenario was applied, which is 780 mm for the annual average. A factor of 3 for the precipitation of the tropical regions of the French oversea territories results from this values. Additional to the amount of precipitation, the precipitation patterns in the annual and daily course are highly different from those of the European Union. Heavy rainfalls every day lead to a water saturation of the soil pores, which ensure that a much higher percentage of surface runoff reaches the running waters instead of penetration into the soil. This also contributes to a higher dilution in the running waters.

Furthermore, an underestimation of biotic degradation processes in the environmental compartments surface water, sediment, soil, groundwater and air has been applied due to the higher average temperature. The half-lives applied in the calculations correspond to the results of several simulation studies at a temperature of 12 °C (285.15 K), which does not fit the climatic conditions in the French oversea territories of interest. According to the van't Hoff's rule a temperature increase of 10 °C leads to a duplication of reaction velocity,

i.e. the bacterial metabolism. In this context the applied half-lives in the environmental compartments are too high by a factor of approximately 2. Therefore all calculated PECs represent high overestimations rather than a real worst case situation. Due to day length of about 12 hours in tropic regions as well as more intensive solar radiation, abiotic degradation by photolysis is highly underestimated. In the calculations no photolysis was considered since at European conditions, this degradation path plays a minor rule. Therefore the calculated PECs are even more overestimated. As shown in the PEC/PNEC tables the Risk Characterisation Ratio does not exceed the trigger value of 1 for all environmental compartments.

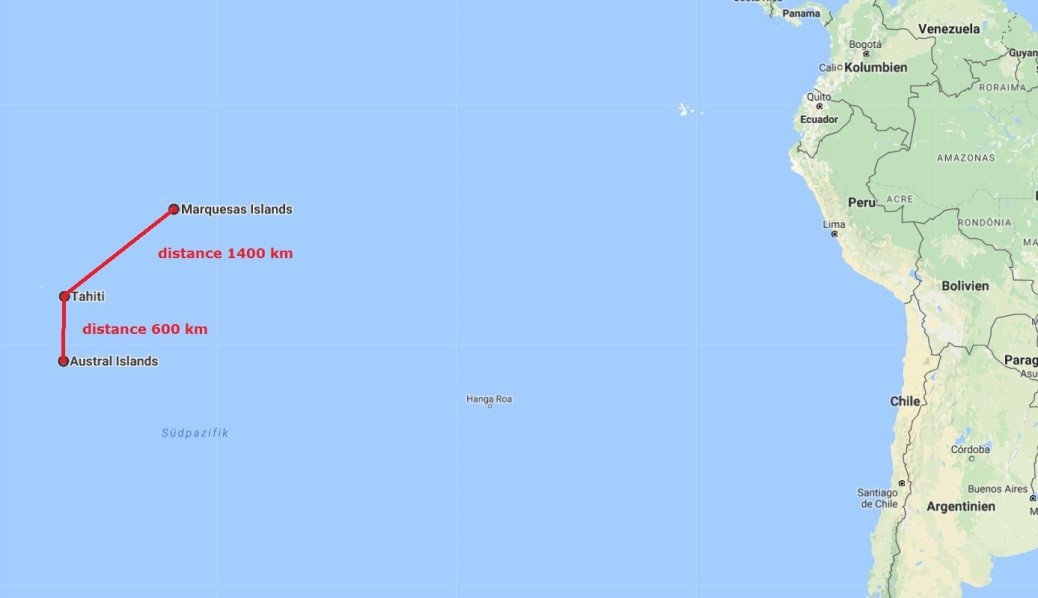
|  |  |  |
| --- | --- | --- |
| **Oversea territory** | **quantity of militaries** | **Distribution within the oversea territory** |
| Antilles | 1000 | At least 2 territories:  Martinique  Guadeloupe |
| French Guyana | 2100 | At least 4 territories:  Cayenne  Saint-Jean-du-Maroni  Kourou  Matoury |
| French Polynesia | 900 | At least 3 territories:  Tahiti  Iles Australes  Iles Marquises |
| New Caledonia | 1450 | At least 4 territories:  Noumea  Plum  Tontouta  Nandai |
| Réunion | 1600 | At least 3 territories:  Dzaoudzi (Isle Mayotte)  Pierrefonds (Isle Reunion)  Terre australes et antarctiques françaises (TAAF) |

****

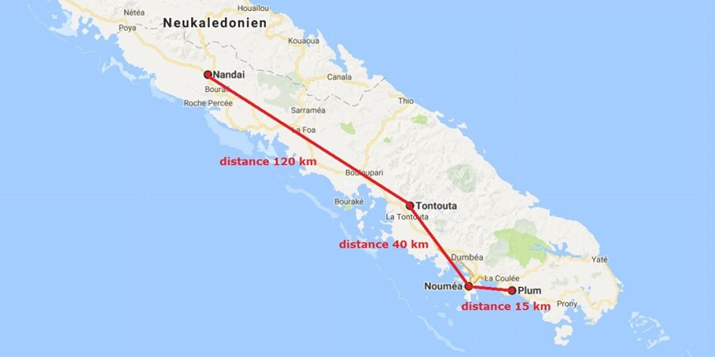
**Antilles**

****

**French Guyana**



**French Polynesia**

****

**New Caledonia**

****

**Réunion**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Service life of the biocidal product KONSERVAN® P 40 – Use 1 Case specific approach | | | |
| Permethrin content per military uniform | 12.1875 | g |  |
| Weight of one uniform | 2 | kg | Source: Thor SARL |
| Uniforms washed per day and location | 50 |  |  |
| Washing cycles per year | 30 |  | Source:  Efficacy data (Thor SARL) |
| Release of Permethrin during service life | 0.601 |  | Source:  Thor SARL (2017) |
| Dilution factor | 500 |  |  |

Calculations of the PEC are presented in Annex 2.2 for the Scenario 2: Service Life step (average consumption based approach), Use 1: Vector protection finishes of textile/Military uniforms

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 20 - FR CA position**  **Scenario 2: For the vector protection finishes of textiles (use 1), during the service life of military uniforms (Average consumption approach)**  A tonnage approach is proposed as a first step and presented in the Confidential PAR.  The consumption approach based on arguments provided by the applicant is not acceptable as several refinements are questionable. In particularly:   * the data on annual precipitation comparing the European and tropical regions are not sufficient to support such a dilution factor of 500. * the consideration of tropical temperature effect on the effectiveness of the elimination in the sewage treatment plant cannot be integrated in the environmental assessment as such as it is not justified according to the European guidances.   In addition, the presence of STP in tropical area is not insured.  In this context, the refinement reducing the calculated emissions as proposed above by the applicant is not acceptable by eCA and harmonised values from BPR Vol IV Part B have been considered.  Furthermore, in the calculation of total release to STP at one location, the applicant considered emissions over 365 days, however emissions must be taken into account only during the uniform washing, which takes place 30 times per year.  In this context, the average consumption approach from the applicant has been revised as presented below:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario 2 -Consumption app.** | | | | | | | | **Parameter** | **Symbol** | | | **Value** | **Unit** | **Remarks** | | **Scenario 2-Consumption app.: Emission during service life step on military uniforms** | | | | | | | | INPUT SCENARIO 2 | | | | | | | | Quantity of active substance | | Qactive | 8.125 | | [g.kg-1] | Input – 1300 mg permthrin/m2 with a surface weight of 160 g textile/m2 | | Weight of one uniform | | Wunif | 2 | | [kg] | Input | | Rate of treated surface | | Rsurf | 0.75 | | - | Input | | Permethrin content per military uniform | | Qunif | 12.1875 | | [g] | = Qactive x Wunif x Rsurf | | Uniforms washed per day and location | | Nunif | 50 | | - | Estimated by applicant | | Washing cycles per year | | Wcleaning | 30 | | - | Estimated by applicant | | Fraction of permethrin released per year over 30 washing cycles | | Freleased year | 0.601 | | - | Study provided by the applicant | | Fraction of permethrin released per year for 1 washing cycle | | Freleased day | 0.020 | | - | = Freleased year / Wcleaning | | OUTPUT SCENARIO 2 | | | | | | | | Local emission of substance to STP at one location | | Elocal | 1.22E-02 | | [kg.d-1] | = Freleased day x Qunif x Nunif |   **Scenario 1: For the vector protection finishes of textiles (use 1), during the service life of military uniforms (Tonnage approach)**  The tonnage approach is presented in the confidential PAR. |

**Use 1: Vector protection finishes of textiles/Forestry clothing Scenario 1: Use/Application step**

The emissions resulting from the application of the biocidal product KONSERVAN® P 40 as vector protection of forestry clothing were calculated using the equations from the ESD spread sheet. Since this application is planned but not yet implemented on the market, the calculations rather represent a worst case situation. Therefore it is not possible to conduct calculations with a tonnage based approach. The calculations are based on average consumption and make use of default values as well as information by CHT. Considering the quantity of treated fibres, the default value for the ennobling of textiles was applied.

