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

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

(submitted by the evaluating Competent Authority)



NEODUST

Product type 18

Permethrin and PBO

Case Number in R4BP: [BC-QQ040524-24]

Evaluating Competent Authority: GREECE

Date: September 2021

Updated November 2023

Table of Contents

[1 CONCLUSION 6](#_Toc151566188)

[2 ASSESSMENT REPORT 8](#_Toc151566189)

[2.1 Summary of the product assessment 8](#_Toc151566190)

[2.1.1 Administrative information 8](#_Toc151566191)

[2.1.1.1 Identifier of the product 8](#_Toc151566192)

[2.1.1.2 Authorisation holder 8](#_Toc151566193)

[2.1.1.3 Manufacturer(s) of the product 8](#_Toc151566194)

[2.1.1.4 Manufacturer(s) of the active substances 8](#_Toc151566195)

[2.1.2 Product composition and formulation 10](#_Toc151566196)

[2.1.2.1 Identity of the active substances 10](#_Toc151566197)

[2.1.2.2 Candidate(s) for substitution 11](#_Toc151566198)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 11](#_Toc151566199)

[2.1.2.4 Information on technical equivalence 11](#_Toc151566200)

[2.1.2.5 Information on the substance(s) of concern 11](#_Toc151566201)

[2.1.2.6 Type of formulation 12](#_Toc151566202)

[2.1.3 Hazard and precautionary statements 12](#_Toc151566203)

[2.1.4 Authorised use(s) 13](#_Toc151566204)

[2.1.4.1 Use description 13](#_Toc151566205)

[2.1.4.2 Use-specific instructions for use 13](#_Toc151566206)

[2.1.4.3 Use-specific risk mitigation measures 13](#_Toc151566207)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 13](#_Toc151566208)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 13](#_Toc151566209)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 14](#_Toc151566210)

[2.1.4.7 Use-specific instructions for use 14](#_Toc151566211)

[2.1.4.8 Use-specific risk mitigation measures 14](#_Toc151566212)

[2.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 15](#_Toc151566213)

[2.1.4.10 Where specific to the use, the instructions for safe disposal of the product and its packaging 15](#_Toc151566214)

[2.1.4.11 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 15](#_Toc151566215)

[2.1.4.12 Use-specific instructions for use 15](#_Toc151566216)

[2.1.4.13 Use-specific risk mitigation measures 16](#_Toc151566217)

[2.1.4.14 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 16](#_Toc151566218)

[2.1.4.15 Where specific to the use, the instructions for safe disposal of the product and its packaging 16](#_Toc151566219)

[2.1.4.16 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 16](#_Toc151566220)

[2.1.4.17 Use-specific instructions for use 16](#_Toc151566221)

[2.1.4.18 Use-specific risk mitigation measures 17](#_Toc151566222)

[2.1.4.19 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 17](#_Toc151566223)

[2.1.4.20 Where specific to the use, the instructions for safe disposal of the product and its packaging 17](#_Toc151566224)

[2.1.4.21 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 17](#_Toc151566225)

[2.1.4.22 Use-specific instructions for use 18](#_Toc151566226)

[2.1.4.23 Use-specific risk mitigation measures 18](#_Toc151566227)

[2.1.4.24 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 18](#_Toc151566228)

[2.1.4.25 Where specific to the use, the instructions for safe disposal of the product and its packaging 18](#_Toc151566229)

[2.1.4.26 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 18](#_Toc151566230)

[2.1.5 General directions for use 19](#_Toc151566231)

[2.1.5.1 Instructions for use 19](#_Toc151566232)

[2.1.5.2 Risk mitigation measures 19](#_Toc151566233)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 19](#_Toc151566234)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 20](#_Toc151566235)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 20](#_Toc151566236)

[2.1.6 Other information 20](#_Toc151566237)

[2.1.7 Packaging of the biocidal product 21](#_Toc151566238)

[2.1.8 Documentation 24](#_Toc151566239)

[2.1.8.1 Data submitted in relation to product application 24](#_Toc151566240)

[2.1.8.2 Access to documentation 24](#_Toc151566241)

[2.2 Assessment of the biocidal product 25](#_Toc151566242)

[2.2.1 Intended use(s) as applied for by the applicant 25](#_Toc151566243)

[2.2.2 Physical, chemical and technical properties 28](#_Toc151566244)

[2.2.3 Physical hazards and respective characteristics 40](#_Toc151566245)

[2.2.4 Methods for detection and identification 44](#_Toc151566246)

[2.2.4.1 Formulation analysis 46](#_Toc151566247)

[2.2.4.2 Analysis of substances of concern 48](#_Toc151566248)

[2.2.5 Efficacy against target organisms 49](#_Toc151566249)

[2.2.5.1 Function and field of use 49](#_Toc151566250)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 49](#_Toc151566251)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 49](#_Toc151566252)

[2.2.5.4 Mode of action, including time delay 49](#_Toc151566253)

[2.2.5.5 Efficacy data 50](#_Toc151566254)

[2.2.5.6 Occurrence of resistance and resistance management 66](#_Toc151566255)

[2.2.5.7 Known limitations 66](#_Toc151566256)

[2.2.5.8 Evaluation of the label claims 66](#_Toc151566257)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 73](#_Toc151566258)

[2.2.6 Risk assessment for human health 74](#_Toc151566259)

[2.2.6.1 Assessment of effects on Human Health 74](#_Toc151566260)

[2.2.6.2 Exposure assessment 83](#_Toc151566261)

[2.2.6.3 Risk characterisation for human health 96](#_Toc151566262)

[2.2.7 Risk assessment for animal health 103](#_Toc151566263)

[2.2.8 Risk assessment for the environmental 103](#_Toc151566264)

[2.2.8.1 Effects assessment on the environment 103](#_Toc151566265)

[2.2.8.2 Exposure assessment 107](#_Toc151566266)

[2.2.8.3 Risk characterisation 122](#_Toc151566267)

[2.2.8.4 Measures to protect man, animals and the environment 129](#_Toc151566268)

[2.2.8.5 Assessment of a combination of biocidal products 129](#_Toc151566269)

[2.2.8.6 Comparative assessment 129](#_Toc151566270)

[3 Annexes 130](#_Toc151566271)

[3.1 List of studies for the biocidal product (family) 130](#_Toc151566272)

[3.2 Model used and exposure calculations 133](#_Toc151566273)

[3.2.1 Human health exposure assessment 133](#_Toc151566274)

[3.2.2 Emission Environmental exposure calculation 133](#_Toc151566275)

[3.3 New information on the active substance 133](#_Toc151566276)

[3.4 Residue behaviour 133](#_Toc151566277)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 133](#_Toc151566278)

[3.6 Confidential annex 133](#_Toc151566279)

[3.7 Other 133](#_Toc151566280)

# CONCLUSION

**Conclusion for Physico-chemistry:**

NEODUST is a Solid Microgranules insecticide (PT 18), containing nominal (pure) active ingredient of 0.5 % w/w Permethrin and 0.05 % w/w Piperonyl Butoxide (PBO).

Its physicochemical properties are considered acceptable. For more information please refer to Table 2.2.2. The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

The product is stable for two years at ambient temperature when stored in its initial commercial packaging (refer to acceptable accelerated and 2 years storage stability studies).

Acceptable analytical methods were provided for the determination of both active substances in the formulation.

**Conclusion for Human Health:**

The biocidal product NEODUST is not classified for health hazards but should carry the precautionary phrase EUH208 “Contains permethrin. May produce an allergic reaction”, to protect already sensitised individuals.

Regarding risk assessment, both the primary (direct) exposure of professional and non-professional users during product application and the secondary (indirect) exposure of the general public following application of the biocidal product do not entail unacceptable risks for human health.

**Conclusion for Environment:**

According to the environmental risk assessment, the risk for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning) is acceptable when the product is used for indoor uses according to label instruction. ~~For the indoor uses, the product cannot be authorised where direct emissions to surface water cannot be prevented.~~ For the indoor uses (2 & 4) concerning animal housings, the product was not authorised as the data was insufficient and in late submission by the applicant to be evaluated. ~~Hence, for Use 2 the product is not authorised, whereas for Use 4 the product is only authorised for indoor use excluding animal housings.~~

Regarding the **outdoor use** of the product, **Use 5** cannot be Authorised as the risk assessments for the soil and secondary poisoning compartments are unacceptable.

**Conclusion for Efficacy:**

Several efficacy studies (laboratory and field studies) were submitted by the applicant with NEODUST containing permethrin 0.5% and PBO 0.05%, to support the intended uses of the product against the claimed target organisms.

Based on the results of the submitted efficacy studies, the product was effective when applied, by both professionals and non-professionals as:

* Surface treatment, including cracks and crevices, indoors (in henhouses) against adults of chicken mites (*D. gallinae*) at 12 g/m2 (Intended Use # 2). The product has a residual effect of at least 1 week.
* Surface treatment indoors (in a band along the perimeter) by spreading, including cracks and crevices, against American cockroaches (*Periplaneta americana*) at 10 g /m2 (Intented Use 3). The product has a residual effect of 3 weeks. Noticeable mortality of American cockroaches is expected 48-96h after exposure of the insects to the treated surfaces.
* Surface (perimetral) application, indoors (in stables, animal housing and rooms) against sheep ticks (*Ixodes ricinus*) at 12 g/m2 (Intended Use # 4). The product has a residual effect of 3 weeks. The product should be applied in the absence of animals or humans. Entrance of humans or animals, in the treated area, should only be permitted after 24 hours. It is noted that, according to the Efficacy Guidance on the BPR, when the product is intended for use in poultry farms, tests should be performed against *Argas persicus*. Hence, if the use in general animal housing is to be claimed, tests with *A. persicus* must be submitted. Otherwise, the label of the product should clearly indicate that the use is limited to animal houses, excluding poultry houses.
* Surface (perimetral and crack and crevice) application, indoor and outdoor, against the black garden ant (*Lasius niger*) at 10 g/m2 (Intended Use # 5). The product has a residual effect of 3 weeks.

The Intended Use # 1 of the product against fleas (*Ctenocephalides felis*) from an efficacy point of view, is not acceptable as applied for by the applicant *(for more details please refer to the conclusion of efficacy of the product in 2.2.5.5).*

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| NEODUST | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Bleu Line S.r.l. |
| **Address** | Via Virgilio, 28, Z.I. Villanova  47122 Forlì (FC)  Italy |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | BLEU LINE S.r.l. |
| **Address of manufacturer** | Via Virgilio, 28, Z.I. Villanova  47122 Forlì (FC)  Italy |
| **Location of manufacturing sites** | (1) BLEU LINE S.r.l  via Tacito, 9  20094 Corsico (MI)  Italy  (2) FERBI S.r.l.  Viale 1° Maggio – C.da Ripoli  64023 Mosciano S. Angelo (TE)  Italy  (3) SINAPAK S.r.l.  Via dell’Industria e dell’Artigianato, 7  27049 Stradella (PV)  Italy |

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

|  |  |
| --- | --- |
| **Active substance 1** | Permethrin |
| **Name of manufacturer** | Tagros Chemicals India Private Ltd. |
| **Name of substance supplier according to art. 95** | Limaru (acting for Tagros) |
| **Address of manufacturer** | Limaru NV  Business Center Mezzo, Paalsesteenweg 170 Bus 7, 3583 Beringen, Belgium  Tagros Chemicals India Limited  No.72, Marshalls Road Jhaver Centre, IV floor, Rajah Annamalai Building Egmore  Chennai 600008,  India |
| **Location of manufacturing sites** | A-4/1&2, Sipcot Industrial Complex, Kudikadu, Cuddalore  607 005 Tamil Nadu  India  The address of the manufacturing plant for the active substance has been evaluated in the dossier for Permethrin PT18. The manufacturer of the active substance is the same. |

|  |  |
| --- | --- |
| **Active substance 2** | Piperonyl Butoxide |
| **Name of manufacturer** | ENDURA S.P.A. |
| **Address of manufacturer** | Viale Pietramellara, 5  40121 Bologna  Italy |
| **Location of manufacturing sites** | Via Baiona 107-111  48123 Ravenna  Italy  The address of the manufacturing plant for the active substance has been evaluated in the dossier for Piperonyl Butoxide PT18. The manufacturer of the active substance is the same.  A statement on the postal code change of the manufacturing site has been submitted. |

### Product composition and formulation

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 substances

|  |  |
| --- | --- |
| **Main constituents** | |
| **Active substance 1** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | 93% (ratio cis:trans 25:75)  Permethrin is a reaction mass of four stereoisomers  1Rcis permethrin content = 5.0 – 10.0% w/w.  1Scis permethrin content = 15.0 – 20.0% w/w.  1Rtrans permethrin content = 45.0 – 55.0% w/w.  1Strans permethrin content = 17.0 – 27.0% w/w.  Content in the biocidal product:  0.538 % w/w (technical)  0.5 % w/w (pure, based on minimuim purity of 93% w/w) |
| **Molecular formula** | C21H20Cl2O3 |
| **Structural formula** |  |
| **Molecular weight (g/mol)** | 391.29 g/mol |
| **Active substance 2** | |
| **ISO name** | Piperonyl Butoxide (BPO) |
| **IUPAC or EC name** | -[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole |
| **EC number** | 200-076-7 |
| **CAS number** | 51-03-6 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | 94%  Content in the biocidal product:  0.053 % w/w (technical)  0.05 % w/w (pure, based on minimuim purity of 94% w/w) |
| **Molecular formula** | C19H30O5 |
| **Structural formula** |  |
| **Molecular weight (g/mol)** | 338.43 g/mol |
|  |  |

#### Candidate(s) for substitution

Permethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

Piperonyl Butoxide does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content**  **(% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.538 (technical)  0.5\*  (pure) |
| Piperonyl Butoxide (PBO) | -[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole | Active substance | 51-03-6 | 200-076-7 | 0.053 (technical)  0.05\*  (pure) |
| Arcosolv DPM | (2-METHOXYME-THYLETHOXY)PROPANOL | Solvent | 34590-94-8 | 252-104-2 | 0.500 |
| Other components | Confidential information. Please refer to the confidential information annex at the end of the document | | | | up to 100 |
| \* based on minimum purity of 93% w/w and 94% w/w for permethrin and PBO respectively | | | | | |

#### 

#### Information on technical equivalence

The source of permethrin in NEODUST biocidal formulation is Tagros Chemicals India Ltd., which supported permethrin inclusion into Annex I of BPD. Thus, technical equivalence is not to be addressed.

The source of PBO in NEODUST biocidal formulation is Endura Spa, which supported PBO inclusion into Annex I of BPD. Thus, technical equivalence is not to be addressed.

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

The biocidal product NEODUST contains the co-formulant Arcosolv DPM (CAS No. 34590-94-8) that should be considered as a substance of concern (SoC).

According to the submitted MSDS, this co-formulant has no classification and therefore there is no impact on the classification of the biocidal product NEODUST.

Further information can be found in the Confidential Annex of this PAR.

#### Type of formulation

|  |
| --- |
| MG - Microgranules |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1,  Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment.  P391: Collect spillage.  P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations. |
|  | |
| Note | EUH208: Contains permethrin. May produce an allergic reaction. |

### Authorised use(s)

#### Use description

**Table 1. Use # 1 – Spreading on fleas (indoor) – NOT AUTHORISED**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor surface treatments against *Ctenocephalides felis* (fleas). The product has a residual action with an efficacy of at least 1 week. |
| **Target organism (including development stage)** | *Ctenocephalides felis* adult |
| **Field of use** | Indoor |
| **Application method(s)** | Spreading .Apply the product directly from the packaging or through the spreader in a homogeneous manner in surface as for examples the carpets. |
| **Application rate(s) and frequency** | 12 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional, Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Apply the product directly from the packaging or through the spreader in a homogeneous manner in surface as for examples the carpets.  Remove (clean) product and dead insects when the presence of live insects is stopped. |

#### 

#### Use-specific risk mitigation measures

|  |
| --- |
| No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.  “Move the animals away during the treatment”  “The treatment premises/room must not accessible to pets”  “Clean the treatead area before the re-entry of the animal”  ”Do not treat directly on the animal”**.** |

#### 

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

|  |
| --- |
| Refer to general direction of use |

#### 

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

|  |
| --- |
| Refer to general direction of use |

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

|  |
| --- |
| Refer to general direction of use |

**Table 2. Use # 2 – Indoor application against chicken mites -NOT AUTHORISED**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor surface treatments, including cracks and crevices, against chicken mites.  The product has a residual action of 1 week. |
| **Target organism (including development stage)** | Scientific name: *Dermanyssus gallinae*  Common name: Chicken mites  Development stage: Adults |
| **Field of use** | Indoor (henhouses) |
| **Application method(s)** | Surface treatment, including cracks and crevices, by spreading.  Apply the product directly from the packaging or through the spreader in a homogeneous manner in henhouses.  The product can be applied to the following henhouses (subcategories), where no connection to the STP is expected:  7. Battery, no treatment, Laying Hens  10. Compact, Laying hens  13. Grating floor, Laying hens |
| **Application rate(s) and frequency** | 12 g product/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

Apply the product directly from the packaging or through the spreader in a homogeneous manner as surface treatment, including cracks and crevices, in henhouses. Remove (clean) product and dead insects when the presence of live insects is stopped.

#### Use-specific risk mitigation measures

Strictly NOT to be used in stables/animal housings connected to a sewage treatment plant (STP) and/or direct emissions to surface water cannot be prevented.

Only for application in animal housing (henhouses) authorised (7,10,13).

After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.

“Move the animals away during the treatment”

“The treatment premises/room must not accessible to pets”

“Clean the treatead area before the re-entry of the animal”

”Do not treat directly on the animal”

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

**Table 3. Use # 3 – Spreading on American cockroaches (indoor)**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Surface treatment indoors (in a band along the perimeter) by spreading, including cracks and crevices, against American cockroaches (*Periplaneta americana*). The product has a residual effect of 3 weeks |
| **Target organism (including development stage)** | Scientific name: *Periplaneta americana*  Common name: American cockroach  Development stage: Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Surface treatment indoors (in a band along the perimeter) by spreading, including cracks and crevices. |
| **Application rate(s) and frequency** | 10 g product/m2  Frequency: one time per month, *if the infestation persists.* |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Apply the product directly from the packaging or via the can dispenser uniformly as surface treatment indoors (in a band along the perimeter) including applications in cracks and crevices.  Remove (clean) product and dead insects when the presence of live insects is not recorded.  For the bottle packaging, turn the bottle upside down 4 times for the dosage of 10g/m2.  Bag packaging contain a measuring cup.  Noticeable mortality of American cockroaches is expected 48-96h after exposure of the insects to the treated surfaces. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Wet cleaning IS NOT applicable. Use only dry-cleaning procedures (vacuum or broom) or use damp paper.  Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. Do not apply directly to surfaces on which food or feed is stored, prepared or eaten. |

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

|  |
| --- |
| Refer to general direction of use |

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

|  |
| --- |
| Refer to general direction of use |

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

|  |
| --- |
| Refer to general direction of use |

**Table 4. Use # 4 – Indoor application against ticks**

|  |  |  |
| --- | --- | --- |
| **Product Type** | | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | | Indoor perimeter treatments against *Ixodes ricinus* (tick). The product has a residual action of 3 weeks. |
| **Target organism (including development stage)** | | Scientific name: *Ixodes ricinus*  Common name: Sheep tick  Development stage: Adults |
| **Field of use** | Indoors, excluding use in animal housings | |
| **Application method(s)** | | Surface treatment by spreading  Apply the product directly from the packaging or via the can dispenser uniformly in the perimeters of rooms. |
| **Application rate(s) and frequency** | | 12 g product/m2  Frequency: one time per month, *if the infestation persists.* |
| **Category(ies) of users** | | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | | Please see the relevant section. |

#### 

#### Use-specific instructions for use

Apply the product directly from the packaging or via the can dispenser uniformly as surface treatment in perimeters of rooms. Remove (clean) product and dead insects when the presence of live insects is not recorded. The product shall not be used in the presence of humans or animals (pets). Humans and animals (pets) can re-enter into the treated area 24 hours after the product application.

For the bottle packaging, turn the bottle upside down 5 times for the dosage of 12g/m2.

Bag packaging contain a measuring cup.

#### Use-specific risk mitigation measures

Wet cleaning IS NOT applicable. Use only dry-cleaning procedures (vacuum or broom) or use damp paper.

The treatment premises/room must not be accessible to pets.

Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.  
Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.

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

Refer to general direction of use

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

Refer to general direction of use

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

|  |
| --- |
| Refer to general direction of use |

**Table 5. Use # 5 – Indoor/~~outdoor~~ application against ants (indoor/~~outdoor~~) (NOT AUTHORISED in outdoor use)**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor ~~or outdoor~~ perimetral crack and crevice applications (to points where ants come into the building) against black garden ant. The product has a residual action of 3 weeks. |
| **Target organism (including development stage)** | Scientific name: *Lasius niger*  Common name: Black garden ant  Development stage: Adults |
| **Field of use** | Indoor  ~~Outdoor, around building in the perimeter~~ |
| **Application method(s)** | Apply the product directly from the packaging or via the can dispenser uniformly as perimetral crack and crevice applications. |
| **Application rate(s) and frequency** | 10 g product/m2  Frequency: one time per month, *if the infestation persists.* |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

Apply the product directly from the packaging or via the can dispenser uniformly as indoor ~~or outdoor~~ perimetral, crack and crevice treatment (to points where ants come into the building) against black garden ant infestation. Remove (clean) product and dead insects when the presence of live insects is not recorded.

For the bottle packaging, turn the bottle upside down 4 times for the dosage of 10g/m2

Bag packaging contain a measuring cup.

#### Use-specific risk mitigation measures

Wet cleaning IS NOT applicable. Use only dry-cleaning procedures (vacuum or broom) or use damp paper.

The treatment premises/room must not be accessible to pets.

Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.  
Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.

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

Refer to general direction of use

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

Refer to general direction of use

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

|  |
| --- |
| Refer to general direction of use |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Apply the product uniformly. * Read the instructions on the product. * The product **should** **only** be used in areas under the restriction of ‘strictly NOT wet-cleaned’ * Remove (clean) product and dead insects, when the presence of live insects is not recorded.   Strategies for managing the development of resistance:   * Where possible, application treatments should be recommended to be combined with non-chemical measures * Products should always be used in accordance with label recommendations. * Applications should always be made against the most susceptible stages in the pest life cycle. * Where an extended period of control is required, treatments should be alternated with products with different modes of action. * Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation. * In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.   The users should inform if the treatment is ineffective and report straightforward to the authorization holder. 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

|  |
| --- |
| - Wet cleaning IS NOT applicable. Perform dry cleaning of treated surfaces and adjacent floor. Use only dry-cleaning procedures (vacuum or broom) or use damp paper.  - After handling and in case of contamination wash thoroughly with soap and water.  -Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. -Do not apply directly to surfaces on which food or feed is stored, prepared or eaten. |

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

|  |
| --- |
| The product is very toxic to aquatic organisms with long lasting effects; can cause an allergic reaction due to Permethrin.  The biocidal product should not be applied in areas where food for human consumption is exposed at the time of treatment.  Avoid the exposure of animals during the treatment.  Do not use the product in agriculture. |

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

|  |
| --- |
| - Do not disperse in the environment.  - After dry cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.  - Empty containers, unused product and other waste generated during the treatment and cleaning (i.e., damp papers, vacuum or brooming waste) are considered hazardous waste. Collect all waste material and place in closable, marked containers.  - Do not throw on unpaved floors, in watercourses, in the sink or in the drain  - Dispose of contents/container in accordance with local regulations. |

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

|  |
| --- |
| In packs kept intact and under normal temperature conditions, the biocidal product keeps its characteristics unaltered for at least 2 years in its initial commercial packaging.  Do not stack the bag. |

### Other information

Not defined

### Packaging of the biocidal product

| **Type of packaging** | **Size packaging** | **Volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| --- | --- | --- | --- | --- | --- | --- |
| Bottle | 250 and 300 g | Diameter: 53 mm  Height: 184 mm  Size of opening: 29 mm | Non transparent waterproof HDPE | PP cap (with spreader). | General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 500 g | Diameter: 61.5 mm  Height: 204.5 mm  Size of opening: 29.8 mm | Non transparent waterproof HDPE | PP cap (with spreader). | Professional/ trained professional / General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 450 g | Diameter: 61.5 mm  Height: 204.5 mm  Size of opening: 29.8 mm | Non transparent waterproof HDPE | PP cap (with spreader). | General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 700 g | Diameter: 70.5 mm  Height: 206.5 mm  Size of opening: 45 mm | Non transparent waterproof HDPE | PP cap (with spreader). | General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 750 and 800 g | Diameter: 88 mm  Height: 150 mm  Size of opening: 40.5 mm | Non transparent waterproof HDPE | PP cap (with spreader). | General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 200 g | Diameter: 53 mm  Height: 184 mm  Size of opening: 29 mm | Non transparent waterproof HDPE | PP cap (with spreader). | Professional/ trained professional / General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| Bottle | 100, 350, 400 | Diameter: 61.5 mm  Height: 204.5 mm  Size of opening: 29.8 mm | Non transparent waterproof HDPE | PP cap (with spreader). | General public | Yes. Extrapolation can be made from bottle of 1000 g packaging size |
| **Bottle** | **1000 g** | Diameter: 76.7 mm  Height: 236 mm  Size of opening: 44.6 mm | Non transparent waterproof HDPE | PP cap (with spreader). | Professional/ trained professional / General public | **Yes. Based on data on storage stability test** |
| **Bag** | **1000 g** | Length: 21 cm  width: 30 cm  Height: 8 cm | non transparent waterproof PET/PE | heat sealing | Professional/ trained professional / General public | **Yes. Based on data on storage stability test** |
| Bag | 1000 g | Length: 20 cm  width: 25 cm  Height: 8 cm | non transparent waterproof Doypack (Paper/Al/PE) | heat sealing | Professional/ trained professional / General public | Yes. Extrapolation can be made from bag of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the same (PE) |
| Bag | 1 kg | Length: 20 cm  width: 25 cm  Height: 8 cm | non transparent waterproof (PET/Al/PE) | heat sealing | Professional/ trained professional / General public | Yes. Extrapolation can be made from bag of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the same (PE) |
| Bag | 200 g  500 g  2 kg  3 kg | It is not possible to define a specific size as they are different in relation to the needs of the customer and the packaging machines. | non transparent waterproof PET/PE | heat sealing | Professional/ trained professional | Yes. Extrapolation can be made from bag of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the same (PE) |
| Bag | 500, 700, 750 g | It is not possible to define a specific size as they are different in relation to the needs of the customer and the packaging machines. | non transparent waterproof PET/PE | heat sealing | General public | Yes. Extrapolation can be made from bag of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the same (PE) |
| Bucket | 1 kg | Upper Diameter: 144 mm  Bottom Diameter: 120 mm  Height: 135 mm | PP | PP cover | Professional/ trained professional | Yes. Extrapolation can be made from bottle of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the similar (PE) |
| Bucket | 5 kg | Upper Diameter: 225 mm  Bottom Diameter: 195 mm  Height: 255 mm | PP | PP cover | Professional/ trained professional | Yes. Extrapolation can be made from bottle of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the similar (PE) |
| Bucket | 2, 3, 10, 20, 25 kg | Specific volume of packaging is not still available. Information will be provided as soon as possibile | PP | PP cover | Professional/ trained professional | Yes. Extrapolation can be made from bottle of 1000 g packaging size as the inner material, which is in contact with the biocidal product, is the similar (PE) |

In **bold** packaging used in the storage stability study.

|  |
| --- |
| **Conclusion on the packaging of the biocidal product** |
| Accelerated storage stability test for 8 weeks at 40°C and 2 years shelf-life storage stability at ambient temperature demonstrated compatibility with the package materials **bottle from HDPE (1 Kg)** and **bag from PET/PE (1 Kg)**.  According to Guidance on the BPR: Volume I Parts A+B+C: “*In solid preparations extrapolation to all types of packaging is acceptable, except to more flexible packs.”* Therefore, all the above mentioned proposed packagings are considered acceptable for commercial use with label implication: **“Do not stack the bags”.** |

### Documentation

#### Data submitted in relation to product application

The applicant Bleu Line Srl is not the owner of data on the active substance permethirn as it is not the notifier which submitted the Annex II complete dossier to RMS Irland.

