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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR A MAJOR CHANGE APPLICATION**

(submitted by the Applicant)



STILL HORSE

Product type PT18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-EH024024-64

Evaluating Competent Authority: Belgium

Date: 07/06/2023

**Changes history table for Still Horse**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP | *BE-CA* | BC-EH024024-64 | 31/03/2021 | Initial assessment |  |
| NA-MAC, | *BE-CA* | *BC-NG074073-44* | 11/07/2023 | *Addition of the NON-PROFESSIONAL user type.*  *Addition of a new metal corrosion study, in order to remove the classification “H290: May be corrosive to metals”. This was required in the previous assessment report from 2021, as a post-approval requirement.*  *As agreed during the 2021 referral, a new field efficacy study is added to confirm the dose of 25ml/horse in the field, against all target species, following the latest guidance on efficacy testing of insecticide applied on animals.*  *Replacement of the ingredient “DOW Corning Emulsion 949” by the substitute “DOWSIL 969 Emulsion”, at the same concentration*  *Addition of a new packaging type : plastic bottle with a dosing chamber, to help dosing the product. Same sizes and material as the already approved plastic bottles.*  *Correction of a mistake in the previous PAR and SPC version. The manufacturer is ARMOSA SA and not ARMOSA TECH SA, which is the authorization holder. Both companies exist at the same address.* | See highlighted |
| NA-MAC | *BE CA* | BC-NG074073-44 |  | The NA-MAC proposed addition of the NON-PROFESSIONAL user type was not accepted.  All the other changes proposed in the NA-MAC application were evaluated and were considered acceptable. The necessary adaptations of the PAR were performed.  However the NA-MAC application submitted contained information that demonstrated that the conditions referred to in article 19 were not satisfied, as described under the article 48(1)(a) of the BPR. In accordance with the article 48(2), BE CA informed the applicant of his intention to cancel the authorization. The applicant was given the opportunity to provide comments on this decision and the conclusion was adapted.  The existing authorization for the professional user can be continued but has to be amended. Following the adapted risk assessment for human health the conditions of use have to be amended. | In track changes |

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# Conclusion

Still Horse is a PT18 biocidal product formulated by ARMOSA TECH SA, with the active substance permethrin concentrated at 0.97 % w/w. The applicant claimed 3 application methods : - Spray application

- Lotion application using external applicator bristles

- Lotion application using a synthetic sponge

Following the NA-APP submitted in refMS BE it was authorised in 2021 as an insecticidal product for the professional user under the following conditions:

* Application rate : 25ml/horse (8.3 ml per m² of horse skin to be treated)
* Frequency : One application each 4 days (96h) during the 3 months of the summer season.
* Application method : only lotion application using a synthetic sponge
* Field of use : Only in order to protect the horses outdoor.

In 2022 a NA-MAC application was submitted in order to expand the use of the product to the non-professional user.

The conclusions of each assessment are summarized below.

For each assessment there are 2 parts : first the conclusion of NA-APP, and second the changes / additions to this conclusion as a result of the NA-MAC evaluation.

With regard to the human health evaluation the NA-MAC application submitted contained information that demonstrated that the conditions referred to in article 19 were not satisfied, as described under the article 48(1)(a) of the BPR. In accordance with the article 48(2), BE CA informed the applicant of his intention to cancel the authorization. The applicant was given the opportunity to provide comments on this decision and the conclusion was adapted taking into account this comments.

So for the HH assessment, there is also a third part in the conclusion taking into account the applicant’s comments.

**APCP**

The product is a white, opaque, homogeneous liquid with lemongrass odor.

Based on the storage stability studies, it can be concluded that the product is stable during 2 years in its commercial package (HDPE). The product must not be stored or applied at temperatures ≤0°C and is a stable oil-in-water emulsion. The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat.

Physical and chemical compatibility with other products are not relevant.

Based on its composition and expert judgement, the product is classified as Met. Corr. 1. To confirm, as a post-authorisation requirement, the applicant must provide the results of a metal corrosion test within 1 year post-authorisation.

No classification related to other physico-chemical risks is necessary.

**After MAC 2022**

A change in the composition was made in the Still Horse product. With the new composition the product still a white, opaque, homogeneous liquid with lemongrass odor. The product must not be stored or applied at temperatures ≤0°C and is a stable oil-in-water emulsion. The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat. Based on the accelerated storage stability studies, a 2 years shelf-life can be granted but the long term storage data will be submitted in a post-authorization to validate this conclusion with the new product formulation.

Physical and chemical compatibility with other products are not relevant.

Corrosion to metals was tested following United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and following Regulation EC No. 1272/2008 (CLP). A small deviation from the method was observed since the minimum volume during the test was not 1,5 L as indicated in the method. However applicant provided graphical proofs (pictures and data) proving that they used enough volume to cover the plates during the test and no corrosion was observed in the plates indicating that Still horse should not be classified as corrosive to metals.

No classification related to other physico-chemical hazards is necessary.

New packaging have been included in the MAC 2022: 1L, 500 mL and 250 mL bottles with a 25 mL dosing chamber or with dosing caps which facilitates the correct dosing (25 mL) for the application. Dosing will be easier and more precise compare to previous packaging.

**Efficacy**

Still horse is a contact insecticide, that aims to prevent nuisance of flies. On the basis of the results of 3 studies submitted and performed with the application rate claimed (25 ml/horse) but considering that no laboratory test was performed on Tabanidae and Simuliidae: The product STILL HORSE is considered effective against *Musca autumnalis* and *Stomoxys calcitrans)* up to 4 days in temperate climatic conditions outdoor at the application rate claimed (25ml/horse).

Only sponge application and only outdoor use will be authorized.

**Efficacy conclusion MAC – 2022:**

The conclusions of the first assessment remain unchanged for the target organisms that are already validated: *Musca autumnalis* and *Stomoxys calcitrans.*

In addition, the following target organisms can also be considered as validated: *Musca domestica* (house fly), *Tabanus bovinus* (horse-fly) and *Hippobosca equina* (forest fly).

**Toxicology and human health:**

During the commenting period, the applicant decided to remove the use for non-professionals. Moreover it was decided to add to following RMM: “*The general public is not allowed to treat horses or ride treated horses*” at the referral.

Acceptable risks for professional users are:

* Regarding bristles application (wearing gloves: EN374 and coated coverall (type 4): EN 14605), the user can:
  + Treat 12 horses and ride 1 horse
  + Or treat and ride 4 horses
* Regarding spray application (wearing gloves: EN374 and coated coverall (type 4): EN 14605), the user can:
  + Treat 12 horses and ride 1 horse.
  + Or treat and ride 4 horses.
* Regarding sponge application (wearing gloves: EN374 and coated coverall (type 4): EN 14605), the user can:
  + Treat 4 horses and rides 1 horse.
  + Or treat and ride 2 horses.

**HH Conclusion after MAC 2022:**

An in Vitro Percutaneous Absorption test has been conducted with the Still horse formulation by the applicant in order to set a more realistic dermal absorption value. Taking into account the results of this study risk assessment for human health was re-evaluated leading to the following adapted conclusions :

###### Acceptable risks for professional users are:

- Regarding spraying application, the user can:

* + Treat horses during 360 minutes/day which is equivalent to 12 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
  + Or only treat and ride 3 horses/day

- Regarding sponge application, the user can:

* + Treat horses during 150 minutes/day which is equivalent to 5 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
  + Or only treat and ride 3 horses/day

- Regarding application with bristles application taking into account that the assessment is limited to reverse scenario for application step it is not possible to make a combined exposure taking into account of secondary exposure of adult users by direct contact with skin of treated horses. Therefore it not possible to assess the combined exposure, the conservative measure to want this type of use not to be allowed.

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

###### Acceptable risks for non-professional users are:

- Regarding spraying application, the user can:

* + Treat horses during 90 minutes/day which is equivalent to 3 horses/day or ride 3 horses/day.
  + Or only treat and ride 1 horse/day

The following risk mitigation measure should be applied:

* + Wear long trousers and shoes during grooming/cleaning and riding.
  + Wear long-sleeved shirt, long trousers and shoes during application.
  + Do not treat horses below 250kg

- The application with bristles has not acceptable risk for non-professional user.

- The sponge application has not acceptable for non-professional user.

For the application step the generic RMM should be mentioned on the label has following:

* + Wear long-sleeved shirt, long trousers and shoes during application

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

###### Acceptable risks for general public (secondary exposure) are:

There is an acceptable risk during ride for children at least 6 years old according to the following RMM:

- The general public (adult, children > 6y) can groom/clean and ride only 1 treated horse/day.

Environmental risks:

The risk characterisation for the environment indicates that the uses of the biocidal product STILL HORSE by lotion – external applicator bristles or sponge applications - do not represent unacceptable risks to the environment if:

* Appropriate risk mitigation measure is considered,

“*To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.*”

* And if the following frequency between two treatments is respected, “One application each 4 days during the 3 months of the summer season.

The use of the biocidal product STILL HORSE by spray application cannot be authorised because there are unacceptable risks for the aquatic compartment.

**ENV conclusion MAC 2022** : no changes

**General conclusion:**

So when combining efficacy, the risk assessment for humans and for the environment we have to come to the conclusion that only synthetic sponge application is approved for the professional user with the following use limitations :

* + Treat horses during 150 minutes/day which is equivalent to 5 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
  + Or only treat and ride 3 horses/day

# Assessment Report

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| STILL HORSE | BELGIUM |
| Same biocidal product:   * DEFEND HORSE * EQUIZEN * PERMEKIN | BELGIUM |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | ARMOSA TECH SA |
| **Address** | Rue des Tuiliers 1, 4480 Engis, Belgium |
| **Authorisation number** | BE2021-0004 | |
| **Date of the authorisation** | 08/02/2021 | |
| **Expiry date of the authorisation** | 08/02/2031 | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | ARMOSA SA |
| **Address of manufacturer** | Rue des Tuiliers 1, 4480 Engis, Belgium |
| **Location of manufacturing sites** | Rue des Tuiliers 1, 4480 Engis, Belgium |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Limaru NV Ziepstraat 5, 3680, Neeroeteren, Belgium (Acting on behalf of Tagros Chemicals India Limited (India)) |
| **Address of manufacturer** | Jhaver Centre, Raja Annamalai  Building, IVth Floor,  72 Marshall Road, Egmore  600008 Chennai  India |
| **Location of manufacturing sites** | Tagros Chemicals India Ltd.  A-4/1&2, Sipcot Industrial Complex  Pachayankuppam  Cuddalore - 607 005, Tamilnadu  India |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | ≥93.0% w/w sum of all isomers |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance Permethrin is not candidate for substitution.

Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the cis isomer) and therefore fulfill the P criteria.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0,97%  (technical)  0,90% (pure) |

The full composition of the product is provided in the Confidential Annex.

#### Information on technical equivalence

The active substance supplier Limaru NV (Acting for Tagros Chemicals India Limited (India)) is an approved supplier of this active substance in accordance with Article 95 List of Regulation No 528/2012.

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

No substance of concern was identified. Please see the confidential annex for further details.

The full composition of the product as well as the results of the ED-assessment of the co-formulants are summarised in the confidential annex to the PAR.

#### Type of formulation

|  |
| --- |
| EW (Emulsion, oil in water) |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1, H400  Aquatic Chronic 1; H410 |
| Hazard statement | H400, H410 |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | **Non-professional**  P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children  P103: Read label before use.  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation  **Professional**  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation |
| Supplemental hazard statements | EUH 208: “Contains Permethrin (CAS : 52645-53-1), Citral (CAS : 5392-40-5) and Cineol (CAS : 470-82-6). May produce an allergic reaction.” |
|  | |
| **Note** |  |

### Authorised use(s)

#### Use description

|  |  |
| --- | --- |
| **Table 1. Use # 1 – Sponge application** | |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | STILL HORSE is a contact insecticide, prevents nuisance of flies and is applied directly on horse’s skin. |
| **Target organism (including development stage)** | Muscidae – Flies - Adults  Musca autumnalis (Autumn fly) – adults  Stomoxys calcitrans (Stable fly)- adults  Musca domestica (house fly) – adults  Tabanus bovinus (horse fly) - adults  Hippobosca equina (forest fly) – adults |
| **Field of use** | To be applied on horses to protect them against flies in an outdoor environment. |
| **Application method(s)** | **Method of application:**   * lotion application using a synthetic sponge |
| **Application rate(s) and frequency** | **Application rates:** 25 mL of product per horse(8.3 ml per m² of horse skin to be treated).  **Frequency:** The product has a duration of action of up to 4 days. The treatment can be repeated after 4 (96h) days during the 3 months of the summer season (23 days/year). |
| **Category(ies) of users** | Professional user |
| **Pack sizes and packaging material** | 250 mL, 500mL and 1L plastic bottle with a 25 mL dosing chamber or dosing caps. |

* + - 1. Use-specific instructions for use

|  |
| --- |
| Check the efficacy of the product on site : if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance  **Method of application:**lotion application using a synthetic sponge  **Detailed description of the method:** The bottle should be shaken before use. The solution should be applied manually using a synthetic sponge. Treat the body parts where the insects tend to gather, ie. around the eyes, on the back, and around their tail  Please see section 2.1.5. General directions for use for further details. |

* + - 1. Use-specific risk mitigation measures

|  |
| --- |
| For professional users:   * Regarding sponge application the user can:   + Treat horses during 150 minutes/day which is equivalent to 5 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.   + Or only treat and ride 3 horses/day   Please see section 2.1.5. General directions for use for further details. |

* + - 1. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please see section 2.1.5. General directions for use for further details. |

* + - 1. Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| Please see section 2.1.5. General directions for use for further details. |

* + - 1. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Please see section 2.1.5. General directions for use for further details. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Always read the label or leaflet before use and respect all the instructions provided  **Dosage for treatment of the whole animal:** 25 ml(8.3 ml per m² of horse skin to be treated).  **Duration of action:** up to 4 days (96h).  **Frequency of the treatment:** Each 4 days (96h) during the summer season. Repeat treatment, depending on weather conditions and the number of flies.  Inform the registration holder if the treatment is ineffective.  The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).  The product is not intended to be used with other biocidal products.  Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).  Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).  Do not use the product in areas where resistance to the active substance contained in this product is suspected or established. |

#### Risk mitigation measures

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| * To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system. * This product is intended to be applied on recreational and/or sport horses only. The use of the product is strictly prohibited on horse destined for consumption/ integrating the food chain. * The frequency of use may not exceed one application each 4 days during the 3 months of the summer season. * The product should be applied to dry skin. It should be avoided to use the product before washing or wet weather to preserve full effectiveness, and enable better protection of the environment. * Do not use in animals with liver problems, anemia and widely spread skin lesions. * The Still Horse application on sensitive parts like the abdomen can cause local edema. * Do not use on pregnant or lactating mare. * Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing vapours. * Do not rinse the sponge after use * Keep out of reach of children. * Keep out of reach of pets, especially cats due to high sensitivity to permethrin toxicity. * Keep children and pets away during treatment. * Do not treat horses below 250kg * Wear long trousers and shoes during grooming/cleaning and riding. * The general public (children > 6y) can groom/clean and ride only 1 treated horse/day. * 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. * Keep cats away from treated surfaces due to the high sensitivity to permethrin toxicity |

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

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| **First-aid measures:**   * After inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. * After skin contact: Wash with plenty of soap and water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. * After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. * After ingestion : Call a poison center or a doctor if you feel unwell. * If medical advice is needed, have product container or label at hand. * Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.   **Hygiene measures**   * Do not eat, drink or smoke when using this product. Always wash hands after handling the product. * Do not store near food, drink and animal feeding stuff. |

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

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| * Regional legislation (waste): Disposal must be done according to official regulations. * Waste treatment methods: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations. * Ecology - waste materials: Avoid release to the environment. |

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

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| Storage conditions: The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat. The product must not be stored or applied at temperatures ≤0°C.  Shelf-life: 24 months |

### Other information

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| Post-authorisation requirement: the applicant must provide the results of a metal corrosion test within 1 year post-authorisation. This was submitted within the NA-MAC change in 2022. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle with dosing caps (DOSY caps) regulated to 25 mL | 250 mL, 500 mL and 1 L | HDPE | Snap-on system | Professional, | Yes |
| Bottle with 25 mL graduated dosing chamber | 250 mL, 500 mL and 1 L | HDPE | Snap-on system | Professional, | Yes |

### Documentation

#### Data submitted in relation to product application

The whole list of data submitted by the applicant is included in the annex.

#### Access to documentation

The applicant has submitted a Letter of Access from Limaru NV, granting access to BE eCA to the data submitted in the Tagros dossier on the active substance permethrin.

## Assessment of the biocidal product

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

|  |  |
| --- | --- |
| **Table 2. Use # 1 – Professionals and non-professionals** | |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | STILL HORSE is a ready-to-use insecticidal product (Product type18). It is intended to be used as insecticide against insect’s species for horses’ hygiene and is applied directly on horse’s skin  The applicant proposed three different application methods:  • Direct spraying on horse’s skin.  • Direct spreading using bristles over the horse’s skin.  • Direct application as a lotion on horse’s skin by a synthetic sponge.. |
| **Target organism (including development stage)** | Scientific name: *Muscidae: Musca autumnalis*, common name: Autumn House fly, development stage: adults.  Scientific name: *Muscidae: Musca domestica*, common name: House fly, development stage: adults.  Scientific name: *Muscidae: Stomoxys calcitrans* common name: stable fly, development stage: adults.  Scientific name: *Tabanidae* common name: horse fly, development stage: adults.  Scientific name: *Simuliidae* common name: black fly, development stage: adults. |
| **Field of use** | To be applied on horses to protect them against flies. |
| **Application method(s)** | **Method of application:** spray application  **Detailed description of the method:** The plastic bottle should be shaken before use. The solution should be sprayed evenly across the horse’s coat. The horse’s head should be intensively treated. The product should be applied to dry skin and grooming has no influence on the activity of the product. It should be avoiding the use of the product before washing or wet weather to preserve full effectiveness, and enable better protection of the environment.  **Method of application:** lotion application using external applicator bristles  **Detailed description of the method:** The applicator should be shaken and the cup of the applicator should be removed before use. The solution should be applied using the external bristles across the horse’s coat. The horse’s head should be intensively treated. The product should be applied to dry skin and grooming has no influence on the activity of the product. It should be avoided to use of the product before washing or wet weather to preserve full effectiveness, and enable better protection of the environment.  A graduated bottle will be supplied to the user. When the product is applied the user should check that the quantity of 25mL is released for each horse. The 200 mL bottle is graduated each 25mL, so as long as the user is applying the product, they can check when the maximum quantity to be applied (25mL) is achieved.  **Method of application:** lotion application using a synthetic sponge.  **Detailed description of the method:** The bottle should be shaken before use. The solution should be applied manually using a synthetic sponge across the horse’s coat. The horse’s head should be intensively treated. The product should be applied to dry skin and grooming has no influence on the activity of the product. It should be avoiding the use of the product before washing or wet weather to preserve full effectiveness, and enable better protection of the environment. |
| **Application rate(s) and frequency** | **Application rates:** 25 mL of product per horse.  **Frequency:** The treatment can be repeated after 4 days during the summer season.  The product can only be used during the 3 months of the summer season. |
| **Category(ies) of users** | Professional user and amateur user |
| **Pack sizes and packaging material** | 200 ml plastic bottle with external bristles, 500mL plastic sprayer, 500mL and 1L plastic bottle |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | Homogeneous liquid | 16-902007-002, Demangel, B., 2016. Belgagri |
| Colour at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | White, opaque | 16-902007-002, Demangel, B., 2016. Belgagri |
| Odor at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | Lemongrass | 16-902007-002, Demangel, B., 2016. Belgagri |
| Acidity / alkalinity | CIPAC MT 75.3  [pH meter WTW Inolab 7310p] | Still Horse (0.97%) | Before storage:  7.54 ± 0.04 (1 min. after immersion)  7.53 ± 0.01 (2 min. after immersion  [undiluted, at 20 ± 2°C]  After long term storage at ambient temperature:  7.55 ± 0.05 (1 min. after immersion)  7.59 ± 0.03 (2 min. after immersion  [undiluted, at 20 ± 2°C] | 16-902007-002, Demangel, B., 2016. Belgagri  16-902007-003, Demangel, B., 2019. Belgagri |
| Relative density / bulk density | EU Test Method A3  OECD 109  EC 440/2008  [using Type 3 (Gay-Lussac) pycnometer] | Still Horse (0.97%) | Relative density: 0.999 ± 0.001 g/cm3  [at 19.6 ± 0.5°C] | 16-902007-001, Demangel, B., 2016. Belgagri |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  [GC-MS using Phenomenex, column: Zebron ZB-1 30m x 0.53mm ID; 1.5 µm film thickness, with FID detector] | Still Horse (0.97%) | For flask/spray samples:  - No change in colour, physical state, or odour observed.  - No signs of degradation or leaking of the packaging.  - Change in container weights: ≤ -0.2 % change  - Change in A.S.: 0.9131 ± 0.0091 % w/v-> 0.9184 ± 0.0423 % w/v  (= 0.0053% w/v change)  [**2 weeks** at 54 ± 2°C. Packaging: opaque HDPE flask and spray]  For brush samples:  - No change in colour, physical state, or odor observed.  - Change in container weights: ≤ -0.3 % change  - Change in A.S.: 0.8493 ± 0.0096 % w/v -> 0.8499 ± 0.0303 % w/v  (= 0.0006% w/v change)  [**2 weeks** at 54 ± 2°C.  Packaging: opaque HDPE flask with brush] | 16-902007-002, Demangel, B., 2016. Belgagri |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph  No. 17 | Still Horse (0.97%) | For flask/spray samples:  - No change in colour, physical state, or odour observed.  - No signs of degradation or leaking of the packaging.  - Change in container weights: ≤ -0.3 % change  - Operation: Satisfactory operation and no blocking throughout. Mean pulverisation volume after application: 6.284 mL -> 6.199 mL  - Change in A.S.: 0.913 % w/v-> 0.886 % w/v  (= -3.0 % change)  [24 months at 20 ± 2°C. Packaging: opaque HDPE flask]  For brush samples:  - No change in colour, physical state, or odor observed.  - Change in container weights: ≤ -0.5 % change  - Operation: Satisfactory operation and no blocking throughout. Mean loss of weight after application: 1.137 g -> 1.293 g  - Change in A.S.: 0.849 % w/v -> 0.790 % w/v  (= -6.9 % change)  [24 months at 20 ± 2°C. Packaging: opaque HDPE flask with brush] | 16-902007-003, Demangel, B., 2019. Belgagri |
| Storage stability test – **low temperature stability test for liquids** | Waived | - | The product must not be stored or applied ≤ 0°C. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waived | - | The packaging, which already is an opaque packaging, should be kept away from direct sunlight and stored in the dark. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived | - | Product should be kept in a cool, dry place and protected from heat. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) |
| Wettability | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Suspensibility, spontaneity and dispersion stability | Waived | - | Not applicable since biocidal product is not a wettable powder, aqueous suspension concentrate, water dispersible granule, water dispersible powder or formulation forming suspension on dilution with water. | - |
| Wet sieve analysis and dry sieve test | Waived | - | Not applicable since biocidal product is not a wettable powder, suspension concentrate, water dispersible granule, aqueous capsule suspension, dispersible concentrate, suspo-emulsion, water soluble granule or powder, dust or granular formation. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | Still Horse (0.97%) | Homogenous white opaque liquid throughout the different test phases, and hence considered stable.  [undiluted, at 30 ± 2 °C] | 17-902007-005, Demangel, B., 2017. Belgagri |
| Disintegration time | Waived | - | Not applicable since biocidal product is not a tablet and is not used in a water soluble bag. | - |
| Particle size distribution, content of dust/fines, attrition, friability | Waived | - | Not applicable since biocidal product is not a granule or tablet. | - |
| Persistent foaming | CIPAC MT 47.2 | Still Horse (0.97%) | Before storage:  70 ± 6 ml (after 10 sec.)  22 ± 2 ml (after 1 min.)  13 ± 1 ml (after 3 min.)  10 ± 0 ml (after 12 min.)  [undiluted, at 20 ± 2 °C]  After accelerated storage:  43 ± 3 ml (after 10 sec.)  4 ± 0 ml (after 1 min.)  0 ± 0 ml (after 3 min.)  [undiluted, at 20 ± 2 °C]  After long term storage at ambient temperature:  69 ± 1 ml (after 10 sec.)  27 ± 3 ml (after 1 min.)  14 ± 2 ml (after 3 min.)  [undiluted, at 20 ± 2 °C] | 16-902007-002, Demangel, B., 2016. Belgagri  16-902007-003, Demangel, B., 2019. Belgagri |
| Flowability/Pourability/Dustability | Waived | - | Not applicable since the biocidal product is not a granular formulation, suspension concentrate, capsule suspension or suspoemulsion. | - |
| Burning rate — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Burning completeness — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Composition of smoke — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Spraying pattern — aerosols | Waived | - | Product is not an aerosol since the spray packaging does not contain a propellant. | - |
| Physical compatibility | Waived | - | Product is not intended to be used with other products. | - |
| Chemical compatibility | Waived | - | Product is not intended to be used with other products. | - |
| Degree of dissolution and dilution stability | Waived | - | The biocidal product is not a water soluble preparation. | - |
| Surface tension | EU Test Method A.5  [using Lauda TD3 Tensiometer] | Still Horse (0.97%) | 23.6 ± 0.2 mN/m  [undiluted, at 20.0 ± 0.1°C] | 16-902007-001, Demangel, B., 2016. Belgagri |
| Viscosity | OECD 114  [using Viscometer Brookfield LV-II+ PRO] | Still Horse (0.97%) | 1.53 ± 0.03 mPa.s  [at 20.0 ± 0.2°C]  1.04 ± 0.06 mPa.s  [at 40.0 ± 0.2°C] | 16-902007-001, Demangel, B., 2016. Belgagri |