According to the applicant, textiles with a surface weight of 220 g/m2 are treated with 200 ppm Permethrin. The fixation rate is calculated from the results of the washing test by Thor SARL (2017). It is intended to make use of flocculation reactions with sodium sulphate as risk mitigation measure. As shown in the PEC/PNEC tables the Risk Characterisation Ratio exceed the trigger value of 1 for the compartments sewage treatment plant, surface water and sediment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Application of the biocidal product KONSERVAN® P 40- Use 1 Average consumption based approach | | | |
| Quantity of fibres treated per day | 7 | t/day | ESD |
| Quantity of active substance applied per ton of fibres/fabrics for one treatment step | 0.909 | kg/t |  |
| Fixation rate | 0.842 |  | Source:  Thor SARL (2017) |
| Elimination rate by site sewage treatment (flocculation) | 0.986 |  | Source: CHT (2017) |

Calculations of the PEC are presented in Annex 2.2 for the Scenario 1: Use/Application step (average consumption based approach), Use 1: Vector protection finishes/Forestry clothing.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 21 - FR CA position**  **Scenario 3: For the vector protection finishes of textiles (use 1), during the application step on forestry clothing (consumption approach)**  The table below presents the input parameters for the calculation of emissions to STP after application of KONSERVAN P40 on forestry clothing in accordance with the characteristics of the product and the ESD for PT9&18.  According to the explanations developed in the infobox 19, the fixation rate is set to 0.7, and the permethrin emissions are estimated with and without the flocculation treatment.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario3- Consumption approach** | | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | | **Scenario 3- Consumption approach: Emission application step on forestry clothing** | | | | | | | INPUTS SCENARIO 3 | | | | | | | Type of fibres/fabric | Cotton | - | - | | Default value - ESD PT9 & 18 | | Quantity of fibres treated per day | Q fibre | 7 | [t/day] | | Default value - ESD PT9 & 18 | | Quantity of active substance applied per ton of fibres | Qx-active | 0.909 | [kg/t] | | 200 mg permethrin/m2 of treated textile with 220 g textile/m2 | | Fixation rate | Ffix | 0.7 | - | | Input | | Elimination rate by site sewage treatment (flocculation) | Fflo | 0.986 | - | | Input | | OUTPUT SCENARIO 3 | | | | | | | Total local emission of active substance (without flocculation) | Elocal,tot,water | 1.91 | [kg.d-1] | | - | | Total local emission of active substance (with flocculation) | Elocal,tot,water | 2.67E-02 | [kg.d-1] | | - |   No tonnage approach is feasible for the moment as this use is planned but not yet implemented. No tonnage data is available. |

**Use 1: Vector protection finishes/Forestry clothing Scenario 2: Service Life step**

Emissions from service life of the biocidal product KONSERVAN®P 40 used for vector protection in forestry clothing were calculated using an average consumption based approach. Tonnage based calculations are not possible since this use is planned but not yet implemented. According to information from the applicant, the surface weight of the textile applied for forestry clothing is typically about 220 g/m2. A Permethrin content of 200 ppm is planned to be applied on forestry uniforms with a total weight of 2 kg. It is further assumed, that 75% of the textile surface is treated with Permethrin. According to the ESD, a service life of one year is assumed. It is estimated that forestry uniforms are washed 20 times per year, which corresponds to a release of a fraction of 0.515. The estimated amount of washing cycles per year is slightly lower than the amount of washing cycles of military uniforms per year. This is justified by the strength of use intensity, which is quite higher for military uniforms. It is further estimated, that a maximum of 10 uniforms per day are washed at the same location. With an average of 10 forestry uniforms washed per day, a group of more than 180 forestry workers can wash their forestry uniforms 20 times per year at the same location. This assumption is considered to be highly conservative, since the washing of forestry clothing seems to be evenly distributed in dependence of the residential address rather than concentrated at one location all together. Further, a group of 180 forestry workers wearing treated forestry clothing at one location highly overestimates the common size of forestry offices within the European Union.

As shown in the PEC/PNEC tables the Risk Characterisation Ratio does not exceed the trigger value of 1 for all environmental compartments.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Service life of the biocidal product KONSERVAN® P 40 – Use 1 Average consumption based approach | | | |
| Permethrin content per forestry uniform | 1.4 | g |  |
| Weight of one forestry uniform | 2 | kg |  |
| Uniforms washed per day and location | 10 |  |  |
| Washing cycles per year | 20 |  |  |
| Release of Permethrin during service life | 0.515 |  | Source:  Thor SARL (2017) |

Calculations of the PEC are presented in Annex 2.2 for the Scenario 2: Service Life step (average consumption based approach), Use 1: Vector protection finishes of textile/Forestry clothing

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 22 - FR CA position**  **Scenario 4: For the vector protection finishes of textiles (use 1), during the service life of forestry clothing (consumption approach)**  No tonnage approach is feasible as this use is planned but not yet implemented. No tonnage data is available.  As in scenario 2 - Consumption approach (service-life of military uniforms), an average consumption approach is proposed by the applicant, and the provided data is based on its assumptions, for instance a restricted number of 10 forestry clothings per STP that does not seem realistic as the application covers workwear (i.e. forest workers), hunting clothes, trekking clothing... . In addition, the calculation of release to STP is considered over 365 days for 10 forestry cloths only. The lack of reliable data does not allow to validate this proposal.  In this context, an average consumption approach is considered based on some parameters issued from the ESD for PT19. From this document, the followings values were taken into account:   * the surface area of treated garments (AREAgarment): 17 838 cm2 for a total surface area of an outdoor garment set, * the default market share of active substance (Fpenetr): 50%, * the fraction of inhabitants using the treated articles (Finh): 20%. This value corresponds to the use of treated textile to protect the skin. Another value of 1 % is proposed in the ESD but it refers to garment treatment to protect the textile.   In the ESD for PT19, it is considered that treated textile releases all the active substance at the first washing. It is not the case for textile treated with KONSERVAN P40 with an emission of 60.1% of the treatment over 30 washings. In the equation of the ESD, it is not possible to consider a steady state release; it was therefore considered that all the active substance included in the textile was emitted over the year.  The calculation of releases of permethrin from service-life of treated garments through washing is presented in the table below:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Input parameters for calculating the local emission in scenario 4- Consumption app. | | | | | | | | Parameter | Symbol | | Value | Unit | | Remarks | | Scenario 4 Consumption app.: Emission during service life step on forestry clothing | | | | | | | | INPUT SCENARIO 4 | | | | | | | | Number of inhabitants feeding one sewage treatment plant | Nlocal | 10000 | | [cap] | Default value - ESD PT19 | | | Fraction released to wastewater over 365 days | Fwater | 1 | | - | Default value - ESD PT19 | | | Quantity of active ingredient in the garment | Qa.i.,garment | 0.02 | | [mg.cm-2] | 200 mg permethrin/m2 for cotton polyester mix (220 g/m2) | | | Surface area of treated garments | AREA garment | 17838 | | [cm-2.d-1] | ESD PT19- Table 3.4 | | | Fraction of inhabitants using the product – Garment application for skin protection | Finh | 0.2 | | - | ESD PT19-3.5 | | | Market share of repellent | Fpenetr | 0.5 | | - | Default value - ESD PT19 | | | OUTPUT SCENARIO 4 | | | | | | | | Local emission rate to wastewater | Elocalwater | 9.77E-04 | | [kg.d-1] | = Nlocalx Fwater x Qa.i.,garment x AREA garment x Finh xFpenetr / 365 | |   For information, calculations have also been carried out with the fraction of inhabitants using the treated articles of 1 %. Nevertheless this value is not in accordance with the ESD for the type of protection intended for this product. Moreover, as the dose rate of 200 mg permethrin/m2 of textiles has not been validated by efficacy data, the highest dose rate of 1300 mg permethrin has also been taken into account.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Input parameters for calculating the local emission in scenario 4 revised - Consumption app. | | | | | | | | Parameter | Symbol | | Value | Unit | | Remarks | | Scenario 4 revised - Consumption app.: Emission during service life step on forestry clothing | | | | | | | | INPUT SCENARIO 4 | | | | | | | | Number of inhabitants feeding one sewage treatment plant | Nlocal | 10000 | | [cap] | Default value - ESD PT19 | | | Fraction released to wastewater over 365 days | Fwater | 1 | | - | Default value - ESD PT19 | | | Quantity of active ingredient in the garment | Qa.i.,garment | 0.02  0.13 | | [mg.cm-2] | 200 or 1300 mg permethrin/m2 for cotton polyester mix (220 g/m2) or (160 g/m2) | | | Surface area of treated garments | AREA garment | 17838 | | [cm-2.d-1] | ESD PT19- Table 3.4 | | | Fraction of inhabitants using the product – Garment application for skin protection | Finh | 0.01 | | - | ESD PT19-3.5 | | | Market share of repellent | Fpenetr | 0.5 | | - | Default value - ESD PT19 | | | OUTPUT SCENARIO 4 revised | | | | | | | | Local emission rate to wastewater 200 mg/m2 | Elocalwater | 4.89E-05 | | [kg.d-1] | = Nlocalx Fwater x Qa.i.,garment x AREA garment x Finh xFpenetr / 365 | | | Local emission rate to wastewater 1300 mg/m2 | Elocalwater | 3.18E-04 | | [kg.d-1] | = Nlocalx Fwater x Qa.i.,garment x AREA garment x Finh xFpenetr / 365 | | |