The applicant Bleu Line Srl is not the owner of data on the active substance PBO as it is not the notifier which submitted the Annex II complete dossier to RMS Greece.

A full new product dossier was submitted by Bleu Line Srl in support of the product NEODUST containing permethrin and PBO.

A 10-year data protection (starting at the date of the registration in Greece) is claimed for the data submitted along with present dossier and summarised in the annex 3.1.

#### Access to documentation

The applicant Bleu Line Srl submits a letter of access by Limaru which cover the Annex II dossier of Tagros Chemicals India Ltd. for all the data on the active substance permethrin in support for the registration of the product NEODUST containing permethrin.

The applicant Bleu Line Srl submit a letter of access by Endura for all the data on the active substance PBO in support for the registration of the product NEODUST containing PBO

## Assessment of the biocidal product

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

Table 6. Intended use # 1 – Spreading on fleas (indoor)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor surface treatments against Ctenocephalides felis (fleas).  The product has a residual action with an efficacy of at least 1 week. |
| **Target organism (including development stage)** | *Ctenocephalides felis* adult |
| **Field of use** | Indoor |
| **Application method(s)** | Spreading  Apply the product directly from the packaging or through the spreader in a homogeneous manner in surface as for examples the carpets. |
| **Application rate(s) and frequency** | 12 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 7. Intended use # 2 – Spreading on chicken mites (indoor)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor surface treatments against chicken mites.  The product has a residual action with an efficacy of at least 1 week. |
| **Target organism (including development stage)** | *Dermanyssus gallinae* adult |
| **Field of use** | Indoor (henhouses) |
| **Application method(s)** | Spreading  Apply the product directly from the packaging or through the spreader in a homogeneous manner in henhouses. |
| **Application rate(s) and frequency** | 12 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 8. Intended use # 3 – Spreading on cockroaches (indoor)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor surface treatments against cockroaches.  The product has a residual action with an efficacy of at least 3 weeks. |
| **Target organism (including development stage)** | *Periplaneta americana* adult |
| **Field of use** | Indoor |
| **Application method(s)** | Spreading  Apply the product directly from the packaging or through the spreader in a homogeneous manner in crack and cervices and/or as spot application. |
| **Application rate(s) and frequency** | 10 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 9. Intended use # 4 – Spreading on ticks (indoor)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor perimeter treatments against ixodes ricinus (tick).  The product has a residual action with an efficacy of at least 3 weeks. |
| **Target organism (including development stage)** | *Ixodes ricinus* adult |
| **Field of use** | Indoor |
| **Application method(s)** | Spreading  Apply the product directly from the packaging or through the spreader in a homogeneous manner in perimeters of stables, animal housing, rooms. |
| **Application rate(s) and frequency** | 12 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 10. Intended use # 5 – Spreading on ants (indoor/outdoor)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Indoor/outdoor spot treatments, crack and crevices or perimeter treatments against ants (crawling insect).  The product has a residual action with an efficacy of at least 3 weeks. |
| **Target organism (including development stage)** | *Lasius niger* adult |
| **Field of use** | Indoor  Outdoor around building |
| **Application method(s)** | Spreading  Apply the product directly from the packaging or through the spreader in a homogeneous manner in crack and cervices and/or as spot applications. |
| **Application rate(s) and frequency** | 10 g/m2  Frequency: one time per week |
| **Category(ies) of users** | Trained professional  Professional  General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

### Physical, chemical and technical properties

Test item NEODUST (Batch no.: LAB1722102 and LAB2004401) has been used for all the submitted experimental test. Composition of the formualtion „NEODUST“ is reported in the confidential section.

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **GLP** | **Reference** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | Powder (microgranules) | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable** |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | White (shortcode: NE 12) | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable** |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | Characteristic odour | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable** |
| Acidity / alkalinity | CIPAC MT 75.3  OECD 122 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | 9.7 at 20 °C, conc. 1% w/v  Test item is solid, thus no pH on net formulation is required. | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable** |
| Relative density / bulk density | CIPAC MT 186 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | Pour density: 1.32 g/mL  Bulk density: 1.51 g/mL | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable** |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | After 8 weeks at 40°C, the test item stored in its commercial packaging (PET/PE inner bag and HDPE bottle) did not show any significant difference in terms of active ingredient content, pH, aspect and particle size distribution, respect the initial conditions. Thus the test item can be considered thermically stable. Summary results are provided in the following table.  Accelerated storage stability test has been performed at reduce temperature due to the potential thermal stability of permethrin. However, on the same batch, additional data on the active ingredients content after storage at 54°C for 2 weeks in HDPE bottle is available and provided below:   |  |  |  | | --- | --- | --- | |  | T 0 | T 2 weeks | | Permethrin | 0.48%w/w | 0.47%w/w | | PBO | 0.062%w/w | 0.060%w/w |   Data confirms that both active substances are thermally stable, thus no restriction on storage condition is proposed.  **Relevant impurities:**  No data submitted for the determination of relevant impurities before and after storage in NEODUST formulation.  No relevant impurities have been identified for Permethrin on April 2014 Assessment Report.  The following ten relevant impurities have been reported for PBO in June 2016 BPC Opinion, January 2017 Assessment Report and September 2019 final updated Assessment Report:  Safrole: max. content <0.004% w/w  Dihydrosafrole: max. content <0.0085% w/w  Dipiperonyl methane: max. content 1.95% w/w  Dipiperonyl ether: max. content 0.9%w/w  Isosafrole: max. content <0.004% w/w  Methyl dihydrosafrole: max. content 0.5%w/w  Piperonyl Butoxide-x (Piperonyl Butoxide homologue): max. content 0.47 % w/w  ortho-Piperonyl Butoxide (Piperonyl Butoxide homologue): max. content 0.51 % w/w  N,N-dimethylformamide: max.content <0.04%w/w  Dichloromethane: max. content <0.05% w/w  No methods have been submitted in the CAR for the determination of any of the proposed relevant impurities in the formulation.  The WG members concluded that since the relevant impurities (except methyl dihydrosafrole) are not formed during storage, the methods for monitoring the relevant impurities in the biocidal product are not required under the BPR.  Regarding methyl dihydrosafrole based on WG III (May 2016), it was decided that a justification or storage stability data must be submitted to prove that relevant impurity methyl dihydrosafrole is not formed during storage in the formulation (final AR September 2019).  A statement is available from the manufacturer that methyl dihydrosafrole it is not formed during storage (Gobbi, 2018). The relevant justification is attached below:    **eCA**: No further data are required based on the data presented above.  **Substances of concern:**  The substance of concern identified in the formulation NEODUST is Arcosolv DPM.  No data submitted for the determination of substance of concern before and after storage in NEODUST formulation and no analytical method for its determination is available.  However since substance of concern can’t be formed during storage, further data are not required under the BPR. | Y  N | Rigamonti E., 2018, CH-020/2018  Bucciarelli B., 2017, 16783/17, 16784/17 and 16785/17. | **Acceptable** |
| Storage stability test – **long term storage at ambient temperature** | EPA OPPTS 830.6313 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | After two years at ambient temperature, the test item stored in the packaging (PET/PE inner bag and HDPE bottle) did not show any significant difference respect the initial conditions. Thus a shelf life of 2 years is proposed. Summary results are provided in the following table.  **eCA:**  Regarding relevant impurities and SoCs please refer to comment above on accelerated study. | Y | Rigamonti E., 2018, CH-021/2018 | **Acceptable** |
| Storage stability test – **low temperature stability test for liquids** | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | **-** |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Justification for non-submission of data | - | The formulation is contained in a closed bottle or bag not transparent and no exposure with light is expected during storage and uses, thus the test is not performed. Please refer to the section 2.1.7. | - | - | **Acceptable** |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC MT 46.3 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | No change in active ingredient content after storage for 8 weeks at 40°C was observed.  No change in active ingredient content after storage for 2 weeks at 54°C was observed. | Y  N | Rigamonti E., 2018, CH-020/2018  Bucciarelli B., 2017, 16783/17, 16784/17 and 16785/17. | **Acceptable** |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | No effects on container material was observed after storage for 8 weeks at 40°C and after storage for two years at ambient temperature. | Y | Rigamonti E., 2018, CH-020/2018  &  Rigamonti E., 2018, CH-021/2018 | **Acceptable** |
| Wettability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | **-** |
| Suspensibility, spontaneity and dispersion stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is microgranules | - | - | **-** |
| Wet sieve analysis and dry sieve test | CIPAC MT 59.2  and analytical method HPLC/UV  no. 018/2018 | Test item: NEODUST  Batch no.: LAB2004401  Permethrin: 0.56 (pure)  PBO: 0.056 (pure) | Dry sieve test:  8.03% retained on a 75 µm sieve  As the result is higher than 5%, the determination of the active ingredients content in the residue give the following results:  Permethrin: 1.13% w/w  PBO: 0.10% w/w | Y | Rigamonti E., 2020, CH-0042/2020 | **Acceptable** |
| Emulsifiability, re-emulsifiability and emulsion stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is microgranules | - | - | **-** |
| Disintegration time | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | **-** |
| Particle size distribution, content of dust/fines, attrition, friability | OECD 110  CIPAC MT 187  (Laser diffraction)  CIPAC MT 178 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure)  Test item: NEODUST  Batch no.: LAB2004401  Permethrin: 0.56 (pure)  PBO: 0.056 (pure) | Particle size distribution:  Dv 10: 13.1 µm  Dv 50: 275 µm (MMAD)  Dv 90: 1040 µm  % under 45 µm: 17.27  % above 75 µm: 80.53  Nominal size range: 100-1000 µm  Attrition: 98.45% | Y  Y | Rigamonti E., 2018, CH-016/2018  Rigamonti E., 2020, CH-0042/2020 | **Acceptable**  **Acceptable** |
| Persistent foaming | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | **-** |
| Flowability/Pourability/Dustability | CIPAC MT 34  CIPAC MT 171  CIPAC MT 172.1 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure)  Test item: NEODUST  Batch no.: LAB2004401  Permethrin: 0.56 (pure)  PBO: 0.056 (pure) | Dustiness:  Before storage the test item is “Essentially non dusty”  (23.1 mg; 0.077 % w/w)  After storage at 54°C for 14 days the test item is “Essentially non dusty”  (28.9 mg; 0.096 % w/w)  Flowability:   |  |  |  | | --- | --- | --- | | Sieve (µm) | Initial T0 (%) | T14 at 54°C (%) | | 500 | 2.91 | 4.62 | | 355 | 9.71 | 9.16 | | 250 | 26.81 | 25.58 | | 125 | 39.40 | 34.72 | | 75 | 8.03 | 8.62 | | 45 | 9.46 | 10.43 | | <45 | 3.37 | 3.31 |   No significant variation in particle size distribution after storage period under pressure | Y  Y | Rigamonti E., 2018, CH-016/2018  Rigamonti E., 2020, CH-0042/2020 | **Acceptable** |
| Burning rate — smoke generators | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Burning completeness — smoke generators | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Composition of smoke — smoke generators | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Spraying pattern — aerosols | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Physical compatibility | Justification for non-submission of data | - | The formulation is not expected to be used with other product, thus the test is not required. | - | - | - |
| Chemical compatibility | Justification for non-submission of data | - | The formulation is not expected to be used with other product, thus the test is not required. | - | - | - |
| Degree of dissolution and dilution stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Surface tension | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |
| Viscosity | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a ready-to-use microgranules | - | - | - |

**Detailed results of storage stability test for the HDPE bottle**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Method** | **Results before storage** | **Results after storage (8w at 40°C (CH-020/2018)** | **Results after storage (2y at room temperature (CH-021/2018)** |
| Permethrin (%) | No. 018/2018 | 0.56 | 0.57 (+1.8% variation) | 0.58 (+4.2 % variation) |
| Cis-permethrin (%) | No. 018/2018 | 0.14 | 0.14 | 0.15 |
| Trans-permethrin (%) | No. 018/2018 | 0.42 | 0.43 | 0.44 |
| PBO (%) | No. 019/2018 | 0.058 | 0.055(-5.2 % variation) | 0.056 (-2.6% variation) |
| Appearance | EPA OPPTS 830.6302, 830.6303, 830.6304 | White powder (microgranules) with characteristic odour | White powder (microgranules) with characteristic odour | White powder (microgranules) with characteristic odour |
| pH (1% w/v aqueous dilution) | CIPAC MT 75.3  OECD 122 | 9.7 | 9.6 | 9.6 |
| Dry sieve test | CIPAC MT 59.2 | 8.03%\*  (Permethrin 1.13% w/w and PBO 0.10% w/w in the residue) | Not performed | 8.17%  (Permethrin 1.38% w/w and PBO 0.12% w/w in the residue) |
| Nominal size range | OECD 110  CIPAC MT 187 | 100-1000 µm | 100-1000 µm | 100-1000 µm |
| Dust content | CIPAC MT 171 | “Essentially non dusty”  (23.1 mg; 0.077 % w/w) | After 1 day at 54°C:  “Essentially non dusty”  (28.9 mg; 0.096 % w/w) | “Dusty”  (31.9 mg; correspond to 0.106% w/w) |
| Particle size distribution and MMAD | OECD 110  CIPAC MT 187 | Dv 10: 13.1 µm  Dv 50: 275 µm (MMAD)  Dv 90: 1040 µm  % under 45 µm: 17.27  % above 75 µm: 80.53 | Dv 10: 11.4 µm  Dv 50: 244 µm (MMAD)  Dv 90: 525 µm  % under 45 µm: 19.52  % above 75 µm: 77.34 | Dv 10: 10.2 µm  Dv 50: 249 µm (MMAD)  Dv 90: 506 µm  % under 45 µm: 20.16  % above 75 µm: 77.59 |
| Attrition resistance (%) | CIPAC MT 178 | 98.45%\* | Not performed | 98.63 |
| Stability of packaging | - | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena |
| Weight variation (%) | - | - | -0.08% | +0.01 |

\*Study performed on different lot no.

**Detailed results of storage stability test for the PET/PE bag**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Method** | **Results before storage** | **Results after storage (8w at 40°C (CH-020/2018)** | **Results after storage (2y at room temperature (CH-021/2018)** |
| Permethrin (%) | No. 018/2018 | 0.56 | 0.51 | 0.58 (+4.1 % variation) |
| Cis-permethrin (%) | No. 018/2018 | 0.14 | 0.13 | 0.15 |
| Trans-permethrin (%) | No. 018/2018 | 0.42 | 0.39 | 0.43 |
| PBO (%) | No. 019/2018 | 0.058 | 0.056 | 0.055 (-4.7% variation) |
| Appearance | EPA OPPTS 830.6302, 830.6303, 830.6304 | White powder (microgranules) with characteristic odour | White powder (microgranules) with characteristic odour | White powder (microgranules) with characteristic odour |
| pH | CIPAC MT 75.3  OECD 122 | 9.7 | Not performed | 9.7 |
| Dry sieve test | CIPAC MT 59.2 | 8.03%\*  (Permethrin 1.13% w/w and PBO 0.10% w/w in the residue) | Not performed | 8.03%  (Permethrin 1.59% w/w and PBO 0.14% w/w in the residue) |
| Nominal size range | OECD 110  CIPAC MT 187 | 100-1000 µm | Not performed | 100-1000 µm |
| Dust content | CIPAC MT 171 | “Essentially non dusty”  (23.1 mg; 0.077 % w/w) | Not performed | “Dusty”  (30.7 mg; correspond to 0.102% w/w) |
| Particle size distribution and MMAD | OECD 110  CIPAC MT 187 | Dv 10: 13.1 µm  Dv 50: 275 µm (MMAD)  Dv 90: 1040 µm  % under 45 µm: 17.27  % above 75 µm: 80.53 | Not performed | Dv 10: 11 µm  Dv 50: 243 µm (MMAD)  Dv 90: 494 µm  % under 45 µm: 20.02  % above 75 µm: 77.31 |
| Attrition resistance (%) | CIPAC MT 178 | 98.45%\* | Not performed | 98.10 |
| Stacked test | - | - | The PET/PE bag is not staked, thus the test is not considered required. | The PET/PE bag is not staked, thus the test is not considered required. |
| Stability of packaging | - | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena |
| Weight variation (%) | - | - | -0.07% | +0.14% |

\*Study performed on different lot no.

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Physical-chemical properties:  The preparation is a white microgranules with a characteristic odour, containing 0.5 % w/w (pure) of permethrtin and 0.05% w/w (pure) of PBO. Its bulk density is 1.51 g/mL. When dispersed at 1% in water, it has a pH of 9.7.  Storage stability:  After storage at 40°C for 8 weeks, the test item did not show any significant difference in terms of active ingredient content, pH, aspect and particle size, respect the initial conditions. Additional acceptable data on storage at 54°C for 2 weeks are also available. Thus no limitation on the storage condition is proposed.  After storage at room temperature for 2 years, the test item did not show any significant difference in terms of active ingredient content and technical characteristis, respect the initial conditions. Thus a shelf life of 2 years is proposed when stored in its initial commercial packaging.  The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. |

### Physical hazards and respective characteristics

Test item NEODUST has been used for all the submitted experimental test. Composition of the formulation „NEODUST“ is reported in the confidential section.

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **GLP** | **Reference** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3. | Test item: NEODUST  Batch no.: LAB2004401  Permethrin: 0.56 (pure)  PBO: 0.056 (pure) | DCS screening:  Two endothermic peak of 50 and 80 J/g, respectively.  No exothermic peak, thus the formulation is not candidate for classification as explosive. | N | Rigamonti E., 2020, CH-0042/2020 | **Acceptable**  Not explosive |
| Flammable gases | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid microgranules | - | - | - |
| Flammable aerosols | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solidmicrogranules | - | - | - |
| Oxidising gases | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid microgranules | - | - | - |
| Gases under pressure | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid microgranules | - | - | - |
| Flammable liquids | Justification for non-submission of data |  | The study does not need to be conducted because the formulation is solid microgranules | - | - | - |
| Flammable solids | EC 440/2008 No. A.10 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | The test item carbonised when the Bunsen burner flame came close, but the combustion did not propagate.  Since test item did not propagate combustion, no further testing was required.  Not flammable. | Y | Rigamonti E., 2018, CH-016/2018 | **Acceptable**  Not flammable |
| Self-reactive substances and mixtures | Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3. | Test item: NEODUST  Batch no.: LAB2004401  Permethrin: 0.56 (pure)  PBO: 0.056 (pure) | DCS screening:  Two endothermic peak of 50 and 80 J/g, respectively.  No exothermic peak, thus the formulation is not candidate for classification as self-reactive mixture. | N | Rigamonti E., 2020, CH-0042/2020 | **Acceptable**  Not self-reacting |
| Pyrophoric liquids | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a microgranules | - | - | - |
| Pyrophoric solids | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | - | - | - |
| Self-heating substances and mixtures | Justification for non-submission of data | - | None of the components are classified as “self-heating substance or mixture”.  Based on DSC screening test no exotermic reaction are showed.  No interection between components is expected as they are almost inert (more than 98%).  Based on the above the test has not been performed. | - | - | - |
| Substances and mixtures which in contact with water emit flammable gases | Justification for non-submission of data | - | The study does not need to be conducted because none of the components is expected to emit flammable gases when they are in contact with water. | - | - | - |
| Oxidising liquids | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a microgranules | - | - | - |
| Oxidising solids | Justification for non-submission of data | - | According to the UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Section 34.4.1, UN Test O.1, Appendix 6, test is not required if the substance does not contain oxygen, fluorine or chlorine, or if these elements are present but bonded only to carbon or hydrogen.  Based on the structural formula reported in the confidential section, none of the components does not contain fluorine or chlorine and the oxygen is bonded only to carbon or hydrogen. Thus test is not required and NEODUST should not be considered as oxidizer. | - | - | **Acceptable**  Not oxidising |
| Organic peroxides | Justification for non-submission of data | - | The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria. | - | - | - |
| Corrosive to metals | Justification for non-submission of data | - | Test is required only for solid with melting point below 55°C. Based on the DSC screening nor endotermic nor exotermic phenomena are showed before 55°C, thus the test is not required and the formulation should not be classified as corrosive.  None of the component are classified as corrosive to metals. No acidic or basic groups, halogens or substances form complexes with metals are present in the formulation. | - | - | **Acceptable** |
| Auto-ignition temperatures of products (liquids and gases) | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a microgranules. | - | - | - |
| Relative self-ignition temperature for solids | EU Method A.16 | Test item: NEODUST  Batch no.: LAB1722102  Permethrin: 0.48 (pure)  PBO: 0.062 (pure) | Positive result using a 20 mm sample cube at 396°C at 1010 mbar.  No classification required according to the CLP criteria (trigger value 140°C). | Y | Mazzei N., 2018, 1800436 | **Acceptable** |
| Dust explosion hazard | Justification for non-submission of data | - | The study does not need to be conducted because the test item has no explosive properties as netier the active ingredient nor other components, did not contain any "plosophore" grouping. | - | - | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The safety relevant physico-chemical properties of the biocidal product NEODUST have been evaluated.  The product is not expected to have explosive or oxidising properties, nor to be flammable or self-igniting. None of the components is known to evolve any flammable gases in contact with water/humid air or to be pyrophoric. The product is not expected to be corrosive to metals. |

### Methods for detection and identification

**Permethrin**

The methods for the analysis of permethirn residues in soil, air and water by HPLC-MS, have been acceptably validated and regarded to be sufficiently sensitive with respect to the levels of concern.

No analytical methods for the determination of residues of permethrin on body fluids and tissues are available as the molecule does not classify as toxic or highly toxic.

No analytical method are required for the determination of residue of permethrin in food/feed of plant/animal origin as the proposed used are not intend to be in contact with any food and feeding stuff.

A summary of all these methods is reported in the Assessment Report (AR) on Permethrin (PT 18) prepared by the RMS-Ireland (April 2014). Access to these data is granted to Bleu Line S.r.l. by LIMARU NV, which covers the complete Tagros Chemicals India Ltd dossier.

**PBO**

The methods for the analysis of PBO residues in soil, air and water by HPLC-MS or GC-MS, have been acceptably validated and regarded to be sufficiently sensitive with respect to the levels of concern.