* **Major change (MAC) 2022**

For the major change dossier, new data below have been submitted to support the Physical, chemical and technical properties.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | Homogeneous liquid | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Colour at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | White, opaque | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Odour at 20 °C and 101.3 kPa | Organoleptic | Still Horse (0.97%) | Lemongrass | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Acidity / alkalinity | CIPAC MT 75.3  [pH meter WTW Inolab 7310p] | Still Horse (0.97%) | Before storage:  The mean pH value of the pure test item was:  5.74 at 19.7 °C after 1 min.  5.74 at 19.8 °C after 2 min.  After accelerated storage:  The mean pH value of the pure test item was:  5.38 at 19.6 °C after 1 min.  5.35 at 19.6 °C after 2 min. | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Relative density / bulk density | EU Test Method A3  OECD 109  EC 440/2008  [using Type 5 (Hubbard) pycnometer] | Still Horse (0.97%) | Relative density: 0.997± 0.001 at 21.3 ± 0.1 °C | 22A-0054, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Storage stability test – **accelerated storage** | CIPAC Handbook P - MT 46.4 method (2021) | Still Horse (0.97%) | For flask/spray samples:  - No change in physical state or odour observed. Colour changed from white opaque to yellow opaque after accelerated storage.  - No signs of degradation or leaking of the packaging.  - No change of container weight was observed  No significant change (-3.2%) was observed in the content of the active substance after the accelerated storage procedure for 14 days at 54 °C ± 2 °C.  [**2 weeks** at 54 ± 2°C. Packaging: White opaque HDPE can and white opaque  HDPE flasks] | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Storage stability test – **long term storage at ambient temperature** | - | - | Long term storage test is started and data will be submitted in a post-authorization. | - |
| Storage stability test – **low temperature stability test for liquids** | Waived | - | The product must not be stored or applied ≤ 0°C. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waived | - | The packaging, which already is an opaque packaging, should be kept away from direct sunlight and stored in the dark. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived | - | Product should be kept in a cool, dry place and protected from heat. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) |
| Wettability | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Suspensibility, spontaneity and dispersion stability | Waived | - | Not applicable since biocidal product is not a wettable powder, aqueous suspension concentrate, water dispersible granule, water dispersible powder or formulation forming suspension on dilution with water. | - |
| Wet sieve analysis and dry sieve test | Waived | - | Not applicable since biocidal product is not a wettable powder, suspension concentrate, water dispersible granule, aqueous capsule suspension, dispersible concentrate, suspo-emulsion, water soluble granule or powder, dust or granular formation. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | Still Horse (0.97%) | Homogenous white opaque liquid throughout the different test phases, and hence the test item at 30 °C ± 2 °C was considered to be stable under the experimental  conditions. | 22A-0054, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Disintegration time | Waived | - | Not applicable since biocidal product is not a tablet and is not used in a water soluble bag. | - |
| Particle size distribution, content of dust/fines, attrition, friability | Waived | - | Not applicable since biocidal product is not a granule or tablet. | - |
| Persistent foaming | CIPAC Handbook O - MT 47.3 method (2017) | Still Horse (0.97%) | Before storage:  No foam was observed after several inversions of the undiluted test item at  25 °C ± 5 °C after 1 min of standing.  Same results were observed after accelerated storage procedure. | 22A-0055, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Flowability/Pourability/Dustability | Waived | - | Not applicable since the biocidal product is not a granular formulation, suspension concentrate, capsule suspension or suspoemulsion. | - |
| Burning rate — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Burning completeness — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Composition of smoke — smoke generators | Waived | - | Not applicable since the biocidal product is not a smoke generator. | - |
| Spraying pattern — aerosols | Waived | - | Product is not an aerosol since the spray packaging does not contain a propellant. | - |
| Physical compatibility | Waived | - | Product is not intended to be used with other products. | - |
| Chemical compatibility | Waived | - | Product is not intended to be used with other products. | - |
| Degree of dissolution and dilution stability | Waived | - | The biocidal product is not a water soluble preparation. | - |
| Surface tension | EU Test Method A.5  [using Lauda TD3 Tensiometer] | Still Horse (0.97%) | 23.5 ± 0.5 mN/m  At 20.2°C | 22A-0054, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Viscosity | OECD 114  [using Viscometer Brookfield LV-II+ PRO] | Still Horse (0.97%) | 2.78 mPa.s at 20.0 °C ± 0.2 °C  1.78 mPa.s at 40.0 °C ± 0.2 °C  The test item was  considered to have newtonian properties under the experimental conditions used. | 22A-0054, Demangel, B., 2022. ARMOSA TECH SA/NV |

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| Conclusion on the physical, chemical and technical properties of the product |
| The product is a white, opaque, homogeneous liquid with lemongrass odor. Its pH is 7.54 and the product has a relative density of 0.999 g/cm3. Based on the storage stability studies, it can be concluded that the product is stable during 2 years in its commercial package (HDPE). The product must not be stored or applied at temperatures ≤0°C and is a stable oil-in-water emulsion. The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat. The amount of persistent foam, generated by the product, was determined to be 22 ml after 1 minute. Physical and chemical compatibility with other products are not relevant. The surface tension is 23.6 mN/m and the product has a viscosity of 1.53 mPa.s and 1.04 mPa.s (at 20 and 40°C, respectively).  **Conclusion after MAC 2022**  The product is a white, opaque, homogeneous liquid with lemongrass odor. Its pH is 5.74 and the product has a relative density of 0.997 g/cm3. The product must not be stored or applied at temperatures ≤0°C and is a stable oil-in-water emulsion. The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat. No presence of persistent foam generated by the product was observed after several inversions. Physical and chemical compatibility with other products are not relevant. The surface tension is 23.5 mN/m and the product has a viscosity of 2.78 mPa.s and 1.78 mPa.s (at 20 and 40°C, respectively).  Based on the accelerated storage stability studies, a 2 years shelf-life can be granted but the long term storage data will be submitted in a post-authorization to validate this conclusion. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Waived | - | None of the ingredients of the product is classified as explosive. | - |
| Flammable gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable aerosols | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Oxidising gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Gases under pressure | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable liquids | EU Test Method A9  [using Normalab NPV 310 closed cup – ISO 3679] | Still Horse (0.97%) | Flash point: >120°C | 16-902007-001, Demangel, B., 2016. Belgagri |
| Flammable solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-reactive substances and mixtures | Waived | - | Product is not self-reactive: no substances in the mixture which contain chemicals groups associated with explosive or self-reactive properties. | - |
| Pyrophoric liquids | Waived | - | Product is not pyrophoric. | - |
| Pyrophoric solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-heating substances and mixtures | Waived | - | The mixture is not self-heating since it is a liquid at room temperature. | - |
| Substances and mixtures which in contact with water emit flammable gases | Waived | - | Product does not emit flammable gasses in contact with water. | - |
| Oxidising liquids | Waived | - | None of the ingredients of the product is classified as oxidising. | - |
| Oxidising solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Organic peroxides | Waived | - | Not applicable since biocidal product does not contain any organic peroxide. | - |
| Corrosive to metals | Method C.1. (Part III, Section 37.4.) | Still Horse (0.97%)  Batch No B1906218 | Neither localised nor uniform corrosion was observed after the test; the test item is not classified as corrosive to metals following United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and following Regulation EC No. 1272/2008 (CLP). | 21-902007-002, Demangel B., 2021. ARMOSA TECH |
| Auto-ignition temperatures of products (liquids and gases) | EU Test Method A15 | Still Horse (0.97%) | Auto-ignition temperature: >603°C  [at 98.3 ± 0.3 kPA; relative humidity: 54 – 41%] | 16-902007-001, Demangel, B., 2016. Belgagri |
| Relative self-ignition temperature for solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Dust explosion hazard | Waived | - | Not applicable since biocidal product is a liquid. | - |

* **Major change (MAC) 2022**

For the major change dossier, after the change of product composition, new data below have been submitted to support the Physical hazards.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | DSC method | - | A DSC test was performed.  One exothermic peak at 178°C; exothermic decomposition energy = e.g. 16.6 J/g  The exothermic reaction energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C, so the test item shall not be classified as explosive. | 22A-0053, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Flammable gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable aerosols | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Oxidising gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Gases under pressure | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable liquids | EU Test Method A9  [Stanhope Setaflash Series 8 closed cup – ISO 3679] | Still Horse (0.97%) | Flash point: >110°C | 22A-0054, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Flammable solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-reactive substances and mixtures | DSC method | - | DSC test performed.  One exothermic peak at 178°C; exothermic decomposition energy = e.g. 16.6 J/g  The exothermic reaction energy is less than 300 J/g and the onset of exothermic decomposition is below 500°C, so the test item shall not be classified as self-reactive. | 22A-0053, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Pyrophoric liquids | Waived | - | Product is not pyrophoric. | - |
| Pyrophoric solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-heating substances and mixtures | Waived | - | In general, the phenomenon of self-heating applies only to solids. Liquids are considered to not have large enough surface to have a reaction with air and the test method is not applicable to liquids. The self-heating can be considered for liquids if they are absorbed on large surfaces which is not the case of the Still Horse product. Therefore, liquids are not classified as self-heating without any further testing. | - |
| Substances and mixtures which in contact with water emit flammable gases | Waived | - | Product does not emit flammable gasses in contact with water. | - |
| Oxidising liquids | Waived | - | No group of concern is present in all the ingredients in the product except for one ingredient of a co-formulant. This might be understand as a chemical alert for oxidising properties based on the CLP guidance. However taking into account that:  - Its small concentration in the whole product (0.24%) compared with other coformulants as the active substance (0.97%), the surfactant (1.95%) or the solvent (water, 85.08%)  - The experience handling the product.  - >85% of the product composition is water.  We consider that neither this coformulant nor the biocidal product have oxidising properties and therefore we deemed acceptable waiving the test. | - |
| Oxidising solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Organic peroxides | Waived | - | Not applicable since biocidal product does not contain any organic peroxide. | - |
| Corrosive to metals | Method C.1. (Part III, Section 37.4.)  Regulation EC No. 1272/2008 (CLP), amendment No.1 (2021) | Still Horse (0.97%) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Initial weight (g) | Weigth after treatement  (g) | Loss of mass (g) | Loss of mass (%) | |  | Steel plates | | | | | Immersed | 15.6157 | 15.5929 | 0.0228 | 0.15 | | Half-immersed | 15.8283 | 15.8156 | 0.0127 | 0.08 | | Gaseus phase | 15.7534 | 15.7568 | /\* | /\* | |  | Aluminium plates | | | | | Immersed | 5.5307 | 5.5308 | /\* | /\* | | Half-immersed | 5.4964 | 5.4967 | /\* | /\* | | Gaseus phase | 5.4832 | 5.4907 | /\* | /\* | | /\* No loss of mass was recorded | | | | |   The maximal loss of mass recorded was 0.15% for the immersed steel plate  which is lower than 13.5% for an exposure time of 7 days. No localised corrosion was  observed on plates.  Neither localised nor uniform corrosion was observed after the test; the test item is not classified as corrosive to metals following United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and following Regulation EC No. 1272/2008 (CLP).  A small deviation from the method was observed since the minimum volume during the test was not 1,5 L as indicated in the method. However applicant provided graphical proofs (pictures and data) proving that they used enough volume to cover the plates during the test and no corrosion was observed in the plates. | 22A-0053, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Auto-ignition temperatures of products (liquids and gases) | EC A.15. method | Still Horse (0.97%) | No auto-ignition temperature was observed  up to 598 °C.  [at 98.2 ± 0.2 kPA; relative humidity: 27 - 32%] | 22A-0053, Demangel, B., 2022. ARMOSA TECH SA/NV |
| Relative self-ignition temperature for solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Dust explosion hazard | Waived | - | Not applicable since biocidal product is a liquid. | - |

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| Conclusion on the physical hazards and respective characteristics of the product |
| The product is not oxidizing, nor explosive. Given its composition, it is considered as Met Corr 1 – H290, pending confirmation of a metal corrosion test within 1y post-authorisation. The product has no self-reactive properties, does not react with air, and is not self-heating since it is a liquid at room temperature. The flash point has been determined to be >120°C, after which the test was ended. The auto-ignition temperature has been determined to be >603°C, after which the test was ended. Hence the product must not be classified as flammable liquid.  **Conclusion after MAC 2022**  The product is not oxidizing, does not react with air, and is not self-heating since it is a liquid at room temperature. A DSC test was performed and the exothermic reaction energy is less than 300 J/g, so the product is not classified as explosive or self-reactive. The flash point has been determined to be >110°C, after which the test was ended. The auto-ignition temperature has been determined to be >598°C, after which the test was ended. Hence the product must not be classified as flammable liquid.  Corrosion to metals was tested following United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and following Regulation EC No. 1272/2008 (CLP). A small deviation from the method was observed since the minimum volume during the test was not 1,5 L as indicated in the method. However applicant provided graphical proofs (pictures and data) proving that they used enough volume to cover the plates during the test and no corrosion was observed in the plates indicating that Still horse should not be classified as corrosive to metals. |

### Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin* | SANCO/3030/99 rev. 4 from 11/07/00.  GC-MS  [GC-MS using Phenomenex, column: Zebron ZB-1 30m x 0.53mm ID; 1.5 µm film thickness, with FID detector] | Fortification levels: 50% - 150%  No. of measurements: 10 | R2= 0.9990 within the range of 92.55 mg/L to 280.00 mg/L | Retention time match | 99.9 – 104.9 | 103 | 0.94 | Not specified | 16-902007-004, Ricau, H., 2016. Belgagri |
| Please refer to the active substance data for further methods | | | | | | | | | |

* **Major change (MAC) 2022**

For the major change dossier, after the change of product composition, new data below have been submitted to support the methods for detection and identification.

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin* | SANCO/3030/99 rev.5 from  22/03/2019.  gas  chromatography using flame ionisation detector (GC-FID)  [GC-MS using Shimadzu GC-2010Plus, column: Supelco 30m x 0.53mm ID; 1.5 µm film thickness, with FID detector] | Fortification range: 50% - 150%  No. of measurements: 10 | R2= 0.9982 within the range of 88.04 mg/L to 259.61 mg/L | Retention time match.  The analytical method showed a good specificity for permethrin in the  formulation | 95.8-100.9 | 98 | 0.72 | Not specified | 22A-0057, Ricau, H., 2022. ARMOSA TECH SA/NV |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| **Analytical methods for monitoring** | | | | | | | | | |
| **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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| **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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| **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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for 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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for animal and human body fluids and tissues** | | | | | | | | | |
| **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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | |
| **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 |
| Please refer to the active substance data for further methods | | | | | | | | | |

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| **Conclusion on the methods for detection and identification of the product** |
| Permethrin content can be determined in the Still Horse product based on a GC-MS method using a Phenomenex (Zebron ZB-1 30m x 0.53mm ID x 1.5 µm film thickness) column. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. The mean recovery rates at each spiking level are around 103%, with a range between 99.9 and 104.9%. Repeated injection of the samples resulted in a coefficient of variation which was less than 0.94%. The limit of quantification (LOQ) has not been specified.  For other analytical methods refer to the CAR of the active substance.  **Conclusion after MAC 2022**  Permethrin content can be determined in the Still Horse product based on a GC-MS method using a Shimadzu GC-2010Plus (Supelco 30m x 0.53mm ID x 1.5 µm film thickness) column. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. The mean recovery rates at each spiking level are around 98%, with a range between 95.8 and 100.9%. Repeated injection of the samples resulted in a coefficient of variation which was less than 0.72%. The limit of quantification (LOQ) has not been specified.  For other analytical methods refer to the CAR of the active substance. |

### Efficacy against target organisms

#### Function and field of use

STILL HORSE is a biocidal product used as insecticide against flying insect’s species for horses’ hygiene. It is a ready to use product which contains 0.97 % (w/w) of PERMETHRIN (CAS No. 52645-53-1) intended to be applied directly by professional and non-professional users on horse’s skin at the rate of 25 ml per horse. The product has a duration of action between 1 to 3 days. The treatment can be repeated after 4 days during the summer season. The product is intended to be used in- and outdoor and applied by three different methods: direct spraying, direct spreading using bristles (lotion application using external applicator bristles), direct application as a lotion on horse’s skin by a synthetic sponge.

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

The target species to be controlled are *Musca autumnalis* (Muscidae), *Stomoxys calcitrans* (Muscidae) and *Musca domestica* (Muscidae).

The following target organisms were claimed at the beginning of process but the applicant no longer wish to claim them : *Haematopota spp. (Tabanidae) and Simulium spp. (Simulidae).*

The active substance of the product, Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately the death of the target organisms which cause nuisances for horses.

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

Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. It is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes.

Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

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

#### Mode of action, including time delay

Permethrin belongs to Pyrethroids’ family which act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect.