**Use 2: Wool protection**

**Scenario 1: Use/Application step**

In a first approach the emissions from the application of the biocidal product KONSERVAN® P 40 used for wool protection were estimated using the calculation spreadsheet according

to the applied ESD, which was provided by the ECHA. According to information by Bezema, wool products are treated at a percentage of 0.06% of the biocidal product as a maximum for protection level 1 and 3. In a worst case an increase of the application amount of 50% could be necessary, which leads to a concentration of a maximum of 0.09% of the biocidal product. This corresponds to a concentration of 0.0036% of the active substance Permethrin. The fixation rate given in the ESD was adopted. As risk mitigation measure the waste water on the application site is treated with sodium sulphate in order to flocculate Permethrin. As shown in the PEC/PNEC tables the Risk Characterisation Ratio exceeds the trigger value of 1 for the compartments surface water and sediment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Application of the biocidal product KONSERVAN® P 40 – Use 2 Average consumption based approach | | | |
| Quantity of treated fibres per day | 1 | t/day | ESD |
| Quantity of active substance applied per ton of fibres/fabric for one treatment step | 0.36 | kg/t | Source: Bezema |
| Elimination rate by site sewage treatment (flocculation) | 0.986 |  | Source: CHT (2017) |

Calculations of the PEC are presented in Annex 2.2 for the Scenario 1: Use/Application step Tier 1 (average consumption based approach), Use 2: Wool protection

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 23 - FR CA position**  **Scenario 5: For the wool protection (use 2), during the application step on treated articles (consumption approach)**  As submitted by the applicant and applied in the Permethrin CAR, the following proposal implements the ESD for biocides used as preservatives in the textile processing industry.  For this scenario, the applicant considers an application rate of biocidal product of 0.09% on textiles as a worst case, however according to the SPC submitted by the applicant, wool/PA blends textiles are treated at a percentage up to 0.13% related to the weight of the textile. On this basis, the worst case of 0.13% of biocidal product on textiles is used to set the quantity of permethrin applied on the treated articles.  As for application step of product KONSERVAN P40 in use 1, a refining proposal of waste water treatment by flocculation reactions with sodium sulfate is suggested to reduce permethrin emissions.     |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario 5 – Consumption app.** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | INPUTS SCENARIO 5 | | | | | | Type of fibres/Fabric | Wool | - | - | Default value - ESD PT9 & 18 | | Quantity of treated fibres | Q fibre | 1\* | [t/day] | Default value for wool textile - ESD PT9 & 18 | | Quantity of active substance | Qx-active | 0.52 | [kg/t] | 0.013% of KONSERVAN P40 (i.e 40% of permethrin) on 1 ton of textiles | | Fixation rate | Ffix | 0.7 | - | Default value - ESD PT9 & 18 | | Elimination rate by site sewage treatment (flocculation) | Fflo | 0.986 | - | Input | | **Scenario 5 - Consumption app.: Emission application step on wool articles** | | | | | | OUTPUT SCENARIO 5 | | | | | | Total local emission of active substance (without flocculation) | Elocal,tot,water | 1.56E-01 | [kg.d-1] | - | | Total local emission of active substance (with flocculation) | Elocal,tot,water | 2.18E-03 | [kg.d-1] | - |   \*The default value of 1t/day has been verified based on actual tonnage data provided by the applicant.  **Scenario 6: For the wool protection (use 2), during the service life of treated articles (worst case tonnage approach and refined tonnage approach)**  Tonnage approaches are submitted in the Confidential PAR. |

***Calculated PEC values***

***Permethrin***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW 1** | **PECair** |
| [µg/l] | [µg/l] | [µg/kgwwt  ] | [µg/l] | [µg/kgwwt] | [µg/kg] | [μg/l] | [mg/m3] |
| Use 1 Military Scenario 1 Tier 1 | 6.542 | 0.021 | 18.030 | Not assessed | Not assessed | 68.505 | 0.036 | 0.000 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.069 | 0.000 | 0.191 | Not assessed | Not assessed | 0.545 | 0.000 | 0.000 |
| Use 1 Forestry Scenario 1 | 0.732 | 0.066 | 100.929 | Not assessed | Not assessed | 7.670 | 0.004 | 0.000 |
| Use 1 Forestry Scenari o 2 | 0.001 | 0.000 | 0.186 | Not assessed | Not assessed | 0.010 | 0.000 | 0.000 |
| Use 2 Scenario 1 | 0.079 | 0.007 | 10.844 | Not assessed | Not assessed | 0.824 | 0.000 | 0.000 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| 1 If the PECGW was calculated by using a simulation tool (e.g Not assessed. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | |

***Metabolite DCVA***

The PECs for the metabolite DCVA were calculated by use of molar reduction as well as percentage reduction using the formula and input data below.

A percentage reduction through measured data was possible for the compartments surface water, sediment and soil.

c(DCVA)COMP  = c(Permethrin)COMP  \* MW(DCVA) \* % DCVACOMP / MW(Permethrin)

with

c(DCVA)COMP = Concentration of DCVA in the compartment

c(Permethrin)COMP = Concentration of Permethrin in the compartment

MW(DCVA)= molecular weight of DCVA

% DCVACOMP= percentage of DCVA in the compartment

MW(Permethrin)= molecular weight of Permethrin

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW 1** | **PECair** |
| [µg/l] | [µg/l] | [µg/kgwwt] | [µg/l] | [µg/kgwwt] | [µg/kg] | [μg/l] | [mg/m3] |
| Use 1 Military Scenari o 1 Tier 1 | 3.496 | 0.004 | 2.090 | Not assessed | Not assessed | 4.136 | 0.019 | 0.000 |
| Use 1 Military Scenari o 1 Tier 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| Use 1 Military Scenari o 2 | 0.037 | 0.000 | 0.022 | Not assessed | Not assessed | 0.033 | 0.000 | 0.000 |
| Use 1 Forestr y Scenari o 1 | 0.391 | 0.022 | 11.702 | Not assessed | Not assessed | 0,463 | 0.002 | 0.000 |
| Use 1 Forestr y Scenari o 2 | 0.001 | 0.000 | 0.022 | Not assessed | Not assessed | 0.001 | 0.000 | 0.000 |
| Use 2 Scenari o 1 | 0.042 | 0.002 | 1.257 | Not assessed | Not assessed | 0.050 | 0.000 | 0.000 |
| Use 2 Scenari o 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| 1 If the PECGW was calculated by using a simulation tool (e.g Not assessed. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | |

***Metabolite PBA***

The PECs for the metabolite PBA were calculated by use of molar reduction as well as percentage reduction using the formula and input data below.

A percentage reduction through measured data was possible for the compartments surface water, sediment and soil.

c(PBA)COMP = c(Permethrin)COMP \* MW(PBA) \* % PBACOMP / MW(Permethrin)