No analytical methods for the determination of residues of PBO on body fluids and tissues are available as the molecule does not classify as toxic or highly toxic.

No analytical method are required for the determination of residue of PBO in food/feed of plant/animal origin as the proposed used are not intend to be in contact with any food and feeding stuff.

A summary of all these methods is reported in the Assessment Report (AR) on PBO (PT 18) prepared by the RMS-Greece (January 2017). Access to these data is granted to Bleu Line S.r.l. by Endura S.p.A. LoA.

| **Analytical methods for soil** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| *Permethrin* | HPLC-MS/MS | No information reported in the AR, April 2014 | | | | | | 5.0 µg/kg | AR, April 2014 |
| *PBO* | HPLC-MS/MS | No information reported in the AR, January 2017 | | | | | | 0.05 mg/kg | AR, January 2017 |

| **Analytical methods for air** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| *Permethrin* | HPLC-MS/MS | No information reported in the AR, April 2014 | | | | | | 5.00 µg/m3 (Sumitomo)  0.1 µg/m3 (Tagros) | AR, April 2014 |
| *PBO* | GC-MS | No information reported in the AR, January 2017 | | | | | | 5.83 µg/m3 | AR, January 2017 |

| **Analytical methods for drinking water** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| *Permethrin* | HPLC-MS/MS | No information reported in the AR, April 2014 | | | | | | 0.05 µg/L | AR, April 2014 |
| *PBO* | HPLC-MS/MS | No information reported in the AR, January 2017 | | | | | | 0.1 µg/L | AR, January 2017 |

| **Analytical methods for ground water** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| *Permethrin* | HPLC-MS/MS | No information reported in the AR, April 2014 | | | | | | 0.05 µg/L | AR, April 2014 |
| *PBO* | HPLC-MS/MS | No information reported in the AR, January 2017 | | | | | | 0.1 µg/L | AR, January 2017 |

| **Analytical methods for surface water** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| *Permethrin* | HPLC-MS/MS | No information reported in the AR, April 2014 | | | | | | 0.05 µg/L | AR, April 2014 |
| *PBO* | HPLC-MS/MS | No information reported in the AR, January 2017 | | | | | | 0.1 µg/L | AR, January 2017 |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Acceptable validated analytical methods are available for detection of permethrin and piperonyl butoxide in soil, air and water reported in the CAR documents for permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2017).  A letter of access covering the complete dossier of each active substance is available from Limaru which cover the Annex II dossier of Tagros Chemicals India Ltd (for Permethrin) and Endura (for Piperonyl Butoxide).  Analytical methods for the detection of Permethrin and Piperonyl Butoxide in body fluids and tissues, and residues in food and feeding stuff or further data are not required. |

#### Formulation analysis

The identification and quantification of permethrin and PBO in the formulated product NEODUST (batch no. LAB1722102) is performed by HPLC/UV methods. The method meet the requirements provided by SANCO/3030/99 rev. 4. Validation data are summarized as follow.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for active ingredient in formulation** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)**  (n=6, 3 levels with duplicate determinations) | | **Repeatability (%)**  (n=6) | | **Reference** |
| Range | Mean | RSD | Horwits |
| *permethrin* | HPLC-UV | 80 %, 100 % and 120 % of the nominal concentration of active ingredient / 6 | 12.16 to 109.48 mg/mL  r2 = 0.99877  Y=274984x+34076 (n=5) | yes | 99.14 – 104.41 | 102.5 | 1.80 | 2.93 at 0.56 % w/w | Rigamonti E., 2018, CH-018/2018 |
| *Permethrin Cis isomer* | HPLC-UV | 80 %, 100 % and 120 % of the nominal concentration of active ingredient / 6 | 4.80 to 43.19 mg/mL  r2 = 0.99901  Y=271001+56250 (n=5) | Yes | 95.04 – 102.96 | 99.1 | 1.80 | 3.62 at 0.14 % w/w |
| *Permethrin Trans isomer* | HPLC-UV | 80 %, 100 % and 120 % of the nominal concentration of active ingredient / 6 | 7.37 to 66.29 mg/mL  r2 = 0.99857  Y=277579-22174 (n=5) | Yes | 98.60 – 104.73 | 101.5 | 1.82 | 3.06 at 0.42 % w/w |
| *PBO* | HPLC-UV | 80 %, 100 % and 120 % of the nominal concentration of active ingredient / 6 | 30.47 to 71.09 mg/mL  r2 = 0.99555  Y=53536+22825 (n=5) | Yes | 100.49 – 106.47 | 103.1 | 2.14 | 4.11 at 0.058 % w/w | Rigamonti E., 2018, CH-019/2018 |

* **PERMETHRIN**

Scope

This method (study CH-018/2018) is applicable to the quantitative determination of Permethrin active ingredient in NEODUST formulation samples. The method has been validated by the analysis of reference material and test item solution.

Principle of the method

The determination o fthe Permethrin is performedby HPLC, using an external standard and UV detection. The quantification of Permethrin is achieved by comparing each analytical standard peak area versus each active ingredient peak area in formulation. The validated method in study CH-018/2018 is able to separate each enantiomer with test solution (relevant chromatograms are available).

Preparation of the formulation solution

Using the analytical balance, weigh about 600 mg of the test item 50.00 mL volumetric flask and make to volume with eluent. Place the solution into ultrasonic bath for 10 minutes and then filter the test item solution by a syringe filter at 0.45 µm. Finally transfer an aliquot into a vial for the HPLC/UV analysis.

Chromatographic conditions

HPLC column: CHIRALPAK IB, 250 × 4.6 mm i.d., 5 μm

Detector: UV/Vis operating at 230 nm

Column temperature: 22°C

Eluent A: n-Heptane/tert-butyl methyl ether (98:2)

Isocratic: 100% of Eluent A

Eluent flow:1.00 mL/min

Volume of injection:10 μL

R. T. Permethrin Cis I : about 17.7 minutes

R. T. Permethrin Cis II : about 21.2 minutes

R. T. Permethrin Trans I : about 26.1 minutes

R. T. Permethrin Trans II : about 28.6 minutes

Total Analysis Time:40 minutes

Conclusions

The analitycial method tested was found to be validated according to the SANCO guideline, therefore it is considered acceptable for the determination of the active substance permethrin in the test material NEODUST.

cis:trans ratio: 25:75

\*R:S (or S:R) ratio: cis isomer pair of 1.7 and trans isomer pair of 1.65

\*The estimation of the ratio between R and S enantiomers which is widely used in practice to determine the enatio exess value (ee%) of chiral compound based on the HPLC peak area shown in chromatograms. Referring to two chromatogram, it can be calculated to have a R:S (or S:R) ratio of *cis* isomer pair of 1.7 and for *trans* pair of 1.65.

* **PBO**

Scope

This method (study CH-019/2018) is applicable to the quantitative determination of PBO active ingredient in NEODUST formulation samples. The method has been validated by the analysis of reference material and test item solution.

Principle of the method

The determination o fthe PBO is performedby HPLC, using an external standard and UV detection. The quantification of Piperonyl butoxide (PBO) is achieved by comparing the ratio of the reference material peak area versus Ethyl benzoate internal standard peak area and the same ratio determined for a sample containing a known amount of internal standard (relevant chromatograms are available).

Preparation of the formulation solution

Using the analytical balance, weigh about 1000 mg of the test item and add, using a volumetric pipette, 0.50 mL of the stock internal standard solution into a 10 mL conical flask. Add 9.5 mL of acetonitrile and place the solution into ultrasonic bath for 10 minutes and then filter the test item solution by a syringe filter at 0.45 µm. Finally transfer an aliquot into a vial for the HPLC/UV analysis.

Chromatographic conditions

HPLC column: Ascentis Phenyl, 250 × 4.6 mm i.d., 5 μm

Detector: UV/Vis operating at 251 nm

Column temperature: 23°C

Eluent A : Water

Eluent B : Acetonitrile

Eluent D : Phosphoric acid at 1% v/v

Gradient : from A:B:D: 20:70:10 to A:B:D: 0:90:10 in 25 minutes

from A:B:D: 0:90:10 to A:B:D: 20:70:10 in 1 minute

A:B:D: 20:70:10 for 4 minutes

Eluent flow:0.6 mL/min

Volume of injection:10 μL

R. T. Ethyl benzoate : about 8.1 minutes

R. T. Piperonyl butoxide : about 12.1 minutes

Total Analysis Time:30 minutes

Conclusions

The analitycial method tested was found to be validated according to the SANCO guideline, therefore it is considered acceptable for the determination of the active substance PBO in the test material NEODUST.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The HPLC-UV analytical methods were found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of Permethrin (including its isomers) and Piperonyl Butoxide, in NEODUST formulation.  Analytical methods for the determination of relevant impurities are not required since waiver argumentations are considered acceptable. Please refer above on accelerated storage data. |

#### Analysis of substances of concern

The biocidal product NEODUST contains a substance of concern Arcosolv DPM. No analytical method for the determination of Substance of Concern have been submitted under this application.

|  |
| --- |
| **Conclusion on the methods for Substances of Concern in the product.** |
| Analytical method for the determination of Substance of Concern in the formulation NEODUST have not been submitted, nor required since SoC can not be formed during storage. |

### Efficacy against target organisms

#### Function and field of use

Function

Main group 3: Pest control.

EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods.

NEODUST is a ready to use microgranule formulation containing 0.5% w/w permethrin and 0.05% w/w piperonyl butoxide (PBO). The product is intended for use, indoor or / and outdoor, by both professional and non-professional users.

Fields of use

The product is intended for use, indoor or / and outdoor, by both professional and non-professional users to control black garden ants, chicken mites, American cockroaches and sheep ticks. The overall use pattern is described in chapter 2.1.4.

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

The product is an insecticide for the control of adults of chicken mites (*Dermanyssus gallinae*), sheep ticks (*Ixodes ricinus*), American cockroaches (*Periplaneta americana*) and black garden ants (*Lasius niger*).

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

NEODUST is intended to be used by both professionals and non-professionals, indoors or/ and outdoors. NEODUST acts on harmful organisms by contact resulting in death.

#### Mode of action, including time delay

The active ingredient permethrin is a contact insecticide affecting the peripheral and central nervous systems of target insects. It acts upon voltage sensitive sodium chanels which affects action potential decay in neural membranes, resulting in repetitive and uncontrolled discharges over the sensory and motor axons.

The mode of action of Piperonyl Butoxide is complex. According to the literature, Piperonyl Butoxide stabilises the co-applied insecticide inside the insect body and potentiates more toxins to reach their target molecules. This results in an increased mortality of the target organism, and likewise, the same effect may be observed by using decreased amounts of insecticide, i.e. synergism. There is strong evidence from the literature, that Piperonyl Butoxide inhibits the oxidative and esterase-based metabolism (detoxification) of the co-applied insecticide. Therefore, Piperonyl Butoxide delays the degradation of co-applied insecticidal substances and thereby prolongs the potential action of the compounds. According to the literature Piperonyl Butoxide is usually applied at a dose that on its own is sublethal to the target species. When Piperonyl Butoxide is applied in combination with a known toxicant, the performance of the latter is enhanced at a rate that becomes lethal when on its own would be sublethal. Nevertheless, Piperonyl Butoxide on its own can exhibit some toxic effects, and hence at sublethal doses is likely to exert some stress on the insect. According to the results of the submitted laboratory efficacy studies and a publication, Piperonyl Butoxide exerts innate lethal effect against houseflies, mosquitoes, cockroaches and house dust mites.

For more details, it is referred to the Assessment Reports of the active substances.

#### Efficacy data

Ten (10) efficacy (laboratory and field) studies on 5 target species were submitted and evaluated to support the killing effect of NEODUST.

An overview on the laboratory tests and field trials and their respective application rates in relation to the claim of the individual uses are presented in the following table:

| **Use #** | **Laboratory tests** | **Field trials** | **Recommended application rate** |
| --- | --- | --- | --- |
| Use # 1  Spreading on fleas (indoor), Professionals /  Non-professionals | BLENDU150917-05   * Product applied at 10 and 12 g/m², on non-porous and porous surface respectively. * Fleas placed to treated non-porous and porous tiles. * Adults * Exposure for 60 minutes. * Evaluation after 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min and every 24 hours, up to 1 week. * Knockdown and mortality |  | 12 gr/m2 |
| BLENED030818 – 05   * Product applied, uniformly, at 12 g/m² on naturally infested carpets used in a cattery. * Adults * Product uniformly applied on the whole carpet, which was covered by a non-woven fabric to prevent fleas from escaping. * Evaluation after 24 and 48 h and 1, 2 and 3 weeks. * Knockdown and mortality. |  | 12 gr/m2 |
| Use # 2  Spreading on chicken mites (indoor)  Professionals /  Non-professionals | BLENDU150917 -04   * Product applied at 10 and 12 g/m², on non-porous and porous surface respectively. * Chicken mites placed to treated non-porous and porous tiles. * Adults * Exposure for 60 minutes. * Assessment after 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min and every 24 hours, up to 1 week. * Knockdown and mortality | BLENED030818 - 02   * Product applied at 12 g/m², on certain parts of henhouses. * Crack and crevice applications. * Adults * Asssessment pre- and post- (24 h and 1, 2 and 3 weeks) treatment. * Mortality | 12 gr/m2 |
| Use # 3  Spreading on cockroaches (indoor)  Professionals /  Non-professionals | BLENDU150917 -01   * Product applied at 10 g/m², on non-porous and porous surface. * Direct contact to treated non-porous and porous tiles. * Adults * Exposure for 60 minutes. * Assessment after 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min and every 24 hours, up to 3 weeks. * Knockdown and mortality | BLENED030818 – 04   * Product applied, indoor, at 10 g/m², in industrial areas. * Surface (perimetral, not wider than 5 cm, and crack and crevice) applications. * Adults * Assessment post treatment (after 24 and 48 hours and at 1, 2 and 3 weeks). * Mortality | 10 gr/m2 |
| Use # 4  Spreading on ticks (indoor)  Professionals /  Non-professionals | BLENDU150917- 02   * Product applied at 12 g/m², on non-porous and porous surface. * Direct contact to treated non-porous and porous tiles. * Adults * Exposure for 60 minutes. * Assessment after 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min and 24 hours. Assessemnts were also carried out after 1, 2 and 3 weeks. * Knockdown and mortality | BLENED030818 – 01   * Product applied, indoor, at 12 g/m², in stables in 3 sites. * Surface application, in perimetral band no wider than 5 cm. * Adults * Asssessment pre- and post (after 24 hours and 1, 2 and 3 weeks) treatment. * Mortality | 12 gr/m2 |
| Use # 5  Spreading on ants (indoor / outdoor) | BLENDU150917 - 03   * Product applied at 10 g/m², on non-porous and porous surface. * Direct contact to treated non-porous and porous tiles. * Adults * Exposure for 60 minutes. * Assessment after 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min and 24 hours. Assessemnts were also carried out after 1, 2 and 3 weeks. * Knockdown and mortality | BLENED030818 – 03   * Product applied in a house, either indoor or outdoor, at 10 g/m². * Perimetral crack and crevice applications. * Adults * Asssessment pre- and post (after 24 and 48 hours and 1, 2 and 3 weeks) treatment. * Mortality | 10 gr/m2 |

The individual laboratory trials for Use # 1 are presented in the following table:

| **Use # 1 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor application against fleas | Use # 1:  Spreading on fleas (indoor), Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Ctenocephalides felis*  Cat fleas  (adults) | Laboratory test (forced contact test on porous and non-porous surface)  Surface treatment | Laboratory conditions.  Fleas placed immediatelly to treated non-porous (ceramic tile - side up) and porous (varnished wood) tiles.  Adult fleas were placed for 60 minutes on treated tiles under transparent plastic cups (12 cm diameter and 6 cm height), to prevent escaping and thus ensuring the contact with the treated surface. Ceramic tiles were 20 x 20 cm.  5 replicates for each treatment (10 adults / replicate).  Untreated tiles were also used as controls.  The product was applied at a dose of 10 gr/m2 (on non-porous surface) and 12 gr/m2 (on porous surface).  Room conditions: temperature of T= 24 ± 1°C, Relative humidity= 70 ± 2%. Light conditions: 12 h light and 12 h dark.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours after the application.  The same observations were carried out after 1 week (T1). | Non – porous surface  T0 - Knockdown:  - 30 min: 0%  - 50 min 34%  ≥60 min: 64%  T0 - Mortality:  - 24h: 84%  - 48h: 92%  - 72h: 94%  T1 - Knockdown:  - 20 min: 0%  - 50 min 42%  ≥60 min: 62%  T1 - Mortality:  - 24h: 72%  - 48h: 98%  - 72h: 100%  Porous surface  T0 - Knockdown  - 10 min: 0%  - 50 min 42%  ≥60 min: 80%  T0 - Mortality  - 24h: 98%  - 48h: 100%  T1 -Knockdown  - 10 min: 0%  - 50 min 66%  ≥60 min: 82%  T1 - Mortality  - 24h: 96%  In all trials, knockdown and mortality was 0% in the untreated controls. | Dutto M. (2017)  Report No:BLENDU 150 917 -05. |
| Insecticide (PT18)  Indoor application against fleas | Use # 1:  Spreading on fleas (indoor), Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Ctenocephalides felis*  Cat fleas (adults) | Laboratory test (forced contact test)  Surface treatment | Laboratory conditions.  The test was performed on naturally infested carpets used in a cattery.  The carpets were collected from the cattery, put into plastic bags and moved to a nearby service room. The carpets were placed on the floor and infestation was measured by counting the number of adult fleas in 100 cm2 areas (6 areas per carpet).  Immediately after measuring flea infestation, the product was uniformly applied on the whole carpet, which was covered by a non-woven fabric to prevent fleas from escaping.  3 replicates for each treatment, with a replication corresponding to a single carpet (1.20m x 0.80m, 1.80m x 0.90m, 1.50m x 0.80m). An untreated carpet was also used as control.  The product was applied at a dose of 12 gr/m2.  knockdown was recorded at 24 hours and mortality at 48, 1, 2 and 3 weeks post-treatment. | Carpet 1  Knockdown:  - 24h: 77.5%  Mortality:  - 48h: 80%  - 1, 2, 3 weeks: 100%  Carpet 2  Knockdown:  - 24h: 71.43%  Mortality:  - 48h: 82.86%  - 1, 2, 3 weeks: 100%  Carpet 3  Knockdown:  - 24h: 86.21%  Mortality:  - 48h: 84.48%  - 1, 2, 3 weeks: 100%  In the untreated control, knockdown was 6.17% and mortality was 3.3%. | Dutto M. (2018)  Report No:  BLENED030818 - 05 |

The individual laboratory and simulated use trials for Use # 2 are presented in the following table:

| **Use # 2 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor application against chicken mites | Use # 2:  Spreading on chicken mites (indoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Dermanyssus gallinae* Chicken mites (adults) | Laboratory test (forced contact test on porous and non-porous surface)  Surface treatment | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile - side up) and porous (ceramic tile - side down, similar to terracotta) tiles.  Adult mites were placed for 60 minutes on treated tiles. A strip of black tape (5 cm) was attached on the surface, to prevent escaping and thus ensuring the contact with the treated surface. Ceramic tiles were 20 x 20 cm.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 10 gr/m2 (on non-porous surface) and 12 gr/m2 (on porous surface).  Room conditions: temperature of T= 24 ± 1°C, Relative humidity= 70 ± 2%. Light conditions: 12 h light and 12 h dark.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours after the application.  The same observations were carried out after 1 week (T1). | Non – porous surface  T0  Knockdown:  - 60 min: 86.00±2.55%  Mortality:  - 24h: 98%  - 48h: 100%  T1  Knockdown:  - 60 min: 82.00±1.87%  Mortality:  - 24h: 96%  - 48h: 100%  Porous surface  T0  Knockdown:  - 60 min: 90.00±1.58%  Mortality:  - 24h: 98%  - 48h: 100%  T1  Knockdown:  - 60 min: 88.00±1.00%  Mortality:  - 24h: 100%  In the untreated controls, knockdown and mortality was 0%. | Dutto M. (2017),  Report no.  BLENDU 150 917 -04 |
| Insecticide (PT18)  Indoor application against chicken mites | Use # 2:  Spreading on chicken mites Indoor (henhouses)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Dermanyssus gallinae*  Chicken mites (adults) | Field test  Crack and crevice application | Test performed in certain parts (4 x 4 m) of 3 henhouses (100 m2).  The infestation was measured by counting the mites walking on perches (wood or steel made) in 10 x 10 cm2 spots. Six (6) spots / replication were selected.  3 replicates (4 x 4 m) for each treatment. Untreated sites were also used as controls.  The product was applied at a dose of 12 gr/m2.  The number of mites present was counted pre- and post- treatment (after 24 hours, 1, 2 and 3 weeks). | % reduction:  Site 1 (verzuolo):  - 24h: 97.71%  - 48h: 100%  - 1 week: 99.06%  - 2 weeks: 88.77%  - 3 weeks: 84.09%  Site 2 (Saluzzo A):  - 24h: 100%  - 48h: 100%  - 1 week: 97.99%  - 2 weeks: 97.40%  - 3 weeks: 93.87%  Site 3 (Saluzzo B):  - 24h: 100%  - 48h: 100%  - 1 week: 100%  - 2 weeks: 91.22%  - 3 weeks: 96.39% | Dutto M. (2018),  Report no.  BLENED030818 - 02 |

The individual laboratory and simulated use trials for Use # 3 are presented in the following table:

| **Use # 3 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor application against cockroaches | Use # 3:  Spreading on cockroaches (indoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Periplaneta americana,* American cockroach(adults) | Laboratory test (forced contact test on porous and non-porous surface)  Surface treatment | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile - side up) and porous (ceramic tile - side down, similar to terracotta) tiles.  Adults were placed for 60 min. on treated tiles (20 x 20 cm), under transparent plastic cups (12 cm diameter and 6 cm height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 10 gr/m2  Room conditions: temperature of T=25 ± 1°C, rel. humidity= 60 ± 5%. Light conditions: 12 h light and 12 h dark.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 3 weeks. Four assessments were carried out: T0 (after treatment), T1 (1 week after treatment), T2 (2 weeks after treatment) and T3 (3 weeks after treatment). | Non – porous surface  T0  Knockdown:  - 2 min: 0%  - 5 min 74.00±11.40%  ≥ 10 min: 100%  Mortality:  - 24h: 30.00±18.71%  - 48h: 76.00±15.17%  - 72h: 100%  T1  Knockdown:  - 2 min: 0%  - 5 min 82.00±8.37%  ≥ 10 min: 100%  Mortality:  - 24h: 4.00±5.48%  - 48h: 56.00±11.40%  - 72h: 82.00±4.47%  - 96h: 100%  T2  Knockdown:  - 2 min: 0%  - 5 min 70.00±15.81%  ≥ 15 min: 100%  Mortality:  - 24h: 10.00±7.07%  - 48h: 68.00±8.37%  - 72h: 100%  T3  Knockdown:  - 2 min: 2.00±4.47%  - 5 min 88.00±13.04%  ≥ 10 min: 100%  Mortality:  - 24h: 2.00±4.47%  - 48h: 92.00±13.04%  - 72h: 100%  Porous surface  T0  Knockdown:  - 2 min: 4.00±5.48%  - 5 min 62.00±8.37%  ≥ 15 min: 100%  Mortality:  - 24h: 60.00±10.00%  - 48h: 88.00±8.37%  - 72h: 100%  T1  Knockdown:  - 2 min: 0%  - 5 min: 64.00±20.74%  ≥ 15 min: 100%  Mortality:  - 24h: 20.00±7.07%  - 48h: 72.00±19.24%  - 72h: 100%  T2  Knockdown:  - 2 min: 2.00±4.47%  - 5 min: 74.00±11.40%  ≥ 10 min: 100%  Mortality:  - 24h: 8.00±8.37%  - 48h: 96.00±5.48%  - 72h: 100%  T3  Knockdown:  - 2 min: 2.00±4.47%  - 5 min: 52.00±16.43%  ≥ 15 min: 100%  Mortality:  - 24h: 0%  - 48h: 52.00±19.24%  - 72h: 100%  In the untreated controls, knockdown and mortality was 0%. | Drago A and Martini S. (2017),  Report no.  BLENDU150 917 -01 |
| Insecticide (PT18)  Indoor application against cockroaches | Use # 3:  Spreading on cockroaches (indoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Periplaneta americana,* American cockroach(Mixed sex adults, nymphs) | Field test  Surface αpplication in the perimeters and in cracks and crevices. | Field conditions (industrial area)  Test performed in small rooms containing electric engines of industrial fridges, in 3 different buildings.  In order to estimate the population density, sticky traps (4/room) baited with specific attractant tablets were set out where cockroaches were expected to be observed and were checked after 24 hours.  Three (3) replicates for each treatment. Untreated sites were also used as controls.  The product was applied at a dose of 10 gr/m2 , along the indoor perimeter of each room. For each test the product was applied in a band not wider than 5 cm. Cracks and crevices were also treated, within the room, when visible.  The number of cockraches present was counted post- treatment (after 24 and 48 hours, 1, 2 and 3 weeks). | Population reduction  Site 1 (6.25 m2):  - 24h: 85.71%  - 48h: 100%  - 1 week: 100%  - 2 weeks: 100%  - 3 weeks: 100%  Site 2 (6 m2):  - 24h: 100%  - 48h: 100%  - 1 week: 100%  - 2 weeks: 100%  - 3 weeks: 98.52%  Site 3 (9 m2):  - 24h: 100%  - 48h: 100%  - 1 week: 98.95%  - 2 weeks: 100%  - 3 weeks: 100%  Overall (mean):  - 24h: 95.24%  - 48h: 100%  - 1 week: 99.65%  - 2 weeks: 100%  - 3 weeks: 99.51% | Dutto (2018),  Report no.  BLENED030818 - 04 |