#### Efficacy data

To support the claim, the applicant has submitted 5 studies to demonstrate the efficacy of the product against the target organisms:

* A Laboratory testing (no choice) of a dose range of an insecticide product performed on the product STILL HORSE (9 g/L Permethrin) by spraying conducted with tiles of leather and 4 replicates on ***Musca domestica*** and ***Stomoxys calcitrans*** in temperate conditions. (Report 2058a-SH/0316R/ 2016-04-20 / T.E.C. Laboratory)
* The study procedure is a TEC methodology according to the following guideline:

CA-Dec12-Doc.6.2.a-Final: PT18 and PT19, draft guidance to replace part of Appendices to chapter 7 (pp. 187-200) from TNsG on Product evaluation

Agreement procedures for Officially Recognized Trials according to the European directive 91/414/CE (French ministry of agriculture)

* The efficacy dosage was assessed under “normal” climatic conditions (25+/-2°C; 65+/-5% RH).
* Batches of insects (25 individuals) are placed onto the materials treated at different doses
* 5 doses were tested (on the basis of a horse’s skin area of 3 m²)
  + - 100 ml /horse ( 900 mg AS/horse) - 33.3 ml/m² (300 mg AS/m²)
    - 75 ml /horse ( 675 mg AS/horse) - 25 ml/m² (225 mg AS/m²)
    - 50 ml /horse ( 450 mg AS/horse) - 16.7 ml/m² (150 mg AS/m²)
    - 25 ml /horse ( 225 mg AS/horse) - 8.3 ml/m² (75 mg AS/m²)
    - 12.5 ml /horse ( 112.5 mg AS/horse) - 4.15 ml/m² (37.5 mg AS/m²)
* The treatments were done by using a one-use hand-held sprayer.
* Determination KT100 and mortality after 24 hours.
* Density of the organisms : 25 mixed sex per replicate onto a treated leather tile of 15\*15 cm in petri box of 14 cm.
* Duration of exposure: until KT100

**Conclusion: test and results validated**

According to this laboratory test, the results obtained on the product STILL HORSE (9 g/L PERMETHRIN)when used at doses between 33.3 ml of product/m² and 8.3 ml of product /m² on the leather, demonstrates a good efficacy against house flies *(Musca domestica)* and stable flies (*Stomoxys calcitrans)* in “normal” climatic conditions.

* Efficacy assessment of insecticide product STILL HORSE containing **9 g/L PERMETHRIN** applied by brushing on horses against flies. This study includes 2 parts:

Report BGG13 STI01/2013-10-23/BELGAGRI

* + a laboratory test (no choice) conducted with tiles of leather on ***Stomoxys calcitrans,*** ***Musca automnalis*** and ***Haematopota spp. (Tabanidae))*** in normal climatic conditions.
* This study is based on the C.E.B. method No. 135 (1st edition: April 1987 Revised: March 2007) and

CEB 159. This method is cited in the "guidance document to replace part of Appendices to chapter 7 (pages 187 to 200) of the TNsG on Product Evaluation" (2012), concerning biocidal products.

* The efficacy of the product was assessed under “normal” climatic conditions (between 20-25+/-2°C).
* The experimenter recorded the mortality of the flies at regular time intervals (1, 2 or 4 hours depending on the speed of action) in order to know the short-term kinetics of the effect
* Density of the organisms : At least 10 flies were exposed per replicate onto a treated leather tile of 15\*15 cm in petri box of 14 cm.
* Number of target organisms tested ( same number used for the control)
  + - *Stomoxys calcitrans* : 64
    - *Musca automnalis*: 55
    - *Haematopota spp*.: 67
* Duration of exposure: 4 hours
* Dose of application: 100 ml of product /horse ( 900 mg AS/horse) - 33.3 ml/m² (300 mg AS/m²)
  + A field trial conducted with 6 horses and 3 replicates (3 days) to demonstrate the persistence effect in real field situation in temperate conditions (mean 7 days: temperature at 13h. 27°C +-5, HR60%, no rain).
* The methodology of this second trial is inspired by the trial N° HIME 84-6, from 6th June 1984, operated by the Wellcome Foundation Ltd in Germany, called “Controlled field trial to test the efficacy of permethrin/citronellol to control non-biting flies, Gasterophilus intestinalis and tabanids on horses.
* Dose of application: 100 ml of product /horse ( 900 mg AS/horse) - 33.3 ml/m² (300 mg AS/m²)
* Each horse is treated on the head, neck and mane, chest, shoulders, forelegs and the hind-legs. Nostrils are excluded because of the sensibility of the horses.
* 3 horses treated (day 1 only) and 3 horses for the control. The horses are let out on pasture. To make them sweat, they are ridden daily for at least 3 hours during the duration of the trial. No information about the colour of the horses.
* The product was applied on 3 horses (horse 1-2-3) (100 ml per horse). 3 non treated horses were used as control (horse 4-5-6). Then, during 3 days, flies settling on the six horses were captured. There is one cage per horse, so there will be 6 cages per day. The fly species will be determined when captured.
* The comparison of mortality of flies on treated and untreated horses will be used to assess the insecticide efficacy of the test product.
* Number of target organisms captured per day (day 1/day 2/day 3) and control
  + - *Stomoxys calcitrans* : 13 / 15 /17 – 10 / 13/ 12
    - *Musca automnalis*: 12 / 17 / 19 – 16 / 18 / 17
    - *Haematopota spp*.: 10 /16 / 19 – 16 / 18 / 17

**Conclusion: tests and results not validated**

The application rate used in both tests don’t correspond at the application rate claimed.

Therefore, the results cannot be used to demonstrate the efficacy of the product.

* A field trial conducted with 14 horses and 2 replicates to demonstrate the efficacy and persistence effect in real field situation. The test is performed on the product STILL HORSE (9 g/L Permethrin) with a dose of 25 ml per horse, applied with sponge.

(Report 16-SH / 2016-09-27 (modified: 2017-05-10 / Michel Alatienne)

* The study is performed to demonstrate the efficacy of the product in real field condition.
* 14 horses were used in order to determine the level of infestation, a first group of 6 horses is treated, a second group of 6 horses as control. A second replicate are done by inverting the two groups. Two horses are used as a control throughout the test.
* The knock down effect was assessed with 10 horses by counting all recovered insects on a light colour tissue placed under treated horse for 15 minutes.
* The test is performed on 5 horses at rest but also on 5 horses after activity (sweating)
* Dose of application: 25 ml of product /horse(8.3 ml per m² of horse skin to be treated)
* Evaluation of insect species and level of infestation : by trapping

Trap system : “Vavoua trap” checked every day

* Assessment knock down proprieties : counting insects below the animal

**Conclusion: test and results validated**

According to this field trial, the results obtained on the product STILL HORSE (8 g/L PERMETHRIN)when used at dose of 25 ml /horse seems to show a good efficacy against horse flies *(Musca autumnalis),* stable flies ( *Stomoxys calcitrans), Simulium spp*. (Simuliidae) and *Haematopota Spp.* (Tabanidae)in “normal” climatic conditions during 4 days. However, it should be mentioned that the amount of tabanid and simulid flies encountered in the test is very low.

* A Laboratory testing (no choice) measure the effectiveness of an the product STILL HORSE (9 g/L) applied by spraying on tiles of leather and 3 replicates on ***Musca automnalis*** in temperate conditions. (Report 16BEL002/ 2016-09-20 / IZIPEST SA)
* The study was performed according to the guideline:

CA-Dec12-Doc.6.2.a-Final: PT18 and PT19, draft guidance to replace part of Appendices to chapter 7 (pp. 187-200) from TNsG on Product evaluation

* The Test Item was applied using a professional pressurized sprayer GLORIA 8L with an antidrop nozzle (1 bar) at a rate of 8.3 mL/m2
* The efficacy of the product was assessed under “normal” climatic conditions (22+/-0.2°C- 73% RH).
* Batches of insects (100 mixed sex adults) are placed onto a raw leather treated (8.3 ml/m²) for a period of 1 hour.
* Determination KT100 and mortality after 24 and 48 hours.
* Density of the organisms : 100 mixed sex adults placed onto a treated leather tile of 15\*15 cm in glass jars of 2 L.
* Duration of exposure: until KT100

**Conclusion: test and results validated**

According to this laboratory test, the results obtained on the product STILL HORSE (8 g/L PERMETHRIN)when used at dose of 8.3 ml of product /m² on the leather, demonstrate a good efficacy against autumn house flies *(Musca automnalis)* in “normal” climatic conditions.

**Major Change application - 2022**

A new semi-field trial was submitted, to further support the efficacy of the product STILL HORSE (9 g/L Permethrin) against flies (*Musca domestica*, *Stomoxys calcitrans*, *Tabanus bovinus*, *Hippobosca equina*, and *Musca autumnalis)*, when 25 ml of product per horse is applied with a sponge. (Report BAS122021.8 Biocidal Alternative Solutions SA, 2022)

* 30 horses (10 saddle horses, 10 breeding horses and 10 untreated); 20 treated and 10 control horses are raised in identical conditions in the same place;
* One saddle horse, one breeding horse and one untreated horse are put individually inside three different paddocks where saddle and breeding horses are treated with the product. A controlled number (20 of each species) of reared/captured insects are into the tent where a sheet is put on the ground to allow easy counting of dead insects.
* Species tested: *Musca domestica*, *Stomoxys calcitrans*, *Tabanus bovinus*, *Hippobosca equina*, and *Musca autumnalis*
* After 1 hour, dead insects are counted. This task is done the day of application and the 4th day after application.
* Horses are tested in sequence, one sequence overlapping another.
* The test is performed on 5 horses at rest but also on 5 horses after activity (sweating)
* Dose of application: 25 ml of product /horse(8.3 ml per m² of horse skin to be treated)
* The efficacy of the test product is assessed by the comparison of mortality of insects in day 1 and day 4.

**Conclusion: test and results validated**

According to this field trial, the results obtained on the product STILL HORSE (9 g/L PERMETHRIN)when used at dose of 25 ml /horse has proved a good insecticidal effect in the field when applied on horses, with three days of persistence, against *Musca domestica*, *Stomoxys calcitrans*, *Tabanus bovinus*, *Hippobosca equina*, and *Musca autumnalis*

* + - * 1. *Efficacy data table*

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
| *PT18*  *Insecticide* | *liquid solution*  *ready-to-use (spray)*  *applied on horse skin*  *Professional & non-professional user*  *to kill house and stable fly*  *Musca domestica*  *Stomoxys calcitrans*  *in temperate areas* | *STILL HORSE (batch SH11507)*  *Active substance:* ***PERMETHRIN: 9 g/L*** | **House fly**  Mixed sex 2-4 days  *Musca domestica*  ***Stable fly***  Mixed sex 2-4 days  *Stomoxys calcitrans* | *Laboratory test*  (no-choice test) | *25 mixed sex per replicate onto a treated leather tile of 15\*15 cm 70in petri box of 14 cm.*  *Determination KT100 and mortality after 24 hours.*  5 doses were tested  100 ml, 75, 50, 25, 12.5 ml /horse  *applied by spraying* | *Results for doses 100 to 25 ml /horse*  *KT100 : 15 minutes and 100 % mortality after 24 h.*  *For the dose 12.5 ml /horse*  *KT100 : 60 minutes and 100 % mortality after 24 h.*  *in normal conditions*  negative control mortality <2% | Report 2058a-SH/0316R/ 2016-04-20 / T.E.C. Laboratory  *LABORATORY TESTING OF A DOSE RANGE OF*  *AN INSECTICIDE PRODUCT* |
| *PT18*  *Insecticide* | *liquid solution*  *ready-to-use (spray)*  *applied on horse skin*  *Professional & non-professional user*  *in temperate areas* | *STILL HORSE (batch M02070064)*  *Active substance:* ***PERMETHRIN: 9 g/L*** | **Stable fly**  Wild strains  *Musca automnalis*  *Stomoxys calcitrans*  *Haematopota spp. (Tabanidae))* | ***Part 1***  *Laboratory test*  (no- choice test) | *At least 10 flies were exposed per replicate onto a treated leather tile of 15\*15 cm in petri box of 14 cm.*  *Duration of exposure: 4 hours*  *Determination KT100 after 1, 2 and 4 hours and mortality after 24 hours.*  Dose of application: 100 ml/horse applied by brushing | ***Results not validated (appl. rate not adapted)*** | *Report BGG13 STI01*  *2013-10-23*  *BELGAGRI*  Efficacy assessment of insecticide product STILL HORSE containing 9 g/L PERMETHRIN applied on horses against flies |
| ***Part 2***  *Field trial*  *on horses* | *3 horses treated and 3 horses for the control. The horses are let out on pasture. Ridden 3 hours daily.*  *Flies settling on the horses will be captured and put in fly cages for observation.*  Dose of application: 100 ml of product /horse applied by brushing | ***Results not validated (appl. rate not adapted)*** |

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| *PT18*  *Insecticide* | | *liquid solution*  *ready-to-use (spray)*  *applied on horse skin*  *Professional & non-professional user*  *in temperate areas* | | *STILL HORSE (batch SH 11507)*  *Active substance:* ***PERMETHRIN: 0.9 %*** | | *Musca automnalis*  *Stomoxys calcitrans*  *Haematopota spp. (Tabanidae))*  *Simulium spp. (Simuliidae)* | | *Field trial on horses* | | Evaluation level of infestation (by trapping) :  14 horses were used, a first group of 6 horses is treated, a second group of 6 horses as control. The second replicate are done by inverting the two groups. Two horses are used as a control throughout the tests.  25 ml product per horse applied by sponge  The knock down effect was assessed by counting all recovered insects on a light colour tissue placed under 5 horses treated during 15 minutes. A second replicate was done after activity and sweating.  This procedure was repeated after 1 h, 24h, 48h, 72h, 96 h. | | Evaluation level of infestation (by trapping) :  Sum 2 tests  Treated groups (insects trapped)  M.A. = 67  S.C. = 30  Sim. = 74  Tab = 46  Untreated groups  M.A. = 38  S.C. = 9  Sim. = 40  Tab. = 20  Insects present in sufficient numbers for the treated and untreated groups  Identification of insect species :  *Musca autumnalis*  *Haematopa spp.*  *Stomoxys calcitrans*  Midges  observation of repellent proprieties:  Significant decrease in the number of insects landing and also time on the animal for the treated groups compared to the control  Insects KD/dead during assessment of KD  (15 min) (sum 5 horses)  Horses without activity  Day 0  M.A. = 10 S.C. = 7  Sim. = 27 Tab. = 8  24 h  M.A. = 13 S.C. = 6  Sim. = 27 Tab. = 7  48h  M.A. = 11 S.C. = 5  Sim. = 23 Tab. = 4  72h  M.A. = 8 S.C. = 4  Sim. = 15 Tab. = 4  96h  M.A. = 6 S.C. = 3  Sim. = 9 Tab. = 1  Horses after activity  Day 0  M.A. = 10 S.C. = 4  Sim. = 26 Tab. = 6  24 h  M.A. = 9 S.C. = 5  Sim. = 31 Tab. = 6  48h  M.A. = 8 S.C. = 5  Sim. = 24 Tab. = 4  72h  M.A. = 4 S.C. = 2  Sim. = 13 Tab. = 3  96h  M.A. = 2 S.C. = 1  Sim. = 5 Tab. = 0  Decrease of KD insects from the 3rd day. | *Report: 16-SH*  *2016-09-27 (modified 2017-05-10)*  *Michel Alatienne*  *Effect of Still Horse (0.9%PERMETHRIN) against insects on horses at pasture.* | |
| *PT18*  *Insecticide* | | *liquid solution*  *ready-to-use (spray)*  *applied on horse skin*  *Professional & non-professional user*  *in temperate areas* | | *STILL HORSE (batch SH1L-1627)*  *Active substance:* ***PERMETHRIN: 9 g/L*** | | **Autumn house Fly**  Mixed sex 2-4 days  *Musca automnalis* | | *Laboratory test*  (no-choice test) | | *100 adults per replicate onto a treated leather tile of 15\*15 cm*  *Determination KT100 and mortality after 24 and 48 hours.*  Application rate: 8.3  ml/m² applied by spraying | | *KT100 : 10 minutes and 100 % mortality after 24 h.*  *in normal conditions*  negative control mortality 1% | Report 16BEL002/ 2016- October/ IZIPEST SA  *LABORATORY TRIAL OF THE EFFICACY OF A PRODUCT AGAINST FLIES* | |
| **Major Change application - 2022** | | | | | | | | | | | | | | |
| PT18  Insecticide | Liquid solution  ready-to-use (sponge application).  applied on horse skin  Professional & non-professional user | | STILL HORSE (batch SH0721)  Active substance: **PERMETHRIN: 9 g/L** | | *Musca domestica (house fly)*  *Stomoxys calcitrans (Stable fly)*  *Tabanus bovinus (horse-fly)*  *Hippobosca equina (forest fly)*  *Musca autumnalis (autumn fly)* | | Semi – field trial  (France) | | 10 saddle and 10 breeding horses were treated with 25 ml/horse product (applied by sponge) and compared with untreated horses.  Horses are placed in a paddock tent, covered with a mosquito net, to prevent flies from escaping. 20 flies per tested species are released into the tents, and mortality for each target organism is assessed on the 1st day (day of application) and 4 days after application.  *\* SH = saddled horses; BH = breeding horses, N.C. = untreated control horses.* | | % mortality *M. domestica:*   |  |  |  | | --- | --- | --- | |  | day 1 | day 4 | | SH | 94.5 | 90 | | BH | 96.5 | 92 | | N.C. | 1 | 2 |   % mortality for *S. calcitrans:*   |  |  |  | | --- | --- | --- | |  | day 1 | day 4 | | SH | 94 | 91.5 | | BH | 96 | 90 | | N.C. | 0.5 | 2 |   % mortality for *T. bovinus:*   |  |  |  | | --- | --- | --- | |  | day 1 | day 4 | | SH | 98 | 93.5 | | BH | 96.5 | 93.5 | | N.C. | 0.5 | 0 |   % mortality for *H. equina:*   |  |  |  | | --- | --- | --- | |  | day 1 | day 4 | | SH | 97.5 | 94.5 | | BH | 99 | 95 | | N.C. | 0.5 | 0 |   % mortality *M. autumnalis:*   |  |  |  | | --- | --- | --- | |  | day 1 | day 4 | | SH | 93 | 92 | | BH | 93.5 | 90 | | N.C. | 0.5 | 1.5 |   Day 1 Mean fly mortality:  95.4% on saddle horses, 96.3% breeding horses and  0.6% in control.  Day 4 Mean fly mortality:  92.3% for saddle horses,  92.1% on breeding horses and 1.1% in control. | | | Report BAS122021.8  Biocidal Alternative Solutions SA, 2022.  EFFICACY ASSESSMENT OF THE INSECTICIDE PRODUCT “STILL HORSE” CONTAINING 9g/L PERMETHRIN APPLIED ON HORSES |

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| **Conclusion on the efficacy of the product** |
| For the evaluation of a product containing permethrin and intended to be used as repellent, no protocol is available. On the other hand, permethrin was only approved for the PT18. As discussed in WGIII2016 EFF: since there is no repellent effect without contact, it cannot be seen as a repellent. The product should be assessed as an insecticide (PT18).  Consequently, the BE CA Efficacy decided to evaluate the product on the basis of laboratory test to show the Knock-down and mortality, and a simulated-use test or a field test to assess the lethal effect of the product.  The test must be designed to mimic the practical use situation. All claimed species of flies must be tested/observed both in laboratory and field trial conditions.  Given the difficulty to perform a simulated-use test with horses in laboratory conditions, the applicant proposed to realize a field trial in pastures.  On the basis of the acceptable field trial submitted, the product Still Horse (9 g/l Permethrin) applied on horse skin at a dose of 25 ml per horse shows mortality in flies landing on the treated horses. The species of flies observed during the field trial are *Musca autumnalis, Stomoxys calcitrans, Haematopota Spp.* (Tabanidae) *and Simulium spp.* (Simuliidae)). The trapping showed a sufficient number of insects in order to validate the test, and demonstrated a reduction in number of flies present at the sites of the treated horses.  The test method (assessment of knock down during the field test) has also permitted to evaluate the rapid effect of the product even if all insects which have come in contact with the product could not be counted.  The laboratory tests have permitted to observe a complete knock down effect after 10 at 15 minutes for *Musca domestica, Musca automnalis* and *Stomoxys calcitrans*. The mortality rate 24 hours after exposure was 100%.  During the discussions with the applicant, BE CA communicated that the species claimed but also species likely encountered in a normal use of the product must be tested both in laboratory (no choice test) and simulated use or field trial. (i.e. *Haematopota spp*. (Tabanidae)) and *Simulium spp*. (Simuliidae).  Thereafter, we were informed that the applicant no longer wished to claim Tabanidae and Simuliidae.  On the basis of 3 studies submitted and performed with the application rate claimed (25 ml/horse), the following claim is supported: “contact insecticide, prevents nuisance of flies”. The validated T.O. are *Musca autumnalis* and *Stomoxys calcitrans,* since the effect of Still Horse was assessed in both lab an field trials on these 2 species. |

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| **MAC – 2020 : Conclusion on the efficacy of the product** |
| The semi-field trial submitted for the Major change (2022) confirms the efficacy of the product STILL HORSE against *Musca autumnalis* and *Stomoxys calcitrans,* when 25ml of the product is applied on a horse, by using a sponge.  This semi-field trial has also shown ≥90% mortality in *Musca domestica* (house fly), *Tabanus bovinus* (horse-fly) and *Hippobosca equina* (forest fly).  The effect is persistent up to 4 days after product application.  “For the target organisms Tabanus bovinus and Hippobosca equina, efficacy is demonstrated in a semi-field trial. BE CA did not request any further laboratory trials to demonstrate the efficacy of the product against these target organisms, since the efficacy is considered sufficiently demonstrated in the semi-field trial. This test set-up is considered as more relevant by BE CA, since the test conditions are closer to the conditions of the intended use.” |

#### Occurrence of resistance and resistance management

Resistance to Permethrin has been documented in wide varieties of insects. These species include pear psylla (Preem D.J. et al -J.Econ.Entomol.83:2159-2163, 1990), fall army worm (Smith, J.E. Pest Biochem, Physiol. 39:84-91, 1991), German cockroach (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), spotted tentiform leafminer (Marshall, D.B. and D.J. Pree. Can.Ent. 118:1123-1130, 1986), diamondback moth (Tabashnik, B.E., N.J. Cushing, and M.W. Johnson. Econ.Entomol. 80:1091-1099), house fly (Khan HAA,2017 and 2019 ; Shen, J and F.W.Plapp. J.Econ.Entomol.83:1689-1697, 1990), Stable fly (Olafson PU, Pitzer JB, Kaufman PE, 2011;Cilek, J.E and G.I. Greena, J.Econ.entomol. 87:275-279, 1994), headlice (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995) (Mumcuoglu, K.Y.et al, med.Vet.Entomol 9:427-432, 447, 1995), (Burgess, I.F. et al, Brit.Med.J. 311 (7007):752 1995), tobacco budworm (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold) (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), lice (up to 385 fold) (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995), and budworm (1400 fold) (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

Resistance to Permethrin has been documented in a wide variety of organisms. In the Colorado potato beetle, it is suggested that resistance is due to low levels of Permethrin hydrolysis. In the fungus gnat, resistance to Permethrin is attributed to changes in monooxidase activity in the resistant population. In H. virescens, altered functioning of the Na+ channels, and a subsequent elevation of the action potential threshold is thought to cause the resistance. Resistance to pyrethroids has developed rapidly (among head lice) since Permethrin was introduced in 1991.