with

c(PBA)COMP = Concentration of PBA in the compartment

c(Permethrin)COMP = Concentration of Permethrin in the compartment

MW(PBA)= molecular weight of PBA

% PBACOMP= percentage of PBA in the compartment

MW(Permethrin)= molecular weight of Permethrin

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | |
|  | **PECSTP** | **PECwate r** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW 1** | **PECair** |
| [µg/l] | [µg/l] | [µg/kgwwt  ] | [µg/l] | [µg/kgwwt] | [µg/k g] | [μg/l] | [mg/m3] |
| Use 1 Military Scenario 1 Tier 1 | 3.582 | 0.002 | 1.619 | Not assessed | Not assessed | 5.62  6 | 0.020 | 0.000 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.038 | 0.000 | 0.017 | Not assessed | Not assessed | 0.04  5 | 0.000 | 0.000 |
| Use 1 Forestry Scenario 1 | 0.401 | 0.010 | 9.062 | Not assessed | Not assessed | 0.63  0 | 0.002 | 0.000 |
| Use 1 Forestry Scenario 2 | 0.001 | 0.000 | 0.017 | Not assessed | Not assessed | 0.00  1 | 0.000 | 0.000 |
| Use 2 Scenario 1 | 0.043 | 0.001 | 0.974 | Not assessed | Not assessed | 0.06  8 | 0.000 | 0.000 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| 1 If the PECGW was calculated by using a simulation tool (e.g Not assessed. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 24 - FR CA position**  Scenario 1: Military uniforms-Application step- Consumption approach  The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following tables.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 1-consumption app. WITHOUT FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 2.35 | 2.26E-01 | 133 | 23 | **3.13E+01** | | DCVA | - | 7.57E-02 | 3.69E-01 | 1.63 | **3.49E+02** | | PBA | - | 3.57E-02 | 5.71E-02 | 2.25E-01 | **4.83E+01** |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 1- consumption app. WITH FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 3.30E-02 | 3.17E-03 | 1.86 | 3.22E-01 | **4.38E-01** | | DCVA | - | 1.06E-04 | 5.17E-03 | 2.28E-02 | **4.89** | | PBA | - | 5.00E-04 | 7.99E-04 | 3.16E-03 | **6.77E-01** |   Scenario 2: Military uniforms-Service life step -Tonnage approach (see confidential PAR) & Average consumption approach  The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following tables.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 2- Consumption app.** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 1.68E-03 | 1.62E-04 | 9.48E-02 | 1.64E-02 | 2.24E-02 | | DCVA | - | 5.41E-05 | 2.64E-04 | 1.16E-03 | **2.50E-01** | | PBA | - | 2.55E-05 | 4.08E-05 | 1.61E-04 | 3.44E-02 |   Scenario 3: Forestry clothing-Application step- Consumption approach  The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following tables.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 3- consumption app. WITHOUT FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 2.63E-01 | 2.53E-02 | 14.8 | 2.57 | **3.5** | | DCVA | - | 8.47E-03 | 4.13E-02 | 1.82E-01 | **3.91E+01** | | PBA | - | 3.99E-03 | 6.38E-03 | 2.52E-02 | **5.39** |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 3- consumption app. WITH FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 3.69E-03 | 3.54E-04 | 2.08E-01 | 3.60E-02 | **4.90E-02** | | DCVA | - | 1.19E-04 | 5.79E-04 | 2.55E-03 | **5.47E-01** | | PBA | - | 5.59E-05 | 8.94E-05 | 3.53E-04 | **7.57E-02** |   Scenario 4: Forestry clothing-Service life step- Consumption approach  Predicted concentrations of permethrin and metabolites in the different environmental compartments are presented in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 4- consumption app.** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 1.35E-04 | 1.30E-05 | 7.60E-03 | 1.32E-03 | 1.79E-03 | | DCVA | - | 4.34E-06 | 2.12E-05 | 9.34E-05 | 2.00E-02 | | PBA | - | 2.04E-06 | 3.27E-06 | 1.29E-05 | 2.76E-03 |   Scenario 4 revised: Forestry clothing-Service life step- Consumption approach  Predicted concentrations of permethrin and metabolites in the different environmental compartments are presented in the following table. For this revised scenario, a fraction of inhabitants using a treated articles has been reduced to 1% (corresponding to 50 personnes wearing one treated clothing item at the scale of the standard STP). Nevertheless this value is not in accordance with the ESD for the inteded use of the product.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 4- consumption app.**  **200 mg/m2 (dose rate not validated by efficacy data)** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 6.74E-06 | 6.48E-07 | 3.80E-04 | 6.58E-05 | 8.97E-05 | | DCVA | - | 2.17E-07 | 1.06E-06 | 4.67E-06 | 1.00E-03 | | PBA | - | 1.02E-07 | 1.63E-07 | 6.46E-07 | 1.34E-04 | | **Summary table on calculated PEC values for the scenario 4- consumption app.**  **1300 mg/m2 (only dose rate validated by efficacy data)** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 4.38E-05 | 4.21E-06 | 2.47E-03 | 4.28E-04 | 5.83E-04 | | DCVA | - | 1.41E-06 | 6.88E-06 | 3.04E-05 | 6.51E-03 | | PBA | - | 6.64E-07 | 1.06E-06 | 4.20E-06 | 8.97E-04 |   Scenario 5: Wool protection-Application step- Consumption approach  Predicted concentrations of permethrin and metabolites in the different environmental compartments are presented in the following tables.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 5- consumption app. WITHOUT FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 2.15E-02 | 2.07E-03 | 1.21 | 2.10E-01 | **2.86E-01** | | DCVA | - | 6.92E-04 | 3.38E-03 | 1.49E-02 | **3.20** | | PBA | - | 3.26E-04 | 5.22E-04 | 2.06E-03 | **4.40E-01** |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 5- consumption app. WITH FLOCCULATION** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 3.01E-04 | 2.90E-05 | 1.70E-02 | 2.94E-03 | **4.01E-03** | | DCVA | - | 9.69E-06 | 4.73E-05 | 2.09E-04 | **4.47E-02** | | PBA | - | 4.57E-06 | 7.30E-06 | 2.89E-05 | **6.17E-03** |   Scenario 6: Wool protection-Service life step- worst case tonnage approach & refinement tonnage approach  See confidential PAR |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not relevant for the foreseen use of the biocidal product since there is no intended direct uptake of non-target organisms like birds or mammals.

|  |
| --- |
| **Infobox 25 - FR CA position**  *Not relevant* |

Secondary poisoning

A secondary poisoning assessment was conducted considering the service life step (Scenario 2). The application of the biocidal product was not considered because it is necessary to implement the disposal of waste water as hazardous waste to get a safe use for the environment. Since the emission via wastewater is the only emission to the environment, the application step is not considered in the secondary poisoning assessment. In order to cover the worst-case, PEC values for the service life of Use 1 (vector protection finishes of textiles)/Military uniforms were applied. The results of the secondary poisoning assessment show that there is a safe use with a high margin of safety.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| Scenario | PECoral predator  [µg/kgwwt] | PEC/PNEC birds | PEC/PNEC mammals | PEC/PNEC fish |
| Use 1 Military  Scenario 2 (Worst case) | 0.04  (aquatic)  17.44  (terrestrial) | 2.1E-06  (aquatic)  1.0E-03  (terrestrial) | 3.0E-07  (aquatic)  1.5E-04  (terrestrial) | Not available |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 26 - FR CA position**  The active substance permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100 (mean BCF in fish = 570 L.kg-1, BMF = 1 and BCF in earthworm = 15108 L.kg-1). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of permethrin in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated.  The results for each scenario are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on estimated theoretical exposition for the permethrin** | | | |  | **PEC in fish** | **PEC in earthworm** | | [mg.kg wet fish-1] | [mg.kg wet earthworm-1] | | Scenario 1– consumption app. WITHOUT FLOCCULATION  Military uniforms-Application step | 64.5 | 214 | | Scenario 1– consumption app. WITH FLOCCULATION  Military uniforms-Application step | 9.03E-01 | 2.99 | | Scenario 1– tonnage app. WITHOUT FLOCCULATION  Military uniforms-Application step | Confidential PAR | Confidential PAR | | Scenario 1– tonnage app. WITH FLOCCULATION  Military uniforms-Application step | Confidential PAR | Confidential PAR | | Scenario 2 – tonnage app.  Military uniforms-Service life step | Confidential PAR | Confidential PAR | | Scenario 2 – consumption app.  Military uniforms-Service life step | 4.61E-02 | 1.53E-01 | | Scenario 3-consumption app. WITHOUT FLOCCULATION  Forestry clothing-Application step | 7.22 | 23.9 | | Scenario 3-consumption app. WITH FLOCCULATION  Forestry clothing-Application step | 1.01E-01 | 3.34E-01 | | Scenario 4-consumption app.  Forestry clothing-Service life step | 3.69E-03 | 1.22E-02 | | Scenario 5-consumption app. WITHOUT FLOCCULATION  Wool protection- Application step | 5.90E-01 | 1.95 | | Scenario 5-consumption app. WITH FLOCCULATION  Wool protection- Application step | 8.26E-03 | 2.73E-02 | | Scenario 6 –worst case tonnage app.  Wool protection- Service life step | Confidential PAR | Confidential PAR | | Scenario 6 –refined tonnage app.  Wool protection- Service life step | Confidential PAR | Confidential PAR | |

#### Risk characterisation

***Atmosphere***

Conclusion:Volatilization of the active substance is expected to be minimal due to low vapour pressure (2.155 x 10-6 Pa), low Henry´s Law constant (>4.5 x 10-2 Pa x m³ x mol-2) and high adsorption potential (Koc = 70003.4 L/kg).

|  |
| --- |
| **Infobox 27 - FR CA position**  Significant exposure of the environment via air is not expected whatever the considered use.  According to the CAR, volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 × 10-6 Pa at 20°C) and Henry constant (4.5 × 10-2 Pa.m3.mole-1). Permethrin would not be transported over large distances in the atmosphere in gaseous phase.  **Conclusion:**Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product KONSERVAN P40 will not pose a significant risk to the atmospheric compartment. |

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values: Permethrin** | |
|  | **PEC/PNECSTP**  **Permethrin** |
| Use 1 Military Scenario 1 Tier 1 | 1.322 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR |
| Use 1 Military Scenario 2 | 0.014 |
| Use 1 Forestry Scenario 1 | 0.148 |
| Use 1 Forestry Scenario 2 | 0.000 |
| Use 2  Scenario 1 | 0.016 |
| Use 2  Scenario 2 | Confidential PAR |

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values: Metabolites** | | |
|  | **PEC/PNECSTP**  **Metabolite DCVA** | **PEC/PNECSTP**  **Metabolite PBA** |
| Use 1 Military Scenario 1 Tier 1 | 0.706 | 0.724 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.007 | 0.008 |
| Use 1 Forestry Scenario 1 | 0.079 | 0.081 |
| Use 1 Forestry Scenario 2 | 0.000 | 0.000 |
| Use 2 Scenario 1 | 0.008 | 0.009 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR |

Conclusion:

The active substance Permethrin does not pose any unacceptable risk to the STP compartment associated with the application step (Scenario 1), if at least a refined approach (Tier 2) is applied, or the service life (Scenario 2).