The individual laboratory and simulated use trials for Use # 4 are presented in the following table:

| **Use # 4 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor application against ticks | Use # 4:  Spreading on ticks (indoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Ixodes ricinus*  Sheep tick(adults) | Laboratory test (forced contact test on porous and non-porous surface)  Surface treatment | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile - side up) and porous (ceramic tile - side down, similar to terracotta) tiles.  Adults were placed for 60 min. on treated tiles (20 x 20 cm), under transparent plastic cups (12 cm diameter and 6 cm height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 12 gr/m2  Room conditions: temperature of T=25 ± 1°C, rel. humidity= 60 ± 5%. Light conditions: 12 h light and 12 h dark.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 3 weeks. Four assessments were carried out: T0 (after treatment), T1 (1 week after treatment), T2 (2 weeks after treatment) and T3 (3 weeks after treatment). | Non – porous surface  T0  Knockdown:  - 2 min: 64%  - 5 min 86%  ≥7 min: 100%  Mortality:  - 24h: 100%  T1  Knockdown:  - 2 min: 84%  ≥5 min: 100%  Mortality:  - 24h: 100%  T2  Knockdown:  - 2 min: 72%  ≥5 min: 100%  Mortality:  - 24h: 100%  T3  Knockdown:  - 2 min: 74%  - 5 min 96%  ≥7 min: 100%  Mortality:  - 24h: 100%  Porous surface  T0  Knockdown:  - 2 min: 72%  - 5 min 90%  ≥10 min: 100%  Mortality:  - 24h: 100%  T1  Knockdown:  - 2 min: 72%  - 5 min 86%  ≥10 min: 100%  Mortality:  - 24h: 100%  T2  Knockdown:  - 2 min: 78%  - 5 min 96%  ≥7 min: 100%  Mortality:  - 24h: 100%  T3  Knockdown:  - 2 min: 84%  ≥5 min: 100%  Mortality:  - 24h: 100%  In the untreated controls, knockdown and mortality was 0%. | Drago A and Martini S. (2017),  Report no.  BLENDU150 91 7- 02 |
| Insecticide (PT18)  Indoor application against ticks | Use # 4:  Spreading on ticks (indoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Ixodes ricinus*  Sheep tick(adults) | Field test  Surface application in the perimeters. | Field conditions (stables)  Test performed in stables for sheeps, deers or goats in 3 sites.  The infestation was measured counting the ticks climbing the walls on 1 m2 areas (spots) on the internal walls of the buildings. 4 spots for each replication were selected. Three (3) replicates for each treatment. Untreated sites were also used as controls.  The product was applied at a dose of 12 gr/m2, as perimetral band application not wider than 5 cm.  The number of ticks was counted pre- and post- treatment (after 24 hours, 1, 2 and 3 weeks). | Population reduction  Site 1 (4x4m, 0.8m2):  - 24h: 100%  - 1 week: 100%  - 2 weeks: 100%  - 3 weeks: 100%  Site 2 (9x13m, 5.85m2):  - 24h: 100%  - 1 week: 100%  - 2 weeks: 100%  - 3 weeks: 100%  Site 3 (3x6m, 0.9m2):  - 24h: 100%  - 1 week: 100%  - 2 weeks: 100%  - 3 weeks: 100% | Drago A and Martini S. (2018),  Report no.  BLENED030818 - 01 |

The individual laboratory and simulated use trials for Use # 5 are presented in the following table:

| **Use # 5 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor / outdoor application against ants | Use # 5:  Spreading on ants (indoor / outdoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Lasius niger* Black garden ant(adults) | Laboratory test (forced contact test on porous and non-porous surface)  Surface treatment | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile - side up) and porous (ceramic tile - side down, similar to terracotta) tiles.  Adults were placed for 60 min. on treated tiles (20 x 20 cm), under transparent plastic cups (12 cm diameter and 6 cm height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (20 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 10 gr/m2  Room conditions: temperature of T=25 ± 1°C, rel. humidity= 60 ± 5%. Light conditions: 12 h light and 10 h dark.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 3 weeks. Four assessments were carried out: T0 (after treatment), T1 (1 week after treatment), T2 (2 weeks after treatment) and T3 (3 weeks after treatment). | Non – porous surface  T0  Knockdown:  - 2 min: 19%  - 5 min 97%  ≥7 min: 100%  Mortality:  - 24h: 100%  T1  Knockdown:  - 2 min: 22%  - 5 min 96%  ≥7 min: 100%  Mortality:  - 24h: 100%  T2  Knockdown:  - 2 min: 17%  - 5 min 95%  ≥7 min: 100%  Mortality:  - 24h: 100%  T3  Knockdown:  - 2 min: 27%  - 5 min 95%  ≥7 min: 100%  Mortality:  - 24h: 100%  Porous surface  T0  Knockdown:  - 2 min: 0%  - 5 min 21%  ≥10 min: 100%  Mortality:  - 24h: 100%  T1  Knockdown:  - 2 min: 10%  - 5 min 18%  ≥15 min: 100%  Mortality:  - 24h: 100%  T2  Knockdown:  - 2 min: 2%  - 5 min 65%  ≥7 min: 100%  Mortality:  - 24h: 100%  T3  Knockdown:  - 2 min: 3%  - 5 min 83%  ≥7 min: 100%  Mortality:  - 24h: 100%  In the untreated controls, knockdown and mortality was 0%. | Drago A and Martini S. (2017),  Report no.  BLENDU150917 -03 |
| Insecticide (PT18)  Indoor / outdoor application against ants ants | Use # 5:  Spreading on ants (indoor / outdoor)  Professionals /  Non-professionals | NEODUST  Batch no.: LAB1722102  Permethrin:  0.5 % w/w  PBO: 0.05 % w/w | *Lasius niger* Black garden ant(adults) | Field test.  Surface (perimetral crack and crevice) applications | Field conditions (infested house)  The infestation was always inside the building but the application of the powder was done inside or outside.  The infestation was evaluated counting the number of ants crossing a line or coming out of a hole for 5 minutes. Three (3) replicates (infested rooms far enough from each other) for each treatment. Untreated rooms were also used as controls.  The product was applied either inside (x3 replicates) or outside (x3 replicates) at a dose of 10 gr/m2, as perimetral crack and crevice treatment (band application not wider than 5 cm) to the points where ants come into the building against black garden ant infestation that occur indoors.  The number of ants was counted pre- (19, 23 and 27 ants for the indoor application and 32, 28 and 42 ants for the outdoor application) and post- (after 24 and 48 h, 1, 2 and 3 weeks) treatment. | Population reduction  Indoor application  - 24h: 100%  - 48h: 100%  - 1week: 100%  - 2weeks: 95.65%  - 3weeks: 98.55%  Outdoor application  - 24h: 100%  - 48h: 100%  - 1week: 100%  - 2weeks: 97.06%  - 3weeks: 90.20% | Dutto M. (2018),  Report no.  BLENED030818 - 03 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Several efficacy studies (laboratory and field studies) were submitted by the applicant with NEODUST MG containing permethrin 0.5% and PBO 0.05%, to support the intended uses of the product against the claimed target organisms.  Based on the results of the submitted efficacy studies, the product was effective when applied indoors against chicken mites, American cockroaches, sheep ticks and black garden ants and outdoors against black garden ants, by both professional and non-professional users as:   * Surface treatment, including cracks and crevices, indoors (in henhouses) against adults of chicken mites (*D. gallinae*) at 12 g/m2 (Intended Use # 2). The product has a residual effect of 1 week. The crack and crevice treatment in the field study, as worst case application method, can be used in support of the claimed surface treatment applied in larger surface areas including cracks and crevices against chicken mites. * Surface treatment (in a band along the perimeter) by spreading, including cracks and crevices, indoors against American cockroaches (*Periplaneta americana*) at 10 g /m2 (Intented Use 3). The product has a residual effect of 3 weeks. Noticeable mortality of American cockroaches is expected 48-96h after exposure of the insects to the treated surfaces. * Surface (perimetral) application, indoor, against ticks (*Ixodes ricinus*) at 12 g/m2 (Intended Use # 4). The product has a residual effect of 3 weeks. In the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): “The product should be used without the presence of animals or humans. Entrance of humans and animals in the treated area should only be permitted after 24 hours”. It is noted that, according to the Efficacy Guidance on the BPR, when the product is intended for use in poultry farms, tests should be performed against *Argas persicus*. Hence, if the use in general animal housing is to be claimed, tests with *A. persicus* must be submitted. Otherwise, the label of the product should clearly indicate that the use is limited to animal houses, excluding poultry houses. * Perimetral, indoor or outdoor, crack and crevice application, to points where ants come into the building, against black garden ant infestation that occur indoors at 10 g/m2 (Intended Use # 5). The product has a residual effect of 3 weeks.   The Intended Use # 1 of the product against fleas (*Ctenocephalides felis*), from an efficacy point of view, is not acceptable as applied for by the applicant, for the following reasons:  • According to the efficacy guidance (TNsG), laboratory (non-choice) and field tests with fleas are required to assess the efficacy of the product against the specific target species. The study by Dutto M. (2018, Report No: BLENED030818-05) is considered by the applicant as a field study. However, the specific study cannot be considered as field (or simulated-use) test as fleas were not given the choice to be (or not) in contact with the biocide (the treated carpet was covered with a non-woven fabric to prevent fleas from escaping).   * According to the guidance, for laboratory (non-choice) tests against fleas, 100% knockdown and ≥90% mortality of the adult fleas should occur within 24 and 48 hours respectively. However, in the study by Dutto M. (2018, Report No: BLENED030818 -05) the application of the product at the claimed dose rate resulted in 71.43-86.21% knockdown and 80-84.48% mortality of adult fleas within 24 and 48 h respectively after treatment. |

#### Occurrence of resistance and resistance management

According to the applicant, no resistance to the two active substances is known.

However, generally, resistance is well known to be a potential problem and strategies to avoid resistance are normal practice.

The principles of strategies for managing the development of resistance are similar for permethrin as they are for other synthetic pyrethroids:

* Where possible, application treatments should be recommended to be combined with non-chemical measures
* Products should always be used in accordance with label recommendations
* Applications should always be made against the most susceptible stages in the pest life cycle
* Where an extended period of control is required, treatments should be alternated with products with different modes of action
* Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
* In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.
* The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

According to the applicant, no limitations on efficacy are known and no observations on undesirable or unintended side effects have been made.

#### Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods for NEODUST are as follows:

| **Use #** | **Label claim and recommendation** | **Evaluation of the label claims** |
| --- | --- | --- |
| Use # 1  Spreading on fleas (indoor), | 12 g product/m2  Apply, one time per week.  Indoor surface treatments against *Ctenocephalides felis* (fleas). The product has a residual action with an efficacy of at least 1 week.  Spreading. Apply the product directly from the packaging or through the spreader in a homogeneous manner in surface as for examples the carpets. | The following laboratory tests were performed:  BLENDU150917 - 05  BLENED030818 - 05  In the BLENDU150917 – 05 study, the product was applied at 10 and 12 g BP/m2 on non-porous and porous surface respectively. Adults of cat fleas were placed to treated non-porous and porous tiles. The exposure time was 60 minutes. Study results showed that the product provided 72-98% knockdown and ≥90% mortality against adult fleas within 24 and 48 hours respectively after treatment.  In the BLENED030818 – 05 study, the product was uniformly applied at 12 gr/m2 on naturally infested carpets, which were covered by a non-woven fabric to prevent cat fleas from escaping. Application of the product at the claimed dose rate resulted in 71.43-86.21% knockdown and 80-84.48% mortality of adult fleas within 24 and 48 h respectively after treatment.  No field studies with fleas were submitted. The submitted efficacy data do not support label claims. |
| Use # 2  Spreading on chicken mites (indoor) | 12 g product/m2  Apply, one time per week. The applicant has proposed the following amendment: *Apply, one time per month*.  Indoor surface treatments against chicken mites. The product has a residual action with an efficacy of at least 1 week.  Spreading. Apply the product directly from the packaging or through the spreader in a homogeneous manner in henhouses. | The following laboratory and field tests were performed:  BLENDU150917 – 04  BLENED030818 – 02  In the laboratory test, the application rate was 10 and 12 g BP/m2 on non-porous and porous surface respectively. Adults of chicken mites were placed to treated non-porous and porous tiles. The exposure time was 60 minutes. The mites were exposed to fresh and 1-week deposits. In all cases, the product resulted in mortality of adults of ≥90% in 24 hours.  In the field study, the application rate was 12 g BP/m2 on certain parts (crack and crevice applications) of henhouses, against adults of chicken mites. Mortality of adults was ≥90% 1 week after treatment.  The submitted efficacy data support label claims. |
| Use # 3  Spreading on cockroaches (indoor) | 10 g product/m2  Apply, one time per week.  Spreading. Apply the product directly from the packaging or through the spreader in a homogeneous manner in crack and cervices and/or as spot application.  The applicant has proposed the following amendments:   * *Apply, one time per month* * *Application method: ”surface treatment (in a band along the indoor perimeter) including applications in cracks and crevices”* | The following laboratory and field tests were performed:  BLENDU150917 - 01  BLENED030818 – 04  In the laboratory test, the application rate was 10 g BP/m2 on non-porous and porous surface. Adults of American cockroaches were placed to treated tiles. The exposure time was 60 minutes. Cockroaches were expose to fresh and 1-3 weeks deposits. Knockdown was 100 % after 10-15 minutes and mortality ≥90% in 48-96 hours.  In the field study, the application rate was 10 g BP/m2  against adults of American cockroaches on certain parts of small rooms containing electric engines of industrial fridges, in 3 different buildings. Surface (perimeter and crack and crevice) applications were carried out. Mortality of adults was ≥90% 3 weeks after treatment.  The submitted data support the amended label claims. |
| Use # 4  Spreading on ticks (indoor) | 12 g product/m2  Apply, one time per week. Indoor perimeter treatments against *ixodes ricinus* (tick). The product has a residual action with an efficacy of at least 3 weeks.  The applicant has proposed the following amendments:   * *Apply, one time per month*. * *The product should be used without the presence of the animals or humans. Entrance of humans and animals in the treated area should only be permitted after one hour*.   This recommendation was based on the following argumentation, provided by the applicant:  “We do not agree with the waiting time of 24 hours for entrance.  In the laboratory test all the ticks are knocked down after 10 minutes since the beginning of exposure to the insecticide. A knocked down tick cannot walk and cannot bite. In the laboratory test the ticks are removed after 60 minutes from the treated surface to observe if any recovery occurred but it didn’t and, after 24 hours these ticks were confirmed as dead. This means that after 10 minutes the ticks cannot be harmful anymore, even if moved away from the insecticide. This is very important because in the field test the ticks are not removed from the insecticide but remain above the treated surface. If the ticks cannot recover if moved away from the insecticide, for sure cannot recover if they stay above the treated surface. Therefore, basing on the data from the laboratory and the field, there is no reason because the treated area cannot be considered safe after 1 hour from the treatment, the risk to be biten by a tick is not different after 24 hours respect than after 1 hour. | The following laboratory and field tests were performed:  BLENDU150917- 02  BLENED030818 – 01  In the laboratory test, the application rate was 12 g BP/m2 on non-porous and porous surface. Adults of the sheep tick were placed to treated tiles. The exposure time was 60 minutes. The product resulted in 100 % knockdown after 5-7 minutes and mortality of ≥90% in 24 hours.  In the field study, the application rate was 12 g BP/m2  against adults of ticks in stables in 3 sites. Surface (perimeter) applications were carried out. Mortality of adults was 100% 3 weeks after treatment.  The submitted efficacy data support the use of the product in surface (perimetral) applications, indoor, against ticks (*Ixodes ricinus*) at 12 g/m2, noting that the product should be used without the presence of animals or humans. In the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): “The product should be used without the presence of animals or humans. Entrance of humans and animals in the treated area should only be permitted after 24 hours.”. The product has a residual effect of 3 weeks. |
| Use # 5  Spreading on ants (indoor / outdoor) | 10 g product/m2  Apply, one time per week. The applicant has proposed the following amendment: *Apply, one time per month*  Indoor/outdoor spot treatments, crack and crevices or perimeter treatments against ants (crawling insect). The product has a residual action with an efficacy of at least 3 weeks.  Spreading. Apply the product directly from the packaging or through the spreader in a homogeneous manner in crack and cervices and/or as spot applications. | The following laboratory and field tests were performed:  BLENDU150917 - 03  BLENED030818 – 03  In the laboratory test, the application rate was 10 g BP/m2 on non-porous and porous surface with fresh and 3-week aged deposits. Adults of the black garden ant were placed to treated tiles. The exposure time was 60 minutes. The product resulted in 100 % knockdown after 7-15 minutes and mortality of 100% in 24 hours.  In the field study, the product was applied either inside or outside of a house at a dose of 10 gr/m2, as perimetral crack and crevice application (not wider than 5 cm) to the points where ants come into the building. Population reduction of ants was ≥90% 3 weeks after treatment.  The submitted efficacy data support the use of the product as indoor or outdoor perimetral crack and crevice applications (to points where ants come into the building) against ants (*Lasius niger*) indoors at 10 g/m2 (Intended Use #5). The product has a residual effect of 3 weeks. |

**Trials submitted by the applicant to substantiate label claims**

**Use # 1**

In the laboratory study by Dutto M. (2017, Report No.: BLENDU150917-05), NEODUST was applied at a dose of 10 gr/m2 (on non-porous surface) and 12 gr/m2 (on porous surface). Adults of cat fleas (*Ctenocephalides felis*) were exposed for 60 minutes to the treated tiles under confined conditions (transparent plastic cups to prevent cat fleas from escaping and thus ensuring the contact with the treated surface). Study results showed that the product provided 72-98% knockdown and ≥90% mortality against adult fleas within 24 and 48 hours respectively after treatment.

In the study by Dutto M. (2018, Report No: BLENED030818-05) NEODUST was uniformly applied at 12 gr/m2 on naturally infested carpets, which were covered by a non-woven fabric to prevent fleas from escaping. Application of the product at the claimed dose rate resulted in 71.43-86.21% knockdown and 80-84.48% mortality of adult fleas within 24 and 48 hours respectively after treatment.

Hence, the intended Use # 1 of the product against fleas, from an efficacy point of view, is not acceptable as applied for by the applicant, for the following reasons:

* According to the efficacy guidance (TNsG), laboratory (non-choice) and field tests with fleas are required to assess the efficacy of the product against the specific target species. The study by Dutto M. (2018, Report No: BLENED030818-05) is considered by the applicant as a field study. However, the specific study cannot be considered as field (or simulated-use) test as fleas were not given the choice to be (or not) in contact with the biocide (the treated carpet was covered with a non-woven fabric to prevent fleas from escaping).
* According to the guidance, for laboratory (non-choice) tests against fleas, 100% knockdown and ≥90% mortality of the adult fleas should occur within 24 and 48 hours respectively. However, in the study by Dutto M. (2018, Report No: BLENED030818 -05) the application of the product at the claimed dose rate resulted in 71.43-86.21% knockdown and 80-84.48% mortality of adult fleas within 24 and 48 h respectively after treatment.

**Use # 2**

In the laboratory study by Dutto M. (2017, Report no. BLENDU150917-04) NEODUST was applied at a dose of 10 gr/m2 (on non-porous surface) and 12 gr/m2 (on porous surface). Adults of chicken mites (*Dermanyssus gallinae*) were exposed for 60 minutes to the treated tiles under confined conditions (a strip of black tape of 5 cm was attached on the surface, to prevent mites from escaping and thus ensuring the contact with the treated surface). The mites were exposed to fresh and 1-week deposits. Study results showed that the product resulted in mortality of adults of ≥90% in 24 hours after treatment.

In the field study by Dutto M. (2018, Report No: BLENED030818-02) NEODUST was applied at the claimed dose rate of 12 gr/m2 in crack and crevices of 3 henhouses. Three (3) replicates were used for each treatment, while untreated sites were also used as controls. Application of the product resulted in ≥90% mortality of adults, 1 week after treatment.

Hence, the intended Use # 2 of the product, from an efficacy point of view, is acceptable as applied for by the applicant, considering the crack and crevice treatment in the field study as worst case application method in support of the claimed surface treatment applied in larger surface areas including cracks and crevices against chicken mites. Also, based on the results of the submitted studies, the residual action of the product is 1 week, not “at least 1 week” as claimed, since there are no efficacy data for more than 1 week effect of the product.

**Use #3**

In the laboratory study by Drago A and Martini S. (2017, Report no. BLENDU150917-01), NEODUST was applied at a dose of 10 gr/m2 on both porous and non-porous surface. Adults of American cockroaches (*Periplaneta americana*) were exposed for 60 minutes to the treated tiles under confined conditions (transparent plastic cups to prevent cockroaches from escaping and thus ensuring contact with the treated surface). Cockroaches were exposed to fresh and 1-3 weeks deposits. According to the guidance, in laboratory residual tests ≥ 90% knockdown should occur in 24h direct after spray and at the end of the claimed residual period (for general surface treatments for consumers) and 100% mortality within 24 hours after placing the cockroaches in the test area, direct after spray and at the end of the claimed residual period (for general surface treatments for consumers). According to the resuts of this study, knockdown was 100 % after 10-15 minutes, and mortality ≥90% within 48-96 hours after placing the insects to the treated tiles. This time delay (in 48-96 hours) for killing effect with respect to the requirement in the guidance (in 24 hous), can be addressed in the PAR on the condition that the specific use is authorized.

In the field study by Dutto M. (2018, Report no. BLENED030818-04) NEODUST was applied at the claimed dose rate of 10 gr/m2 against adults of American cockroaches in industrial buildings (on certain parts of small rooms, where electric engines of industrial fridges were stored) as surface treatment (in a band along the indoor perimeter) including applications in cracks and crevices. Three (3) replicates were used for each treatment, whereas untreated sites were also used as controls. Mortality of adults was ≥90% 3 weeks after treatment.

Initially, it was claimed that the product is intended to be used as crack and cervices and /or spot application against adults of American cockroaches (*Periplaneta americana*)*.* However, the applicant proposed the following amendment of the application method: ”surface treatment (in a band along the indoor perimeter) including applications in cracks and crevices”.In the field study by Dutto M (2018) the product was applied as surface treatment indoors (including crack and crevice treatment) in a band along the perimeter of treated rooms, and therefore supports the new claimed application method.

**Based on the results of the aforementioned efficacy studies, and considering the conclusions of the outcome of the discussions of the 60th CG meeting on 13 February 2024 concerning the Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR) for Neodust,** the Intended Use # 3 of the product against American cockroaches (*Periplaneta americana*), from an efficacy point of view, is acceptable as applied for by the applicant with the following limitation:

1. Since only efficacy against *Periplaneta americana* has been presented, the title of use #1 in the SPC will be changed from “*Spreading on cockroaches (Indoor)*” to “*Spreading on American cockroaches (Indoor)*”.
2. The laboratory test performed with *Periplaneta americana* is acceptable, but the limitation “*Noticeable mortality of American cockroaches is expected 48-96h after exposure of the insects to the treated surfaces*.” will be included for use #1 in section 4 `Use-specific instructions for use’ of the SPC.

**Use #4**

In the laboratory study by Drago A and Martini S. (2017, Report no. BLENDU150917-02), NEODUST was applied at a dose of 12 gr/m2 on both porous and non-porous surface. Adults of the sheep tick (*Ixodes ricinus*) were exposed for 60 minutes to the treated tiles under confined conditions (transparent plastic cups to prevent ticks from escaping and thus ensuring contact with the treated surface). The ticks were exposed to fresh and 1-3 weeks deposits. The product resulted in 100 % knockdown after 5-7 minutes and mortality of ≥90% in 24 hours.

In the field study by Drago A and Martini S. (2018, Report no. BLENED030818-01), the application rate was 12 g BP/m2 against adults of the sheep tick in stables of 3 sites. Three (3) replicates were used for each treatment, while untreated sites were also used as controls. Surface (perimeter) applications were carried out. Mortality of adults was 100% 3 weeks after treatment.

According to the guidance, for products with knockdown effect against ticks, 100% knockdown before ticks start feeding and ≥80% kill effect within 24h should occur. For products with kill effect against ticks, ≥95% kill before ticks start feeding is also required. However, in the submitted lab study by Drago and Martini (2017, Report No: BLENDU150917- 02) and in the field study by Drago and Martini (2018, Report No BLENED030818 – 01) the product was not tested in the presence of a person or an arm or foot or animal, as mentioned in the guidance, to evaluate if the knockdown and kill effect are achieved before ticks start feeding.