In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists.

Because of the anticipated low level of selection pressure from the proposed uses, no specific strategy for management of the development of resistance is required. Resistance should be managed at the renewal of authorisation with appropriate guidelines.

According to Permethrin’s CAR and the most updated information provided by the active substance supplier, the following recommendations must be followed in order to avoid any possible resistance by target organisms:

* 1. Where possible, application treatments is recommended to be combined with non-chemical measures.
  2. Products should always be used in accordance with label recommendations.
  3. Where an extended period of control is required, treatments should be alternated with products with different modes of action.
  4. Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

Since resistance in some fly species has already been reported, the following risk mitigation measures should be included in the SPC:

professional and non-professional users:

- Always read the label or leaflet before use and respect all the instructions provided) - Inform the registration holder if the treatment is ineffective.

- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

For professional users:

- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).

- Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).

- Do not [use/apply] the product in areas where resistance to the active substance contained in this product is suspected or established

- Check the efficacy of the product on site : if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance

#### Known limitations

No undesirable or unintended side effects have been observed in any of the tests performed.

BELGAGRI, the owner of the product has marketed STILL HORSE for more than 30 years and no notification nor information has been recorded on any side-effects on non-target species.

#### Evaluation of the label claims

The product STILL HORSE is found to be efficacious in lab test against *Musca autumnalis*, *Musca domestica* and *Stomoxys calcitrans,* and against *Musca autumnalis*, *Stomoxys calcitrans Similidae* and *Tabanidae* in a field trial. Since both lab and simulated-use or field trials are required for PT18 against flies, that can be used in the environment of stables, only the following fly species are considered as validated: *Musca autumnalis* and *Stomoxys calcitrans.* The following claim is supported: “*contact insecticide, prevents nuisance of flies”*

The product is applied by using a sponge, at an application rate of 25 ml product per horse, for a total of 3 m² body surface. The following instruction for use should be added to the SPC:

* Treat the body parts where the insects tend to gather, ie. around the eyes, on the back, and around their tail

**Major change – 2022:**

The conclusions of the first assessment remain unchanged for the target organisms that are already validated: *Musca autumnalis* and *Stomoxys calcitrans.*

In addition, the following target organisms can also be considered as validated: *Musca domestica* (house fly), *Tabanus bovinus* (horse-fly) and *Hippobosca equina* (forest fly).

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

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

### Risk assessment for human health

#### Assessment of effects on Human Health

##### Skin corrosion and irritation

| **Summary table of in vitro studies on skin corrosion/irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method,Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks *(e.g. major deviations)*** | **Reference** |
| O.E.C.D. Test Guideline No.439 (In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method) adopted 28 July 2015 and the Test method B.46 (In Vitro Skin Irritation: Reconstructed Human Epidermis Model Test) of Council regulation No. 761/2009 dated 23 July 2009 (EU Journal L220) - ATP Council regulation No. 440/2008 of 30 May 2008 (E.U. Journal L142). According to GLP | Still horse spray – insecticide 16 µl  Batch No. SH1641CPN | Applied to 3 living reconstructed human epidermis (SkinEthic RHE model) at the dose of 16 μL during 42 minutes at room temperature. In the same experimental conditions, a positive control (5% SDS), and a negative control (DPBS – Dutscher - Batch No. 7530417) were carried out. | The mean percent viability of the treated tissues was 84.4%, versus 2.2% in the positive control (5% Sodium Dodecyl Sulfate).  In accordance with the Regulation EC No. 1272/2008, the test item Still Horse Spray- Insecticide has to be considered as Non-irritant to skin. It corresponds to UN GHS ***No Category***. No hazard statement or signal word is required. | No deviation was registered during the study | Floriot, L.; 2017. IN VITRO SKIN IRRITATION: Reconstructed Human Epidermis Test Method |
| O.E.C.D. Test Guideline No. 431 (In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method) dated 28 July 2015 and the method B.40bis of the Council regulation No. 440/2008. According to GLP | Still horse spray – insecticide 50 µl | Still Horse Spray-Insecticide. Batch No.: SH1641CPN The test item was applied, as supplied, at the dose of 50 μL, during 3 minutes at room temperature and during 1 hour at 37°C ± 1°C, 5% ± 1% CO2, to the epidermal surface of 2 living human skin models.  In the same experimental conditions, a positive control (8N KOH – Sigma, Batch No. SLBD3295V) and a negative control (distilled water– Prochilab, Batch No. 20160914) were carried out. | Not corrosive:  3 minutes after the test item application, the mean percent viability of the epidermis skins treated with the test item was 126.45%(considered as 100% ) versus 6.81% with the positive control item (potassium hydroxide 8N)  1 hour after the test item application, the mean percent viability of the epidermis skins treated with the test item was 113.54% (considered as 100% ) versus 1.04% with the positive control item (potassium hydroxide 8N). | Acceptability criteria: Means OD of negative control tissues were 0. 0.916 for 1 hour exposure instead of ≤ 0.9 as initially scheduled.  Even when considering the value maximal of range i.e 0.9, the test item remain clearly classified as noncorrosive.  This deviation is considered as without any impact on the conclusion and the validity of the study | Floriot, L.; 2017. IN VITRO SKIN CORROSION: Reconstructed Human Epidermis (RhE) Test Method. |

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The product is not irritant or corrosive to the skin. |
| Justification for the value/conclusion | The applicant provided two tests on the biocidal product according to O.E.C.D. Test Guideline No. 439 and O.E.C.D. Test Guideline No. 431. Details information on these tests could be found above. Based on these tests it could be concluded that no classification is warrant for the product Still Horse for skin corrosion or irritation endpoint. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Eye Irritation

| **Summary table of in vitro studies on serious eye damage and eye irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks *(e.g. major deviations)*** | **Reference** |
| OEO.E.C.D. Test Guideline No. 438 (Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage) adopted 26 July 2013 and the test method B.48 (Isolated chicken eye test method for identifying occular corrosives and severe irritants) – Commission Regulation (EU) No. 1152/2010 dated 08 December 2010 (EU Journal L324) - ATP Council regulation No. 440/2008 of 30 May 2008 (E.U. Journal L142). According to GLP.CD test guideline no 438 | Still horse spray insecticide 30 µl to 3 enucleated chicken eyes during 10 seconds. Damages were assessed at 30, 75, 120, 180 and 240 min post dose  Three eyes were treated in the same manner with a positive control (5% Benzalkonium chloride) and one eye with a negative control (physiological saline) | The study complies with the guide method requirements | No classification for eye irritation and serious eye damage  The combination of the three endpoints for the test Still Horse Spray-Insecticide was 2 x I, 1 x II. Therefore, the tested product is classified as “No Category”. | No deviation was registered during the study. | Floriot, L., 2017. Isolated Chicken Eye Test Method for Identifying (i) Chemicals Inducing Serious Eye Damage and (ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage. Report: ICE-PH-17/0380 |

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The product is not irritant or corrosive to eyes. |
| Justification for the value/conclusion | The applicant provided a test on the biocidal product according to O.E.C.D. Test Guideline No. 438. Details information on this test could be found above. Based on this test it could be concluded that no classification is warrant for the product Still Horse for eye corrosion or irritation endpoint. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Respiratory tract irritation

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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). |

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| **Conclusion used in Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to respiratory tract |
| Justification for the value/conclusion | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient is not irritant to the respiratory tract. None of the other ingredients have respiratory tract irritation properties. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Skin sensitization

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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).  Information on the active substance : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4  In addition, there are others co-formulants present in the product classified as H317 – Skin Sens 1. Additional information is available in the confidential annex.  Two of these co-formulants, Citral and Cineol are present at a concentration sufficient for triggering the additional labelling EUH208. |

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| **Ingredient** | | **Classification** | **Generic concentration limits triggering classification of a mixture** | **Concentration (% w/w)** |
| **Name** | **CAS N°** |
| Permethrin | 52645-53-1 | Skin Sens. 1, H317 | 1% | 0.9 |
| Citral | 5392-40-5 | Skin Sens. 1, H317 | 1% | 0.1 < Citral < 1 |
| Cineol | 470-82-6 | EUH208 | 0.1% | 0.1 |

The mixture is not classified as a skin sensitizer because the mixture contains no ingredient classified as a skin sensitizer with a concentration present at or above the appropriate generic concentration limit.

The concentration limits for elicitation of components of a mixture is fixed at 0,1% for these 2 ingredients. The special labelling requirements to protect already sensitized individuals, the additional sentence EUH208, must be applied for Permethrin, Citral and Cineol. So the mixture must be additionally labelled with the sentence EUH208 Contains Permethrin, Citral and Cineol. **May produce an allergic reaction.**

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| **Conclusion used in Risk Assessment – skin sensitisation** | |
| Value/conclusion | The mixture is not classified as a skin sensitizer.  The additional sentence EUH 208 must be applied for Permethrin. |
| Justification for the value/conclusion | The mixture is not classified as a skin sensitizer because the mixture contains no ingredient classified as a skin sensitizer with a concentration present at or above the appropriate generic concentration limit.  The concentration limits for elicitation of components of a mixture is fixed at 0,1% for these 3 ingredients. The special labelling requirements to protect already sensitized individuals, the additional sentence EUH 208, must be applied. |
| Classification of the product according to CLP and DSD | The biocidal product must be additionally labelled with the sentence EUH 208: *“Contains Permethrin (52645-53-1), Citral (5392-40-5) and Cineol (470-82-6). May produce an allergic reaction.”* |

##### Respiratory sensitization (ADS)

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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). |

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| **Conclusion used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | No classification |
| Justification for the value/conclusion | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient is not classified as respiratory sensitizer. None of the other ingredients are not classified as respiratory sensitizer respiratory. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Acute toxicity

###### Acute toxicity by oral route

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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).  Information on the active substance : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4  In addition, there is others co-formulants presents in the product classified as H302 or H301. Additional information are available in the confidential annex.  However, none of these co-formulants has to be taken into account for calculation according section 1.1.2.2. of annex 1 of CLP regulation. |

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| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not available |
| Justification for the selected value | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient is classified for acute oral toxicity. Some others co-formulants are also classified for acute oral toxicity. However, none of these substances are present at a concentration above the cut-off values set in section 1.1.2.2. of annex 1 of CLP regulation, therefore none of these substances need to be taken into account for the purposes of classification of the mixture. |
| Classification of the product according to CLP and DSD | No classification needed |

###### Acute toxicity by inhalation

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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).  Information on the active substance : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4 |

The active substances is present at a concentration below the cut-off values set in section 1.1.2.2. of annex 1 of CLP regulation, therefore this substance not need to be taken into account for the purposes of classification of the mixture.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | - |
| Justification for the selected value | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient is classified for acute inhalation toxicity. However, this substance is present at a concentration below to the cut-off values set in section 1.1.2.2. of annex 1 of CLP regulation. Therefore this substance not need to be taken into account for the purposes of classification of the mixture. |
| Classification of the product according to CLP and DSD | No classification needed |

###### Acute toxicity by dermal route

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified. |
| Justification | 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).  There is co-formulant present in the product classified as H311, whose concentration is higher than 0.1% (generic cut off value) and therefore it must be taken into account in the CLP calculation. Additional information are available in the confidential annex. |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Above to 2000 mg/kg ATE |
| Justification for the selected value | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient is not classified for acute dermal toxicity. One other co-formulant is classified for acute dermal toxicity (H311). However, one co-formulant is present at a concentration above the cut-off values set in section 1.1.2.2. of annex 1 of CLP regulation, therefore it must be taken into account in the CLP calculation |
| Classification of the product according to CLP and DSD | No classification needed |

##### Information on dermal absorption

An in Vitro Percutaneous Absorption test has been conducted with Still horse formulation by the applicant in order to set a realistic dermal absorption value. The following table summarize the results of this study:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of *in vitro* studies on dermal absorption** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Remarks** *(e.g. major deviations)* | **Reference** |
| • OECD Guideline for Testing of Chemicals, Guideline 428: Skin Absorption: In Vitro Method (2004).  • OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 28. Guidance Document for the Conduct of Skin Absorption Studies (2004).  • European Commission Guidance Document on Dermal Absorption – Sanco/222/2000/ Rev.7 (19 March 2004).  • Guidance on Dermal Absorption (EFSA Journal, 2017; 15(6); 4873.  GLP yes | Human skin,  8 samples | Still horse (Permethrin 0.97%) | The following percentages are in function of the applied dose:  Absorbed dose: 0.10% (0.09 µg equiv./cm2)  Dermal delivery: 1.73% (1.56 µg equiv./cm2)  Potentially absorbable dose (mean): 3.03% (2.73 µg equiv./cm2)  Mass balance: 99.08% (89.1 µg equiv./cm2)  SD: 2.48 | See note below\* | Charles River Ref No. 787961 |

\*Potentially absorbable dose was calculated as less than 75% of the absorption occurred within the first half of the experiment, therefore absorption was deemed to be incomplete, as defined in the EFSA Guidance on Dermal Absorption 2017; 15(6): 4873 (absorption is considered essentially complete when >75% of the absorption occurred in the first half of the experiment). The potentially absorbable dose value was therefore calculated and is presented in the report. The potentially absorbable dose (3.03%) represents the sum of the absorbed dose, exposed skin and stratum corneum 3-20. It should be noted that this represents a ‘‘worst-case’’ risk assessment value and is possibly an over-estimate.

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 5.1% |
| Justification for the selected value(s) | As it was mentioned before, the potentially absorbable dose (3.03%) represents the sum of the absorbed dose, exposed skin and stratum corneum 3-20. According to EFSA Guidance on dermal Absorption (2017), the variability between the replicates needs to be addressed in the calculation. Applying the corresponding formula (mean absorption value + ks = 3.03 + (0.84 x 2.48)), results in a corrected dermal absorption value of 5.1 % |

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

There is no Substance of concern identified for human health in the biocidal product Still Horse. Please refer to the confidential annex for further details.

##### Available toxicological data relating to a mixture

Please refer to the confidential annex for further details.

#### Exposure assessment

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

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

Insecticides pest control biocides are considered persistent after skin application. The human health risk assessment for STILL HORSE is performed on the basis of the three intended method of application:

* spray application
* lotion application using external applicator bristle
* lotion application by using a synthetic sponge

The intended application dose in all cases is 25 mL per horse as proved in the most recent laboratory efficacy tests.

STILL HORSE is intended to be used by professionals and non-professionals. In general, human exposure during the application of insecticide products is restricted to the dermal route. However for spray applications, inhalation exposure is also possible resulting from respiring aerosols after spraying and therefore this route of exposure is also considered in the present assessment.

The estimation of exposure is based on the Technical Notes for Guidance (TNsG), Human Exposure to Biocidal Products (2002) as revised by User Guidance version 2 (April 2007), TGD and values from RIVM reports.

Following these guides, the total systemic dose is calculated with values of 100% for inhalation absorption, 100% for oral absorption and 5.1% for dermal absorption (Charles River Study (2021) No. 787961: The In Vitro Percutaneous Absorption of a Single Radiolabelled Permethrin in a Single Formulation Trough Human Skin Split-Thickness Skin).

Human exposure to permethrin via food is not considered to be relevant because STILL HORSE is not used for and/or during food production, or in rooms where food is produced, processed or stored. This is also the case for feeding stuffs. In addition, this product is not intended to be used in animals destined for food consumption.

##### List of scenarios

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Spraying application | According to the Annex I of the Guidance for Human Health Risk Assessment (2015), the model 2 of Hand-held trigger spray application method has been chosen as the most suitable model (HSL 2001: ACP-SC 1100- *Consumer exposure to non-agricultural pesticide products*) for the method of spray application. Hence, operator exposure has been evaluated by this model in the present dossier. No task of “mixing and loading” is taken in account because the product is a ready-to-use formulation. | Professional, non-professional |
| 2. | Direct lotion spreading by using external bristles | In relation to the application method based on direct spread by a ready-to-use Stick over the horse’s skin, there is no standard methodology available to evaluate the potentially human systemic exposure. The product is applied directly to the skin of horses with the help of external bristles which are present on the top of the package. No task of “mixing and loading” is taken in account because the product is a ready-to-use formulation. | Professional, Non-professional |
| 3. | Lotion application by using a synthetic sponge | As in the case before, there is no standard methodology to evaluate the systemic exposure of an operator who spread the lotion by a synthetic sponge over the horse’s head. However, the model of *Disinfecting surfaces by wiping through a mop, sponge or a wet clothes* for a ready for use products of Type 3 was considered as the most suitable model. Therefore according to BHHEM (ECHA, 2015) a model of wiping surfaces with a sponge has been used to assess the operator exposure. No task of “mixing and loading” is taken in account because the product is a ready-to-use formulation. | Professional, Non-professional |
| 4. | Direct contact with skin of treated horses | The secondary exposure for professional user can occur via dermal contact (hands, forearms and legs (during ride)) with horse’s skin. Oral exposure by the route "hand-to mouth” is also possible. | Professional  Non-professional  General-public (Adult or child) |

Please note that a secondary exposure scenario for a bystander is not necessary since an adult bystander will not be more exposed than the user. Therefore, scenarios for primary exposure already cover this risk.

For a child bystander, the following RMM is added: “Keep children and pets away during treatment”

##### Industrial exposure

*The product is not intended for industrial user. Therefore, no industrial exposure is foreseen.*

##### Professional exposure

Professional pest control operators are exposed to Permethrin during the use of STILL HORSE. Any potential risk to operators would only be related to dermal and inhalation routes of exposure.

###### Scenario [1] (Spray application - Primary exposure)

| **Description of Scenario 1 - Spray application - Primary exposure** | | |
| --- | --- | --- |
| The biocidal product “Still Horse” is intended to be used to treat horse by spraying application. It’s RTU containing 0.97% w/w of permethrin, the application rate validate by the efficacy expert is 25 mL of product per horse.  The treatment can be repeated after 4 days (96h) during the 3 months of the summer season (23 days/year).    According to the Annex I of the Guidance for Human Health Risk Assessment (2015), the model 2 of Hand-held trigger spray application method has been chosen as the most suitable model (HSL 2001: ACP-SC 1100- *Consumer exposure to non-agricultural pesticide products*) for the method of spray application. Hence, professional exposure has been evaluated by this model in the present dossier. No task of “mixing and loading” is taken in account because the product is a ready-to-use formulation.  Tier 1: Without PPE (minimal clothing)  Tier 2: gloves + coated coverall | | |
|  | Parameters | Value |
| Tier 1 | Active substance concentration | 0.97% |
| Inhalation rate | 1.25 m³/h |
| Body weight | 60 kg |
| Density of the product | 1.001 g/cm³ |
| Potential body exposure (75th) | 9.7 mg/min |
| Hand / forearm exposure (75th) | 36.1 mg/min |
| Inhalation exposure (75th, product concentration in air) | 10.5 mg/m³ |
| Time exposure | 360 min |
| Dermal absorption (Charles River Study (2021) No. 787961) | 5.1% |
| Following TNsG (2002), p245: application days that corresponds to the period of time that this product is intended to be used for the fly season (summer time) | 23 days |
| Tier 2 | PPE (gloves + coated coverall) | 10% penetration gloves  20% penetration coated coverall |

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

*[Please include any relevant calculations in Annex 3.2]*

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] | 1/no PPE (minimal clothing) | 0.013 | 0.136 | - | 0.148 |
| Scenario [1] | 2/PPE (gloves + coated coverall) | 0.013 | 0.0243 | - | 0.037 |
| Scenario [1] | 2.a/only one horse  PPE (gloves + coated coverall) | 0.001 | 0.002 | - | 0.003 |

*Scenario [2] (Direct lotion spreading by using external applicator bristles – primary exposure)*

| **Direct lotion spreading by using external bristles (primary exposure – reverse scenario 2)** |
| --- |
| The biocidal product “Still Horse” is intended to be used to treat horse by brushing application. It’s RTU containing 0.97% w/w of permethrin.  No need to rinse the bristles after application.  Professional may be exposed to volatilised residues from treated wood installed indoors. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance (permethrin), it might not be necessary to calculate the exposure to volatilised residues:  Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Permethrin (RMS IE, April 2014).  The result of this equation is lower than 1 for permethrin. The **exposure to volatilised residues indoor** can be considered **negligible** for professional for permethrin.  Taking into account the default value for dermal absorption of 5.1 %, to exceed this AEL medium term, the active substance contamination to the skin would need to exceed:  0.05 mg /kg bw / day / 0,051 = 0.98 mg a.s. /kg bw / day  If the user weighs 60 kg then active substance contamination would need to exceed:  0.98 mg /kg bw / day x 60kg = 58.8 mg a.s. /day  As the maximum concentration of active substance in the ready-for-use product is 0.97 % w/w, then the weight of product containing active substance will be  (58.8/0.97) x100 = 6061.86 mg  Taking into account the density of 0,999 g/cm³ of the product :  6.062 g / 0,999 g/cm³ gives 6.062 cm³ or approximately 6 ml of product that can come directly in contact with user’s skin (medium term).  Taking into account that the application rate validate by the efficacy expert is 25 mL of product per horse.  The user may apply the product on 0.24 ~~four horses~~ without PPE before to reach unacceptable risk, therefore the risk seems not acceptable :  6 ml / 25 ml = 0.24  The professional user will be wearing gloves and a coverall with a relative penetration of 10% (gloves) and 20% (coverall). We are assuming that dermal exposure will be predominantly to the hands and forearms. Therefore the user may apply the product on 1.2 horse before to reach unacceptable risk:  (6 ml / 25 ml) × 5 = 1.2 |