The metabolites DCVA and PBA in all assessed scenarios do not pose an unacceptable risk to the STP compartment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 28 - FR CA position**   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for permethrin** | | **Conclusion** | |  | **PEC/PNECSTP** | | Scenario 1– consumption app. WITHOUT FLOCCULATION  Military uniforms-Application step | **476** | **Unacceptable** | | Scenario 1– consumption app. WITH FLOCCULATION  Military uniforms-Application step | **6.66** | **Unacceptable** | | Scenario 1–tonnage app. WITHOUT FLOCCULATION  Military uniforms-Application step | Confidential PAR | **Unacceptable** | | Scenario 1– tonnage app. WITH FLOCCULATION  Military uniforms-Application step | Confidential PAR | Acceptable | | Scenario 2 – tonnage app.  Military uniforms-Service life step | Confidential PAR | Acceptable | | Scenario 2 –consumption app.  Military uniforms-Service life step | 3.40E-01 | Acceptable | | Scenario 3- consumption app. WITHOUT FLOCCULATION  Forestry clothing-Application step | **53.2** | **Unacceptable** | | Scenario 3- consumption app. WITH FLOCCULATION  Forestry clothing-Application step | 7.45E-01 | Acceptable | | Scenario 4- consumption app. (Finh 0.2 and 200 mg/m2)  Forestry clothing-Service life step | 2.72E-02 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 200 mg/m2)  Forestry clothing-Service life step | 1.36E-03 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 1300 mg/m2)  Forestry clothing-Service life step | 8.86E-03 | Acceptable | | Scenario 5- consumption app. WITHOUT FLOCCULATION  Wool protection- Application step | **4.35** | **Unacceptable** | | Scenario 5- consumption app. WITH FLOCCULATION  Wool protection- Application step | 6.09E-02 | Acceptable | | Scenario 6 –worst case tonnage app.  Wool protection- Service life step | Confidential PAR | Acceptable | | Scenario 6 –refined tonnage app.  Wool protection- Service life step | Confidential PAR | Acceptable |   The assessment of permethrin metabolites is not relevant for the STP compartment.  **Conclusion:**  For the application step, risks to the STP are only acceptable with flocculation. It should be noted that for scenario 1, risk is acceptable only for tonnage approach.  For service-life of treated articles, no unacceptable risks are foreseen for the STP. |

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values: Permethrin** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Use 1 Military Scenario 1 Tier 1 | 25.195 | 83.087 |
| Use 1 Military Scenario 1  Tier 2 | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.267 | 0.879 |
| Use 1 Forestry Scenario 1 | 141.037 | 465.111 |
| Use 1 Forestry Scenario 2 | 0.259 | 0.855 |
| Use 2 Scenario 1 | 15.153 | 49.971 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values: Metabolites** | | | | |
|  | **PEC/PNECwater**  **Metabolite DCVA** | **PEC/PNECsed**  **Metabolite DCVA** | **PEC/PNECwater**  **Metabolite PBA** | **PEC/PNECsed**  **Metabolite PBA** |
| Use 1 Military Scenario 1 Tier 1 | 0.000 | 0.174 | 0.000 | 0.180 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.000 | 0.002 | 0.000 | 0.002 |
| Use 1 Forestry Scenario 1 | 0.001 | 0.975 | 0.001 | 1.007 |
| Use 1 Forestry Scenario 2 | 0.000 | 0.002 | 0.000 | 0.002 |
| Use2 Scenario 1 | 0.000 | 0.105 | 0.000 | 0.108 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR | Confidential PAR | Confidential PAR |

Conclusion: Considering all scenarios assessed the active substance Permethrin in parts poses a risk to the aquatic compartment. The risks are restricted to the application step.

The service life does not pose any risk to the aquatic compartment.

The metabolites DCVA and PBA do not pose any unacceptable risk to the aquatic compartment except for the application step of forestry clothing, which slightly exceeds the trigger value of 1 in case of PBA.

In order to realize a safe use, it is necessary to implement another risk mitigation measure for the application step of the biocidal product KONSERVAN® P 40. The waste water of the industrial sewage treatment plant has to be disposed therefore as hazardous waste to avoid any unacceptable risk in the aquatic compartment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 29 - FR CA position**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | | **Conclusion** | |  |  | **PEC/PNECwater** | | **PEC/PNECsed** | | Scenario 1- Consumption app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | **482000** | | **611000** | **Unacceptable** | | DCVA | **5.05** | | **30.8** | **Unacceptable** | | PBA | **3.57** | | **6.34** | **Unacceptable** | | Scenario 1- Consumption app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | **6740** | | **8560** | **Unacceptable** | | DCVA | 7.07E-02 | | 4.31E-01 | Acceptable | | PBA | 5.00E-02 | | 8.88E-02 | Acceptable | | Scenario 1 –Tonnage app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | | | **Unacceptable** | | DCVA | **Unacceptable** | | PBA | **Unacceptable** | | Scenario 1- Tonnage app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | | | **Unacceptable** | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 2 – Tonnage app.  Military uniforms-Service life step | Permethrin | Confidential PAR | | | **Unacceptable** | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 2 –Consumption app.  Military uniforms-Service life step | Permethrin | **344** | **437** | | **Unacceptable** | | DCVA | 3.60E-03 | 2.20E-02 | | Acceptable | | PBA | 2.55E-03 | 4.53E-03 | | Acceptable | | Scenario 3 - Consumption app.  WITHOUT FLOCCULATION  Forestry clothing-Application step | Permethrin | **53900** | | **68400** | **Unacceptable** | | DCVA | 5.65E-01 | | **3.44** | **Unacceptable** | | PBA | 3.99E-01 | | 7.09E-01 | Acceptable | | Scenario 3 - Consumption app.  WITH FLOCCULATION  Forestry clothing-Application step | Permethrin | **754** | | **958** | **Unacceptable** | | DCVA | 7.91E-03 | | 4.82E-02 | Acceptable | | PBA | 5.59E-03 | | 9.93E-03 | Acceptable | | Scenario 4 - (Finh 0.2 and 200 mg/m2)  Consumption app.  Forestry clothing-Service life step | Permethrin | **27.6** | | **35** | **Unacceptable** | | DCVA | 2.89E-04 | | 1.76E-03 | Acceptable | | PBA | 2.04E-04 | | 3.63E-04 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 200 mg/m2)  Forestry clothing-Service life step | Permethrin | **1.38** | | **1.75** | **Unacceptable** | | DCVA | 1.45E-05 | | 8.82E-05 | Acceptable | | PBA | 1.02E-05 | | 1.82E-05 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 1300 mg/m2)  Forestry clothing-Service life step | Permethrin | **8.96** | | **11.4** | **Unacceptable** | | DCVA | 9.4E-05 | | 5.73E-04 | Acceptable | | PBA | 6.64E-05 | | 1.18E-04 | Acceptable | | Scenario 5- Consumption app.  WITHOUT FLOCCULATION  Wool protection- Application step | Permethrin | **4400** | | **5590** | **Unacceptable** | | DCVA | 4.61E-02 | | 2.82E-01 | Acceptable | | PBA | 3.26E-02 | | 5.80E-02 | Acceptable | | Scenario 5- Consumption app.  WITH FLOCCULATION  Wool protection- Application step | Permethrin | **61.6** | | **78.3** | **Unacceptable** | | DCVA | 6.46E-04 | | 3.94E-03 | Acceptable | | PBA | 4.57E-04 | | 8.11E-04 | Acceptable | | Scenario 6 –worst case tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | | | **Unacceptable** | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 6 –refined tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | | | **Unacceptable** | | DCVA | Acceptable | | PBA | Acceptable |   **Conclusion:**  For all scenario considered, the risk characterisation ratios for permethrin in water and sediment are above 1. Except for the scenario 1- consumption approach without flocculation, the risk characterisation ratios for metabolites are below 1 in the aquatic compartments.  The risks related to the use of KONSERVAN P40 are not acceptable for the aquatic compartments. |

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values: Permethrin** | |
|  | **PEC/PNECsoil** |
| Use 1 Military Scenario 1 Tier 1 | 0.782 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR |
| Use 1 Military Scenario 2 | 0.006 |
| Use 1 Forestry Scenario 1 | 0.088 |
| Use 1 Forestry Scenario 2 | 0.000 |
| Use2 Scenario 1 | 0.009 |
| Use 2 Scenario 2 | Confidential PAR |

*\*As a worst case for PEC soil the concentration in agricultural soil after 30 days was used. Calculations for180 day lead to lower concentrations.*

|  |  |  |
| --- | --- | --- |
| **Calculated PEC/PNEC values: Metabolites** | | |
|  | **PEC/PNECsoil**  **Metabolite DCVA** | **PEC/PNECsoil**  **Metabolite PBA** |
| Use 1 Military Scenario 1 Tier 1 | 0.001 | 0.004 |
| Use 1 Military Scenario 1 Tier 2 | Confidential PAR | Confidential PAR |
| Use 1 Military Scenario 2 | 0.000 | 0.000 |
| Use 1 Forestry Scenario 1 | 0.000 | 0.000 |
| Use 1 Forestry Scenario 2 | 0.000 | 0.000 |
| Use2 Scenario 1 | 0.000 | 0.000 |
| Use 2 Scenario 2 | Confidential PAR | Confidential PAR |

*\*As a worst case for PEC soil the concentration in agricultural soil after 30 days was used. Calculations for180 day lead to lower concentrations.*

Conclusion:

There is not any unacceptable risk for the terrestrial compartment originating from active substance Permethrin as well as the metabolites DCVA and PBA.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 30 - FR CA position**   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC soil values** | | | **Conclusion** | |  |  | **PEC/PNECsoil** |  | | Scenario 1 -Consumption app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | **262** | **Unacceptable** | | DCVA | 3.55E-01 | Acceptable | | PBA | 1.57E-01 | Acceptable | | Scenario 1 - Consumption app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | **3.67** | **Unacceptable** | | DCVA | 4.96E-03 | Acceptable | | PBA | 2.19E-03 | Acceptable | | Scenario 1 -Tonnage app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | **Unacceptable** | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 1 -Tonnage app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 2- Tonnage app.  Military uniforms-Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 2- Consumption app.  Military uniforms-Service life step | Permethrin | 1.87E-01 | Acceptable | | DCVA | 2.53E-04 | Acceptable | | PBA | 1.12E-04 | Acceptable | | Scenario 3- Consumption app.  WITHOUT FLOCCULATION  Forestry clothing-Application step | Permethrin | **29.4** | **Unacceptable** | | DCVA | 3.97E-02 | Acceptable | | PBA | 1.75E-02 | Acceptable | | Scenario 3- Consumption app.  WITH FLOCCULATION  Forestry clothing-Application step | Permethrin | 4.11E-01 | Acceptable | | DCVA | 5.55E-04 | Acceptable | | PBA | 2.45E-04 | Acceptable | | Scenario 4- Consumption app. (Finh 0.2 and 200 mg/m2)  Forestry clothing-Service life step | Permethrin | 1.50E-02 | Acceptable | | DCVA | 2.03E-05 | Acceptable | | PBA | 8.97E-06 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 200 mg/m2)  Forestry clothing-Service life step | Permethrin | 7.52E-04 | Acceptable | | DCVA | 1.02E-06 | Acceptable | | PBA | 4.48E-07 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 1300 mg/m2)  Forestry clothing-Service life step | Permethrin | 4.89E-03 | Acceptable | | DCVA | 6.60E-06 | Acceptable | | PBA | 2.91E-06 | Acceptable | | Scenario 5- Consumption app.  WITHOUT FLOCCULATION  Wool protection- Application step | Permethrin | **2.4** | **Unacceptable** | | DCVA | 3.24E-03 | Acceptable | | PBA | 1.43E-03 | Acceptable | | Scenario 5- Consumption app.  WITH FLOCCULATION  Wool protection- Application step | Permethrin | 3.36E-02 | Acceptable | | DCVA | 4.54E-05 | Acceptable | | PBA | 2.00E-05 | Acceptable | | Scenario 6- Worst case tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 6- refined tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable |   **Conclusion:**  For the application step, risks to the terrestrial compartment are unacceptable even with flocculation, considering the consumption approach. For service-life of treated articles, no unacceptable risks are foreseen for soil. |

***Groundwater***

As shown in the “Summary table on calculated PEC values” the trigger value of 0.1 µg/L was not exceeded in the assessed scenarios.

Conclusion:

The risk for the groundwater compartment can be considered as acceptable for all scenarios assessed.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 31 - FR CA position**   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Comparison with the limit value of 0.1 µg/L.** | | | **Conclusion** | |  |  | **PECGW** |  | | Scenario 1- Consumption app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | **3.13E+01** | **Unacceptable** | | DCVA | **3.49E+02** | **Unacceptable** | | PBA | **4.83E+01** | **Unacceptable** | | Scenario 1- Consumption app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | **4.38E-01** | **Unacceptable** | | DCVA | **4.89** | **Unacceptable** | | PBA | **6.77E-01** | **Unacceptable** | | Scenario 1-Tonnage app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | **Unacceptable** | | DCVA | **Unacceptable** | | PBA | **Unacceptable** | | Scenario 1-Tonnage app.  WITH FLOCCULATION  Military uniforms-Application step | Permethrin | Confidential PAR | Acceptable | | DCVA | **Unacceptable** | | PBA | Acceptable | | Scenario 2- Tonnage app.  Military uniforms-Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 2- Consumption app.  Military uniforms-Service life step | Permethrin | 2.24E-02 | Acceptable | | DCVA | **2.5E-01** | **Unacceptable** | | PBA | 3.44E-02 | Acceptable | | Scenario 3 - Consumption app.  WITHOUT FLOCCULATION  Forestry clothing-Application step | Permethrin | **3.5** | **Unacceptable** | | DCVA | **3.91E+01** | **Unacceptable** | | PBA | **5.39** | **Unacceptable** | | Scenario 3 - Consumption app.  WITH FLOCCULATION  Forestry clothing-Application step | Permethrin | 4.9E-02 | Acceptable | | DCVA | **5.47E-01** | **Unacceptable** | | PBA | 7.57E-02 | Acceptable | | Scenario 4- Consumption app. (Finh 0.2 and 200 mg/m2)  Forestry clothing-Service life step | Permethrin | 1.79E-03 | Acceptable | | DCVA | 2E-02 | Acceptable | | PBA | 2.76E-03 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 200 mg/m2)  Forestry clothing-Service life step | Permethrin | 8.97E-05 | Acceptable | | DCVA | 1.00E-03 | Acceptable | | PBA | 1.38E-03 | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 1300 mg/m2)  Forestry clothing-Service life step | Permethrin | 5.83E-04 | Acceptable | | DCVA | 6.51E-03 | Acceptable | | PBA | 8.97E-04 | Acceptable | | Scenario 5- Consumption app.  WITHOUT FLOCCULATION  Wool protection- Application step | Permethrin | **2.86E-01** | **Unacceptable** | | DCVA | **3.2** | **Unacceptable** | | PBA | **4.4E-01** | **Unacceptable** | | Scenario 5- Consumption app.  WITH FLOCCULATION  Wool protection- Application step | Permethrin | 4.01E-03 | Acceptable | | DCVA | 4.47E-02 | Acceptable | | PBA | 6.17E-03 | Acceptable | | Scenario 6- Worst case tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable | | Scenario 6- refined tonnage app.  Wool protection- Service life step | Permethrin | Confidential PAR | Acceptable | | DCVA | Acceptable | | PBA | Acceptable |   **Conclusion:**  Concentrations in groundwater for permethrin or its metabolites (DCVA and/or PBA) are above the limit value of 0.1 µg/L in scenarios 1, 2-consumption approach, 3 and 5 without flocculation. The risk for the groundwater compartment when using the product KONSERVAN P40 for the application step of the product KONSERVAN P40 and for the service life of military uniforms is unacceptable.  Knowing that for each scenario presented, at least one compartment shows unacceptable risks, no refining with FOCUS-PEARL model is submitted here. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not relevant for the foreseen use of the biocidal product since there is no intended direct uptake of non-target organisms like birds or mammals.

|  |
| --- |
| **Infobox 32 - FR CA position**  *Not relevant* |

Secondary poisoning

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| **Scenario** | **PEC oral predator**  **[µg/kgwwt]** | **PEC/PNECbirds** | **PEC/PNECmammals** | **PEC/PNECfish** |
| Use 1 Military  Scenario 2 (Worst case) | 0.04  (aquatic) 17.44  (terrestrial) | 2.1E-06  (aquatic) 1.0E-03  (terrestrial) | 3.0E-07  (aquatic) 1.5E-04  (terrestrial) | Not available |

Conclusion: The secondary poisoning assessment calculations show a safe use with a high margin of safety.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 33 - FR CA position**  Birds (PNEC oral bird≥16.7 mg.kg food ) are more sensitive species than mammals (PNEC oral small mammals =120 mg.kg food). Thus, only the most conservative ratio PEC/PNECbirds are presented.  The results for each scenario are summarised in the following table.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on table on secondary poisoning for permethrin** | | | | | |  | **PECoral predator**  [mg.kg wet fish-1] | **PEC/PNECbirds** | **PEC oral predator**  [mg.kg wet earthworm-1] | **PEC/PNECbirds** | | Scenario 1-Consumption app.  WITHOUT FLOCCULATION  Military uniforms-Application step | 64.5 | **3.86** | 214 | **12.8** | | Scenario 1-Consumption app.  WITH FLOCCULATION  Military uniforms-Application step | 9.03E-01 | 5.41E-02 | 2.99 | 1.79E-01 | | Scenario 1-Tonnage app.  WITHOUT FLOCCULATION  Military uniforms-Application step | Confidential PAR | Confidential PAR  acceptable | Confidential PAR | Confidential PAR  acceptable | | Scenario 1-Tonnage app.  WITH FLOCCULATION  Military uniforms-Application step | Confidential PAR | Confidential PAR  acceptable | Confidential PAR | Confidential PAR  acceptable | | Scenario 2-Tonnage app.  Military uniforms-  Service life step | Confidential PAR | Confidential PAR  acceptable | Confidential PAR | Confidential PAR  acceptable | | Scenario 2 -Consumption app.  Military uniforms-  Service life step | 4.61E-02 | 2.76E-03 | 1.53E-01 | 9.13E-03 | | Scenario 3- Consumption app.  WITHOUT FLOCCULATION  Forestry clothing-Application step | 7.22 | 4.32E-01 | 23.9 | **1.43** | | Scenario 3- Consumption app.  WITH FLOCCULATION  Forestry clothing-Application step | 1.01E-01 | 6.05E-03 | 3.34E-01 | 2E-02 | | Scenario 4- Consumption app.  Forestry clothing-  Service life step | 3.69E-03 | 2.21E-04 | 1.22E-02 | 7.33E-04 | | Scenario 5- Consumption app.  WITHOUT FLOCCULATION  Wool protection- Application step | 5.90E-01 | 3.53E-02 | 1.95 | 1.17E-01 | | Scenario 5- Consumption app.  WITH FLOCCULATION  Wool protection- Application step | 8.26E-03 | 4.94E-04 | 2.73E-02 | 1.64E-03 | | Scenario 6 -worst case tonnage app.  Wool protection-  Service life step | Confidential PAR | Confidential PAR  acceptable | Confidential PAR | Confidential PAR  acceptable | | Scenario 6 -refined tonnage app.  Wool protection-  Service life step | Confidential PAR | Confidential PAR  acceptable | Confidential PAR | Confidential PAR  acceptable |   **Conclusion:**  Except for the scenario 1-consumption approach and the scenario 3, without flocculation treatment in both case, all secondary poisoning assessment presents RCRs values below 1 for the birds (and small mammals) in the aquatic and/or the terrestrial food chains.  Therefore, the risk of secondary poisoning in terrestrial food chains when using the product KONSERVAN P40 for the application step of the product without flocculation treatment on military uniforms or forestry clothing is unacceptable.  Furthermore, the risk of secondary poisoning is acceptable when using the product KONSERVAN P40 for the service life step of military uniforms and for the use of the product for the forestry clothing and the wool protection. |