Hence, the intended Use # 4 of the product, from an efficacy point of view, is acceptable as applied for by the applicant, noting however that in the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): “The product should be used without the presence of animals or humans. Entrance of humans and animals in the treated area should only be permitted after 24 hours. The product has a residual effect of 3 weeks”. Also, based on the results of the submitted studies, the residual action of the product is 3 weeks, not “at least 3 weeks” as claimed, since there are no efficacy data for more than 3 weeks effect of the product. It is noted that, according to the Efficacy Guidance on the BPR, when the product is intended for use in poultry farms, tests should be performed against *Argas persicus*. Hence, if the use in general animal housing is to be claimed, tests with *A. persicus* must be submitted. Otherwise, the label of the product should clearly indicate that the use is limited to animal houses, excluding poultry houses.

The applicant proposed the addition of the following label warning: “*The product should be used without the presence of the animals or humans. Entrance of humans and animals in the treated area should only be permitted after one hour*”.

The applicants argumention is as follows: “We do not agree with the waiting time of 24 hours for entrance. In the laboratory test all the ticks are knocked down after 10 minutes since the beginning of exposure to the insecticide. A knocked down tick cannot walk and cannot bite. In the laboratory test the ticks are removed after 60 minutes from the treated surface to observe if any recovery occurred but it didn’t and, after 24 hours these ticks were confirmed as dead. This means that after 10 minutes the ticks cannot be harmful anymore, even if moved away from the insecticide. This is very important because in the field test the ticks are not removed from the insecticide but remain above the treated surface. If the ticks cannot recover if moved away from the insecticide, for sure cannot recover if they stay above the treated surface. Therefore, basing on the data from the laboratory and the field, there is no reason because the treated area cannot be considered safe after 1 hour from the treatment, the risk to be biten by a tick is not different after 24 hours respect than after 1 hour”.

However, the applicant’s argumentation cannot be accepted on the grounds that in the lab test, although 100% knockdown was recorded in 60 minutes, there are no data for the recovery status and biting behaviour of ticks until >95% killing effect observed in 24 hours.

**Use #5**

In the laboratory study by Drago A and Martini S. (2017, Report no. BLENDU150917-03), NEODUST was applied at a dose of 10 gr/m2 on both porous and non-porous surface. Adults of the black garden ant (*Lasius niger*) were exposed for 60 minutes to the treated tiles under confined conditions (transparent plastic cups to prevent ants from escaping and thus ensuring contact with the treated surface). The ants were exposed to fresh and 1-3 weeks deposits. The product resulted in 100 % knockdown after 7-15 minutes and mortality of 100% in 24 hours.

In the field study by Dutto M. (2018, Report no. BLENED030818-03), the product was applied at the claimed dose of 10 gr/m2 against adults of the black garden ant. Perimetral crack and crevice applications, to points where ants come into the building, were carried out in domestic premises inside or outside the buildings and the population of ant population was recorded indoors. Three (3) replicates were used for each treatment (indoor or outdoor), whereas untreated sites were also used as controls. Population reduction of ants indoors was ≥90% 3 weeks after treatment.

It is claimed that the product is intended to be used indoors or outdoors as spot treatment, crack and crevices or perimeter treatment against adults of the black garden ant (*Lasius niger*)*.* According to the submitted field study against ants, the product was proved efficacious when applied either indoors or outdoors as perimetral crack and crevice treatment to points where ants come into the building against black garden ant infestations that occured inside the building.

Hence, the intended Use # 5 of the product, from an efficacy point of view, is acceptable as applied for by the applicant, amending the application method and use pattern of the product in accordance with the field study, i.e. “Indoor or outdoor perimetral crack and crevice applications (to points where ants come into the building) against black garden ant infestation that occur indoors”. Also, based on the results of the submitted studies, the residual action of the product is 3 weeks, not “at least 3 weeks” as claimed, since there are no efficacy data for more than 3 weeks effect of the product.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.4.

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

The biocidal product is not intended to be used in combination with other biocidal products.

### Risk assessment for human health

NEODUST is a ready to use microgranules formulation containing 0.5% w/w permethrin and 0.05% w/w piperonyl butoxide, for use both outdoor and indoor by professionals and non-professionals for the control of crawling (fleas, mites, cockroaches, ticks and ants) insects (Product Type 18).

The product should be applied directly from the packaging with the spreader in a homogeneous way in surfaces such as the carpets, in cracks and crevices and/or as spot application.

The biocidal product product contains the following active substances:

* 0.5% w/w permethrin (CAS No. 52645-53-1)
* 0.05% w/w piperonyl butoxide (CAS No. 51-03-6).

The active substance permethrin was approved for use in biocidal products for product-type 18 in Regulation (EU) No 1090/2014 of 16 October 2014. Ireland acted as the Rapporteur Member State and the Assessment Report was finalised in the Standing Committee on Biocidal Products and published in April 2014. The current harmonised classification of permethrin has been used for the toxicological hazard assessment of the biocidal product NEODUST.

The active substance piperonyl butoxide (PBO) was approved for use in biocidal products for product-type 18 in Regulation (EU) No 2016/2288 of 16 December 2016. Greece acted as the Rapporteur Member State and the Assessment Report was finalised in the Standing Committee on Biocidal Products and published in September 2019. The classification of piperonyl butoxide has been recently discussed in RAC-53 (June 2020). The agreed classification has been used for the toxicological hazard assessment of the biocidal product NEODUST.

No toxicological studies have been conducted with the biocidal product NEODUST. The toxicological hazard assessment for the biocidal product relies on the information available for the individual components (please refer to the Confidential annex of this PAR).

#### Assessment of effects on Human Health

#### 

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritating to skin. |
| Justification for the value/conclusion | No new *in vitro* or animal studies are available. No human data are available.  The classification of the product was estimated by the calculation method using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the product.  The biocidal product NEODUST does not contain any ingredient classified for skin corrosion and irritation. As a consequence, no classification is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion and irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | No data for NEODUST is provided. The classification of the product was estimated by the calculation method using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the product.  The biocidal product NEODUST does not contain any ingredient classified for skin corrosion and irritation. As a consequence, no classification is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not ocular irritant. |
| Justification for the value/conclusion | No new *in vitro* or animal studies are available. No human data are available.  The classification of the product was estimated by the calculation method using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the product.  According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified for eye irritation (Eye Irritant, Category 2). In addition a co-formulant of NEODUST is also classified for eye damage, Category 1. However, their concentration in the biocidal product does not exceed the generic concentration limit triggering classification. As a consequence, no classification for eye irritation is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | No data for NEODUST is provided. The classification of the product was estimated by the calculation method using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the product.  According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified for eye irritation (Eye Irritant, Category 2). In addition a co-formulant of NEODUST is also classified for eye damage, Category 1. However, their concentration in the biocidal product does not exceed the generic concentration limit triggering classification. As a consequence, no classification for eye irritation is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the value/conclusion | There are no designated tests for respiratory tract irritation. No data is available. No human data is available.  The classification of the product was estimated by the calculation method, using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product.  According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified as irritating to the respiratory tract (STOT SE Category 3; H335). However, as the concentration of piperonyl butoxide in the product does not exceed the generic concentration limit triggering classification for respiratory irritation, the biocidal product should not be classified as a respiratory tract irritant according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | There are no designated tests for respiratory tract irritation. In the absence of available data, the classification of the product was estimated by the calculation method, using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product.  According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified as irritating to the respiratory tract (STOT SE Category 3; H335). However, as the concentration of piperonyl butoxide in the product does not exceed the generic concentration limit triggering classification for respiratory irritation, the biocidal product should not be classified as a respiratory tract irritant according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to skin. |
| Justification for the value/conclusion | No new animal studies are available. No human data available.  The classification of the product was estimated by the calculation method, using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product.  According to the Assessment Report of permethrin, the a.s. is currently classified as skin sensitizer Category 1 (H317). However, as the concentration of permethrin in the product is below 1% (w/w), which is the concentration limit that triggers classification of a mixture as a skin sensitizer, the biocidal product should not be classified for skin sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  However, as the concentration of permethrin in the product is above 0.1% (w/w), EUH208 special precautionary phrase should be added on the label of the biocidal product to protect already sensitised individuals. |
| Classification of the product according to CLP and DSD | Not classified.  EUH208 special precautionary phrase should be added on the label of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitisation.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | No new animal studies are available. No human data available.  The classification of the product was estimated by the calculation method, using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product.  According to the Assessment Report of permethrin, the a.s. is currently classified as skin sensitizer Category 1 (H317). However, as the concentration of permethrin in the product is below 1% (w/w), which is the concentration limit that triggers classification of a mixture as a skin sensitizer, the biocidal product should not be classified for skin sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  However, as the concentration of permethrin in the product is above 0.1% (w/w), EUH208 special precautionary phrase should be added on the label of the biocidal product to protect already sensitised individuals. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not a respiratory sensitizer. |
| Justification for the value/conclusion | There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation and there is no testing requirement for this endpoint under the BPR.  No study is available for NEODUST.  In the absence of a specific study, the respiratory sensitization of the biocidal product NEODUST has to be estimated by the calculation method, using the endpoints included in the Assessment Reports (PT18) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product.  Neither the active substances nor all the co-formulants are classified as respiratory sensitizers. Therefore, the biocidal product does not meet the criteria for classification for respiratory sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization (ADS).  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Testing of the product is not deemed necessary. Classification may be based on read across to the active substances and reference to the components and their concentration in the biocidal product. As neither the active substances nor the other components of the biocidal product are classified for respiratory sensitisation, the product does not meet the criteria for classification for respiratory sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

Acute oral toxicity values of the active substances permethrin (Assessment report; Ireland, 2014) and piperonyl butoxide (Assessment report; Greece, 2019) are detailed below.

|  |  |
| --- | --- |
| **Permethrin** | |
| Rat LD50 oral | 480 - 554 mg/kg bw |
| Permethrin is classified for acute oral toxicity (H302). However, as their concentration in the biocidal product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). | |
| **Piperonyl butoxide** | |
| Rat LD50 oral | > 2000 mg/kg bw (male) |
| Rat LD50 oral | > 5000 mg/kg bw (female) |
| Piperonyl butoxide is not classified for acute oral toxicity. | |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Non-toxic *via* the oral route. |
| Justification for the selected value | No new animal studies are available. No human data available.  Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Permethrin and a co-formulant of NEODUST are classified for acute oral toxicity (H302). However, as their concentration in the biocidal product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | NEODUST does not contain substances with acute oral toxicity hazards at a concentration equal or greater than 1%, therefore, no classification for acute oral toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

*Acute toxicity by inhalation*

Acute inhalation toxicity values of the active substances permethrin (Assessment report; Ireland, 2014) and piperonyl butoxide (Assessment report; Greece, 2019) are detailed below.

|  |  |
| --- | --- |
| **Permethrin** | |
| Rat LC50 inhalation | 4.638 - 23.5 mg/L |
| Permethrin is classified for acute inhalation toxicity (H332). However, as the concentration of permethrin in the biocidal product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). | |
| **Piperonyl butoxide** | |
| Rat LC50 inhalation | > 5.9 mg/L/4h (male and female; whole body exposure) |
| Piperonyl butoxide is not classified for acute inhalation toxicity. | |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Non-toxic *via* the inhalation route. |
| Justification for the selected value | No new animal studies are available. No human data available.  Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Permethrin and a co-formulant of NEODUST are classified for acute inhalation toxicity (H332). However, as their concentration in the biocidal product is below 1%, no classification for acute inhalation toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | NEODUST does not contain substances with acute inhalation toxicity hazards at a concentration equal or greater than 1%, therefore, no classification for acute inhalation toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

*Acute toxicity by dermal route*

Acute dermal toxicity values of the active substances permethrin (Assessment report; Ireland, 2014) and piperonyl butoxide (Assessment report; Greece, 2019) are detailed below.

|  |  |
| --- | --- |
| **Permethrin** | |
| Rat LD50 dermal | > 2000 mg/kg bw |
| Permethrin is not classified for acute dermal toxicity. | |
| **Piperonyl butoxide** | |
| Rat LD50 dermal | > 2000 mg/kg bw (male and female) |
| Piperonyl butoxide is not classified for acute dermal toxicity. | |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Non-toxic *via* the dermal route. |
| Justification for the selected value | No new animal studies are available. No human data available.  Application of rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  The biocidal product does not contain ingredients that are classified for acute dermal toxicity, hence no classification of the biocidal product is triggered, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP and DSD | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute dermal toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | The biocidal product does not contain ingredients that are classified for acute dermal toxicity, hence no classification of the biocidal product is triggered, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Additional information on the classification of the active substances***

The current harmonised classification of permethrin (Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Sensitization Cat. 1B, H317) has been used for the toxicological hazard assessment of the biocidal product NEODUST.

The classification of piperonyl butoxide has been recently discussed in RAC-53 (June 2020). The agreed classification (Eye irritation, Cat. 2, H319; STOT SE Cat. 3, H335; EUH066) has been used for the toxicological hazard assessment of the biocidal product NEODUST.

***Information on dermal absorption***

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Permethrin | Piperonyl butoxide |
| Value(s) | 50% | |
| Justification for the selected value(s) | In the absence of relevant dermal absorption data with the biocidal product NEODUST, the default dermal absorption value of 50% for solid-formulated products containing ≤ 5% active substance has been used for the risk assessment according to EFSA Guidance on Dermal Absorption, 2017 (EFSA Journal 2017;15(6):4873). | |

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

The biocidal product NEODUST contains the co-formulant Arcosolv DPM (CAS No. 34590-94-8). Based on the submitted MSDS, Arcosolv DPM [(2-methoxymethylethoxy)propanol] has no classification and therefore there is no impact on the classification of the biocidal product NEODUST.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health – Part B and C Risk Assessment– Version 4.0 – December 2017), Arcosolv DPM should be considered as a substance of concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The occupational exposure limit of Arcosolv DPM is 308 mg/m3 (<https://echa.europa.eu/el/substance-information/-/substanceinfo/100.047.353>).

According to the BPR Guidance (p. 424), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. If the IOELV is associated with a “skin notation” and is driven by systemic rather than local effects, then a dermal quantitative risk assessment for the professional operator should be performed.

However, in case of Arcosolv DPM, a dermal quantitative risk assessment has not been performed as a dermal NOAEC value for this co-formulant [(2-methoxymethylethoxy)propanol] has not been peer reviewed and agreed under the BPR. Therefore, only an inhalation quantitative risk assessment has been undertaken for this co-formulant.

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

NEODUST contains only one mixture: Denatonium benzoate 5%. Available toxicological data relating to the mixture contained in the biocidal product NEODUST is provided in the MSDS attached to current submission. Further information can be found in the Confidential Annex of this PAR.

***Other***

No other relevant information available.

***Screening non-active substance(s) for endocrine-disrupting potential***

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product NEODUST has been performed according to the instructions described in the document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The sources of information, the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product NEODUST are presented in detail in the Confidential Annex of this PAR.

Based on existing knowledge and available scientific information, there is no indication of concern regarding endocrine-disrupting properties of any of the co-formulants present in the biocidal product NEODUST.

#### Exposure assessment

The biocidal product NEODUST is a ready-to-use microgranules formulation containing 0.5% w/w permethrin and 0.05% w/w piperonyl butoxide, for domestic and civil use both outdoor and indoor for the control of crawling (fleas, mites, cockroaches, ticks and ants) insects (Product Type 18).

It is indicated that the product should be applied directly from the packaging with the spreader in a homogeneous way in surfaces such as carpets, in cracks and crevices and/or as spot application.

- For ticks, fleas and chicken mites, it is suggested to use 12 g of product per 1 m2 of surface.

- For ants and cockroaches, it is suggested to use 10 g of product per 1 m2 of surface.

The product can be used by professionals and non-professionals which are exposed by primary/direct exposure. General public (infant, toddler, child and adult) could be inadvertently exposed to the product without actually using the biocidal product themselves; this is the case of secondary/indirect exposure that has to be evaluated too. The relevant paths of human exposure are fully described in Table 1.

The assessment of primary exposure to the active substances permethrin and piperonyl butoxide resulting from the professional and non-professional use of NEODUST follows the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, version 3, “Methods and models to assess exposure to biocidal products in different product types” (February 2017). In particular, the model no. 40 for PT18 and the approach 2 were used to assess the primary (direct) exposure of professionals and non-professionals to the biocidal product NEODUST.

The assessment of secondary (indirect) exposure of the general public to the active substances permethrin and piperonyl butoxide was performed using the ConsExpo Web, version 1.0.6 and particularly the scenario for dusting powders: post-application.

The assessed worst case referred to the indoor use of NEODUST by professional and non-professional users at the maximum dose rate of 12 g/m2. Professional and non-professional uses differ in frequency and duration as will be pointed out in the next pages.

The assessment of human exposure during the mixing and loading phase is not necessary, because NEODUST is a ready-to-use product, but the assessment of human exposure after the application of the product (secondary/indirect exposure) is required.

**Identification of main paths of human exposure towards active substances and substances of concern from the use of the biocidal product NEODUST.**

| **Table 1: relevant paths of human exposure to permethrin and piperonyl butoxide from the use of the biocidal product NEODUST.** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | |
| **Industrial use1** | **Professional use** | **Non-professional use** | **General public** | **Via**  **environment2** | **Via food** |
| Inhalation | No | Yes | Yes | No | Not relevant | Not relevant |
| Dermal | No | Yes | Yes | Yes | Not relevant | Not relevant |
| Oral | No | Not relevant | Not relevant | No | Not relevant | Not relevant |

1 Exposure resulting from the production of the active substance is not considered as the manufacturing processes are not performed in the EU. Exposure resulting from the formulation and packaging processes which take place in Italy is also not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

2 From TNsG on Human Exposure, 2007: “Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food.” Those scenarios are not considered relevant in this case.

***List of scenarios***

| **Table 2: scenarios** **of intended uses of the biocidal product NEODUST.** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 01 | Application; Indoor and Outdoor Surface and Crack and Crevice | **Primary Exposure**  Direct spreading of the product against crawling insects and arachinds. | Professionals |
| 02 | Application; Indoor and Outdoor Surface and Crack and Crevice | **Primary Exposure**  Direct spreading of the product against crawling insects and arachinds. | Non-professionals |
| 03 | Post-application (indoor and outdoor) | **Secondary Exposure**  Secondary exposure is relevant to the general public entering to treated areas after the product application and is derived *via* inhalation and dermal route. | General public: infants, toddlers, children, adults |
| 02 + 03 | Combined;  Application and post-application | **Combined Exposure**  Combined exposure is expected only for the adult non-professional user who is exposed *via* inhalation and dermal route during the application of the product and at the re-entry to treated areas following product application. | Adult non-professional users |

***Industrial exposure***

Industrial users are involved in manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products. Industrial users have received suitable information, instruction and training in their use. Thus no industrial exposure is foreseen and it is not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

***Professional exposure***

**Scenario 01: Indoor and Outdoor Surface Treatment, Crack and Crevices and/or Spot Application**

Exposure will be *via* inhalation and dermal route. The exposure is anticipated to be chronic in nature.

NEODUST may be used by professionals both indoors and outdoors and is a ready-to-use microgranules formulation containing 0.5% w/w of permethrin and 0.05% w/w of piperonyl butoxide as active substances and 0.5% of Arcosolv DPM as SoC.

The recommended usage concentration of the microgranules product is 10 g product/m2 (corresponding to 50 mg/m2 permethrin, 5 mg/m2 piperonyl butoxide and 50 mg/m2 Arcosolv DPM)for cockroaches and ants and 12 g product/m2 (corresponding to 60 mg/m2 permethrin, 6 mg/m2 piperonyl butoxide and 60 mg/m2 Arcosolv DPM) for fleas, ticks and mites. For the present risk assessment the maximum dose rate of 12 g/m2 has been considered to represent the worst case scenario.

These concentrations are suitable for professional, indoor and outdoor uses of the product.

The product should be applied directly from the packaging with the spreader in a homogeneous way in surfaces such as carpets, in cracks and crevices and/or as spot applications. As there is no indication for crack and crevice application, the worst case of room application has been considered.

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor surface treatments (i.e., it is considered to be within the ‘risk envelope’ as defined by the indoor use). The scenario for the indoor uses for the control of fleas, ticks and mites (12 g product/m2) is considered to represent the worst case for professional users.

The model and the parameters used for the professional exposure to NEODUST are summarised below, while the calculations are presented in the Annex 3.2 of this document.

| **Description of Scenario 01:** **Application of NEODUST by professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professionals | - |
| Scenario | Application | - |
| Application rate | 12 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction substance | Permethrin: 0.5% | Concentration of permethrin in the biocidal product. |
| Piperonyl butoxide: 0.05% | Concentration of piperonyl butoxide in the biocidal product. |
| Application duration | 120 minutes | The application duration default value for spreading/scattering a granule formulation on a surface is 120 min, according to the Biocides Human Health Exposure Methodology, ECHA, October 2015, p.81 (embedded Excel spreadsheet). |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% for both active substances. | Default dermal absorption value for both active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| **Inhalation exposure** |  |  |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% for both active substances. | Assessment Reports of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019). |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

**Calculations for Scenario 01**

| **Summary table: estimated exposure from professional uses - Application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| Scenario 01  Application | Permethrin | 0.00052 | 0.02735 | **0.028** |
| Piperonyl butoxide | 0.000052 | 0.002735 | **0.0028** |

*Combined scenarios*

The product NEODUST is a ready-to-use formulation, therefore only individual application task is foreseen. The exposure estimates from the different routes of exposure (inhalation, dermal) *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous table.

***Non-professional exposure***

**Scenario 02: Indoor and Outdoor Surface Treatment, Crack and Crevices and/or Spot Application**

Exposure will be *via* inhalation and dermal route. The exposure is anticipated to be chronic in nature.

NEODUST may be used by non-professionals both indoors and outdoors and is a ready-to-use microgranules formulation containing 0.5% w/w of permethrin and 0.05% w/w of piperonyl butoxide as active substances and 0.5% of Arcosolv DPM as SoC.

The recommended usage concentration of the microgranules product is 10 g product/m2 (corresponding to 50 mg/m2 permethrin, 5 mg/m2 piperonyl butoxide and 50 mg/m2 Arcosolv DPM)for cockroaches and ants and 12 g product/m2 (corresponding to 60 mg/m2 permethrin, 6 mg/m2 piperonyl butoxide and 60 mg/m2 Arcosolv DPM) for fleas, ticks and mites. For the present risk assessment the maximum dose rate of 12 g/m2 has been considered to represent the worst case scenario.

The biocidal product should be applied directly from the packaging with the spreader in a homogeneous way in surfaces such as carpets, in cracks and crevices and/or as spot applications. As there is no indication for crack and crevice application, the worst-case of room application has been considered.

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor surface treatments (i.e., it is considered to be within the ‘risk envelope’ as defined by the indoor use). The scenario for the indoor uses for the control of fleas, ticks and mites (12 g product/m2) is considered to represent the worst case for professional users.

The model and the parameters used for the non-professional exposure to NEODUST are summarised below, while the calculations are presented in the Annex 3.2 of this document.

| **Description of Scenario 02:** **Application of NEODUST by non-professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non-professionals | - |
| Scenario | Application | - |
| Application rate | 12 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction substance | Permetrhrin: 0.5% | Concentration of permethrin in the biocidal product. |
| Piperonyl butoxide: 0.05% | Concentration of piperonyl butoxide in the biocidal product. |
| Application duration | 30 minutes | The time required for the application depends on the type of application and the required quantity of product.  For dusting powders, the only available data for quantity of dust applied per min is an assumption of dusting 60 g/m2 in 5 min equivalent to 12 g/min (TNsG, 2002, p.280).  Based on this and taking into account the application rate of NEODUST (12 g/m2), the default value of 22 m2 for surface broadcast dusting of powder (TNsG, 2002, p.279), the application duration for NEODUST is calculated as follows:  (12 g/m2  x 22 m2) / 12 g/min = 22 min.  Therefore, an application duration of 30 min was selected as a worst-case value**.** |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration, assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% for both active substances. | Default dermal absorption value for both active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| **Inhalation exposure** |  |  |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% for both active substances. | Assessment Reports of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019). |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

**Calculations for Scenario 02**

| **Summary table: estimated exposure from non-professional uses - Application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| Scenario 02  Application | Permethrin | 0.00013 | 0.0068 | **0.007** |
| Piperonyl butoxide | 0.000013 | 0.00068 | **0.0007** |

***Exposure of the general public***

**Scenario 03: Post-application exposure**

Subsequent to the use of the biocidal product, indirect secondary exposure of general public could occur in the residential environment. Secondary exposure is derived *via* inhalation and dermal route.

Inhalation exposure to volatilised residues of active substances is expected to occur for infants, toddlers, children and adults entering to treated areas.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocides on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period and adults accidentally touching contaminated surfaces with their bare hands.

It is noted that the biocidal product NEODUST contains denatonium benzoate which is a substance inserted in the formulation specifically to give it a bitter taste and prevent it from being ingested by the children. Therefore, the oral exposure of infants and toddlers to the active substances would be negligible.

It is assumed that infants, toddlers and children would not be permitted to be present during the application operation and therefore, there would be no acute exposure. Secondary exposure for the general puclic occurs as long-term event and may be continuous (chronic exposure).