*Scenario [3] (Lotion application by using a synthetic sponge – primary exposure)*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario [3] – Lotion application by a synthetic sponge (Primary exposure)** | | |
| The biocidal product “Still Horse” is intended to be used to treat horse with a synthetic sponge impregned. It’s EW formulation ready-for-use product containing 0.97% w/w of permethrin, the application rate validate by the efficacy expert is 25 mL of product per horse.  No need to rinse the sponge after application.  The treatment can be repeated after 4 days (96h) during the 3 months of the summer season (23 days/year).  According to the Biocides Human Health Exposure Methodology, *professional operator diluting and mixing disinfectant and wiping surfaces using a cloth. Surface disinfection model 1 and model 3 TnsG 2002 User guidance – version 1 p 28.*  The following tiered approach has been considered for pest control operator:  Tier 1: the initial assessment, it is assumed that no protective equipment is used (minimal clothing) during 360 minutes  Tier 2: the second assessment, it is assumed that no protective equipment is used (minimal clothing) during 150 minutes  Tier 3: the third assessment, it is assumed that no protective equipment is used (minimal clothing) during 90 minutes  Tier 4: the fourth assessment where gloves as PPE + coated coverall and the longest exposure time (90 min) are considered  Tier 4: the fifth assessment where gloves as PPE + coated coverall and the longest exposure time (150 min) are considered | | |
|  | Parameters | Value |
| Tier 1 | Active substance concentration | 0.97% |
| Inhalation rate | 1.25 m3/h |
| Body weight | 60 kg |
| Density of the product | 1.001 g/cm3 |
| Potential body exposure (75th) | 87.6 mg/min |
| Potential hand exposure (75th) | 1030 mg/min |
| Inhalation exposure (75th, product concentration in air) | 22.9 mg/m³ |
| Minimal clothing (No PPE) | 50% |
| Application days per year\* | 23 days |
| Dermal absorption (Charles River Study (2021) No. 787961) | 5.1% |
| Time exposure | 360 min |
| Tier 2 | Time exposure | 150 min |
| Tier 3 | Time exposure | 90 min |
| Tier 4 | Time exposure | 90 min |
| PPE (gloves + coated coverall) | 10.3 mg/min penetration gloves  20% (coverall) |
| Tier 5 | Time exposure | 150 min |
| PPE (gloves + coated coverall) | 10.3 mg/min penetration gloves  20% (coated coverall) |

\* Following TNsG (2002), p245: application days that corresponds to the period of time that this product is intended to be used for the fly season (summer time)

***Calculations for Scenario [3]***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3] | 1/no PPE (minimal clothing)-360 minutes | 0.028 | 3.187 | - | 3.2 |
| Scenario [3] | 2/no PPE (minimal clothing)-150 minutes | 0.0116 | 1.328 | - | 1.339 |
| Scenario [3] | 3/no PPE (minimal clothing)- 90 minutes | 0.0069 | 0.797 | - | 0.803 |
| Scenario [3] | 4/PPE (gloves)-360 minutes | 0.028 | 0.161 | - | 0.188 |
| Scenario [3] | 5/PPE (gloves + coated coverall)-360 minutes | 0.028 | 0.083 | - | 0.110 |
| Scenario [3] | 4/ PPE (gloves + coated coverall)-90 minutes | 0.0069 | 0.021 | - | 0.028 |
| Scenario [3] | 5/ PPE (gloves + coated coverall)-150 minutes | 0.011 | 0.034 | - | 0.046 |

*Scenario [4] Secondary exposure of adult users by direct contact with skin of treated horses-Tier1*

| Description of Scenario 4: Secondary exposure of professional users by direct contact with skin of treated horses | | | |
| --- | --- | --- | --- |
| The secondary exposure for professional users can occur via dermal contact with horse’s skin.  Human’s arms and forearms have been taken into account; the rest of the body is usually covered with riding clothes.  For this exposure, no PPE are taken into account. | | | |
|  | **Parameters** | **Value** | **Source** |
| Tier 1 | Weight of horse | 250 kg | Lower body weight autorised for treatment according to the following RMM: |
| Skin surface of a horse | 39809cm² | 0,11\* Weight0.65,  *Wildlife Exposure Factors Handbook, Volume I, 3.4.2. Mammals*  0.11 \* 4000.65= 0.11 \* 36.1960 |
| Dislodgeable factor | 30% | Default |
| Rubbing surface (hands + forearms) | 1948.8 cm² | Recommendation 14 |
| Fingers surface | 410 cm² | 50% of hands surface |
| Factor for oral intake by hand-mouth transfer | 21% | *% of fingers surface compared to the total surface (hands + forearms)*  410\*100 /1948.8 |
| Oral absorption | 100% | Default |
| Dermal absorption | 5.1% | Study value |

**Calculations for scenario 4**

**Amount of a.s./cm² on horse (A.S.):**

|  |
| --- |
| Amount bp used (25 000 mg) × % active substance (0.97%) |
| Horse surface (39809 cm²) |

**External dermal amount of a.s. on human:**

Rubbing surface (1948.8 cm²) × Amount of a.s. on the horse (0.0061 mg/cm²) × dislodgeable factor (30%)

**Oral systemic exposure via hand-mouth transfer is:**

|  |
| --- |
| External dermal amount of a.s. (3.56 mg) × Factor for oral intake (21%) × oral absorption (100%) |
| Body weight (60kg) |

**Estimated dermal uptake:**

|  |
| --- |
| External dermal amount of a.s (3.56 mg) × (100% - Factor for oral intake) × Dermal absorption (5.1%) |
| Body weight (60kg) |

| **Summary table: estimated exposure from professional users** | | | | |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake**  **mg/kg bw/d** | **Estimated oral uptake (hand to mouth transfer)**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** |
| Scenario 4.b – professional | 1/no PPE | / | 0.0024 | 0.01246 | 0.015 |

###### Combined scenarios

*Scenarios 1, 2 and 3 are independent*

The product cannot be used in all 3 applications (spray, bristle and sponge) modes simultaneously. Please use only one application mode at a time.

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined/tiers** | **Estimated inhalation uptake**  **mg/kg bw/d** | **Estimated dermal uptake**  **mg/kg bw/d** | **Estimated oral uptake**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** |
| Scenario [1/1 + 4/1] | 0,0154 | 0,136 | 0,01246 | 0,16386 |
| Scenario [1/2 + 4/1] | 0,0154 | 0,037 | 0,01246 | 0,06486 |
| Scenario [1/2a + 4/1] | 0,0034 | 0,003 | 0,0092 | 0,0156 |
| Scenario [3/1 + 4/1] | 0,0304 | 3,187 | 0,0092 | 3,2266 |
| Scenario [3/2 + 4/1] | 0,014 | 1,328 | 0,0092 | 1,3512 |
| Scenario [3/3 + 4/1] | 0,0093 | 0,797 | 0,0092 | 0,8155 |
| Scenario [3/4 + 4/1] | 0,0093 | 0,021 | 0,0092 | 0,0395 |
| Scenario [3/5 + 4/1] | 0,0134 | 0,034 | 0,0092 | 0,0566 |

##### Non-professional exposure

Non-professional users are expected to use the biocidal product only intermittently for a few events per year. Therefore, comparison of exposure to limits for chronic exposure could be considered overestimation however, in order to assess the worst case.

The same tasks as for professional operator have been considered for non-professional user. Therefore, exposure to the product during manual spreading task using a synthetic sponge is also considered for dermal and inhalation routes.

###### Scenario [1] (Spray application - Primary exposure)

| **Description of Scenario 1 - Spray application - Primary exposure** | | |
| --- | --- | --- |
| The biocidal product “Still Horse” is intended to be used to treat horse by spraying application. It’s RTU containing 0.97% w/w of permethrin, the application rate validate by the efficacy expert is 25 mL of product per horse.  The product has a duration of action between 1 to 3 days therefore. The treatment can be repeated after 4 days during the 3 months of the summer season (23 days/year).  According to the Annex I of the Guidance for Human Health Risk Assessment (2015), the model 2 of Hand-held trigger spray application method has been chosen as the most suitable model (HSL 2001: ACP-SC 1100- Consumer exposure to non-agricultural pesticide products) for the method of spray application. Hence, professional exposure has been evaluated by this model in the present dossier. No task of “mixing and loading” is taken in account because the product is a ready-to-use formulation.  Tier 1: the initial assessment, it is assumed that no protective equipment is used (minimal clothing, 50% penetration) during 90 minutes. According to HEAdhoc Recommendation No. 8 “a protection factor of 50 % for non-professional users can be assumed for one layer of clothing against dry contamination or light liquid contamination. The following RMM will be added in the instruction of use  “Wear long-sleeved shirt, long trousers and shoes during spray application”.  Tier 2: the user treat 1 horse per day, 30 min/day | | |
|  | Parameters | Value |
| Tier 1 | Active substance concentration | 0.97% |
| Inhalation rate | 1.25 m³/h |
| Body weight | 60 kg |
| Density of the product | 1.001 g/cm³ |
| Potential body exposure (75th) | 9.7 mg/min |
| Hand exposure (75th) | 36.1 mg/min |
| Inhalation exposure | 10.5 mg/m³ |
| Time exposure | 90 min (if you take into account that 30 min/horse, 3 horses per day) |
| Dermal absorption | 5.1% |
| Following TNsG (2002), p245: application days that corresponds to the period of time that this product is intended to be used for the fly season (summer time) | 23 days |
| Protection factor (long-sleeved shirt, long trousers and shoes) | 50 % |
| Tier 2 | Time exposure | 30 min/horse |

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/Protection factor (PF)** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] | 1/no PPE (minimal clothing)-90 minutes | 0.0032 | 0.030 | - | 0.0346 |
| Scenario [1] | 2/no PPE (minimal clothing)-30 minutes | 0.0011 | 0.0101 | - | 0.011 |

*Scenario [2] (Direct lotion spreading by using external applicator bristles – primary exposure)*

| **Direct lotion spreading by using external bristles (primary exposure – reverse scenario 2)** |
| --- |
| The biocidal product “Still Horse” is intended to be used to treat horse by brushing application. It’s RTU containing 0.97% w/w of permethrin.  No need to rinse the bristles after application.  Professional may be exposed to volatilised residues from treated wood installed indoors. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance (permethrin), it might not be necessary to calculate the exposure to volatilised residues:  Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Permethrin (RMS IE, April 2014).  The result of this equation is lower than 1 for permethrin. The **exposure to volatilised residues indoor** can be considered **negligible** for professional for permethrin.  Taking into account the default value for dermal absorption of 5.1 %, to exceed this AEL short term, the active substance contamination to the skin would need to exceed:  0.05 mg /kg bw / day / 0,051 = 0.98 mg a.s. /kg bw / day  If the user weighs 60 kg then active substance contamination would need to exceed:  0.98 mg /kg bw / day x 60kg = 58.8 mg a.s. /day  As the maximum concentration of active substance in the ready-for-use product is 0.97 % w/w, then the weight of product containing active substance will be  (58.8/0.97) x100 = 6061.85 mg  Taking into account the density of 0,999 g/cm³ of the product :  6.0618 g / 0,999 g/cm³ gives 6.0618 cm³ or approximately 6.0618 ml of product that can come directly in contact with user’s skin (short term).  Taking into account that the application rate validate by the efficacy expert is 25 mL of product per horse.  The user may apply the product on 0.242 horses without PPE, therefore the risk seems not acceptable:  6.0618 ml / 25 ml = 0.242 |

*Scenario [3] Lotion application by using a synthetic sponge - primary exposure*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario [3] – Lotion application by a synthetic sponge (Primary exposure)** | | |
| The biocidal product “Still Horse” is intended to be used to treat horse with a synthetic sponge impregned. It’s RTU product containing 0.97% w/w of permethrin, the application rate validate by the efficacy expert is 25 mL of product per horse.  No need to rinse the sponge after application.  The treatment can be repeated after 4 days (96h) during the 3 months of the summer season (23 days/year).  According to the Biocides Human Health Exposure Methodology, *professional operator diluting and mixing disinfectant and wiping surfaces using a cloth. Surface disinfection model 1 and model 3 TnsG 2002 User guidance - version 1 p 28.*  As in the case of application, one tier has been considered for pest control operator:  Tier 1: the initial assessment, it is assumed that no protective equipment is used (minimal clothing, 50% penetration) during 90 minutes.  Tier 2: the user treat 1 horse per day, 30 min/day | | |
|  | Parameters | Value |
| Tier 1 | Active substance concentration | 0.97% |
| Inhalation rate | 1.25 m3/h |
| Body weight | 60 kg |
| Density of the product | 1.001 g/cm3 |
| Potential body exposure (75th) | 87.6 mg/min |
| Potential hand exposure (75th) | 1030 mg/min |
| Inhalation exposure (75th, product concentration in air) | 22.9 mg/m³ |
| Time exposure | 90 min (if you take into account that 30 min/horse, 3 horses per day) |
| Following TNsG (2002), p245: application days that corresponds to the period of time that this product is intended to be used for the fly season (summer time) | 23 days |
| Minimal clothing (No PPE) | 50% |
| Dermal absorption (value from study) | 5.1% |
| Tier 2 | Time exposure | 30 min |

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3] | 1/no PPE (minimal clothing)-90 minutes | 0.0069 | 0.797 | - | 0.80 |
| Scenario [3] | 2/no PPE (minimal clothing)-30 minutes | 0.0023 | 0.266 | - | 0.268 |

*Scenario [4] Secondary exposure of adult users by direct contact with skin of treated horses*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [4]: Secondary exposure of non-professional users by direct contact with skin of treated horses** | | | |
| The secondary exposure for non-professional users can occur via dermal contact with pony’s skin and via oral because of the transference hand to mouth, during preparation for, riding and riding step  Human’s hands, forearms and legs (as worse case) have been taken into account during riding step  For this exposure, no PPE are taken into account. | | | |
|  | **Parameters** | **Value** | **Source** |
| Tier I |  | Default | Applicant |
|  | Animal weight | 250 kg | Lower body weight autorised for treatment according to the following RMM:  “Do not treat horses below 250kg” |
| Weight adult | 60 kg | BPR Biocides Human Health Exposure Methodology. Default values for body weight & body part surface areas for the infant, toddler, child & adult (US EPA Exposure Factors Handbook 2011) |
| Skin surface of a horse | 39809cm² | 0,11\* Weight0.65,  *Wildlife Exposure Factors Handbook, Volume I, 3.4.2. Mammals*  0.11 \* 4000.65= 0.11 \* 36.1960 |
| Dislodgeable factor | 30% | Default |
| Rubbing surface (hands + forearms + legs) | 3725.46 cm² | HEEG Recommendation no. 14  Regarding legs the assumption is that the general public could come into contact with the product when wearing shorts (mounted raw) we can consider that 1/3 of the thigh and legs (anterior part) will be exposed. |
| Fingers surface | 410 cm² | 50% of hands surface |
| Factor for oral intake by hand-mouth transfer | 11% | % of fingers surface compared to the total surface (hands + forearms+ legs)  (%= 410×100 /3725.46) |

**Calculations for scenario 4**

**Amount of a.s./cm² on horse (A.S.):**

|  |
| --- |
| Amount bp used (25 000 mg) × % active substance (0.97%) |
| Horse surface (39809 cm²) |

**External dermal amount of a.s. on human:**

Rubbing surface (3725.46 cm²) × Amount of a.s. on the horse (0.0061 mg/cm²) × dislodgeable factor (30%)

**Oral systemic exposure via hand-mouth transfer is:**

|  |
| --- |
| External dermal amount of a.s. ( 6.82 mg) × Factor for oral intake (11%) × oral absorption (100%) |
| Body weight (60kg) |

**Estimated dermal uptake:**

|  |
| --- |
| External dermal amount of a.s (6.82 mg) × (100% - Factor for oral intake) × Dermal absorption (5.1%) |
| Body weight (60kg) |

| **Summary table: estimated exposure from non-professional users** | | | | |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake**  **mg/kg bw/d** | **Estimated oral uptake (hand to mouth transfer)**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** |
| Scenario 4.b – non-professional | 1/no PPE | / | 0.0052 | 0.0125 | 0.014 |

###### Combined scenarios

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined/tiers** | **Estimated inhalation uptake**  **mg/kg bw/d** | **Estimated dermal uptake**  **mg/kg bw/d** | **Estimated oral uptake**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** |
| Scenario [1/1 + 4/1] | 0,0084 | 0,03 | 0,0125 | 0,0509 |
| Scenario [1/2 + 4/1] | 0,0063 | 0,0101 | 0,0125 | 0,0289 |
| Scenario [3/1 + 4/1] | 0,0121 | 0,797 | 0,0125 | 0,8216 |
| Scenario [3/2 + 4/1] | 0,0075 | 0,266 | 0,0125 | 0,286 |

##### Exposure of the general public

The degree of indirect exposure as a result of use of the active substance in this biocidal product is considered negligible, as the primary route of exposure is direct application to the horses’ skin. However, worse case secondary exposure scenarios have been considered for a child.

*Scenario [5] Secondary exposure of general public by direct contact with skin of treated ponies following application of the product (child)*

After product application, a rider (child) can take contact with the treated skin and therefore, this potential exposure should be estimated.

| **Description of Scenario 5: Secondary exposure general public (child) by direct contact with skin of treated ponies** | | | |
| --- | --- | --- | --- |
| The secondary exposure for general public can occur via dermal contact with pony’s skin and via oral because of the transference hand to mouth, during preparation for riding and riding  Human’s hands, forearms and legs (as worse case) have been taken into account during riding step  For this exposure, no PPE are taken into account. | | | |
|  | **Parameters** | **Value** | **Source** |
| Tier 1 | Weight of horse | 250 kg | Lower body weight autorised for treatment according to the following RMM:  “Do not treat horses below 250kg” |
| Weight child | 23.9kg | BPR Biocides Human Health Exposure Methodology. Default values for body weight & body part surface areas for the infant, toddler, child & adult (US EPA Exposure Factors Handbook 2011) |
| Skin surface of a horse | 39809cm² | 0,11\* Weight0.65,  *Wildlife Exposure Factors Handbook, Volume I, 3.4.2. Mammals*  0.11 \* 4000.65= 0.11 \* 36.1960 |
| Dislodgeable factor | 30% | Default |
| Rubbing surface (hands + forearms + legs) | 1838.47 cm² | HEEG Recommendation no. 14  Regarding legs the assumption is that the general public could come into contact with the product when wearing shorts (mounted raw) we can consider that 1/3 of the thigh and legs (anterior part) will be exposed. |
| Fingers surface | 213.9 cm² | 50% of hands surface |
| Factor for oral intake by hand-mouth transfer | 11.6% | *% of fingers surface compared to the total surface*  213.9\*100 /1837.47 |
| Oral absorption | 100% | Default |
| Dermal absorption | 5.1% | Study value |

**Calculations for scenarios 5**

**Amount of a.s./cm² on horse (A.S.):**

|  |
| --- |
| Amount bp used (25 000 mg) × % active substance (0.97%) |
| Horse surface (39809 cm²) |

**External dermal amount of a.s. on human:**

Rubbing surface (1838.47 cm²) × Amount of a.s. on the horse (0.0061 mg/cm²) × dislodgeable factor (30%)

**Oral systemic exposure via hand-mouth transfer is:**

|  |
| --- |
| External dermal amount of a.s. (3.3644 mg) × Factor for oral intake (11.64%) × oral absorption (100%) |
| Body weight (23.9kg) |

**Estimated dermal uptake:**

|  |
| --- |
| External dermal amount of a.s (3.3644 mg) × (100% - Factor for oral intake) × Dermal absorption (5.1%) |
| Body weight (23.9 kg) |

| **Summary table: estimated exposure from General public** | | | | |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake**  **mg/kg bw/d** | **Estimated oral uptake (hand to mouth transfer)**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** |
| Scenario 5 – General public | 1/no PPE | / | 0.0063 | 0.016 | 0.0223 |

##### Monitoring data

Not relevant.

##### Dietary exposure

Human exposure to Permethrin via food is not considered to be relevant because STILL HORSE is not used for and/or during food production, or in rooms where food is produced, processed or stored. This is also the case for feeding stuffs. In addition, the product is not intended to be used in horses that are destined for food consumption.

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

Permethrin

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection product (PPP) | Permethrnin is not approuved.  (2000/817/EC) | MRL : 0.05 – 0.5 mg/kg1  MRL range of different crops and products of animal origin |
| 2. | veterinary medicinal product | Antiparasitic agents/Agents against ectoparasites | MRL : 50 - 500 μg/kg2  MRL for food producing species (Bovine) |

1 Reg. (EU) 2017/623 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products.

2 Reg. (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

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

Occupational exposure during production and formulation of biocidal product is not covered by the BPR. It is expected that production and formulation are performed in conformity with European and national worker protection legislation.

##### Aggregated exposure

Not relevant.