***Mixture toxicity***

Mixture toxicity is not relevant as the biocidal product will not be used in combination with other substances of concern.

|  |
| --- |
| **Infobox 34 - FR CA position**  *Not relevant* |

***Aggregated exposure (combined for relevant emmission sources)***

Conclusion: No aggregated exposure assessment required.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| No risks could be identified for the environment based on the exposure and risk assessment for the service life of the biocidal product provided above (Scenario 2). For the application step (Scenario 1) of the biocidal product it is necessary to make use of an additional risk mitigation measure. In order to avoid indirect emissions to the environment via sewage treatment plant, the wastewater of the application process has to be disposed as hazardous waste. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 35 - FR CA position**  **Overall conclusion on the risk assessment for the environment of the product**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Scenario | STP | Surface water | Sediment | Soil | Groundwater | Secondary Poisoning | | Scenario 1- consumption app. WITHOUT FLOCCULATION  Military uniforms-Application step | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | | Scenario 1- consumption app. WITH FLOCCULATION  Military uniforms-Application step | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | Acceptable | | Scenario 1- tonnage app. WITHOUT FLOCCULATION  Military uniforms-Application step | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | Acceptable | | Scenario 1- tonnage app. WITH FLOCCULATION  Military uniforms-Application step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 2 –tonnage app.  Military uniforms-Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 2 –consumption app.  Military uniforms-Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | **Unacceptable** | Acceptable | | Scenario 3– consumption app. WITHOUT FLOCCULATION  Forestry clothing-Application step | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | | Scenario 3- consumption app. WITH FLOCCULATION  Forestry clothing-Application step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | **Unacceptable** | Acceptable | | Scenario 4 – consumption app. (Finh 0.2 and 200 mg/m2)  Forestry clothing-Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 200 mg/m2)  Forestry clothing-Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 4 revised- consumption app. (Finh 0.01 and 1300 mg/m2)  Forestry clothing-Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 5– consumption app. WITHOUT FLOCCULATION  Wool protection- Application step | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** | Acceptable | | Scenario 5- consumption app. WITH FLOCCULATION  Wool protection- Application step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 6 –worst case tonnage app.  Wool protection- Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | | Scenario 6 –refined tonnage app.  Wool protection- Service life step | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable |   To conclude, risks for environmental compartments are unacceptable with a concentration of permethrin of 40%. As technical concentration in the KONSERVAN P40 is 43% (see Infobox 17), the correct RCR are higher than those calculated above and risk to the environment are also unacceptable. The use of the product without unacceptable risk for the environement is possible only with risk mitigation measure that prevent any realase of the active subtances in the aquatic comparment.  **Application of KONSERVAN P40**  Industrial use of product KONSERVAN P40 is only possible with the following RMM “Application solutions must be collected and reused or disposed as a hazardous waste. They may not be released to soil, ground, surface water or any kind of sewer”. ..  **Use of articles treated with KONSERVAN P40**    Use of KONSERVAN P40 is only possible for the treatment of non-washable wool. The following instruction must appear on the label: “for production of non-washable wool only”.  Any other possible use of treated textiles would lead to unacceptable risks. Hence, they should be considered ny each member state only in the frame of authorization according to Article 19(5) |

### Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC)*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Not relevant*

# Annexes[[20]](#footnote-21)

## List of studies for the biocidal product (family)

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author(s)** | | **Year** | | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | | **Data Protection Claimed (Yes/No)** | | **Owner (PUB / ORG)** | | **Date of first submission** | |
| Wannenwetsch | | 2016 | | Determination of colour, physical state and odour of KONSERVAN P 40  Report No 1512-K4002-20-UWA-0454-1 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the pH value of an aqueous 1% solution of KONSERVAN P 40  Report No 1512-K 4002-2-UWA-0455-2 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the density of KONSERVAN P 40  Report No 1512-K 4002-6-UWA-0456-3 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the accelerated storage stability, the corrosion characteristics and the pH value of KONSERVAN P 40 at 54°C over 14 days and sample specific validation  Report No 1512-K4002-13.1-UWA-0466-7 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the foaming of KONSERVAN P 40  Report No 1512-K 4002-15-UWA-0459-6 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the surface tension and the critical micelle concentration of an aqueous solution of KONSERVAN P 40  Report No 1512-K 4002-3-UWA-0458-5 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the viscosity of KONSERVAN P 40  Report No 1512-K 4002-5-UWA-0457-4 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Simonides | | 2016 | | Determination of the explosive properties of KONSERVAN P 40  Report No MSI2016-01 | | Yes | | Thor GmbH | |  | |
| Smeykal | | 2016 | | Determination of physico-chemical properties Flash Point  Report No CSL-16-0059.01 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Smeykal | | 2016 | | Determination of physico-chemical properties Thermal Stability (OECD 113) Self-Reactive Substances (UN Class 4, division 4.1)  Report No CSL-16-0059.02 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Simonides | | 2016 | | Determination of the oxidising properties of KONSERVAN P 40  Report No MSl2016-02 | | Yes | | Thor GmbH | |  | |
| Bäßler | | 2016 | | EVALUATION OF THE CORROSIVE EFFECT OF BIOCIDE PRODUCT  Report No 16001095 (6.1/15272) | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Smeykal | | 2016 | | Determination of physico-chemical properties Auto-Ignition Temperature  Report No CSL-16-0059.03 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Möller M | | 2017 | | Colorimetric Method for Determination of the Stability of Dilute Emulsions  Study CSL-17-0525.01 | | Yes | | Thor SARL | |  | |
| Wannenwetsch | | 2016 | | Determination of the foaming of KONSERVAN P 40  Report No 1512-K 4002-15-UWA-0459-6 | | Yes | | CHT R. Beitlich GmbH / Thor SARL | |  | |
| Kröckel, | 2016 | | Screening of different insecticide impregnated textiles for their toxicity on the yellow fever mosquito *Aedes aegypti* using WHO susceptibility tubes  Report N° TL-8305-0331 | |  | |  | | 2016 | |
| Kröckel, | 2016 | | Laboratory study on the knock-down efficacy of permethrin treated fabrics (Bematin Per 40) by CHT R. beitlich GmbH on malaria mosquitoes (*Anopheles gambiae)* using WHO susceptibility tubes  Report N° BG-36325/02 | |  | |  | | 2016 | |
| Kröckel, | 2016 | | Laboratory study on the knock-down efficacy of permethrin treated fabrics (Bematin Per 40) by CHT R. beitlich GmbH on southern house mosquitoes (*Culex quinquefasciatus*) using WHO susceptibility tubes  Report N° BG-36325/01 | |  | |  | | 2016 | |
| Dautel | 2016 | | Laboratory study on knock-down efficacy of permethrin treated fabrics on *Ixodes ricinus* ticks  Report N° CHT\_IR\_0116\_01 | |  | |  | | 2016 | |
| Serrano | 2008 | | Mesure de l'efficacité de traitements d'un textile destine à lutter contre les moustiques  Report N° 1302/1208R | |  | |  | | 2008 | |
| Serrano | 2015 | | Assessment of the insecticide efficacy of an impregnated fabric affect against mosquito  Report N° 1949a/0615 | |  | |  | | 2015 | |
| Linn | 2016 | | Efficacy test against clothes moths *Tineola bisselliella* (larvae and adults) and Carpet beetles *Anthrenus flavipes* (larvae and adults) with treated fabric  Report N° BIO151b-16 | |  | |  | | 2016 | |
| Dautel | 2017 | | Evaluation of the repellent efficacy of treated textiles against *Ixodes ricinus* ticks using the Moving Object Bioassay  Report N° CHT\_IR\_0207\_01 | |  | |  | | 2017 | |
| Dautel | 2017 | | Evaluation of the knock-down efficacy of a treated fabric against *Ixodes ricinus*  Report N° CHT\_IR\_0117\_01 | |  | |  | | 2017 | |
| Serrano | 2016 | | Konservan P 40:  Assessment of the insecticide efficacy of an anti-mosquito fabric treatment  Efficacy against mosquitoes and ticks  Report N° 2085/0516 | |  | |  | | 2016 | |
| Serrano | 2017 | | Fabric K4380:  Assessment of the insecticide efficacy of an anti-mosquito impregnated  Efficacy against mosquitoes  Report N° 2204/0317 | |  | |  | | 2017 | |
| Serrano | 2017 | | Fabric K4380:  Assessment of the insecticide efficacy of an anti-ticks fabric treatment  Efficacy against ticks  (choice test) | |  | |  | | 2017 | |
| Serrano | 2017 | | Assessment of the anti-bite efficacy of an anti-mosquito impregnated fabric  (arm in cage)  Report N°2204b/0317 | |  | |  | | 2017 | |
| Serrano | 2017 | | Assessment of the anti-bite efficacy of an anti-mosquito impregnated fabric  (arm in cage)  Report N° 2178a/0117 | |  | |  | | 2017 | |
| Kochan | 2016 | | Fabric finished with BEMATIN PER 40 ( KONSERVAN P 40) (contains Permethrin) linked with TUBICOAT MOP NEU (acrylate/ polyurethane dispersion) Local Lymph Node Assay (OEC 429)  Thor/ GmbH | | Yes | | Thor | | 2017 | |