The models used for the secondary exposure assessment for the general public are summarized in the following table.

|  |  |  |
| --- | --- | --- |
| **Overview of models used for secondary human health exposure assessment.** | | |
| **Inhalation route** | **Models** | **Population** |
| Vapours (volatilised residues) | HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active substances. | Infant  Toddler  Child  Adult |
| **Dermal route** | **Model** | **Population** |
| Dermal contact with treated surfaces | ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off. | Infant  Toddler  Child  Adult |

**Assessment of Inhalation Exposure of Volatilised Biocidal Active Substances**

Inhalation exposure to volatilised residues of active substances is expected to occur for infants, toddlers, children and adults entering to treated areas.

Volatization of permethrin and piperonyl butoxide is expected to be minimal due to low vapour pressure, low Henry’s Law constant and high adsorption potential. However, the assessment of inhalation exposure of volatilised residues of active substances was performed for completeness.

*Tier-1 screening tool*

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m3/24 hr and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d, if

0.328 × [(mw x vp) / AELlong-term] ≤ 1

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is

negligible, then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Tier-1 screening tool has been applied for each active substance as detailed in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Screening tool of inhalation exposure of volatilised biocidal active substances** | | | | | |
| **Active substance** | **MW (g/mol)** | **vp**  **(Pa)** | **AELlong-term**  **(mg/kg bw day)** | **0.328 × mw x vp/AELlong-term** | **Result** |
| permethrin | 391.29 | 2.155 × 10⁻6 (20°C) | 0.05 | 0.0055 | <1  risk from inhalation exposure for the toddler is negligible |
| piperonyl butoxide | 338.43 | 1.33 x 10-5 (25°C) | 0.2 | 0.0074 | <1  risk from inhalation exposure for the toddler is negligible |

As a result of the application of Tier-1 screening tool, the risk from the inhalation exposure for toddlers is negligible in long-term exposure. Therefore, the inhalation risk for infants, children and adults is also considered negligible.

**Dermal exposure to residues on the floor – infants, toddlers, children, and adults.**

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocides on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period and adults accidentally touching contaminated surfaces with their bare hands.

The dermal exposure assessment has been performed using ConsExpo Web, version 1.0.6, considering the worst-case application rate of the product (12 g/m2).

The models and the parameters used to calculate the secondary exposure assessment for the general public are described in detail in the following table, while the calculations are presented in the Annex 3.2 of this document.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 03: Secondary exposure of the general public.** | | |
| The assessment for the dermal exposure of the general public has been performed using ConsExpo Web, version 1.0.6.  The parameters used were from the RIVM report 320005002/2006, Chapter 7, Dusting powders, Exposure after application (p. 71-73). | | |
| **Parameter** | **Value** | **Comments** |
| Exposed group | General public:  infant, toddler, child, adult | - |
| Product database | Pest control products | - |
| Product category | Dusting powders | - |
| Product | Dusting powders | - |
| Scenario | Post-application (child) | - |
| Application rate | 12 g/m2 | Product label claim. |
| Body weight | Infant: 8 kg  Toddler: 10 kg  Child: 23.9 kg  Adult: 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction substance | permethrin: 0.5% | Concentration of permethrin in the biocidal product. |
| piperonyl butoxide: 0.05% | Concentration of piperonyl butoxide in the biocidal product. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Rubbing off | - |
| Exposure frequency | 70 per year | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Exposed area  (palms and backs of both hands) | Infant: 196.8 cm2  Toddler: 230.4 cm2  Child: 427.8 cm2  Adult: 820 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Transfer coefficient | Infant/toddler/child: 0.2 m2/hr  Adult: 0.78 m2/hr | Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: “New default values for indoor Transfer Coefficient” (agreed at the Human Health Working Group V on 22 November 2016). |
| Dislodgeable amount  (product) | Tier 1: 3.06 g/m2 | Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 71), using the worst-case application rate of NEODUST (12 g/m2).  According to RIVM report 320005002 (p.71), “the default value for the dislodgeable fraction is set at 30%. The airborne fraction is taken to be 15%, so 85% of the powder is sprinkled onto 1 m2”.  Therefore, the dislodgeable amount for NEODUST is calculated as follows:  12 g/m2 x 0.85 x 0.3 = 3.06 g/m2 |
| Tier 2: 0.306 g/m2 | Dislodgeable amount has been calculated using the worst-case application rate of NEODUST (12 g/m2) and considering the permethrin-specific fraction transferred value of 3% for hard surfaces from US-EPA SOPs.  Therefore, the dislodgeable amount for NEODUST is calculated as follows:  12 g/m2 x 0.85 x 0.03 = 0.306 g/m2 |
| Contact time | 60 min/day | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Rubbed surface | 1 m2 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Dermal absorption | 50% for both active substances. | Default dermal absorption value for both active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |

**Calculations for Scenario 03**

| **Summary table: estimated secondary exposure of general public** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Tier 1** | **Active Substance** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  |  | **mg/kg bw/day** | | | |
| Scenario 03  Post application Infant | Tier 1 | permethrin | - | 1.9 × 10-1 | - | **1.9 × 10-1** |
| piperonyl butoxide | - | 1.9 × 10-2 | - | **1.9 × 10-2** |
| Tier 2 | permethrin | - | 1.9 × 10-2 | - | **1.9 × 10-2** |
| piperonyl butoxide | - | 1.9 × 10-3 | - | **1.9 × 10-3** |
| Scenario 03  Post application Toddler | Tier 1 | permethrin | - | 1.5 × 10-1 | - | **1.5 × 10-1** |
| piperonyl butoxide | - | 1.5 × 10-2 | - | **1.5 × 10-2** |
| Tier 2 | permethrin | - | 1.5 × 10-2 | - | **1.5 × 10-2** |
| piperonyl butoxide | - | 1.5 × 10-3 | - | **1.5 × 10-3** |
| Scenario 03  Post application Child | Tier 1 | permethrin | - | 6.4 × 10-2 | - | **6.4 × 10-2** |
| piperonyl butoxide | - | 6.4 × 10-3 | - | **6.4 × 10-3** |
| Tier 2 | permethrin | - | 6.4 × 10-3 | - | **6.4 × 10-3** |
| piperonyl butoxide | - | 6.4 × 10-4 | - | **6.4 × 10-4** |
| Scenario 03  Post application Adult | Tier 1 | permethrin | - | 9.9 × 10-2 | - | **9.9 × 10-2** |
| piperonyl butoxide | - | 9.9 × 10-3 | - | **9.9 × 10-3** |
| Tier 2 | permethrin | - | 9.9 × 10-3 | - | **9.9 × 10-3** |
| piperonyl butoxide | - | 9.9 × 10-4 | - | **9.9 × 10-4** |

*Combined scenarios*

The biocidal product NEODUST is a ready-to-use formulation, therefore only individual application task is foreseen. The exposure estimates from the different routes of exposure *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous table.

***Monitoring data***

No monitoring data available.

***Dietary exposure***

The biocidal product is to be used for control of ants, crawling, ticks and mites insect by application to localised areas so that the biocidal product does not come into contact with food and feedstuff.

No dietary exposure is foreseen since the product is not intended for the use on food, drinking water or livestock. Moreover dietary exposure is considered as not relevant, as the biocidal product is applied only in a band around the perimeter of the room in a directed manner and should not be applied in areas where food for human consumption is exposed at the time of treatment. Thus dietary exposure has not been assessed.

Nevertheless, to ensure that contact of the biocidal product with food or feed is avoided (in case of canteens, kitchens, hotels, restaurants, food industries), the following precautionary risk mitigation measures are proposed:

* “Do not place food or feed in areas where the product is or will be applied”
* “Avoid any direct or indirect contact with food and feed”
* “Keep away from food/feed stuff, eating utensils or food contact surfaces”

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

The active substances permethrin and piperonyl butoxide are authorised for the use as biocide. Non-biocidal use foreseen.

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

Based on intended uses of the biocidal product, human exposure through residues in livestock is not foreseen and feeding and metabolism studies in livestock to permit evaluation of residues in food of animal origin are not required. Therefore, animal exposure and transfer to animal food commodities has not be investigated.

Nevertheless, to ensure that contact of the biocidal product with livestock is avoided for the use on stable and animal house, the following precautionary risk mitigation measures are proposed:

* “Move the animals away during the treatment”
* “The treatment premises/room must not accessible to pets”
* “Clean the treatead area before the re-entry of the animal”
* ”Do not treat directly on the animal”

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

No transfer of active substance into foods as results of professional and/or industrial application of NEODUST is expected since the product is not applied by spraying such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

No transfer of active substance into foods as results of non-professional use of NEODUST is expected since the product is not applied in such a way that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

***Aggregated exposure***

Non-professional users handling the biocidal product may be exposed to the active substances not only during the application stages but also after application as general public in their daily environment. For this reason it is necessary to assess the total exposure that a person may be exposed to.

Aggregated exposure (combined scenarios 02 + 03) has been assessed for the non-professional user who is exposed *via* the dermal route during the application of the product (primary exposure) and resides in the treated area, therefore coming into dermal contact with treated surfaces following product application (secondary exposure).

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario**  **Number / application** | **Exposed**  **Group (e.g. professionals, non-professionals, bystanders)** | **Active substance** | **Application rate / Exposure duration** | **Estimated total internal uptake (mg/kg bw/day)** |
| Scenario 01  Application | Professionals | Permethrin | 12 g/m2  240 min/day | **2.8 x 10-2** |
| Piperonyl butoxide | **2.8 x 10-3** |
| Scenario 02  Application | Non-professionals | Permethrin | 12 g/m2  240 min/day | **7.0 x 10-3** |
| Piperonyl butoxide | **7.0 x 10-4** |
| Scenario 03  Post-application | General public  Infant | Permethrin | 12 g/m2  240 min/day  Tier 1 | **1.9 × 10-1** |
| Piperonyl butoxide | **1.9 × 10-2** |
| Permethrin | 12 g/m2  240 min/day  Tier 2 | **1.9 × 10-2** |
| Piperonyl butoxide | **1.9 × 10-3** |
| Scenario 03  Post-application | General public Toddler | Permethrin | 12 g/m2  240 min/day  Tier 1 | **1.5 × 10-1** |
| Piperonyl butoxide | **1.5 × 10-2** |
| Permethrin | 12 g/m2  240 min/day  Tier 2 | **1.5 × 10-2** |
| Piperonyl butoxide | **1.5 × 10-3** |
| Scenario 03  Post-application | General public  Child | Permethrin | 12 g/m2  240 min/day  Tier 1 | **6.4 × 10-2** |
| Piperonyl butoxide | **6.4 × 10-3** |
| Permethrin | 12 g/m2  240 min/day  Tier 2 | **6.4 × 10-3** |
| Piperonyl butoxide | **6.4 × 10-4** |
| Scenario 03  Post-application | General public  Adult | Permethrin | 12 g/m2  240 min/day  Tier 1 | **9.9 × 10-2** |
| Piperonyl butoxide | **9.9 × 10-3** |
| Permethrin | 12 g/m2  240 min/day  Tier 2 | **9.9 × 10-3** |
| Piperonyl butoxide | **9.9 × 10-4** |
| Scenarios  02 + 03  Application & post-application | Adult non-professional user | Permethrin | 12 g/m2  240 min/day  Tier 1 | **1.1 x 10-1** |
| Piperonyl butoxide | **1.1 x 10-2** |
| Permethrin | 12 g/m2  240 min/day  Tier 2 | **1.7 x 10-2** |
| Piperonyl butoxide | **1.7 x 10-3** |

#### Risk characterisation for human health

The reference values for the active substances permethrin (Assessment report; Ireland, 2014) and piperonyl butoxide (Assessment report; Greece, 2019) that were used in risk characterisation for human health are described in the following tables.

**Reference values for permethrin to be used in risk characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF** | **Correction for oral absorption** | **Value** |
| AEL short term | 2 year oral study rat | 59.46 mg/kg bw/day | 100 | - | 0.5 mg/kg bw/day |
| AEL medium term | 12-month study dog | 5 mg/kg bw/day | 100 | - | 0.05 mg/kg bw/day |
| AEL long term | 12-month study dog | 5 mg/kg bw/day | 100 | - | 0.05 mg/kg bw/day |

**Reference values for piperonyl butoxide to be used in risk characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF** | **Correction for oral absorption** | **Value** |
| AEL short term | developmental study rabbit | 100 mg/kg bw/day | 100 | - | 1 mg/kg bw/day |
| AEL medium term | 1-year dietary study dog | 16 mg/kg bw/day | 100 | 100 % | 0.2 mg/kg bw/day |
| AEL long term | 1-year dietary study dog | 16 mg/kg bw/day | 100 | 100 % | 0.2 mg/kg bw/day |

**Reference value for Arcosolv DPM [(2-methoxymethylethoxy)propanol] to be used in risk characterisation**

|  |  |
| --- | --- |
| European Union-agreed Indicative Occupational Exposure Limit Value (IOELV) | 308 mg/m3 |

***Risk for industrial users***

As previously stated, no relevant exposure is foreseen considering that industrial users are adequately trained in the safe handling of the active substance and the product, and adequate protective measures are in place in industrial facilities. Thus no risk is envisaged for industrial users.

**Combined scenarios**

The product NEODUST is a ready-to-use formulation, therefore only individual application task is foreseen. The exposure estimates from the different routes of exposure *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous table.

**Local effects**

No risk assessment for local effects should be carried out, as the biocidal product is a ready-to-use formulation containing active substances in concentrations which do not trigger classification of the biocidal product for local effects.

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

The risk characterisation for human health considers the primary exposure during the application of the product by professional and non-professional users. Based on the frequency of product applications, the AEL long-term is used in the risk characterisation for the primary exposure of both professional and non-professional users.

The risk characterisation for the application of the product by professionals and non-professionals is summarised in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Risk assessment results for human health, primary exposure** | | | | |
| **Scenario** | **Substance** | **Total uptake**  **(mg/kg bw/d)** | **AEL long term (mg/kg bw/d)** | **HQ\***  **(Exposure/AEL)** |
| Scenario 01  Application  Professional | permethrin | 2.8 x 10-2 | 0.05 | 0.56 |
| piperonyl butoxide | 2.8 x 10-3 | 0.2 | 0.014 |
| Scenario 02  Application  Non-professional | permethrin | 7.0 x 10-3 | 0.05 | 0.14 |
| piperonyl butoxide | 7.0 x 10-4 | 0.2 | 0.0035 |

\* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

**Combined scenarios**

The product NEODUST is a ready-to-use formulation, therefore only individual application task is foreseen. The exposure estimates from the different routes of exposure *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous table.

**Local effects**

No risk assessment for local effects should be carried out, as the biocidal product is a ready-to-use formulation containing active substances in concentrations which do not trigger classification of the biocidal product for local effects.

**Conclusion**

The ratios Exposure/AEL (HQs) for both active substances of the biocidal product are well below 1. Therefore, primary exposure to permethrin and piperonyl butoxide predicts an acceptable risk for both professional and non-professional users during application of the biocidal product NEODUST.

***Substance of Concern (SoC)***

The biocidal product NEODUST contains the co-formulant Arcosolv DPM [(2-methoxymethylethoxy)propanol] at levels of 0.5%. An IOELV of 308 mg/m3 for (2-methoxymethylethoxy)propanol is available (<https://echa.europa.eu/el/substance-information/-/substanceinfo/100.047.353>) and as such, it should be considered as a SoC.

According to the Guidance on the Biocidal Product Regulation (Volume III Human Health – Part B and C Risk Assessment– Version 4.0 – December 2017), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. Based on the above, a quantitative inhalation risk assessment for the professional user should be performed.

Considering the indicative inhalation exposure value of 2.47 mg/m3 (professional exposure, hand-held flexible duster, TNsG 2007, p. 63) and the concentration of (2-methoxymethylethoxy)propanol in the product i.e. 0.5%, the aerial concentration of (2-methoxymethylethoxy)propanol is calculated to be 0.01235 mg/m3 for Scenario 1. This value corresponds to 0.004% of the IOELV of 308 mg/m3. Therefore, an acceptable risk is identified for the professional user due to the presence of (2-methoxymethylethoxy)propanol in the biocidal product NEODUST.

***Risk for the general public***

The risk characterisation for human health considers also the secondary (indirect) exposure of the general public after indoor application of the biocidal product. The AEL long-term is used in the risk characterisation for secondary exposure of the general public.

The risk characterisation for the general public is summarised in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Risk assessment results for human health, secondary exposure** | | | | | |
| **Scenario** | **Substance** | **Total exposure (mg/kg bw/d)** | **AEL long term**  **(mg/kg bw/d)** | **HQ\***  **(Exposure/AEL)** | **Acceptable** |
| Scenario 03  Post-application  Infant  Tier 1 | Permethrin | 1.9 × 10-1 | 0.05 | 3.8 | **No** |
| Piperonyl butoxide | 1.9 × 10-2 | 0.2 | 0.095 | **Yes** |
| Scenario 03  Post-application  Infant  Tier 2 | Permethrin | 1.9 × 10-2 | 0.05 | 0.38 | **Yes** |
| Piperonyl butoxide | 1.9 × 10-3 | 0.2 | 0.0095 | **Yes** |
| Scenario 03  Post-application  Toddler  Tier 1 | Permethrin | 1.5 × 10-1 | 0.05 | 3 | **No** |
| Piperonyl butoxide | 1.5 × 10-2 | 0.2 | 0.075 | **Yes** |
| Scenario 03  Post-application  Toddler  Tier 2 | Permethrin | 1.5 × 10-2 | 0.05 | 0.3 | **Yes** |
| Piperonyl butoxide | 1.5 × 10-3 | 0.2 | 0.0075 | **Yes** |
| Scenario 03  Post-application  Child  Tier 1 | Permethrin | 6.4 × 10-2 | 0.05 | 1.28 | **No** |
| Piperonyl butoxide | 6.4 × 10-3 | 0.2 | 0.032 | **Yes** |
| Scenario 03  Post-application  Child  Tier 2 | Permethrin | 6.4 × 10-3 | 0.05 | 0.128 | **Yes** |
| Piperonyl butoxide | 6.4 × 10-4 | 0.2 | 0.0032 | **Yes** |
| Scenario 03  Post-application  Adult  Tier 1 | Permethrin | 9.9 × 10-2 | 0.05 | 1.98 | **No** |
| Piperonyl butoxide | 9.9 × 10-3 | 0.2 | 0.05 | **Yes** |
| Scenario 03  Post-application  Adult  Tier 2 | Permethrin | 9.9 × 10-3 | 0.05 | 0.198 | **Yes** |
| Piperonyl butoxide | 9.9 × 10-4 | 0.2 | 0.005 | **Yes** |

\* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

**Combined scenarios**

The product NEODUST is a ready-to-use formulation, therefore only individual application task is foreseen. The exposure estimates from the different routes of exposure *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous table.

**Local effects**

No risk assessment for local effects should be carried out, as the biocidal product is a ready-to-use formulation containing active substances in concentrations which do not trigger classification of the biocidal product for local effects.

**Conclusion**

The ratios Exposure/AEL (HQs) for both active substances of the biocidal product are well below 1. Therefore, secondary exposure to permethrin and piperonyl butoxide predicts an acceptable risk for the general public from application of the biocidal product NEODUST.

***Aggregated exposure***

Aggregated exposure (combined scenarios 02 + 03) has been assessed for the non-professional user who is exposed *via* the dermal route during the application of the product (primary exposure) and resides in the treated area, therefore coming into dermal contact with treated surfaces following product application (secondary exposure).

The risk characterisation for the aggregated exposure of the adult non-professional user is summarised in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Risk assessment results for human health, aggregated exposure** | | | | |
| **Scenario** | **Substance** | **Total uptake**  **(mg/kg bw/d)** | **AEL long term (mg/kg bw/d)** | **HQ\***  **(Exposure/AEL)** |
| Scenarios 02 & 03  Adult non-professional user Application & post-application  Tier 1 | permethrin | 1.1 x 10-1 | 0.05 | **2.2** |
| piperonyl butoxide | 1.1 x 10-2 | 0.2 | **0.055** |
| Scenarios 02 & 03  Adult non-professional user Application & post-application  Tier 2 | permethrin | 1.7 x 10-2 | 0.05 | **0.34** |
| piperonyl butoxide | 1.7 x 10-3 | 0.2 | **0.0085** |

\* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

**Conclusion**

The ratios Exposure/AEL (HQs) for both active substances of the biocidal product are well below 1. Therefore, regarding aggregated exposure, the use of the biocidal product NEODUST is considered safe for the adult non-professional user, as the risk is acceptable for both active substances.

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

NEODUST is not intended for the use on food ~~neither~~ directly. In caseof treatment of areas where food is stored, keep away food during treatment and clean the area before re-allocation. No transfer of active substance into foods as results of professional and/or industrial application is expected since the product is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess risk to consumers via residues in food.

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

A risk characterisation from combined exposure to several active substances is relevant for the biocidal product NEODUST, as it contains two active substances: permethrin and piperonyl butoxide.

Based on the ECHA BPR Guidance[[1]](#footnote-1), a Tiered approach was implemented. According to the guidance, the “Tier 1” of this method is an intermediary step to verify risk acceptability for each substance used in the product. The calculations for this level were performed in the sections presented above. This step is to be followed by “Tier 2”, which involves assessing the combined exposure to the substances of the biocidal product.

According to the ECHA guidance, the “Tier 1” step calculations must be undertaken in accordance with the methodology that is currently used for the assessment of products. Each active substance is assessed in terms of risks to primary and secondary exposure following all the scenarios which are relevant to the product use. The decision-making criterion for acceptability of risk remains as in the case of quantitative risk: the estimated level of exposure to each substance must be lower than its AEL. The Hazard Quotient which is defined by the ratio of internal exposure and AEL has to remain below 1.

Risk characterisation from combined exposure to permethrin and piperonyl butoxide has been calculated and results are reported in the previous sections named “*Risk for professional and non-professional users*” and “*Risk for the general public*”. The calculations presented above have shown acceptable risks (and hazard quotients) for all relevant scenarios for the active substances when considered separately (for details see above).

According to the ECHA Guidance on BPR, the “Tier 2” - level assessment of combined exposure to mixture is performed by concentration (dose) addition. This means that the effects of the active substances in the biocidal product are assumed to be concentration or dose-additive. The Tier 2 assessment is performed with the same parameters as the first tier. The HQ for each substance is used to calculate a HI (Hazard Index) for the biocidal product according to the following method:

**HI = Σ HQa.s.**

The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

The HI is the sum of the HQs for each substance.

HI should be ≤1 to show an acceptable risk related to the use of the biocidal product.

Based on this approach, the additive risks from both active substances have been calculated for professional and non-professional users (primary exposure) as well as for the general public (secondary exposure).

**Professional and non-professional users**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Combined risks from both active substances for professional and non-professional user (additive effect)** | | | | |
| **Scenario** | **HQ permethrin** | **HQ piperonyl butoxide** | **HI product** | **Acceptable** |
| Scenario 01  Application  Professional | 0.56 | 0.014 | 0.574 | **Yes** |
| Scenario 02  Application  Non-professional | 0.14 | 0.0035 | 0.1435 | **Yes** |

Conclusion for professional and non-professional users

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the two active substances) which is below 1 for both professional and non-professional users.

Therefore, combined additive risk calculations for the two active substances show acceptable risks for both professional and non-professional users.

**General public: infant, toddler, child, adult**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Combined risks from both active substances for general public (additive effect)** | | | | |
| **Scenario** | **HQ permethrin** | **HQ piperonyl butoxide** | **HI product** | **Acceptable** |
| Scenario 03  Post-application  Infant | 0.38 | 0.0095 | 0.39 | **Yes** |
| Scenario 03  Post-application  Toddler | 0.3 | 0.0075 | 0.31 | **Yes** |
| Scenario 03  Post-application  Child | 0.128 | 0.0032 | 0.13 | **Yes** |
| Scenario 03  Post-application  Adult | 0.198 | 0.005 | 0.2 | **Yes** |

Conclusion for the general public

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the three active substances) which is below 1 for all the exposed groups.

Therefore, combined additive risk calculations for both active substances show acceptable risks for the general public.

**Aggregated exposure: adult non-professional users**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Combined risks from both active substances for adult non-professional users (additive effect)** | | | | |
| **Scenario** | **HQ permethrin** | **HQ piperonyl butoxide** | **HI product** | **Acceptable** |
| Scenarios 02 & 03  Adult non-professional user Application & post-application | 0.34 | 0.0085 | 0.35 | **Yes** |

Conclusion for the aggregated exposure of adult non-professional users

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the three active substances) which is below 1 for the adult non-professional user .

Therefore, combined additive risk calculations for both active substances show acceptable risks for the adult non-professional user.

### Risk assessment for animal health

As shown previsously, the product NEODUST should be unclassified with respect to toxicity and non-target species are not likely to be exposed in sufficient quantity to produce toxic effects. Thus no risk is envisaged for animal health.