##### Summary of exposure assessment

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| 1 | Professionals | 1/no PPE (minimal clothing) | 0,148 |
| 2/PPE (gloves + coated coverall) | 0,037 |
| 2.a/only one horse  PPE (gloves + coated coverall) | 0,003 |
| Non-professionals | 1/no PPE (minimal clothing)-90 minutes | 0,034 |
| 1/no PPE (minimal clothing)-30 minutes | 0,011 |
| 3 | Professionals | 1/no PPE (minimal clothing)-360 minutes | 3.2 |
| 2/no PPE (minimal clothing)-150 minutes | 1.359 |
| 3/no PPE (minimal clothing)- 90 minutes | 0.803 |
| 4/PPE (gloves + coated coverall)-90 minutes | 0.028 |
| 5/PPE (gloves + coated coverall)-150 minutes | 0.046 |
| Non-professionals | 1/no PPE (minimal clothing)-90 minutes | 0.8 |
| 2/no PPE (minimal clothing)-30 minutes | 0.268 |
| 4 | Professionals | 1/no PPE | 0.01246 |
| Non-professionals | 1/no PPE | 0.014 |
| 5 | General public (child) | 1/no PPE | 0.0223 |

#### Risk characterisation for human health

##### Reference values to be used in Risk Characterisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Value** |
| AELshort-term | Rat 2 year oral study (acute effect) BAYER/SUMITOMO | 59.43 mg/kg bw/day | 100 | 0.5 mg/kg bw/day |
| AELmedium-term | 12-month dog study.  BAYER/SUMITOMO | 7.9 mg/kg bw/ day | 100 | 0.05 mg/kg bw/day |
| AELlong-term | 12-month dog study.  BAYER/SUMITOMO | 5 mg/kg bw/day | 100 | 0.05 mg/kg bw/day |
| ARfD(\*) |  |  |  | 0.5 mg/kg bw/day |
| ADI(\*) |  |  |  | 0.05 mg/kg bw/day |

##### Risk for professional users

###### Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **1.spray** | 1/no PPE (minimal clothing) | 5.00 | 0.05 | 0,148 | 296 | np |
| 2/PPE (gloves + coated coverall) | 0,037 | 74 | yes |
| 2.a/only one horse  PPE (gloves + coated coverall) | 0,003 | 6.0 | yes |
| **3.sponge** | 1/no PPE (minimal clothing)-360 minutes | 5.00 | 0.05 | 3,2 | 640 | no |
| 2/no PPE (minimal clothing)-150 minutes | 1,339 | 2678 | no |
| 3/no PPE (minimal clothing)- 90 minutes | 0,803 | 960.6 | no |
| 4/PPE (gloves + coated coverall)-90 minutes | 0,028 | 56 | yes |
| 5/PPE (gloves + coated coverall)-150 minutes | 0,046 | 92 | yes |
| **4.direct contact** | 1/no PPE | 5.00 | 0.05 | 0.01246 | 24.92 | yes |

**Combined scenarios**

*Scenarios 1, 2 and 3 are independent*

The product cannot be used in all 3 applications (spray, bristle and sponge) modes simultaneously. Please use only one application mode at a time.

| **Summary table: combined systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined/tiers** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [1/1 + 4/1] | 5.00 | 0.05 | 0,16386 | 327.72 | no |
| Scenario [1/2 + 4/1] | 5.00 | 0.05 | 0,06486 | 129.72 | yes |
| Scenario [1/2a + 4/1] | 5.00 | 0.05 | 0,0156 | 31.2 | yes |
| Scenario [3/1 + 4/1] | 5.00 | 0.05 | 3,2266 | 6452 | no |
| Scenario [3/2 + 4/1] | 5.00 | 0.05 | 1,3512 | 6440 | no |
| Scenario [3/3 + 4/1] | 5.00 | 0.05 | 0,8155 | 1631 | no |
| Scenario [3/4 + 4/1] | 5.00 | 0.05 | 0,0395 | 79 | yes |
| Scenario [3/5 + 4/1] | 5.00 | 0.05 | 0,0566 | 113.2 | no |

###### Local effects

n.r.

###### Conclusion

Primary exposure:

The spraying application has an acceptable risk if performed the whole day (360 min) with gloves and coated coverall clothes (the following RMM should be added).

The application with bristles has an acceptable risk for one worker which treat theoretically 3 horses per day taking into account the wearing of PPE (gloves and coated coverall).

The sponge application has an acceptable risk taking into account the wearing of personal protective equipment gloves and coated coverall during an application phase not exceeding 150 min/d (5 horses per day)

Primary + secondary exposure:

- Regarding spraying application, the user can:

* + Treat horses during 360 minutes/day which is equivalent to 12 horses/day (witht PPE: gloves and coated coverall) or ride 4 horses/day
  + Or treat and ride only 3 horses.

- Regarding sponge application, the user can:

* + Treat horses during 150 minutes/day and ride which is equivalent to 5 horses/day (gloves and coated coverall) or ride 4 horses/day
  + Or treat and ride 3 horses/day

- Regarding application with bristles application taking into account that the assessment is limited to reverse scenario for application step it is not possible to make a combined exposure taking into account of secondary exposure of adult users by direct contact with skin of treated horses. Therefore it not possible to assess the combined exposure, the conservative measure to want this type of use not to be allowed.

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

##### Risk for non-professional users

###### Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **1.spray** | 1/no PPE (minimal clothing)-90 minutes | 5.00 | 0.05 | 0.034 | 68 | yes |
| 1/no PPE (minimal clothing)-30 minutes | 0.011 | 22 | yes |
| **3.sponge** | 1/no PPE (minimal clothing)-90 minutes | 5.00 | 0.05 | 0.8 | 1600 | no |
| 2/no PPE (minimal clothing)-30 minutes | 0.2658 | 531.6 | no |
| **4.direct contact** | 1/ no PPE | 5.00 | 0.05 | 0.014 | 28.00 | yes |

**Combined scenarios**

*Scenarios 1, 2 and 3 are independent*

| **Summary table: combined systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined/tiers** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated total uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [1/1 + 4/1] | 5.00 | 0.05 | 0,0509 | 101.8 | no |
| Scenario [1/2 + 4/1] | 5.00 | 0.05 | 0,0289 | 57.8 | yes |
| Scenario [3/1 + 4/1] | 5.00 | 0.05 | 0,8216 | 1642 | no |
| Scenario [3/2 + 4/1] | 5.00 | 0.05 | 0,286 | 572 | no |

###### Local effects

n.r.

###### Conclusion

Primary exposure:

The spraying application has an acceptable risk even if performed during 90 min/d (3 horse/d) without PPE and minimal clothes.

The application with bristles has not acceptable risk for non-professional user.

The sponge application has not acceptable for non-professional user.

For the application step the generic RMM should be mentioned on the label has following:

“Wear long-sleeved shirt, long trousers and shoes during application”.

Primary + secondary exposure:

- Regarding spraying application, the user can:

* + Treat horses during 90 minutes/day which is equivalent to 3 horses/day or ride 3 horses.
  + Or only treat and ride 1 horse/day

For the application step the generic RMM should be mentioned on the label has following:

* + Wear long-sleeved shirt, long trousers and shoes during application.

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

- The application with bristles has not acceptable risk for non-professional user.

- The sponge application has not acceptable for non-professional user.

##### Risk for the general public

###### Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **5. riders (child-pony)** secondary exposure | 1/no PPE (minimal clothing) | 59.43 | 0.05 | 0.017 | 34 | yes |

**Combined scenarios**

*Not relevant*

###### Local effects

n.r.

###### Conclusion

There is an acceptable risk during ride for children at least 6 years old according to the following RMM:

- The general public (adult, children > 6y) can groom/clean and ride only 1 treated horse/day.

##### Risk for consumers via residues in food

Human exposure to Permethrin via food is not considered to be relevant because STILL HORSE is not used for and/or during food production, or in rooms where food is produced, processed or stored. This is also the case for feeding stuffs. In addition, the product is not intended to be used in horses that are destined for food consumption.

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

No substances of concern

##### Overall conclusion

Since both professional and non-professional users can sometimes ride horses, the combined primary and secondary exposure have to be considered to conclude.

###### Acceptable risks for professional users are:

- Regarding spraying application, the user can:

* + Treat horses during 360 minutes/day which is equivalent to 12 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
  + Or only treat and ride 3 horses/day

- Regarding sponge application, the user can:

* + Treat horses during 150 minutes/day which is equivalent to 5 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
  + Or only treat and ride 3 horses/day

- Regarding application with bristles application taking into account that the assessment is limited to reverse scenario for application step it is not possible to make a combined exposure taking into account of secondary exposure of adult users by direct contact with skin of treated horses. Therefore it not possible to assess the combined exposure, the conservative measure to want this type of use not to be allowed.

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

###### Acceptable risks for non-professional users are:

- Regarding spraying application, the user can:

* + Treat horses during 90 minutes/day which is equivalent to 3 horses/day or ride 3 horses/day.
  + Or only treat and ride 1 horse/day

The following risk mitigation measure should be applied:

* + Wear long trousers and shoes during grooming/cleaning and riding.
  + Wear long-sleeved shirt, long trousers and shoes during application.
  + Do not treat horses below 250kg

- The application with bristles has not acceptable risk for non-professional user.

- The sponge application has not acceptable for non-professional user.

For the application step the generic RMM should be mentioned on the label has following:

* + Wear long-sleeved shirt, long trousers and shoes during application

General risk mitigation measure to protect riders:

* Do not treat horses below 250kg
* Wear long trousers and shoes during grooming/cleaning and riding.

###### Acceptable risks for general public (secondary exposure) are:

There is an acceptable risk during ride for children at least 6 years old according to the following RMM:

- The general public (adult, children > 6y) can groom/clean and ride only 1 treated horse/day.

### Risk assessment for animal health

* + - 1. *Exposure assessment*

HORSE Exposure

Still horse is intended to be applied on horses. Since the product is formulated as a ready-for-use product, no dilution or other preparation is necessary.

**Identification of main paths of horse exposure towards active substance from its use in biocidal product**

| **Summary table: relevant paths of horse exposure** | | |
| --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | **Secondary (indirect) exposure** |
| Inhalation | Yes (during spraying only) | No |
| Dermal | Yes | Yes but negligible |
| Oral | No | Yes (grooming a treated horse or itself) |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Application on horse | Primary exposure, dermal  The product is spread on the exposed area of horse skin. | horses |
| 2. | Application on horse | Primary exposure, inhalation  Inhalation exposure during spraying. | Horses |
| 3. | Grooming | Secondary exposure, oral  During fur care or social interaction, the horse can dislodge the product and ingest it. | Horses |

*Scenario [1] Application on horse*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| The exposure by dermal route can be calculated according to the following equations:  ED External dose (mg/kg b.w./day)  ARp Average dose of product applied on skin (mg)  C Average concentration of substance in product (%)  BW Body weight (kg)  ARp, C and absorption remain the same but weight vary according to the horse profile.  As a worst case, a small weight is chosen (corresponding to a poney or a young horse): 100 kg.  No protection factor is taken into account. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Average dose of product applied on skin | 25 ml per horse = 25000 mg  (Relative density: 0.999) | Efficacy/applicant data |
| Average concentration of substance in product | 0.97% w/w | Applicant data |
| Body weight (kg) | 100 | Worst case |

**Calculations for Scenario [1]**

= 2.42 mg/ kg bw/ day

**Further information and considerations on scenario**

None.

*Scenario [2] Primary exposure, inhalation exposure during spraying*

| **Description of Scenario [2]** |
| --- |
| During spraying the horse is exposed to the product.  ID Internal dose (mg/kg b.w./day)  Pc Product concentration in the air (mg/m³)  C Average concentration of substance in product (%)  V Ventilation rate (m³/h)  d Application duration (h)  Ai Inhalation absorption (%)  BW Body weight (kg)   |  |  |  | | --- | --- | --- | |  | Value | Source | | Inhalation exposure (75th, product concentration in air) | 10,5 mg/m³ | Model 2 Hand-held trigger spray (indicative inhalation exposure) | | Average concentration of substance in product | 0,97% | Applicant data | | Ventilation rate  Horse 400 kg | 1773 L /h = 1,773 m³/h | Default value\* | | Application duration | 0,5 h | Applicant data | | Inhalation absorption | 100% | Default value | | Body weight | 400 kg | Default value\* |   \*In this scenario, since the ventilation rate is related to the body weight, a small horse/poney will not be the worst case and will have a similar internal dose/kg than a normal horse. Therefore, default values (from the Guidance on the BPR) are taken into account. |
| **Calculations for Scenario [2]**  = 0,000226 mg/ kg bw/ day |

*Scenario [3] Secondary exposure, grooming*

| **Description of Scenario [3]** |
| --- |
| During fur care or social interactions, the horse can dislodge the product and ingest it.  ID Internal dose (mg/kg b.w./day)  ARp Average dose of product applied on skin (mg)  C Average concentration of substance in product (%)  Sl Licked surface by the horse (on another horse or on himself)  D Dislodgeable amount  Ao Oral absorption  St Total surface of the horse  BW Body weight (kg)   |  |  |  | | --- | --- | --- | |  | Value | Source | | Average dose of product applied on skin | 25 000 mg | Applicant data | | Average concentration of substance in product | 0,97 % | Applicant data | | Licked surface | 20 cm\* 20 cm = 400 cm² | Expert judgment | | Dislodgeable amount | 50 % | Expert judgment | | Oral absorption | 100% | Default value | | Body weight | 100 kg | Worst case | | Total body surface | 21947 cm² | 0,11\* Weight0.65 according to *Wildlife Exposure Factors Handbook, Volume I, 3.4.2. Mammals*. | |
| **Calculations for Scenario [3]**  = 0.022 mg/ kg bw/ day |

* + - 1. *Risk characterisation for horse*

Reference values to be used in Risk Characterisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Value** |
| AELshort-term | Rat 2 year oral study (acute effect) BAYER/SUMITOMO | 59.43 mg/kg bw/day | 100 | 0.5 mg/kg bw/day |
| AELmedium-term | 12-month dog study.  BAYER/SUMITOMO | 7.9 mg/kg bw/ day | 100 | 0.05 mg/kg bw/day |
| AELshort-term  dermal | Rats, 90 days, dermal  BAYER/SUMITOMO | 1000 mg/kg bw/ day | 100 | 10 mg/kg bw/day |

*Systemic effects*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **AEL**  **mg/kg bw/d** | **Justification for AEL** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 1 | Short-term  10 | Dermal application  23 days / summer | 2,42 | 24,2% | Yes |
| Scenario 2 | Short-term 0.5 | Inhalation during spraying 23 days / summer | 0,000226 | 0,045% | Yes |
| Scenario 3 | Medium-term 0.05 | Oral contact with fur of another treated horse  All summer (90 days) | 0,022 | 44% | yes |

*Combined exposure*

As a worst case, we consider that a horse is concerned by all scenario.

**Risk characterisation : 24,2 + 0,045 + 44 = 68,245 %**

* + - * Risk is acceptable

**Conclusion:**

According to the risk assessment, acceptable risk for horses.

### Risk assessment for the environment

#### Effects assessment on the environment

All data used for the effect assessment of STILL HORSE is based on the available information on the active substance Permethrin, such as it is presented in its respective CAR.

No new data relevant for the environmental evaluation, nor on the product, nor on the active substance, have been submitted. Apart from the active substance, the product does not contain any formulants that are of ecotoxicological concern.

An overview of the environmental fate and behaviour for the active substance, taken from the EU CAR, is presented in the first two titles below.

**As a kind reminder: this dossier was submitted in April 2016. Only the guidelines/data which were applicable at that time were taken into account for the evaluation of this dossier.**

##### Environmental fate and behavior of the active substance

* **Permethrin**

**Aquatic compartment including STP and sediment**

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT50 values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)).

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT50 values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days).

The degradation scheme proposed for the behaviour of permethrin in aerobic watersediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively).

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT50 values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days). Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT50 values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT50 value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season.

**Atmosphere**

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3 mol-1). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. Permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

**Terrestrial compartment**

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT50s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106d. The *cis* isomer degraded more slowly than the *trans* isomer based on the *cis:trans* ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12oC of permethrin samples containing a cis:trans ratio of 25:75.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO DT50 12°C 33.1-~175 d) and PBA (max 15.0 % AR, 1.7-2.5 d at 12°C), and ultimately converts to CO2.

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT50 of 200 d was estimated. No transformation product greater than 10 %AR was observed.

Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was 141.2 L/kg.

**Metabolites**

As described in the CAR, the metabolites of Permethrin are considered to be transient or less persistent than their parent, and are less toxic. In the CAR, the risk quotients are more favorable for the metabolites than for the active substance for both the aquatic and terrestrial environment and therefore the metabolites are not considered further in the risks assessment.

Therefore, the environmental risk assessment for metabolites is considered to be covered by the risk assessment for the parent, and emissions and PEC values were calculated for permethrin only.

##### Effect assessment of the active substance

All the data refer to the chapter Effects assessment are from Doc IIA as well as from Doc IIB for the active substance Permethrin.

The PNEC values used in the risk assessment are the following:

|  |  |
| --- | --- |
| **Summary of PNEC values for the active substance** | |
| **Compartment** | **PNEC value** |
| PNECaquatic | 4.7E-07 mg/l |
| PNECsediment | 2.17E-04 mg/kg wwt |
| PNECmicro-organisms (STP) | 4.95E-03 mg/l |
| PNECsoil | 8.76E-02 mg/kg wwt\* |
| PNECoral (birds) | 1.67E+01 mg/kg food |
| PNECoral (small mammals) | 1.2E+02 mg/kg food |

\*A new PNECsoil value was validated by ECHA in 2017 (0.175 mg/kg wwt) and therefore after the submission of this dossier. The impact of this new endpoint is developed further in the PAR.

##### 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 other constituent apart from the active substance has an influence on the environmental classification and labelling of the product. Permethrin is very toxic compared to other substances in the formulation.

**Harmonised environmental classification of the active substances**

The environmental classification of the active substances are the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Harmonised env. Classification for the substance** | | | |
| **substance** | **Env. Classification** | **M-Factor** | **Concentration of a.s. in the product (%)** |
| **Permethrin** | H400, H410 | M=100  M(chronic)=10000 | 0.97 |

Regarding the ecotoxicological properties, the formulation is very toxic to aquatic organisms. According to Regulation (EC) No 1272/2008 the product is classified as Aquatic Acute 1 (H400: Very toxic to aquatic life)/Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects) with the signal word “Warning”.

|  |
| --- |
| **Conclusion on the environmental classification and labelling of the product** |
| ***Classification:***  Aquatic Acute cat. 1 (H400)  Aquatic Chronic cat. 1 (H410)  ***Labelling:***  GHS09 Warning H410 |

##### Further Ecotoxicological studies

No new data is available compared to CAR (see 2.2.8) and no further ecotoxicological studies are required.

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

No new data is available compared to CAR (see 2.2.8).

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

The product is not in the form of bait or granules, so none such data is required.

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

The product is not in the form of bait or granules, so none such data is required.

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

Not relevant.

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

According to Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (ESD Nº14-PT18) for Insecticides for Stables and Manure Storage Systems, horses will often be in stables during the fly season, especially at riding stables. The manure is often stored in the open at manure heaps. As it is mentioned in this ESD Nº14-PT18 Guide, the situation of insecticides for directly application on skin of horses is not clear and is therefore not considered in this emission scenario document. Also, for this animal category intensive livestock farming is not considered to be relevant. Furthermore and following this ESD Nº14-PT18, formulations against flies will only necessary during the warmest months (fly season).

In view of this lack of emission scenario, we have decided to use the model of insect repellents applied on animal skin which is described in the Emission Scenario Document for Product type 19 (ESD PT19) as the most suitable case. The reason to use this last guide is because their applications over the skin of animals are similar to this product and its emission paths are considered identical. Following this guide, hobby riders have a clear preference for applying ready-to-use formulations.

STILL HORSE is intended to be used by professional and non-professional users and emissions to the environment can take place during and after the application of the product on horses’ skin. Treatments of horses with an insecticide are generally done before taking a ride (either as a leisure activity or participation in a horse riding tournament) or before the horses are brought out to pasture for grazing. Emissions to environmental compartments can take place during the application and after application of the product onto animals’ skin. In this context, spray application is a noteworthy emission to the environment.

The main emissions of STILL HORSE to the environment can occur during the application, after application and in the removal phases of the insecticide. Removal of the product from horses’ skin can take place through direct release to soil if the horse is kept outdoors because of the rain’s contact with the skin which may cause to leach the product from the animal to the soil.

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

No new data was submitted or is required. Information on the active substances suffices for the environmental risk assessment of the product. Moreover, the product does not contain any other substances relevant for the environment apart from the active substance.

##### Leaching behaviour (ADS)

Not relevant.

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

[If no data is available, delete the tables and indicate only that no data is available.]

No new data was submitted or is required.

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

No new data was submitted or is required.

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

No new data was submitted or is 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 new data was submitted or is 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)

No new data was submitted or is required.