## Output tables from exposure assessment tools

****

## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)

Not relevant (See IUCLID file available)

Supportive efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisa ged** | **Test substance** | **Test**  **Organism (s)** | **Test method** | **Test system / concentrat ions applied / exposure time** | **Test results: effects** | **Reference** |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with Konservan P 40 | *Aedes aegypti*  (10 adults female/ replication) | WHO Tube test  Test conditions :  Temperature 27 +/-1°C  RH 60-80%  Post monitoring:  Temperature 27-29 °C  RH 75-85% | A test sample is inserted into a standard WHO plastic tube. 10 mosquitoes are collected into a transfer tube with an aspirato, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 10 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  5 replication/ sample  5 samples of fabric were tested:  S 1-O: original fabric (unwashed), permethrin content **1943 mg/m²**, S1-W:washed 30 times at 40°C, permethrin content **1964mg/m²**  S 2-O: original (unwashed) **4652 mg/m²**  S2-W: washed fabric 30 times at 40°C, permethrin content **4316** mg/m²  S3-W: washed 30 times at 40°C, permethrin content **3617** **mg/m²**  S4-W: washed 30 times at 40°C, permethrin content **2792 mg/m²**  S5-O: original (unwashed) permethrin content **3225 mg/m²**  S5-W: washed fabric 30 times at 40°C, permethrin content **1840 mg/m²** | O= original, W = washed   |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | Untreated (control) | 0 | 0 | | S1- O  S1- W | 78  66 | 40  26 | | S-2-O  S2-W | 96  96 | 90  56 | | S3-W | 80 | 44 | | S4-W | 82 | 40 | | S5-O  S5-W | 98  90 | 80  28 |   Kd and mortality for some samples don’t fulfill requirement of TNsG PT 18.  This study was considered as a supportive data. | Kröckel, 2016 TL-8305-0331 |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without Bematin Per 40 | *Anopheles gambiae*  (10 adults female/ replication) | WHO Tube test  Test conditions:  Temperature 26 +/-1°C  RH 60-80%  Post monitoring:  Temperature 27-29 °C  RH 75-85% | A test sample is inserted into a standard WHO plastic tube. 10 mosquitoes are collected into a transfer tube with an aspirator, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 5 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  5 replication/ sample  3 samples of fabric were tested:  BEMATIN PER 40: permethrin content **1400 mg/m²**  BEMATIN PER 40 + binding agent: permethrin content **1300 mg/m²**, Binding agent: 100 g/L | |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | Untreated (control) | 0 | 6 | | BEMATIN PER 40 | 76 | 38 | | BEMATIN PER 40 + binding agent | 45 | 13 | | Binding agent | 0 | 0 |   Kd and mortality don’t fulfill requirement of TNsG PT 18  This study was considered as a supportive data | Kröckel, 2016 BG-36325/02 |
| MG 3,  Pest control | PT 18  Insectici des | Various fabrics treated with/without Bematin Per 40 | *Culex quinquefasciatus*  (10 adults female/ replication) | WHO Tube test  Test conditions:  Temperature 26 +/-1°C  RH 60-80%  Post monitoring:  Temperature 27-29 °C  RH 75-85% | A test sample is inserted into a standard WHO plastic tube. 10 mosquitoes are collected into a transfer tube with an aspirator; the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 5 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  5 replication/ sample  3 samples of fabric were tested:  BEMATIN PER 40: permethrin content **1400 mg/m²**  BEMATIN PER 40 + binding agent: permethrin content **1300 mg/m²**, Binding agent: 100 g/L | |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | Untreated (control) | 2 | 2 | | BEMATIN PER 40 | 30 | 22 | | BEMATIN PER 40 + binding agent | 6 | 6 | | Binding agent | 4 | 0 |   Kd and mortality don’t fulfill requirement of TNsG PT 18  This study was considered as a supportive data | Kröckel, 2016 BG-36325/01 |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without Konserva n P 40 | *Anopheles gambiae*  5 female adults/  replication | WHO Tube test  Test conditions :  Temperature 25 +/-1°C  RH 70+/-5%  Post monitoring  (tropical conditions):  Temperature 28+/- 1°C  RH 80+/-5% | A test sample is inserted into a standard WHO plastic tube and fastened in position with two spring-wire clips, in a way that it lines with the inner wall of the tube.  5 mosquitoes are collected into a transfer tube with an aspirator, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 3 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One hour after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  10 replications/ sample  3 samples of fabric were tested:  S1 untreated fabric (control)  S 2: original fabric (unwashed)  S3: washed fabric 30 times  **The rate application tested was unknown** | |  |  |  | | --- | --- | --- | | sample | Kd (%) | Mortality (%) | | S1 (control) | 0 | 1 | | S2 | 100 | 100 | | S3 | 100 | 100 |   The textile treated with Permethrin showed a sufficient efficacy against *Anopheles gambiae* (> 80%), nevertheless, the report doesn’t mention a rate of application  This study was considered as a supportive data | Serrano  , (2008) 1302/1208R |
| MG 3,  Pest control | PT 18  Insecticide | Various fabrics treated with/without Konserva n P 40 | *Aedes aegypti*  5 female adults/  replication | WHO Tube test  Test conditions:  Temperature 25 +/-1°C  RH 75+/-5%  Post monitoring:  Temperature 24-26+/-1 °C  RH 70-80+/-5% | A test sample is inserted into a standard WHO plastic tube and fastened in position with two spring-wire clips, in a way that it lines with the inner wall of the tube.  5 mosquitoes are collected into a transfer tube with an aspirator, the transfer tube is then closed with a plastic slide and connected to the exposure tube, containing the textile sample. The slide is opened and test mosquitoes are gently blown into the exposure tube and the slide is closed again. The exposure time is 3 min.  Post monitoring: Mosquitoes are kept in insecticide free air. One and two hours after the exposure the number of knocked-down mosquitoes is counted. The mortality is determined after 24 h.  10 replications/ sample  2 samples of fabric were tested:  S1: untreated fabric (control)  S 2: washed fabric 50 times  **The rate application tested was unknown** | |  |  |  |  | | --- | --- | --- | --- | | sample | Kd (%) at 60 min | Kd (%) at 120 min | Mortality (%) | | S1  (control) | 0 | 0 | 2 | | S2 | 52 | 100 | 100 |   The textile treated with Permethrin showed a sufficient efficacy against *Aedes aegypti* (> 80%), nevertheless, the report doesn’t mention a rate of application  This study was considered as a supportive data | Serrano  , (2015) 1949a/0615 |

## Confidential annex

See in a document annex

## Biocidal Products Committee (BPC) Opinion on a request according to Article 38 of Regulation (EU) No 528/2012 on Questions on unresolved objections during the mutual recognition procedure of the PT 18 biocidal product Konservan P 40 containing permethrin



1. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
2. WHO\_CDS\_NTD\_WHOPES\_GCDPP-2006.3-page 21 (tube test) [↑](#footnote-ref-3)
3. WHO\_HTM\_NTD\_WHOPES\_2013.1 at § 2.2.1”WHO cone bioassays” [↑](#footnote-ref-4)
4. Technical guideline TL 8305-0331 of the German Armed Forces (Bundesamt für Wehrtechnik und Beschaffung) [↑](#footnote-ref-5)
5. OPPTS 810.3700 (2010) [↑](#footnote-ref-6)
6. WHO\_HTM\_NTD\_WHOPES\_2009.4 [↑](#footnote-ref-7)
7. Method BPD Bio B 940-03 (modified) [↑](#footnote-ref-8)
8. Contact toxicity and residual activity of different permethrin-based fabric impregnation methods for Aedes aegypti (Diptera: Culicidae), Ixodes ricinus (Acari: Ixodidae), and Lepisma saccharina (Thysanura: Lepismatidae). [↑](#footnote-ref-9)
9. PT18 and PT 19, Draft guidance to replace part of appendices to chapter 7 (page 187 to 200) from TNsG on Product Evaluation [↑](#footnote-ref-10)
10. Pyrethroid resistance and synergism in a field strain of the German cockroach (Dictyoptera: *Blattellidae*). [↑](#footnote-ref-11)
11. House fly (Diptera: *Muscidae*) resistance to permethrin on southern California dairies. [↑](#footnote-ref-12)
12. Assessing permethrin resistance in the stable fly (Diptera: *Muscidae*) in Florida by using laboratory selections and field evaluations. [↑](#footnote-ref-13)
13. Development of permethrin resistance in *Culex quinquefasciatus* Say in Kuala Lumpur, Malaysia. [↑](#footnote-ref-14)
14. Quantitative trait loci mapping of genome regions controlling permethrin resistance in the mosquito *Aedes aegypti*. [↑](#footnote-ref-15)
15. Dosage-dependent effects of permethrin-treated nets on the behaviour of *Anopheles gambiae* and the selection of pyrethroid resistance [↑](#footnote-ref-16)
16. Insecticide susceptibility tests of *Anopheles minimus* s.l., *Aedes aegypti*, *Aedes albopictus*, and *Culex quinquefasciatus* in northern Thailand. [↑](#footnote-ref-17)
17. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-18)
18. Emission scenario document for biocides uses as preservatives in the textile processing industry (Product type 9 &18); May,2001. [↑](#footnote-ref-19)
19. Prevention, Integrated Pollution, Control” (IPPC) Reference Document on Best Available Techniques for the Textiles Industry." European Commission (2003)” [↑](#footnote-ref-20)
20. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-21)