### Risk assessment for the environmental

#### Effects assessment on the environment

***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***

No aquatic, terrestrial or secondary poisoing toxicity studies were conducted with the product NEODUST, as it was considered that the acute and chronic studies on the active ingredients were adequate for the classification and labelling of the product and for the environmetal risk assessment. Therefore, it is concluded that the product should be classified with respect to aquatic toxicity as Aquatic Acute 1 (H400) and Aquatic Chronic ~~Tox~~ 1 (H410).

| **Summary on PNEC used for the risk assessment** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Substance** | **Surface water [PNECaquatic (mg/L)]** | **Sediment [PNECsediment (mg/kg wwt)]** | **STP microorganism [PNECSTP (mg/L)]** | **Soil [PNECsoil (mg/kg wwt)]** | **Birds [PNECoral, birds (mg/kg diet)]** | **Mammals [PNECoral, mammals (mg/kg diet)]** | **Reference** |
| Permethrin | 4.7 x 10-7 | 2.17 x 10-4 | 0.00495 | ~~0.0876~~  0.198 | 16.7 | 120 | AR, 2014 |
| DCVA | 0.015 | 0.055 | Not relevant | 4.6 | Not relevant | Not relevant | AR, 2014 |
| PBA | >0.01 | 0.042 | Not relevant | 1.44 | Not relevant | Not relevant | AR, 2014 |
| Piperonyl Butoxide (PBO) | 0.00148 | 0.0004 | 2.89 | 0.0980 | 10 | 20 | AR, 2017 |
| Metabolite M-1 | 0.0028 | - | Not relevant | 0.0980 | Not relevant | Not relevant | AR, 2017 |
| Metabolite M-2 | 0.0033 | - | Not relevant | 0.0980 | Not relevant | Not relevant | AR, 2017 |
| Metabolite M-8 | Not relevant | Not relevant | Not relevant | 0.0980 | Not relevant | Not relevant | AR, 2017 |
| Metabolite M-12 | 0.0023 | - | Not relevant | 0.0980 | 10 | 20 | AR, 2017 |
| Metabolite EN 1-101/4 | Not relevant | Not relevant | Not relevant | 0.0980 | Not relevant | Not relevant | AR, 2017 |

For risk assessment of permethrin only the active substance is considered to be ecotoxicologically relevant (worst case) since the metabolites are far less toxic to organisms than the parent compound.

In the AR, 2017 for PBO, the PEC/PNEC ratio for metabolites resulted lower than the ones for the active substance, therefore the risk of metabolites is considered covered by the risk assessment of the active substance.

***Further Ecotoxicological studies***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies |
| Justification | Ecotoxicological studies on the formulation are generally not required for biocidal products as long as sufficient information can be extrapolated from the active substance.  The ecotoxicological testing of the active substance permethrin and PBO were adequately covered in the AR (2014) and AR (2017), respectively and there are no other components in the NEODUST formulation which are of ecotoxicological relevance (confidential information, see Section B2.2), therefore no additional studies were performed and reference is made to the CAR, document IIA, section 4.2. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

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

No data is available.

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

For the biocidal product NEODUST used as insecticide and acaricide, the following life cycle stages are identified:

1. Manufacturing of permethrin and PBO
2. Formulation of NEODUST
3. Intended Use of NEODUST
4. Mixing and Loading of NEODUST
5. Application of NEODUST

**1 - Information regarding the environmental exposure during the manufacturing process of the biocidal product/active substance**

According to the “EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0” emissions from active substance production and product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

**2 - Information regarding the environmental exposure during the formulation of the biocidal product**

According to the “EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0” emissions from active substance production and product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

The formulation step is not covered by the ESD for PT 18; nevertheless it was no risk is identified for freshwater, air and agricultural soil compartments, provided that solid and liquid spills and cleaning waters are collected and dispose of as dangerous waste and all operations are conducted under aspiration and the collected emissions are treated before release to air.

**3 - Information regarding expected environmental exposure during application of the formulated product**

NEODUST may be used by users (professionals and non-professionals) both indoors and outdoors and is a ready to use microgranules formulation containing 0.5% w/w Permethrin and 0.05 % w/w PBO which is not diluted prior to use.

In the ESD for PT18 it is generally assumed that insecticides used indoors will not directly reach the environmental compartments, but it is concluded that after the application of the insecticide, the cleaning step will lead the releases to waste water through wet cleaning methods.

For outdoor applications, it is assumed that the fate of the substance depends on the location of the treated structures, i.e. either in countryside or within a city. In urban area, insecticides will be washed with rain to the rainwater/sewer system and reach the sewage treatment plant (STP). Releases can then occur to the surface water from STP discharge, to agricultural soil from sludge application and eventually to groundwater. In rural area, losses will end up directly on unpaved soil and eventually to groundwater.

On this basis, the environmental exposure assessment has been performed for both active substances.

Nevertheless, the potential environmental exposure to metabolites should also be considered. Since no clear recommendations are available for metabolites at the time of writing, the chosen approach was to estimate the concentrations of relevant metabolites as a percentage of the concentrations of the parent compound permethrin and PBO. There are only minor differences between molecular weights of etofenprox and its metabolites. Hence, correction based on the molecular weights was considered negligible.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

***Leaching behaviour (ADS)***

No data is available.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for distribution and dissipation in soil has been conducted on NEODUST. |
| Justification | The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for dissipation and distribution in water and sediment has been conducetd on NEODUST. |
| Justification | The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for dissipation and distribution in air has been conducted in NEODUST |
| Justification | The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required. |

***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)***

No data required.

***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)***

Not relevant

#### Exposure assessment

NEODUST is a biocidal product used as insecticide, containing the active substances: Permethrin 0.538% w/w and Piperonyl butoxide 0.053% w/w (% w/w technical grade active ingredients, TGAI). The product is in microgranules formulation and it is a ready to use product (RTU).

The environmental exposure assessment has been performed for both active substance permethrin and PBO and was conducted for the local scale only, as required for biocidal products. ~~The risk of their metabolites is considered covered by the risk assessment of the active substances. As the metabolites of permethrin are far less toxic to organisms than the parent compound (worst case), exposure assessment was only presented for the active substance. Moreover, in the AR, 2017 for PBO, the PEC/PNEC ratio for metabolites resulted lower than the ones for the active substance.~~

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios/uses | Scenario 1: Indoor (domestic houses & larger buildings), spot application, for professional users agαinst ants (use 5)  Scenario 2: Indoor (domestic houses), spot application, for non-professional users against ants (use 5)  Scenario 3: Indoor (domestic houses and larger buildings), barrier application, for professional users agαinst fleas (use 1), cockroaches (use 3) and ticks (use 4).  Scenario 4: Indoor (domestic houses), barrier application, for non-professional users agαinst fleas (use 1), cockroaches (use 3) and ticks (use 4).  Scenario 5: Outdoor spot application for professional and non-professional users against ants (use 5) |
| ESD(s) used | ESD for PT18 (2008): Series on Emission Scenario Documents Number 18 , Emissions Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses ENV/JM/MONO(2008)14).  ESD for PT18 (2006): OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, 25-Jan-2006, ENV/JM/MONO(2006) |
| Approach | All scenarios by Average consumption |
| Distribution in the environment | Calculated based on Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C). Version 2.0. October 2017.  Technical Agreements for Biocides (TAB) Version 2.0, August 2018) & (TAB ENV 2.1, December 2019)  Fate and distribution in the STP was estimated using Simple Treat 4 (EUSES 2.2.0). |
| Groundwater simulation | YES, FOCUS PEARL was used for refinement of gw |
| Confidential Annexes | NO |
| Life cycle steps assessed | For all scenarios:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | None |

**Assessed scenarios: Intended uses and application rates for NEODUST**

Exposure assessment of the product has been performed for the claimed Uses by the applicant under the described 5 Scenarios, as presented in the table below. The scenarios were grouped based on the application method, field of and target organism.

|  |
| --- |
| **Exposure scenarios** |
| **Scenario 1** –**Indoor** (**domestic houses & larger buildings**), **spot**  application, for **professional** users agαinst **ants** (use 5), application dose of 10g/m2. |
| **Scenario 2** –**Indoor** (**domestic houses**), **spot** application, for **non-professional** users against **ants** (use 5), application dose of 10g/m2. |
| **Scenario 3** –**Indoor** (**domestic houses and larger buildings**), **barrier application**, for **professional** users agαinst **fleas** (use 1) and **ticks** (use 4) with application dose of 12g/m2 and **cockroaches** (use 3) wtih application dose of 10g/m2 |
| **Scenario 4** –**Indoor** (**domestic houses**), **barrier application**, for **non-professional** users agαinst fleas (use 1) and ticks (use 4) with application dose of 12g/m2 and **cockroaches** (use 3) with application dose of 10g/m2. |
| **Scenario 5** – Scenario 5: **Outdoor** **spot** application for **professional** and **non-professional** users against ants (use 5) |

**Note**: For the indoor use in animal housings, the APPLICANT did not provide on time and with sufficient data for the evaluation of the RA against ticks (intended use 4), thus the field of use in stables, is excluded by the eCA from the current assessment. The same as for Intened Use 2 for chicken mites in henhouses.

***Emission estimation***

**General aspects**

NEODUST is sold under ready to use (RTU) form. **Thus, no emissions were calculated for the preparation (mixing/loading) step.** The product is intended to be used by professional and non-professional users, applied by spreading on the targeted surface. The calculations are based on the ESD for Insecticides, acaricides and products to control other arthropods for household and professional uses (PT18), applying the ‘dusting’ scenario.

The product is essentially a ‘non-dusty’ product, assigned to be in micro-granule formulation. For granulated products zero exposure can be assumed (ENV WG-I-2018), i.e., considering as having zero emissions to the STP. **~~Only direct exposure to soil and groundwater is thus assessed for this product.~~**

For all Scenarios applied indoors intended uses consider applications in only **NON-wet cleaned** domestic premises, various larger buildings, means of transport (excluding sea means of transport) and animal houses (henhouses). In the case of animal housings, the applicant did not provide on time sufficient data (and not in alignment with the product label claim) for the risk assessment, thus it is considered as non-evaluated and thus not authorised. For scenario application against ants the product is also intended for outdoor use.

The environmental emission estimation of NEODUST is based on targeted, surface treatment scenarios. The total surface for targeted, product application, depends on the way (application method), treated area (considering field of use) and target organism, considering 2.0 m2 (for houses) and 9.3m2 (for larger buildings) for spot applications, or >2m2 in larger scale crack and crevice treatments, i.e., barrier treatments, 22m2 (for houses), 93m2 (for larger buildings)) (TAB, ENV 142 & 144 ENV v.2.1, December 2019).

The product application method indoors of spreading against ants considers crack and crevice/ spot treatment, whereas the adapted scenario from barrier treatment covers treatment against fleas, cockroaches and ticks.

In the case of outdoor application of spreading against ants, the treatment approach considers spot application relevant for powder and granules (ESD 4.4.5).

The relevant scenarios adapted for each use were after the ‘Generic Treatment Areas assigned to each specific pest’ (WGII2018\_ENV\_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019).

In the case of barrier treatment, indoors, an area of 22 m2 reflects the application area, with 5.9 m² to reflect the relevant area for indoor wet cleaning in a domestic home. Accordingly, the default area for larger buildings is 93m2 for the application area, whereas in relation to wet cleaning 27 m². The cleaning efficiency is taken as 0.5 (i.e., 50% accessibility to cleaning, for dust/powders - surface).

Regarding the category of users, larger building applications are not considered for non-professionals, where for professional users, emission estimation concerns domestic houses and buildings (for indoor applications).

Indoor receiving materials are considered as “intermediate compartments”. Most surfaces (either targeted or not) will be cleaned and this may lead to releases either to waste (e.g. through dry cleaning methods vacuum or broom or use of damp paper) or to waste water (e.g. through wet cleaning methods, including those emitted by the applicator when washing coveralls (PPE). ~~The sewage treatment plant (STP) is considered as the main “receiving compartment” where insecticides could potentially be released through wet cleaning events, emitted indirectly to waste water~~ *~~via~~* ~~application in houses and large buildings per day. The final receiving environmental compartments will be the surface water, the sediment, the soil (from sludge application) and groundwater, and the outdoor air.~~ It is considered that emissions to indoor air are completely released to the outdoor air compartment during e.g. venting of the room. However according to the OECD ESD for PT18, releases to air are not taken into account, because of instant dilution and turbulence in air. Exposure of the air compartment is limited in time and restricted to local scale.

~~The relevant parameter that quantifies the amount of a product reaching the STP is E~~~~local water~~~~. In order to take into account the simultaneity of the treatment for indoor uses the calculated local emission rates were multiplied by:~~

* ~~the number of houses and larger buildings, connected to STP (4000 for private houses & 300 for larger buildings for indoor uses, whereas 2500 houses for the outdoor use, Urban (Technical Agreement for Biocides (TAB), August 2018 and ESD).~~

As explained in the OECD ESD PT 18, during the cleaning step, two cases are considered:

* cleaning events resulting only in emissions to waste: 100% of the surfaces are cleaned by vacuum/broom (Fw = 1, Fww = 0) and the clothes of the operator are disposable (Fapplicator, w= 1, Fapplicator, ww = 0),
* cleaning events resulting only in emissions to waste water: 100% of the surfaces are washable (Fww = 1, Fw = 0) and the clothes of the operator are washed (Fapplicator, ww = 1, Fapplicator, w = 0).

~~A refinement to the second case, will involve the use of wipes as a cleaning device of the treated surfaces (to be disposed off) for use in small defined areas, as in targeted crack and crevice applications. It is stated as a use restriction that “~~**~~Wet cleaning of treated surfaces~~** ~~should be avoided”.~~

For NEODUST formulation, the cleaning approach is considered as ‘non-wet’, then the total local emissions are directed to waste, leaving non-affected the aquatic environment from product risk of exposure.

In this product case cleaning events would result only in emissions to waste., i.e for NEODUST, no emissions to the STP due to cleaning will be considered. It is stated as a use restriction that “Wet cleaning of treated surfaces should be avoided”.

Emissions from indoor uses to solid waste are not evaluated as they considered to be negligible and it is expected that they will be managed according to solid waste regulations. **Therefore exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.**

For emission calculations of the RTU product, NEODUST, the following formulas (ESD for PT18 products, July 2008) is used to calculate daily local emission, which in this case is not directed to the unique point source, the STP. The input parameters and the following formulas for calculating the local emission of permethrin and PBO are only provided for completeness. ~~, but to a waste collection point and from there to soil and further to groundwater. Therefore for the risk assessment of NEODUST, PECsoil and PECgroundwater were estimated.~~

Application step

(1) *Eapplication,air = Nappl,building × Fappl.,air × Qprod × FAI × AREAtreated*

(2) *Eapplication,applicator= Nappl,building × Fappl.,applicator × Qprod × FAI × AREAtreated*

(3) *Eapplication,floor = Nappl,building × Fappl.,floor × Qprod × FAI × AREAtreated floor*

(4) *Eapplication,treated= Nappl,building × Fappl.,treated× Qprod × FAI × AREAtreated*

~~Releases to wastewater and STP~~

~~(5)~~ *~~E~~~~applicator,ww~~ ~~= (E~~~~prep,applicator~~ ~~+ E~~~~appl.,applicator~~~~) × F~~~~applicator,ww~~*

~~(6)~~ *~~E~~~~treated,w~~ ~~= (E~~~~prep,floor~~ ~~+ E~~~~appl.,floor~~ ~~+ E~~~~appl.,treated~~~~) × F~~~~w~~ ~~× F~~~~CE~~*

~~(7)~~ *~~E~~~~waste~~ ~~= E~~~~applicator,ww~~ ~~+ E~~~~treated,w~~*

~~(8)~~ *~~Elocal~~~~waste,total~~ ~~= ((E~~~~waste~~ ~~× N~~~~houses~~~~) + (E~~~~waste~~ ~~× N~~~~larger buildings~~~~)) × F~~~~simultaneity~~*

From the above equations the eq. (2) ~~and (5)~~ result in a zero value as for spreading/dusting application scenario, the fraction emitted to the applicator during application is zero.

**Indoor Scenarios 1 & 2**

The input parameters for calculating the local emission of permethrin & piperonyl butoxide arising from indoor use of NEODUST, **Scenarios 1 & 2** are reported in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| Input parameters for calculating the local emission of permethrin &, piperonyl butoxide**[[2]](#footnote-2)** | | | |
| Input | Value | Unit | Remarks |
| ***Scenario 1 & 2:*** Indoor (domestic houses and larger buildings), spot application, for professional and non-professional users agαinst **ants** (use 5), application dose of 10g/m2. | | | |
| General | | | |
| Fraction of **permethrin** in the product | 0.538 | % | Technical grade active ingredient (TGAI). |
| Fraction of **piperonyl butoxide** in the product | 0.053 | % | Technical grade active ingredient (TGAI). |
| Application method | Targeted spot application  ‘Generic Treatment Areas assigned to each specific pest’ (WGII2018\_ENV\_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019) for ants | | |
| Quantity of product used in houses | 2E-02 | kg | Total amount per application in domestic houses |
| Quantity of product used in buildings | 9.3E-02 | kg | Total amount per application in buildings |
| Application | | | |
| Number of applications per day, house | 1 | - | As reported in ESD |
| Application rate of biocidal product | E-02 | kg/m2 | Claimed by the applicant |
| Area of treated surface, house | 2 | m2 | Considering spot treatment for domestic houses |
| Area of treated surface, buildings | 9.3 | m2 | Considering spot treatment for larger buildings |
| Fraction emitted to air during application | 0.02 | - | As reported in ESD, p 51 |
| Fraction emitted to the applicator during application | 0 | - | According to ESD for PT18, for dusting type of application |
| Fraction emitted to the floor during application | 0.18 | - |
| Fraction emitted to treated surfaces during application | 0.8~~5~~ | - |
| Cleaning | | | |
| Cleaning efficiency | 0.5 |  | For dusting applications, the max % area exposed to cleaning is 50 % |
| Number of houses per STP | 4000 | - | Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017). |
| Number of larger buildings per STP | 300 | - | Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017). |
| Frequency of product use | 1.39 | % | Claimed by the applicant, 1 application per month\* |

**Calculations of Total local Emissions of the a.i. for the assessed scenarios 1 & 2:**

| **Resulting total local emission of *Permethrin* to waste** | |
| --- | --- |
| Professional use in houses and large buildings, ants, spot application, 10g/m2 | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~4.16E-03~~ |
| Non- Professional use in houses, spot application, 10g/m2 | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~3.08E-03~~ |

| **Resulting total local emission of *Piperonyl butoxide* to waste** | |
| --- | --- |
| Professional use in houses and large buildings, ants, spot application, 10g/m2 | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~4.09E-04~~ |
| Non-Professional use in houses, spot application, 10g/m2 | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~3.04E-04~~ |

**Indoor Scenarios 3 & 4**

The input parameters for calculating the local emission of permethrin & piperonyl butoxide arising from indoor use of NEODUST, **Scenarios 3 & 4** are reported in the table below.

Note:The use for cockroaches was assessed, grouped under the same scenario as for fleas and ticks, based on the similar application method (barrier treatment) regardless its application dose of 10g/m2 and frequency of use of 1 time/month, as it is covered by the most conservative, (worst case) **12 g/m2 application dose** for ticks and fleas and **1 time/week frequency of use** (for fleas) and it resulted from the RA having a safe use. (The applicant amended the frequency of use for cockroaches from 1 time per week (original claim) to 1 application per month- in late applicant comments submission- but the exposure did not affected by this late in time amendment, as cockroaches were already covered by the worst case scenario for fleas and ticks).

Emissions from indoor uses to solid waste are not evaluated as they considered to be negligible and it is expected that they will be managed according to solid waste regulations. Therefore exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

|  |  |  |  |
| --- | --- | --- | --- |
| Input parameters for calculating the local emission of permethrin &, piperonyl butoxide[[3]](#footnote-3) | | | |
| Input | Value | Unit | Remarks |
| ***Scenario 3 & 4:*** Indoor (domestic houses and larger buildings), barrier application, for professional and non-professional users agαinst **fleas** (use 1), **ticks** (use 4) and **cockroaches** (use 3). | | | |
| General | | | |
| Fraction of **permethrin** in the product | 0.538 | % | Technical grade active ingredient (TGAI). |
| Fraction of **piperonyl butoxide** in the product | 0.053 | % | Technical grade active ingredient (TGAI). |
| Application method | Targeted barrier application  ‘Generic Treatment Areas assigned to each specific pest’ (WGII2018\_ENV\_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019) for fleas, ticks and cockroaches. | | |
| Application | | | |
| Number of applications per day, house | 1 | - | As reported in ESD |
| Application rate of biocidal product | 1.2E-02 | kg/m2 | Claimed by the applicant |
| Area treated, house | 22 | m2 | Considering barrier treatment for domestic houses |
| Area treated, buildings | 93 | m2 | Considering barrier treatment for larger buildings |
| Area of wet cleaned zone, house | 5.9 | m2 | Considering barrier treatment for domestic houses |
| Area of wet cleaned zone, buildings | 27 | m2 | Considering barrier treatment for larger buildings |
| Fraction emitted to air during application | 0.02 | - | As reported in ESD, p 51 |
| Fraction emitted to the applicator during application | 0 | - | According to ESD for PT18, for dusting type of application |
| Fraction emitted to the floor during application | 0.18 | - |
| Fraction emitted to treated surfaces during application | 0.8~~5~~ | - |
| Cleaning | | | |
| Washable or disposable applicators | NR | - | Default value. |
| Cleaning efficiency | 0.5 |  | For dusting applications, the max % area exposed to cleaning is 50 % |
| Number of houses per STP | 4000 | - | Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017). |
| Number of larger buildings per STP | 300 | - | Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017). |
| Frequency of product use | 2.75 | % | Claimed by the applicant, 1 application per week for fleas was assessed for the grouped scenario as worst case\* |

|  |  |  |  |
| --- | --- | --- | --- |
| Fraction emitted to solid waste ~~water~~ from cleaning treated surfaces | 1 | - | Dry cleaning method for treated surface |
| Fraction emitted to waste water from cleaning treated surfaces | 0 | - | Dry cleaning method for treated surface |
| Local emission to wastewater from wet cleaning the floor | 0 |  | Set by the applicant (dry cleaning of the floor after application) |

**Calculations of Total local Emissions of the a.i. for the assessed scenarios 3 & 4: ‘**Indoor (domestic houses and larger buildings), barrier application, for professional and non-professional users agαinst **fleas** (use 1), **ticks** (use 4) ‘and **cockroaches** (use 3)

| **Resulting total local emission of *Permethrin* to waste** | | | |
| --- | --- | --- | --- |
| Professional use in houses and large buildings, barrier application, 12g/m2 | | | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~9.24E-02~~ | Remarks | |
| Non- Professional use in houses, barrier application, 12g/m2 | | | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~7.01E-02~~ | |  |

| **Resulting total local emission of *Piperonyl butoxide* to waste** | | |
| --- | --- | --- |
| Professional use in houses and large buildings, barrier application, 12g/m2 | | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~9.10E-03~~ | Remarks |
| Non-Professional use in houses, barrier application, 12g/m2 | | |
| **Local emission (Elocalww) [kg/d]** | Negligible and not further assessed ~~6.90E-03~~ |  |

**Note**: For the indoor use in animal housings, the APPLICANT did not provide on time and with sufficient data for the evaluation the RA against ticks (use 4), thus the field of use in stables, is considered by the eCA to be excluded from the current assessment. The same as for Use 2 for chicken mites in henhouses.