#### Exposure assessment

##### General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | **Scenario [1]:** (ESD PT19, May 2015, §3.2.4.1)  - Emissions to soil during application.  **Scenario [2]:** (ESD PT19, May 2015, §3.2.4.1)  - Emissions during application to paved ground and discharge to STPs or surface water bodies.  **Scenario [3]:** (ESD PT19, May 2015, §3.2.4.2)  - Emissions through rolling of horses.  **Scenario [4]:** (ESD PT19, May 2015, §3.2.4.3)  - [4.1]Emissions due to water hosing of horses (outdoor scenario) to soil  - [4.2] Emissions due to water hosing of horses (outdoor scenario) to paved ground and discharge to STPs or surface water bodies. |
| ESD(s) used | Emission Scenario Documents for Product Type 18:   * Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OCDE Nº18, 2008). * Emission Scenario Document for insecticides for stables and manure storage systems (OCDE Nº14, 2006).   Environmental Emission Scenarios for Product Type 19:   * Repellents and attractants. |
| Approach | Average consumption |
| Distribution in the environment | Calculations based on the ESD for PT 19: Emission scenarios for repellents and attractants (ECHA, May 2015) |
| Groundwater simulation | No higher tier simulation is required for groundwater, because the estimated concentrations are below of the triger value of 0.1 µg/l. |
| Confidential Annexes | No |
| Life cycle steps assessed | All Scenarios:   * Production: No * Formulation No * Use: Yes * Service life: No |
| Remarks | **Tier 1:**  Worse-case dose of 25mL/horse (Qformappl,tier1=0.43 mg/cm2)    **Tier 2: (Only for sponge application)**  Taking in account the practical test about the absorption of still horse on different types of commercial sponges (Report n° SH-BOB-2017) where next to 33% of applied product is remained in the sponge. A “practical” amount of 16.75 mL of product is regarded as a Tier 2 for an environmental risk assessment (Qformappl,tier2=0.28 mg/cm2). |

##### Emission estimation

**Scenario 1: Emissions to soil during application**

The first assessment approach, Scenario [1], considers that horses are kept in loose barns which are groomed and prepared for riding on bare soil or grassland places. It is assumed that a spray application leads to spray drift, entering the bare soil beneath and around the treated horse. This scenario is only relevant for the spray application being insignificant for the other application methods (lotion application).

| **Input parameters for calculating the local emission and concentration** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario [1]- Direct emissions to soil during application* | | | | | |
| Active substance in the product | | *Cformweight* | 9.7 | g/kg |  |
| Consumption per application | Tier 1 | *Qformappl,tier1* | 0.43 | mg/cm2 |  |
| Number of applications per day | | *Nappl* | 0.25 | d-1 | According to product's label, no repeated application should be done before 4 days.  *Frequency validated by the Efficacy.* |
| Treated area of skin | | *AREAskin* | 58 300 | cm2 |  |
| Soil volume | | *Vsoil* | 3 | m3 |  |
| Fraction released to soil by spray drift | | *Fsoil* | 0.1 |  |  |
| Bulk density of wet soil | | *RHOsoil* | 1700 | kgwwt.m-3 |  |
| First order rate constant for biodegradation in soil | | *Kdegsoil* | 0.006539124 | d-1 |  |
| Number of emission days (for horses) | | *Temissions,1d* | 1 | d |  |
| Number of emission days (for horses) | | *Temissions,91d* | 91 | d |  |
| Number of emission events | | *Nemmision,91d-ref* | 91 | - |

* **Calculations**

The local emission to soil during the day of application is calculated according to the equation 3.16 from the revised ESD PT19 as following:

*Elocal,soil=Nappl . Qformappl . AREAskin . Cformweight . Fsoil . 10-9*

The local concentrations into the soil at the end of the day of application and after 91 days are calculated according to the equations 3.17/3.18/3.19 from the revised ESD PT19 as following:

*Clocalsoil,1d = Elocal,soil . Temissios,1d . 106/ (Vsoil . RHOsoil)*

*Clocalsoil,91d = Elocal,soil . Temissios,91d . 106/ (Vsoil . RHOsoil)*

*Clocal,91d-réf=Clocalsoil,1d . ((1-(e-Kdegsoil.Temission,1d)Nemission,91d)/1-e-Kdegsoil\*Temission,1d)*

The results are presented in the following table:

| **Resulting local emission to soil compartment** | |
| --- | --- |
| **Active substance** | **Local emission (Elocalsoil) [kg.d-1]** |
| **Permethrin** | 6.08E-06 |

| **Resulting local concentrations to soil compartment** | |
| --- | --- |
| **Permethrin** | |
| **Local concentration from one day [mg.kgwwt-1]** | 1.19E-03 |
| **Local concentration over 91 days [mg.kgwwt-1]** | 1.08E-01 |
| **Refined**  **Local concentration over 91 days (including degradation)**  **[mg.kgwwt-1]** | 8.20E-02 |

**Scenario 2: Emissions to paved ground and discharge to STPs or surface water bodies**

On the other hand, an additional exposure scenario has been considered and relates to an equestrian facility with a paved yard, where a number of horses are treated the same day with an insecticide. Remains entering paved ground by spray drift are washed off with rainwater and are assumed to be discharged to the municipal wastewater treatment plant, Scenario [2]. This scenario is only relevant for the spray application being insignificant for the other application methods (lotion application).

| **Input parameters for calculating the local emission and concentration** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario [2]- Emissions during application to paved ground and discharge to STPs or surface water bodies* | | | | | |
| Number of horses | | *Nhorses* | 50 | - |  |
| Fraction of riders treating the complete horse | | *Frider* | 0.2 | - |  |
| Active substance in the product | | *Cformweight* | 9.7 | g/kg |  |
| Consumption per application | Tier 1 | *Qformappl,tier1* | 0.43 | mg/cm2 |  |
| Number of applications per day | | *Nappl* | 1 | d-1 |  |
| Treated area of skin | | *AREAskin* | 58 300 | cm2 |  |
| Fraction released to water by spray drift | | *Fwater* | 0.1 | - |  |
| Volume of receiving water body | | *FLOWsurfacewater* | 25920 | m3/d |  |

* **Calculations**

The local emission to wastewater is calculated according to the equation 3.20 from the revised ESD PT19 as following:

*Elocal,water=Nhorses . Nappl . Qformappl . AREAskin . Cformweight . Frider . Fwater . 10-9*

The local concentration in the surface water is calculated according to the equation 3.21 from the revised ESD PT19 as following:

*Clocal,water= Elocal,water / FLOWsurfacewater . 103*

The results are presented in the following table:

| **Resulting local emission and concentration to surface-water compartment** | | |
| --- | --- | --- |
| **Active substance** | **Local emission (Elocalwater)**  **[kg.d-1]** | **Local concentration**  **[mg.l]** |
| **Permethrin** | 2.43E-04 | 9.4E-06 |

**Scenario 3: Emissions through rolling of horses**

Horses may also be treated with an insecticide when being brought to pasture for grazing. Since rolling of horses is a typical body care behavioural element (Matsui et al., 2009), it cannot be excluded that insecticide product remnants on horse skin are transferred to soil. This scenario is considered as Scenario [3].

| **Input parameters for calculating the local emission and concentration** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario [3]- Emissions through rolling of horses* | | | | | |
| Active substance in the product | | *Cformweight* | 9.7 | g/kg |  |
| Consumption per application | Tier 1 | *Qformappl,tier1* | 0.43 | mg/cm2 |  |
| Tier 2 **(only for sponge application)** | *Qformappl,tier2* | 0.28 | mg/cm2 | Based on Report n° SH-BOB-2017 |
| Number of applications per day | | *Nappl* | 0.25 | d-1 | According to product's label, no repeated application should be done before 4 days.  *Frequency validated by the Efficacy.* |
| Treated area of horse skin | | *AREAskin* | 17490 | cm2 |  |
| Number of horses kept per hectare | | *Nhorses* | 4 | - |  |
| Number of rolling per day | | *Nrolling* | 2 | - |  |
| Soil volume | | *Vsoil* | 100 | m3 |  |
| Fraction released to soil by rolling | | *Fsoil* | 0.01 | - |  |
| Bulk density of wet soil | | *RHOsoil* | 1700 | kgwwt.m-3 |  |
| First order rate constant for biodegradation in soil | | *Kdegsoil* | 0.006539124 | d-1 |  |
| Number of emission days (for horses) | | *Temissions,1d* | 1 | d |  |
| Number of emission days (for horses) | | *Temissions,91d* | 91 | d |  |
| Number of emission events | | *Nemmision,91d-ref* | 91 | - |

* **Calculations**

The local emission to soil during the day of application is calculated according to the equation 3.22 from the revised ESD PT19 as following:

*Elocal,soil=Nappl . Qformappl . AREAskin . Cformweight . Nhorses . Nrolling .Fsoil . 10-9*

The local concentration into the soil at the end of the day of application and after 91 days are calculated according to the equations 3.17/3.18/3.19 from the revised ESD PT19 as following:

*Clocalsoil,1d = Elocal,soil . Temissios,1d . 106/ (Vsoil . RHOsoil)*

*Clocalsoil,91d = Elocal,soil . Temissios,91d . 106/ (Vsoil . RHOsoil)*

*Clocal,91d-réf=Clocalsoil,1d . ((1-(e-Kdegsoil.Temission,1d)Nemission,91d)/1-e-Kdegsoil\*Temission,1d)*

The results are presented in the following tables:

**TIER 1**

| **Resulting local emission to soil compartment** | |
| --- | --- |
| **Active substance** | **Local emission (Elocalsoil) [kg.d-1]** |
| **Permethrin** | 1.46E-06 |

| **Resulting local concentrations to soil compartment** | |
| --- | --- |
| **Permethrin** | |
| **Local concentration from one day [mg.kgwwt-1]** | 8.58E-06 |
| **Local concentration over 91 days [mg.kgwwt-1]** | 7.81E-04 |
| **Refined**  **Local concentration over 91 days (including degradation)**  **[mg.kgwwt-1]** | 5.91E-04 |

**TIER 2 (only for sponge application)**

| **Resulting local emission to soil compartment** | |
| --- | --- |
| **Active substance** | **Local emission (Elocalsoil) [kg.d-1]** |
| **Permethrin** | 9.50E-07 |

| **Resulting local concentrations to soil compartment** | |
| --- | --- |
| **Permethrin** | |
| **Local concentration from one day [mg.kgwwt-1]** | 5.59E-06 |
| **Local concentration over 91 days [mg.kgwwt-1]** | 5.09E-04 |
| **Refined**  **Local concentration over 91 days (including degradation)**  **[mg.kgwwt-1]** | 3.85E-04 |

**Scenario 4: Emissions due to hosing of horses**

A further conceivable route for insecticide release after application on horses is through water hosing, Scenario [4]. The hosing of horses is a common practice (especially in the summer) for cooling down horses after riding or any other activity, or just to relieve horses at elevated temperatures, making them feel more comfortable.

In the context of “emissions due to hosing of horses” I developed two sub-scenarios, one considering direct emissions to the soil (as presented in the ESD) and another considering the emissions on paved ground and discharge to STPs or surface water bodies. I developed this last scenario [4.2] because the scenario "application on paved ground" does not cover the use of the product by lotion (bristle or sponge) but only the use by spray.

* **(4.1) : To soil**

| **Input parameters for calculating the local emission and concentration** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario [4]- Emissions due to hosing of horses (To soil)* | | | | | |
| Number of horses | | *Nhorses* | 50 | - |  |
| Fraction released to soil | | *Fsoil* | 0.01 | - |  |
| Active substance in the product | | *Cformweight* | 9.7 | g/kg |  |
| Consumption per application | Tier 1 | *Qformappl,tier1* | 0.43 | mg/cm2 |  |
| Tier 2 **(only for sponge application)** | *Qformappl,tier2* | 0.28 | mg/cm2 | Based on Report n° SH-BOB-2017 |
| Number of applications per day | | *Nappl* | 0.25 | d-1 | According to product's label, no repeated application should be done before 4 days.  *Frequency validated by the Efficacy.* |
| Treated area of skin | | *AREAskin* | 58 300 | cm2 |  |
| Soil volume | | *Vsoil* | 2.75 | m3 |  |
| Fraction of riders hosing their horses | | *Friders,hosing* | 0.1 | - |  |
| Bulk density of wet soil | | *RHOsoil* | 1700 | kgwwt.m-3 |  |
| First order rate constant for biodegradation in soil | | *Kdegsoil* | 0.006539124 | d-1 |  |
| Number of emission days (for horses) | | *Temissions,1d* | 1 | d |  |
| Number of emission days (for horses) | | *Temissions,91d* | 91 | d |  |
| Number of emission events | | *Nemmision,91d-ref* | 91 | - |

* **Calculations**

The local emission to soil during the day of application is calculated according to the equation 3.23 from the revised ESD PT19 as following:

*Elocal,soil=Nhorses . Nappl . Qformappl . AREAskin . Cformweight Frider,hosing . Fsoil . 10-9*

The local concentration into the soil at the end of the day of application and after 91 days are calculated according to the equations 3.17/3.18/3.19 from the revised ESD PT19 as following:

*Clocalsoil,1d = Elocal,soil . Temissios,1d . 106/ (Vsoil . RHOsoil)*

*Clocalsoil,91d = Elocal,soil . Temissios,91d . 106/ (Vsoil . RHOsoil)*

*Clocal,91d-réf=Clocalsoil,1d . ((1-(e-Kdegsoil.Temission,1d)Nemission,91d)/1-e-Kdegsoil\*Temission,1d)*

The results are presented in the following tables:

**TIER 1**

| **Resulting local emission to soil compartment** | |
| --- | --- |
| **Active substance** | **Local emission (Elocalsoil) [kg.d-1]** |
| **Permethrin** | 3.04E-06 |

| **Resulting local concentrations to soil compartment** | |
| --- | --- |
| **Permethrin** | |
| **Local concentration from one day [mg.kgwwt-1]** | 6.5E-04 |
| **Local concentration over 91 days [mg.kgwwt-1]** | 5.92E-02 |
| **Refined**  **Local concentration over 91 days (including degradation)**  **[mg.kgwwt-1]** | 4.47E-02 |

**TIER 2 (only for sponge application)**

| **Resulting local emission to soil compartment** | |
| --- | --- |
| **Active substance** | **Local emission (Elocalsoil) [kg.d-1]** |
| **Permethrin** | 1.98E-06 |

| **Resulting local concentrations to soil compartment** | |
| --- | --- |
| **Permethrin** | |
| **Local concentration from one day [mg.kgwwt-1]** | 4.23E-04 |
| **Local concentration over 91 days [mg.kgwwt-1]** | 3.85E-02 |
| **Refined**  **Local concentration over 91 days (including degradation)**  **[mg.kgwwt-1]** | 2.91E-02 |

* **(4.2) :** **On paved ground and discharge to STPs or surface water bodies**

| **Input parameters for calculating the local emission and concentration to STP** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario [4]: Emissions due to hosing of horses (on paved ground and discharge to STPs or surface water bodies)* | | | | | |
| Number of horses | | *Nhorses* | 50 | - |  |
| Fraction of riders hosing their horses | | *Frider,hosing* | 0.1 | - |  |
| Active substance in the product | | *Cformweight* | 9.7 | g/kg |  |
| Consumption per application | Tier 1 | *Qformappl,tier1* | 0.43 | mg/cm2 |  |
| Tier 2 **(only for sponge application)** | *Qformappl,tier2* | 0.28 | mg/cm2 | Based on Report n° SH-BOB-2017 |
| Number of applications per day | | *Nappl* | 1 | d-1 |  |
| Treated area of skin | | *AREAskin* | 58 300 | cm2 |  |
| Fraction released to water | | *Fwater* | 0.01 | - |  |
| Volume of receiving water body | | *FLOWsurfacewater* | 25920 | m3/d |  |

* **Calculations**

The local emission to wastewater is calculated according to the equation 3.22 from the revised ESD PT19 as following:

*Elocal,water=Nhorses . Nappl . Qformappl . AREAskin . Cformweight . Frider,hosing . Fwater . 10-9*

The local concentration in the surface water is calculated according to the equation 3.21 from the revised ESD PT19 as following:

*Clocal,water= Elocal,water / FLOWsurfacewater . 103*

The results are presented in the following tables:

**TIER 1**

| **Resulting local emission and concentration to surface-water compartment** | | |
| --- | --- | --- |
| **Active substance** | **Local emission (Elocalwater)**  **[kg.d-1]** | **Local concentration**  **[mg.l]** |
| **Permethrin** | 1.22E-05 | 4.68E-07 |

**TIER 2 (only for sponge application)**

| **Resulting local emission and concentration to surface-water compartment** | | |
| --- | --- | --- |
| **Active substance** | **Local emission (Elocalwater)**  **[kg.d-1]** | **Local concentration**  **[mg.l]** |
| **Permethrin** | 7.92E-06 | 3.06E-07 |

##### Fate and distribution in exposed environmental compartments

[If no data is available, delete the tables and indicate only that no data is available.]

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Fresh-water** | **Fresh-water sediment** | **STP** | **Air** | **Soil** | **Ground-water** | **Biota** |
| Scenario [1]- Emissions to soil during application | No | No | No | No | **Yes** | No | No |
| Scenario [2]- Emissions during application to paved ground and discharge to STPs or surface water bodies | **Yes** | **Yes** | **Yes** | No | (Yes) | (Yes) | (Yes) |
| Scenario [3]- Emissions through rolling of horses | No | No | No | No | **Yes** | No | No |
| Scenario [4.1]- Emissions due to water hosing of horses (direct to soil) | No | No | No | No | **Yes** | No | No |
| Scenario [4.2]- Emissions due to water hosing of horses (discharge to STPs or surface water bodies) | **Yes** | **Yes** | **Yes** | No | (Yes) | (Yes) | (Yes) |

The compartments marked with “Yes” are those of concern for which predicted emissions and local concentrations have been determined for the active substance.

The compartments marked with “(Yes)” are those of concern for which predicted emissions and local concentrations have been determined for the active substance at secondary exposures.

In the table below the relevant parameters from the active substance dossier are presented. For a general assessment of the environmental fate and behaviour refers to the active substances CAR.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 391.29 | g/mol |  |
| Melting point | 35 | °C |  |
| Boiling point | 305 | °C |  |
| Vapour pressure (at 20°C) | 2.155E-06 | Pa |  |
| Water solubility (at 20°C) | 5.30E-03 | mg/l |  |
| Log Octanol/water partition coefficient | 4.67 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 26930 | l/kg |  |
| Henry’s Law Constant (at 20°C) | 4.5E-02 | Pa/m3/mol |  |
| Biodegradability | Not biodegradable | - |  |

##### Calculated PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) (2015)).

The PECs Permethrin in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 19. The PEC values presented in the following tables are rounded values from EXCEL spread sheets from ECHA. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

The metabolites of Permethrin are considered to be transient or less persistent than the Permethrin, and are not more toxic. Therefore, the environmental risk assessment for metabolites is considered to be covered by the risk assessment for Permethrin, and emissions and PEC values were calculated for Permethrin only.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values TIER 1** | | | | | |
| **Permethrin** | PECSurface water (mg/L) | PECSTP (mg/L) | PECSediment (mg/kgwwt) | PECsoil (mg/kgwwt) | PECGroundwater (mg/L) |
| ***Emissions during application (only for spray application)*** | | | | | |
| Scenario [1]: Direct emissions to soil | | | | | |
| from 1 day | / | / | / | 1.19E-03 | / |
| over 91 days | / | / | / | 1.08E-01 | / |
| over 91 days (including degradation) | / | / | / | 8.20E-02 | / |
| Scenario [2]: Emissions to paved ground | | | | | |
| Discharge to STPs | 3.23E-06 | 3.36E-05 | 1.89E-03 | 3.64E-04 | *7.68E-07\** |
| Discharge to surface water bodies | *9.38E-06\** | / | 5.50E-03 | / | / |
| ***Emissions after application*** | | | | | |
| Scenario [3]: Emissions through rolling of horses | | | | | |
| from 1 day | / | / | / | 8.58E-06 | / |
| over 91 days | / | / | / | 7.81E-04 | / |
| over 91 days (including degradation) | / | / | / | 5.91E-04 | / |
| Scenario [4.1]: Emissions due to hosing of horses (direct to soil) | | | | | |
| from 1 day | / | / | / | 6.50E-04 | / |
| over 91 days | / | / | / | 5.92E-02 | / |
| over 91 days  (including degradation) | / | / | / | 4.47E-02 | / |
| Scenario [4.2]: Emissions due to hosing of horses (to STPs or surface water) | | | | | |
| Discharge to STPs | 1.61E-07 | 1.68E-06 | 9.45E-05 | 1.82E-05 | *1.92E-07\** |
| Discharge to surface water bodies | *4.69E-07\** | / | 2.75E-04 | / | / |

*\*Values in italics are those taken into account to determine the secondary poisoning (as worse case values).*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values TIER 2 (only for sponge application)** | | | | | |
| **Permethrin** | PECSurface water (mg/L) | PECSTP (mg/L) | PECSediment (mg/kgwwt) | PECsoil (mg/kgwwt) | PECGroundwater (mg/L) |
| ***Emissions after application*** | | | | | |
| Scenario [3]: Emissions through rolling of horses | | | | | |
| from 1 day | / | / | / | 5.59E-06 | / |
| over 91 days | / | / | / | 5.09E-04 | / |
| over 91 days (including degradation) | / | / | / | 3.85E-04 | / |
| Scenario [4.1]: Emissions due to hosing of horses (direct to soil) | | | | | |
| from 1 day | / | / | / | 4.23E-04 | / |
| over 91 days | / | / | / | 3.85E-02 | / |
| over 91 days  (including degradation) | / | / | / | 2.91E-02 | / |
| Scenario [4.2]: Emissions due to hosing of horses (to STPs or surface water) | | | | | |
| Discharge to STPs | 1.05E-07 | 1.09E-06 | 6.16E-05 | 1.19E-05 | 2.50E-08 |
| Discharge to surface water bodies | 3.05E-07 | / | 1.79E-04 | / | / |

##### Primary and secondary poisoning

1. *Primary poisoning*

Direct uptake of Permethrin after application of STILL HORSE in indoor premises is not likely, therefore primary poisoning is not relevant.

1. *Secondary poisoning*

The log Kow of Permethrin was calculated as 4.67: 99% technical a.s. 25:75 indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. Biomagnification may also occur via the terrestrial food chain. A similar approach as for the aquatic route can be used here. The following food-chains are considered:

* soil → earthworm → worm-eating birds or mammals
* water → fish → fish-eating birds or mammals

The risks of secondary poisoning were calculated for scenarios representing a large-scale risk (emissions via surface water bodies or STPs). The emissions to the soil compartment for the other scenarios represent only very localized emissions (stables, small pasture,…) and are therefore negligible in the determination of risks by secondary poisoning.

| **Summary table on calculated PECoral, predator values** | | |
| --- | --- | --- |
|  | **Aquatic food chain** | **Terrestrial food chain** |
| **PECoral,predator**  **(mg/kgwet fish)** | **PECoral,predator**  **(mg/kgwet earthworm)** |
| Scenario [2]- Emissions during application to paved ground and discharge to surface water bodies or to STPs) | 5.36E-03 | 1.94E-04 |
| Scenario [4.2]- Emissions due to water hosing of horses (on paved ground and discharge to surface water bodies or to STPs) | 2.67E-04 | 9.68E-06 |

#### Risk characterisation

##### Atmosphere

Conclusion:

According to the TGD on Risk Assessment (ECB Part II, 2003), there is currently no appropriate guidance to calculate a PNECair. The physical-chemical properties of Permethrin in the environment, such as vapour pressure (2.15 x 10-6 Pa), and molecular weight (391.29), indicate that Permethrin will not readily volatilise into the atmosphere at ambient temperature and pressure. In conclusion, Permethrin is not expected to have any adverse impact on the atmosphere, birds and non-target insects.