**Scenario 5, outdoor use**

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario:Outdoor application for professional user (permethrin & PBO), spot treatment, 10g/m2* | | | |
| Quantity of commercial product applied | 30 | g | Assuming 1m2 accounting for a nest area, i.e., 10g/nest |
| Concentration of Permethrin in the product | 0.538 | % w/w |  |
| Concentration of PBO in the product | 0.053 | % w/w |  |
| Type of spot application | Powder |  | Non-dusty |
| Fraction emitted to soil during application | 0.9 | - | D |
| Number of application site | 3 |  | Set by the applicant |
| Number of application during a campaign | 1 | - | S |
| **Output local emission in soil** | | | |
| **Espot,soil (g)** | 6.836E-01 | | |
| **Espot,soil (g)** | 6.734E-02 | | |

***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 |
| Scenario 1 & 2 | No | No | No | No | No | Yes | **No**  **~~Yes~~** | **No**  **~~Yes~~** | No |
| Scenario 3 & 4 | No | No | No | No | No | Yes | **No**  **~~Yes~~** | **No**  **~~Yes~~** | No |
| Scenario 5 | No | No | No | No | No | Yes | **Yes** | **Yes** | No |

* Only negligible emissions to air

| **Input parameters (only set values) for calculating the fate and distribution in the environment for permethrin** | | | |
| --- | --- | --- | --- |
| Input | Value | Unit | Remarks |
| Molecular weight | 391.29 |  |  |
| Melting point | 35 | °C |  |
| Boiling point | 305 | °C |  |
| Vapour pressure (at 20°C) | 2.155E-6 | Pa |  |
| Water solubility (at 20°C) | 0.00495 | mg/l |  |
| Log Octanol/water partition coefficient | 4.67 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 26930 | l/kg | arithmetic mean, n=10 |
| Henry’s Law Constant (at 20°C)*[if measured data available]* | 4.6E-3 | Pa/m3/mol |  |
| Biodegradability | *Not Ready biodegradable* |  |  |
| DT50 for degradation in soil | 106 | d (at 12ºC) | geometric mean, n=5 |
| DT50 for degradation in air | 0.701 | d | geometric mean, n=5 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment for PBO** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 338.43 |  |  |
| Melting point | <-10 | °C |  |
| Boiling point | 203 | °C |  |
| Vapour pressure (at 25°C) | 2.53E-06 | Pa |  |
| Water solubility (at 20°C and pH 7.01) | 28.9 | mg/l |  |
| Log Octanol/water partition coefficient | 4.8 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 3745.3 | l/kg | Note: ENV\_7.2 WG2019, e-consultation\_new end points: 2506.5 l/kg  However the worst case value from the CAR was used. |
| Henry’s Law Constant (at 20°C)*[if measured data available]* | 1.648E-04 | Pa/m3/mol |  |
| Biodegradability | *Not readily biodegradable* |  |  |
| DT50 for degradation in soil | 58.3 | d (at 12ºC) | geometric mean, n=4 |
| DT50 for degradation in air | 3.597 | hrs |  |

***Calculated PEC values***

***~~(1) For the Indoor uses~~***

| **~~Summary table on calculated PEC values~~** | | | |
| --- | --- | --- | --- |
|  | **~~PEC soil~~** | **~~PECsoil10(180)~~** | **~~PEC groundwater~~** |
| ~~[mg/kg~~~~wwt~~~~]~~ | ~~[mg/kg~~~~wwt~~~~]~~ | ~~[μg/l]~~ |
| **~~Scenario 3 for Permethrin, professional use for the Indoor Uses 1, 2, 4~~** | | | |
| **~~Houses & buildings~~** | ~~1.359E-04~~ | ~~3.889E-05~~ | ~~8.181E-08~~ |
| **~~Scenario 4 for Permethrin, non-professional use for the Indoor Uses 1, 2, 4~~** | | | |
| **~~Houses only~~** | ~~1.030E-04~~ | ~~6.637E-05~~ | ~~1.396E-07~~ |
| **~~Scenario 3 for PBO, professional use for the Indoor Uses 1, 2, 4~~** | | | |
| **~~Houses & buildings~~** | ~~1.338E-05~~ | ~~5.592E-06~~ | ~~8.446E-08~~ |
| **~~Scenario 4 for PBO, non-professional use for the Indoor Uses 1, 2, 4~~** | | | |
| **~~Houses only~~** | ~~1.015E-05~~ | ~~4.240E-06~~ | ~~6.404E-08~~ |
| **~~Scenario 1 for Permethrin, professional use for the Indoor Uses 3, 5~~** | | | |
| **~~Houses & buildings~~** | ~~6.681E-06~~ | ~~1.749E-06~~ | ~~3.680E-09~~ |
| **~~Scenario 2 for Permethrin, non-professional use for the Indoor Uses 3, 5~~** | | | |
| **~~Houses only~~** | ~~3.368E-03~~ | ~~1.984E-03~~ | ~~4.175E-06~~ |
| **~~Scenario 1 for PBO, professional use for the Indoor Uses 3, 5~~** | | | |
| **~~Houses & buildings~~** | ~~4.143E-04~~ | ~~1.709E-04~~ | ~~2.581E-06~~ |
| **~~Scenario 2 for PBO, non-professional use for the Indoor Uses 3, 5~~** | | | |
| **~~Houses only~~** | ~~3.080E-04~~ | ~~1.270E-04~~ | ~~1.919E-06~~ |

***(2) For the Outdoor Use***

The concentration in the soil around the spot application after direct release was estimated after Equation 60 of ESD and the result is given in the table below.

| **USE # 5** | | **PEC soil** | | **PEC groundwater** |
| --- | --- | --- | --- | --- |
| [mg/kgwwt] | | [μg/l] |
| **Permethrin** | | 6.836E-01 | | 1.438E-03 |
| **PBO** | | 6.734E-02 | | 1.017E-03 |
|  | |  |

**Metabolites**

No metabolite exposure was performed considering that exposure of all relevant environmental compartments is negligible and indoor uses of NEODUST are not further assessed.

***Primary and secondary poisoning***

Primary poisoning

According to the ESD for PT 18 primary poisoning is only a matter of concern if insecticides are applied together with food attractants. As this is not the intended use of the product, the assessment in not required.

Secondary poisoning

The log octanol/water partition coefficient of permethrin and PBO (4.67 and 4.8, respectively) are above the trigged value of 3 suggesting that the two substances may have significant potential for bioconcentration in both aquatic and terrestrial biota.

**Permethrin:**

An experimentally BCF of 500 ‐ 570 L/kg in fish (AR, 2014) and 15108 L/kg in earthworm are available for permethrin

**PBO:**

The aquatic bioaccumulation potential of Piperonyl Butoxide was experimentally investigated using the Bluegill sunfish *Lepomis macrochirus* ( 1992; A7.4.3.3). The kinetic (mean) BCF values in edible, non-edible and whole fish were calculated to be 99, 450 and 290 L/kg. The bioaccumulation potential of Piperonyl Butoxide in terrestrial organisms was predicted by using the relationship of Jager (1998) since no experimentally derived earthworm bioconcentration data were available. The earthworm bioconcentration factor (BCFearthworm) was estimated to be 757 mg/kg. As regards metabolite M-12, the bioaccumulation potential in both aquatic (fish) and terrestrial (earthworms) organisms was predicted by using the equations developed by Veith et al. (1979) and Jager (1998), respectively. The fish and earthworm BCF values were estimated to be 89.5 L/kg and 15.8 mg/kg, respectively.

BCF used in the assessment are summarized in the table below.

|  |  |  |
| --- | --- | --- |
| **Summary table of Bioconcentration Factor (BCF)** | | |
|  | **BCFfish** | **BCFearthworm** |
| [L/kgwwt] | [L/kgwwt] |
| Permethrin | 570 | 15108 |
| PBO | 290 (whole fish) | 757 |

In the EUSES calculations for secondary poisoning the PECregional is added to the PEClocal assuming that 50% of the food is sourced from the local environment and 50% from the regional environment. According to the TGD, the foraging area of fish-eating predators may be very large and therefore using the PEClocal may lead to an overestimation of the risk, especially as biodegradation in surface water is not taken into account.

PECregional may have the opposite effect. It has therefore been decided that a scenario where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is the most appropriate for the assessment. As the PECregional is not calculated for the biocide assessment, the PEClocal divided by two was used for the calculation.

For the assessment of secondary poisoning in the aquatic food chain (water → fish → predator) the concentration of contaminant in food (fish) of fish-eating predators (PECoralpredator) is calculated from the PEC for surface water, the measured BCF for fish and the biomagnification factor (BMF) according to the following formula:

*PECoral, fish-eating predator=PECwater x BCFfish x BMF*

For the assessment of secondary poisoning in the terrestrial food chain (soil 🡪 worm 🡪 predator) the exposure of the predators may be affected by the amount of substance that is in the soil, since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil. The PECoral,predator is calculated as:

*PECoral, earthworm-eating predator=*

*Cearthworm=(BCFearthworm x Cporewater + Csoil x Fgut x CONVsoil) / (1 + Fgut x CONVsoil)*

Where Fgut=0.1 kgdwt/kgwwt and CONVsoil= 1.13 kgwwt/kgdwt.

According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition values (ETE) via food chain** | | |
| **Scenario** | ***PECoral, fish-eating predator*** | ***PECoral, earthworm-eating predator*** |
| **Permethrin** | | |
| ~~Scenario 1,3,4a-professional-barrier~~ | ~~0~~ | ~~1.24E-03~~ |
| ~~Scenario 1,3,4a- non-professional-barrier~~ | ~~0~~ | ~~2.12E-03~~ |
| ~~Scenario 5a- professional- spot~~ | ~~0~~ | ~~5.58E-05~~ |
| ~~Scenario 5a- non professional- spot~~ | ~~0~~ | ~~6.33E-02~~ |
| Scenario 5a-outdoor | ~~0~~ | 2.18E+01 |
| **PBO** | | |
| ~~Scenario 1,3,4b-professional-barrier~~ | ~~0~~ | ~~6.45E-05~~ |
| ~~Scenario 1,3,4b- non-professional-barrier~~ | ~~0~~ | ~~4.89E-05~~ |
| ~~Scenario 5b- professional- spot~~ | ~~0~~ | ~~1.97E-03~~ |
| ~~Scenario 5b- non professional- spot~~ | ~~0~~ | ~~1.47E-03~~ |
| Scenario 5b-outdoor | ~~0~~ | 7.77E-01 |

#### Risk characterisation

Risk characterisation for environment is conducted by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC) according to the guidance in Technical Guidance Document on Risk Assessment (TGD, 2003, Part II). If the predicted environmental concentration is greater than the predicted no-effect concentration, i.e. the PEC/PNEC ratio is greater than one, the substance is “of concern” and further action has to be taken.

***Atmosphere***

Conclusion:

The low vapour pressure (Pure) and Henry’s Law constant of the active substance permethrin (K = 4.6E-03 Pa m3 mol‐1) and PBO (K = 1.68E-04) indicate that there will be negligible loss of permethrin and PBO to the atmosphere.

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

~~The risk characterization for microorganisms in STPs compartment is carried out by comparing the PEC~~~~STP~~ ~~with the PNEC~~~~microorganisms~~~~. The PEC/PNEC ratio has been calculated and the results are shown in the table below.~~

|  |  |
| --- | --- |
| According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed. **~~Summary table on calculated PEC/PNEC values~~** | |
|  | **~~PEC/PNEC~~~~STP~~** |
| **~~Permethrin~~** | |
| ~~Scenario 1,3,4a-professional-barrier~~ | ~~0~~ |
| ~~Scenario 1,3,4a- non-professional-barrier~~ | ~~0~~ |
| ~~Scenario 5a- professional- spot~~ | ~~0~~ |
| ~~Scenario 5a- non professional- spot~~ | ~~0~~ |
| ~~Scenario 5a-outdoor~~ | ~~0~~ |
| **~~PBO~~** | |
| ~~Scenario 1,3,4b-professional-barrier~~ | ~~0~~ |
| ~~Scenario 1,3,4b- non-professional-barrier~~ | ~~0~~ |
| ~~Scenario 5b- professional- spot~~ | ~~0~~ |
| ~~Scenario 5b- non professional- spot~~ | ~~0~~ |
| ~~Scenario 5b-outdoor~~ | ~~0~~ |

Conclusion: ~~According to the obtained PEC/PNEC ratios,~~ ~~t~~ The use of NEODUST is safe for the microorganisms involved in biodegradation processes in the STP. ~~since the ratio between the predicted environmental concentration and the predicted no-effect concentration is zero for all scenarios.~~

***Aquatic compartment***

~~The risk characterization for aquatic compartment is carried out by comparing the PEC~~~~sw~~ ~~with the PNEC~~~~sw~~~~.~~

~~The risk characterization for sediment compartment is carried out by comparing the PEC~~~~sed~~ ~~with the PNEC~~~~sed~~~~.~~

~~The PEC/PNEC ratio has been calculated and the results are shown in the table below~~

According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~Summary table on calculated PEC/PNEC values~~** | | | | |
|  | **~~PEC/PNEC~~~~water~~** | **~~PEC/PNEC~~~~sed~~** | **~~PEC/PNEC~~~~seawater~~** | **~~PEC/PNEC~~~~seased~~** |
| **~~Permethrin~~** | | | | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-outdoor~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| **~~PBO~~** | | | | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |
| ~~Scenario 5-outdoor~~ | ~~0~~ | ~~0~~ | ~~Not relevant~~ | ~~Not relevant~~ |

Conclusion for surface water:

~~According to the obtained PEC/PNEC ratio, the combined~~ The use of NEODUST is safe for the aquatic environment, ~~since the PEC~~~~sw~~~~/PNEC~~~~sw~~ ~~ratio is zero~~.

Conclusion for sediment:

~~According to the obtained PEC/PNEC ratio,~~ The use of NEODUST is safe for the sediment drewlling organisms, ~~since the PEC~~~~sw~~~~/PNEC~~~~sw~~ ~~ratio is zero~~.

***Terrestrial compartment***

According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

The risk characterization for terrestrial compartment was carried out by comparing the PECsoil with the PNECsoil for the outdoor use.

The PEC/PNEC ratio has been calculated and the results are shown in the table below.

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| **Permethrin** | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~1.55E-03~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~1.18E-03~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~7.626E-05~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~3.845E-02~~ |
| Scenario 5-outdoor | **~~7.80E+00~~ 3.45E+00** |
| **PBO** | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~1.37E-04~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~1.04E-04~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~4.228E-03~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~3.143E-03~~ |
| Scenario 5-outdoor | 6.87E-01 |

Conclusion: According to the obtained PEC/PNEC ratio, the use of NEODUST is safe for the soil compartment in all indoor scenarios except for scenario 5, outdoor use, in which the PECsoil/PNECsoil ratio is higher than 1. Thus, the outdoor use (Outdoor spot application for professional and non-professional users against ants (use 5) is **NOT AUTHORISED**.

***Groundwater***

Conclusion: ~~According to the obtained PEC~~~~gw~~~~, the use of NEODUST is safe for the groundwater compartment, since the PEC~~~~gw~~ ~~is lower than the trigger value for drinking water of 0.1 µg/L, except for Use 5.~~

Risk to groundwater is considered to be negligible, considering that exposure of all relevant environmental compartments is negligible and indoor uses of NEODUST are not further assessed. Regarding outdoor use of NEODUST is NOT safe for the groundwater compartment, based on the obtained PECgw that is higher than the trigger value for drinking water of 0.1 µg/L.

**Tier 2 for PECgw for the outdoor use 5**

As a second tier a refinement of the ground water assessment has been carried out using FOCUS PEARL.

Since in the outdoor scenario the product is applied directly on soil at a rate of 10 g/m2, the application rate used in the assessment with FOCUS PEARL was converted in 100.000 g/ha corresponding to 0.5kg/ha of permethrin and 0.05 Kg/ha of PBO. The assessmnent was carried out for the grass (alfalfa) crop for all the scenarios.

OVERALL RESULT: PECgw ~~for all scenarios~~ and for both substances resulted lower than 0.0001 µg/L, therefore the sum of PECgw of permethrin and PBO is below the trigger of 0.1 µg/L.

***Primary and secondary poisoning***

Primary poisoning

Not relevant

Secondary poisoning

The exposure due to secondary poisoning via the terrestrial and aquatic food chain has been evaluated according to the TGD Part II (2003).

The risk to the predators is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake (PNECoral, terrestrial food chain). ~~The concentration of permethrin and PBO in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm.~~

The risk to the fish-eating birds and mammals is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake (PNECoral, fish food chain). ~~The concentration of permethrin and PBO in fish has been calculated from the PEC in surface water and the estimated bioconcentration factor for fish.~~

According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

~~Since PECwater was equal to 0 in all scenarios,~~ The risk for secondary poisoning is calculated only for earthworm-eating predators for the outdoor use.

The PEC/PNEC ratio has been calculated and the results are shown in tables below:

| **Summary table on secondary poisoning via the terrestrial food chain** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | ***PECoral, earthworm-eating predator*** | **PNECbirds** | **PNECmammals** | **PEC/PNECbirds** | **PEC/PNECmammals** |
| **Permethrin** | | | | | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~1.24E-03~~ | ~~16.7~~ | ~~120~~ | ~~7.43E-05~~ | ~~1.03E-05~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~2.12E-03~~ | ~~16.7~~ | ~~120~~ | ~~1.27E-04~~ | ~~1.76E-05~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~5.58E-05~~ | ~~16.7~~ | ~~120~~ | ~~3.34E-06~~ | ~~4.65E-07~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~6.33E-02~~ | ~~16.7~~ | ~~120~~ | ~~3.79E-03~~ | ~~5.27E-04~~ |
| Scenario 5-outdoor | 2.18E+01 | 16.7 | 120 | **1.31E+00** | 1.82E-01 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PBO** | | | | | |
| ~~Scenario 1,3,4-professional-barrier~~ | ~~6.45E-05~~ | ~~10~~ | ~~20~~ | ~~6.45E-06~~ | ~~3.23E-06~~ |
| ~~Scenario 1,3,4- non-professional-barrier~~ | ~~4.89E-05~~ | ~~10~~ | ~~20~~ | ~~4.89E-06~~ | ~~2.45E-06~~ |
| ~~Scenario 5-indoor- professional- spot~~ | ~~1.97E-03~~ | ~~10~~ | ~~20~~ | ~~1.97E-04~~ | ~~9.86E-05~~ |
| ~~Scenario 5-indoor- non professional- spot~~ | ~~1.47E-03~~ | ~~10~~ | ~~20~~ | ~~1.47E-04~~ | ~~7.33E-05~~ |
| Scenario 5-outdoor | 7.77E-01 | 10 | 20 | 7.77E-02 | 3.88E-02 |

Conclusion: ~~As can be observed, the PEC/PNEC ratio is lower than 1 for all uses/scenarios combination,~~ ~~indicating~~ ~~acceptable~~ no risk of secondary poisoning trough the terrestrial food-chain via earthworm is indicated for the indoor use, however for scenario 5 (use 5- outdoor) the risk is unacceptable. Thus use 5 is **NOT AUTHORISED.**

***Mixture toxicity***

According to Environmental Fate’s assessment, the exposure of all relevant environmental compartments is considered to be negligible and indoor uses of NEODUST are not further assessed.

No synergism between PBO and Permethrin is expected to occur in realistic exposure situations towards non-target organisms (Moores and Thom, 2018)[[4]](#footnote-4).

The synergistic effect of PBO - both in susceptible as well as in resistant insects - results from the inhibition of enzymes, which are then no longer available to detoxify insecticides such as pyrethrins and pyrethroids. Synergistic effects are generally considered relevant when they are greater than a factor of 5X for environmental effects (ECHA, 2014).

Synergism in non-target arthropods: The mode of action of PBO implies that the corresponding enzyme systems of non-target insects may also be affected. However, at typical application rates, both in field as well as in laboratory studies, no discernable effect was found on bee mortality or behaviour. The addition of PBO has not overly sensitised the bees to the effects of the pyrethrins. The synergism factor would be <5X.

Synergism in aquatic organisms: Synergistic effects have also been studied in aquatic organisms. For instance, a synergism factor of 1.7-fold was determined for invertebrates and up to 3.2X for fish. The synergism factory would be <5X.

In conclusion, synergistic effects towards non-target organisms such as terrestrial arthropods, aquatic organisms as well as mammalian organisms, should not be considered relevant with regard to mixture toxicity assessments under the European regulatory frameworks.

As a first tier PEC/PNEC ratios for permethrin and PBO were summarized for outdoor use only:

PEC/PNECmixture=PEC/PNECpermethrin+PEC/PNECPBO

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Summary table of calculated ∑PEC/PNEC values | | | | |
|  | ∑PEC/PNECsoil | ∑PECgw | ∑PEC/PNECbirds | ∑PEC/PNECmammals |
| ~~Scenario 1,3,4-professional Indoor~~ | ~~1.69E-03~~ | ~~1.66E-07~~ | ~~8.07E-05~~ | ~~1.36E-05~~ |
| ~~Scenario 1,3,4-non-professional Indoor~~ | ~~1.28E-03~~ | ~~2.04E-07~~ | ~~1.32E-04~~ | ~~2.01E-05~~ |
| ~~Scenario 5-professional Indoor~~ | ~~4.30E-03~~ | ~~2.59E-06~~ | ~~2.00E-04~~ | ~~9.90E-05~~ |
| ~~Scenario 5-non-professional Indoor~~ | ~~4.16E-02~~ | ~~6.09E-06~~ | ~~3.94E-03~~ | ~~6.01E-04~~ |
| Scenario 5-Outdoor | **8.49E+00** | 2.46E-03 | **1.38E+00** | 2.20E-01 |

The exposure for all indoor uses of NEODUST is considered negligible. ~~mixture toxicity doesn’t exceed the trigger value of 1 for the indoor application of NEODUST~~. However for the outdoor application of NEODUST the trigger value of 1 **is exceeded.**

~~PEC~~~~gw~~ ~~for all scenarios and for both substances resulted lower than 0.0001 µg/L, therefore the sum of PEC~~~~gw~~ ~~of permethrin and PBO is below the trigger of 0.1 µg/L.~~

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| **Atmosphere**  The low vapour pressure (Pure) and Henry’s Law constant of the active substance permethrin (K = 4.6E-03 Pa m3 mol‐1) and PBO (K = 1.68E-04) indicate that there will be negligible loss of permethrin and PBO to the atmosphere. According to these results, an accumulation of permethrin and PBO in the air is not expected, thus risk characterization is not necessary.  According to the environmental risk assessment, the risk for all relevant environmental compartments **(STP, terrestrial, aquatic, primary and secondary poisoning)** is acceptable when the product is used for indoor uses (please note that the intended uses 2 & 4 in stables/henhouses where not assessed) according to label instruction~~. For the indoor uses, the product cannot be authorised where direct emissions to surface water cannot be prevented.~~  Regarding the outdoor use of the product, Use 5 **cannot be Authorised** as the risk assessments for the soil and secondary poisoning compartments are unacceptable. |

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

Please refer to summary of the product assessment (SPC) and to the relevant sections of the assessment report.

#### Assessment of a combination of biocidal products

Not relevant as the biocidal products are not intended to be authorised for the use with other biocidal products.

#### Comparative assessment

Not relevant

# Annexes

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

| Author(s) | Year | Title Company Report No. Source (where different from company) | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- |
| Rigamonti E. | 2018 | NEODUST: Determination of the Physico-chemical Properties  Report no. CH-016/2018  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Rigamonti E. | 2018 | NEODUST: Determination of the Accelerated Storage Stability And Corrosion Characteristics  Report no. CH-020/2018  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Rigamonti E. | 2020 | NEODUST: Two Years Storage Stability and Corrosion Characteristics  Report no. CH-021/2018  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Mazzei N. | 2018 | Determination of relative Self-Ignition Temperature for Solids on the Sample NEODUST  Report no. 1800436  Innovhub - Stazioni Sperimentali per l'Industria | N | BLEU LINE S.r.l. |
| Rigamonti E. | 2018 | NEODUST: Validation of the Analytical Method for the Determination of Permethrin Active Ingredient Content  Report no. CH-018/2018  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Rigamonti E. | 2018 | NEODUST: Validation of the Analytical Method for the Determination of Piperonyl butoxide Active Ingredient Content  Report no. CH-019/2018  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Drago A. | 2017 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST CTENOCEPHALIDES FELIS (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)  Report no. BLENDU150 91 7 -05  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2017 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST LASIUS NIGER (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)  Report no. BLENDU150 91 7 -03  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2017 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST IXODES RICINUS (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)  Report no. BLENDU150 91 7- 02  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2017 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST DERMANYSSUS GALLINAE (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)  Report no. BLENDU150 91 7 -04  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2017 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST PERIPLANETA AMERICANA (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)  Report no. BLENDU150 91 7 -01  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A., Martini S. | 2018 | EVALUATION OF THE EFFICACY OF  “NEODUST” AGAINST *IXODES RICINUS*  IN INDOOR CONDITIONS (FIELD TEST)  Report no. BLENED030818 – 01  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2018 | EVALUATION OF THE EFFICACY OF “NEODUST” AGAINST *DERMANYSSUS GALLINAE* (FIELD TEST)  Report no. BLENED030818 – 02  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2018 | EVALUATION OF THE EFFICACY OF  “NEODUST” AGAINST *LASIUS NIGER*  IN INDOOR AND OUTDOOR CONDITIONS (FIELD TEST)  Report no. BLENED030818 – 03  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2018 | EVALUATION OF THE EFFICACY OF  “NEODUST” AGAINST *PERIPLANETA AMERICANA* IN INDOOR CONDITIONS (FIELD TEST)  Report no. BLENED030818 – 04  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Drago A. | 2018 | EVALUATION OF THE EFFICACY OF  “NEODUST” AGAINST *CTENOCEPHALIDES FELIS* IN INDOOR CONDITIONS (FIELD TEST)  Report no. BLENED030818 – 05  Entostudio s.n.c. | N | BLEU LINE S.r.l. |
| Rigamonti E. | 2020 | NEODUST: Determination of the Physico-chemical Properties  Report no. CH-0042/2020  ChemServcie Srl - Controlli e Ricerche | N | BLEU LINE S.r.l. |
| Bucciarelli B. | 2017 | Accelerated Storage Stability Test at 54°C ±2°C of NEODUST, A Ready to Use Insectidice Powder Based on PErmethrin and Piperonylbutoxide  Report no. 16783/17, 16784/17 and 16785/17  Bucciarelli Laboratori srl | N | BLEU LINE S.r.l. |

## Model used and exposure calculations

### Human health exposure assessment

****

### Emission Environmental exposure calculation

## New information on the active substance

None

## Residue behaviour

Not required

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

Not required, please refer to the IUCLID file.

## Confidential annex

See separate file.

## Other

No other information required.

1. ECHA (2017) Guidance on the BPR: Volume III Human Health Assessment & Evaluation (Parts B+C) V2.1, ECHA-17-G-04-EN [↑](#footnote-ref-1)
2. The input parameters for indoor scenarios are only provided for completeness [↑](#footnote-ref-2)
3. The input parameters for indoor scenarios are only provided for completeness [↑](#footnote-ref-3)
4. Moores G and Thom E (2018) Piperonyl butoxide: Synergism with natural pyrethrins and synthetic pyrethroids. Version 1.0. Company whitepaper. Endura S.p.A.) [↑](#footnote-ref-4)