##### Sewage treatment plant (STP)

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario [2]: Emissions to paved ground discharge to STPs during the application (only for spray application) | 6.79E-03 |
| Scenario [4.1]: Emissions due to hosing of horses discharge to STPs – TIER 1 | 8.48E-05 |
| Scenario [4.1]: Emissions due to hosing of horses discharge to STPs – TIER 2 (only for sponge application) | 5.52E-05 |

Conclusion:

There is no risk posed to micro-organisms in a sewage treatment plant (STP) resulting from losses occurring product application and cleaning in any of the treatment scenarios for STILL HORSE containing Permethrin. The PEC/PNEC ratio (<1) does not indicate unacceptable concentrations of the active substance Permethrin in local STPs.

##### Aquatic compartment

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| ***Discharge to surface water bodies*** | | |
| Scenario [2]: Emissions to paved ground during the application (**only for spray application**) | **2.00E+01** | **2.53E+01** |
| Scenario [4.2]: Emissions due to hosing of horses – TIER 1 | 9.98E-01 | **1.27E+00** |
| Scenario [4.2]: Emissions due to hosing of horses – TIER 2 (only for sponge application) | 6.49E-01 | 8.25E-01 |
| ***Discharge to STPs*** | | |
| Scenario [2]: Emissions to paved ground during the application (**only for spray application**) | **6.87E+00** | **8.71E+00** |
| Scenario [4.2]: Emissions due to hosing of horses – TIER 1 | 3.43E-01 | 4.35E-01 |
| Scenario [4.2]: Emissions due to hosing of horses – TIER 2 (only for sponge application) | 2.23E-01 | 2.84E-01 |

Conclusion:

The PEC/PNEC ratios indicate that there are unacceptable risks for aquatic and sediment organisms following the use of STILL HORSE but only by spray application. This scenario is not relevant for the other two application methods by lotion application (with a synthetic sponge or with external bristles) as there no spray drift.

In this context the application of the product by spray presents unacceptable risks for the environment and therefore the use of the product by spray cannot be accepted.

The PEC/PNEC ratios also indicate that there are unacceptable risks for sediment organisms following the use of STILL HORSE due to hosing of horses on paved ground and discharge to surface water bodies. Appropriate risk mitigation measure is considered:

“To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.”

##### Terrestrial compartment

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| ***Emissions during application (only for spray application)*** | |
| Scenario [1]: Direct emissions to soil | |
| from 1 day | 1.36E-02 |
| over 91 days | **1.23E+00** |
| over 91 days (including degradation) | 9.36E-01 |
| Scenario [2]: Emissions to paved ground discharge to STPs (sludge) | 4.16E-03 |
| ***Emissions after application (TIER 1)*** | |
| Scenario [3]: Emissions through rolling of horses | |
| from 1 day | 9.79E-05 |
| over 91 days | 8.92E-03 |
| over 91 days (including degradation) | 6.75E-03 |
| Scenario [4.1]: Emissions due to hosing of horses (direct to soil) | |
| from 1 day | 7.42E-03 |
| over 91 days | 6.76E-01 |
| over 91 days (including degradation) | 5.10E-01 |
| Scenario [4.2]: Emissions due to hosing of horses discharge to STPs (sludge) | 2.08E-04 |
| ***Emissions after application (TIER 2 – only for sponge application)*** | |
| Scenario [3]: Emissions through rolling of horses | |
| from 1 day | 6.38E-05 |
| over 91 days | 5.81E-03 |
| over 91 days (including degradation) | 4.39E-03 |
| Scenario [4.1]: Emissions due to hosing of horses (direct to soil) | |
| from 1 day | 4.83E-03 |
| over 91 days | 4.39E-01 |
| over 91 days (including degradation) | 3.32E-01 |
| Scenario [4.2]: Emissions due to hosing of horses discharge to STPs (sludge) | 1.6E-043 |

Conclusion:

The PEC/PNEC ratios indicate that there are unacceptable risks for soil organisms after a period of 91 days (summer period) but only by spray application and without considering de degradation of the active substance in the compartment. This scenario is not relevant for the other two application methods by lotion application (with a synthetic sponge or with external bristles) as there no spray drift.

There is no unacceptable risk for soil organisms for the other scenarios and when the degradation of the active substance is taken into account so, in conclusion, there is no concern for the soil compartment.

In addition, The assessment was made with the PNECsoil value applicable at the time of the submission of the dossier (worst case). A new PNECsoil value was validated by ECHA in 2017 (0.175 mg/kg wwt). This new parameter almost halves the RCR values obtained and therefore reduces the calculated risks.

##### Groundwater

The risk for the groundwater has been determined by the emission values from the sludge (via the STPs). Emissions to groundwater have not been determined for other scenarios because the emissions for these scenarios are considered very localized (stables, small pasture,…) and therefore negligible.

There are no concerns for the groundwater compartment, because the estimated concentrations are below of the trigger value of 0.1µg/l.

##### Primary and secondary poisoning

###### Primary poisoning

The product is an insecticide (Product Type 18). The product is ready to use and is applied in liquid form by spraying, by brushing or by sponge. A direct uptake of the product is unlikely.

###### Secondary poisoning

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
|  | **Aquatic food chain** | | **Terrestrial food chain** | |
| **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** | **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** |
| Scenario [2]- Emissions during application to paved ground and discharge to surface water bodies or STPs) | 3.21E-04 | 4.48E-04 | 1.16E-05 | 1.62E-06 |
| Scenario [4.2]- Emissions due to water hosing of horses (on paved ground and discharge to surface water bodies or STPs) | 1.6E-05 | 2.22E-06 | 5.8E-07 | 8.08E-08 |

Conclusion:

In view of outcomes above, no risk for secondary poisoning is derived from the use of STILL HORSE on horses.

##### Mixture toxicity

Not relevant.

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

Not relevant.

**General conclusion**

**In conclusion,**

The risk characterisation for the environment indicates that the uses of the biocidal product STILL HORSE by lotion – external applicator bristles or sponge applications - do not represent unacceptable risks to the environment if:

• Appropriate risk mitigation measure is considered,

“To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.”

• And if the following frequency between two treatments is respected, “One application each 4 days during the 3 months of the summer season.

The use of the biocidal product STILL HORSE by spray application cannot be authorised because there are unacceptable risks for the aquatic compartment.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The risk characterisation for the environment indicates that the uses of the biocidal product STILL HORSE by lotion – external applicator bristles or sponge applications - do not represent unacceptable risks to the environment if:  • Appropriate risk mitigation measure is considered,  “To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.”  • And if the following frequency between two treatments is respected, “One application each 4 days during the 3 months of the summer season.  The use of the biocidal product STILL HORSE by spray application cannot be authorised because there are unacceptable risks for the aquatic compartment. |

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

[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]

Necessary label restrictions:

* Do not use in animals with liver problems, anemia and widely spread skin lesions.
* Do not use in pregnant or lactating mare.
* It is forbidden that horses (leisure horses included) treated with this product are found in the food chain.
* Do not use the product before washing or wet weather to preserve full effectiveness and enable better protection of the environment.
* To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.

**Recommended methods and precautions concerning handling, use, storage, transport or fire:**

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing vapours. Wear personal protective equipment (only for professional users as recommended in the risk assessment results).

Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Do not store near food, drink and animal feeding stuff.

Transport:

UN No: 3082

UN Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

Transport hazard class(es) (ADR): 9

Packaging group: III

Dangerous for the environment: Yes

Marine pollutant: Yes

Fire:

Suitable extinguishing media: All extinguishing agents can be used

Special hazards arising from the substance or mixture: No additional information available

Advice for firefighters:

- Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete

protective clothing.

- Other information: Prevent fire-fighting water from entering environment

Storage:

Store in a well-ventilated place. Keep cool.

**Particulars of likely direct or indirect adverse effects:**

* Reactivity: Stable under normal conditions of use.
* Chemical stability: Stable under normal conditions.
* Possibility of hazardous reactions: None under normal conditions.
* Conditions to avoid: Extremely high or low temperatures.
* Incompatible materials: No additional information available.
* Hazardous decomposition products: No additional information available.

**Emergency measures in case of an accident:**

Description of first aid measures:

* First-aid measures after inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
* First-aid measures after skin contact: Wash with plenty of soap and water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
* First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
* First-aid measures after ingestion: Call a poison center or a doctor if you feel unwell.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

**Emergency measures to protect the environment:**

Personal precautions, protective equipment and emergency procedures:

* General measures: Equip clean-up crew with proper protection.
* For non-emergency personnel: No additional information available
* For emergency responders:
  + Protective equipment: Do not attempt to take action without suitable protective equipment

Environmental precautions: Avoid release to the environment. Prevent entry to sewers and public waters.

Procedures for product and container waste management and disposal:

Regional legislation (waste): Disposal must be done according to official regulations.

Waste treatment methods: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

Empty containers should not be reused. Only one use is recommended.

Ecology - waste materials : Avoid release to the environment.

Procedures, if any, for cleaning application equipment:

For containment: Collect spillage.

Methods for cleaning up: Take up liquid spill into absorbent material.

Other information: Dispose of materials or solid residues at an authorized site.

Possibility of destruction or decontamination following release in or on the following environmental compartments:

- Air: Potential contamination of this compartment is considered negligible due to the physical-chemical properties of the active substance, so no decontamination measures are applicable.

- Water: Due to low water solubility of the active substance, in case of accidental release in water, it will sediment very quickly so it will not be present in water. In order to decontaminate the sediment surface, the Applicant propose to remove the upper layer of the sediment with the adhered active substance and dispose it as a hazardous waste. This decontamination task should be performed by a specialized professional in water/sediment decontamination. This environmental dredging should be carried out using proper equipment to limit the spread of the active substance by sediment resuspension. Various technique are available for such purposes as can be found in National Academy of Science (1997)[[1]](#footnote-1). In the case that this in-situ techniques are not possible, in situ immobilization techniques such as solidification and stabilization can be followed to isolate the active substance from the benthic and aquatic ecosystem. The specific decontamination technique will vary in function of the characteristics of the sediment to be treated and should be discussed on a case by case basis.

- Soil: Due to low water solubility of the active substance, in case of accidental release to soil, the substance will not leach immediately to the ground and it will remain on the soil surface for some time. Therefore, the Applicant propose to remove the upper layer of the soil with the adhered active substance and dispose it as a hazardous waste. This decontamination task should be performed by a specialized professional in soil decontamination. Various decontamination techniques are available and the most appropriate technique should be applied depending on the soil characteristics.

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Not relevant.

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **List of new data submitted in support of the evaluation of the biocidal product STILL HORSE** | | | | | | | | | | | |
| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of access** | | **Data protection claimed** | | **Essential studies for evaluation** | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| 5 | DEFITRACES, Study No. 16-902007-004 | Ricau, H. | 2011 | Validation of the analytical method for the determination of permethrin in STILL HORSE | BELGAGRI, S.A. |  | x | x |  | x |  |
| 2.2 | DEFITRACES, Study No. 16-902007-001 | Trigaux, A. & Demangel, B. | 2016 | Physico-chemical tests on STILL HORSE | BELGAGRI, S.A. |  | x | x |  | x |  |
| 3 | DEFITRACES, Study No. 16-902007-002 | Demangel, B. | 2016 | Physico-chemical tests and analyses before and  after an accelerated storage procedure for 14 days at  54 °C ± 2 °C on STILL HORSE | BELGAGRI, S.A. |  | x | x |  | x |  |
| 3 | DEFITRACES, Study No. 16-902007-003 | Demangel, B. | 2019 | Physico-chemical tests and chemical stability after a  storage procedure for 24 months at 20 °C ± 2 °C  on STILL HORSE (ongoing) | BELGAGRI, S.A. |  | x | x |  | x |  |
| 4 | DEFITRACES, Study No. 16-902007-005 | Demangel, B. | 2017 | Emulsion characteristics and re-emulsification properties test on STILL HORSE | BELGAGRI, S.A. |  | x | x |  | x |  |
| 4 | DEFITRACES, Study No. 21-902007-002 | Demangel, B. | 2021 | Test methods for corrosion to metals on STILL HORSE | ARMOSA TECH |  | x | x |  | x |  |
| 6 | BELGAGRI S.A.  Ref. BGG13 STI01 | Trigaux, A. | 2013 | EFFICACY ASSESSMENT OF THE INSECTICIDE PRODUCT “STILL HORSE” CONTAINING 9g/L PERMETHRIN APPLIED ON HORSES AGAINST FLIES | BELGAGRI, S.A. |  | x | x |  | x |  |
| 6 | T.E.C. Laboratory  Ref. 2058a-SH/0316R | Serrano, B. | 2016 | LABORATORY TESTING OF A DOSE RANGE OF AN INSECTICIDE PRODUCT | BELGAGRI, S.A. |  | x | x |  | x |  |
| 6 | BELGAGRI Rapport: 16-H | Alatienne, M. | 2017 | EFFET DE « STILL HORSE » (0,9% perméthrine) CONTRE LES INSECTES SUR LES CHEVAUX AUX PATURAGES | BELGAGRI, S.A. |  | x | x |  | x |  |
| 6 | Report 16BEL002/ 2016- October/ IZIPEST SA |  | 2016 | *LABORATORY TRIAL OF THE EFFICACY OF A PRODUCT AGAINST FLIES* | BELGAGRI, S.A. |  | x | x |  | x |  |
| 6 | Biocidal Alternative Solutions S.A.  BAS122021.8 | Hans, M. | 2021 | EFFICACY ASSESSMENT OF THE INSECTICIDE PRODUCT “STILL HORSE” CONTAINING 9g/L PERMETHRIN APPLIED ON HORSES | ARMOSA TECH |  | x | x |  | x |  |
| 8 | PHYCHER.  Report: ICE-PH-17/0380 | Floriot, L., | 2017 | Isolated Chicken Eye Test Method for Identifying (i) Chemicals Inducing Serious Eye Damage and (ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage. | BELGAGRI, S.A. |  | x | x |  | x |  |
| 8 | PHYCHER.  Report: ICE-PH-17/0380 | Floriot, L., | 2017 | N VITRO SKIN CORROSION: Reconstructed Human Epidermis (RhE) Test Method. | BELGAGRI, S.A. |  | x | x |  | x |  |
| 8 | PHYCHER.  Report: ICE-PH-17/0380 | Floriot, L., | 2017 | IN VITRO SKIN IRRITATION: Reconstructed Human Epidermis Test Method. | BELGAGRI, S.A. |  | x | x |  | x |  |
| 8.6 | Charles river  Test Facility Study No. 787961 | Dickson, L. | 2021 | The In Vitro Percutaneous Absorption of a Single Radiolabelled Permethrin in a Single Formulation Through Human Skin Split-Thickness Skin | ARMOSA TECH |  | x | x |  | x |  |
| 10.2 | Report n° SH-BOB-2017 | Trigaux, A. | 2017 | ABSORPTION OF STILL HORSE ON DIFFERENT TYPES OF COMMERCIAL SPONGES | BELGAGRI, S.A. |  | x | x |  | x |  |

## Output tables from exposure assessment tools

Please consider the following tables including in this Annex section as confidential information

**HUMAN EXPOSURE ASSESSMENT**

* Professional

Scenario 1 tier 1 : spray application – primary exposure



Scenario 1 tier 2 : spray application – primary exposure



Scenario 1 tier 2a (30 min):



Scenario 3 - Tier 1 (360 min): sponge application – primary exposure



Scenario 3 - Tier 2 (150 min): sponge application – primary exposure



Scenario 3 - Tier 3 (90 min): sponge application – primary exposure



Scenario 3 - Tier 4 (90 min + gloves and coated coverall): sponge application – primary exposure

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Unit |  |
|  |  |  |  |
| Concentration a.s. in product | 0,97 | % |  |
| Concentration a.s. in used product | 0,97 | % |  |
|  |  |  |  |
| Duration | 90 | min |  |
| Bodyweight | 60 | kg | adult |
| Number of events per day | 1 | / d |  |
| Number of contactdays per year | 23 | / year |  |
|  |  |  |  |
| Dermal exposure |  |  |  |
|  |  |  |  |
| Product on clothing rate | 87,6 | mg / min | coated coverall |
|  |  |  |  |
| Relative penetration of clothing | 20 | % |  |
| Deposit of product on skin | 1577 | mg |  |
|  |  |  | no gloves |
| Product on gloves rate | 10,30 | mg / min |  |
| Relative penetration of gloves | 100 | % |  |
| Deposit of product on hands | 927 | mg |  |
|  |  |  |  |
|  |  |  |  |
| Total deposit of product | 2504 | mg |  |
| Total deposit of active substance | 24,3 | mg |  |
|  |  |  |  |
| Exposure to active substance via the skin | 24,3 | mg / event |  |
| Dermal exposure on contact day | 405 | µg / kg bw |  |
| Year averaged dermal exposure | 25,5 | µg / kg bw / d |  |
| dermal absorption | 5% |  |  |
|  |  |  |  |
| acute systemic dermal | 20,644 | µg / kg bw |  |
| chronic systemic dermal | 1,301 | µg / kg bw / d |  |
|  |  |  |  |
| Inhalatory exposure |  |  |  |
|  |  |  |  |
| Product concentration | 22,9 | mg / m³ |  |
| Respiratory rate | 1,25 | m³ / h | adult |
| Percentage reaching respiratory organs | 100 | % |  |
| Amount product inhaled | 43 | mg |  |
| Amount active substance via inhalation | 0,416 | mg |  |
| Exposure to active substance via inhalation | 0,416 | mg / event |  |
|  |  |  |  |
| Inhalatory exposure on contact day | 6,942 | µg / kg bw |  |
| Year averaged inhalatory exposure | 0,437 | µg / kg bw / d |  |
|  |  |  |  |
| Total systemisch |  |  |  |
| acuut | 27,6 | µg / kg bw |  |
| chronisch | 1,7 | µg / kg bw / d |  |
|  |  |  |  |
| lokaal inhalatoir | 0,222 | mg/m³ |  |

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Scenario 3 - Tier 5 (150 min + gloves + coated coverall): sponge application – primary exposure

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Unit |  |
|  |  |  |  |
| Concentration a.s. in product | 0,97 | % |  |
| Concentration a.s. in used product | 0,97 | % |  |
|  |  |  |  |
| Duration | 150 | min |  |
| Bodyweight | 60 | kg | adult |
| Number of events per day | 1 | / d |  |
| Number of contactdays per year | 23 | / year |  |
|  |  |  |  |
| Dermal exposure |  |  |  |
|  |  |  |  |
| Product on clothing rate | 87,6 | mg / min | coated coverall |
|  |  |  |  |
| Relative penetration of clothing | 20 | % |  |
| Deposit of product on skin | 2628 | mg |  |
|  |  |  | no gloves |
| Product on gloves rate | 10,30 | mg / min |  |
| Relative penetration of gloves | 100 | % |  |
| Deposit of product on hands | 1545 | mg |  |
|  |  |  |  |
|  |  |  |  |
| Total deposit of product | 4173 | mg |  |
| Total deposit of active substance | 40,5 | mg |  |
|  |  |  |  |
| Exposure to active substance via the skin | 40,5 | mg / event |  |
| Dermal exposure on contact day | 675 | µg / kg bw |  |
| Year averaged dermal exposure | 42,5 | µg / kg bw / d |  |
| dermal absorption | 5% |  |  |
|  |  |  |  |
| acute systemic dermal | 34,406 | µg / kg bw |  |
| chronic systemic dermal | 2,168 | µg / kg bw / d |  |
|  |  |  |  |
| Inhalatory exposure |  |  |  |
|  |  |  |  |
| Product concentration | 22,9 | mg / m³ |  |
| Respiratory rate | 1,25 | m³ / h | adult |
| Percentage reaching respiratory organs | 100 | % |  |
| Amount product inhaled | 72 | mg |  |
| Amount active substance via inhalation | 0,694 | mg |  |
| Exposure to active substance via inhalation | 0,694 | mg / event |  |
|  |  |  |  |
| Inhalatory exposure on contact day | 11,569 | µg / kg bw |  |
| Year averaged inhalatory exposure | 0,729 | µg / kg bw / d |  |
|  |  |  |  |
| Total systemisch |  |  |  |
| acuut | 46,0 | µg / kg bw |  |
| chronisch | 2,9 | µg / kg bw / d |  |
|  |  |  |  |
| lokaal inhalatoir | 0,222 | mg/m³ |  |



Scenario 2 - Tier 1 – Secondary exposure: see corresponding calculation present in the PAR

* Non-Professional

###### Scenario 1 – Tier 1 (90 min/d): Spraying application

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Unit |  |
|  |  |  |  |
| Concentration a.s. in product | 0,97 | % |  |
| Concentration a.s. in used product | 0,97 | % |  |
|  |  |  |  |
| Duration | 90 | min |  |
| Bodyweight | 60 | kg | adult |
| Number of events per day | 1 | / d |  |
| Number of contactdays per year | 23 | / year |  |
|  |  |  |  |
| Dermal exposure |  |  |  |
|  |  |  |  |
| Product on clothing rate | 9,7 | mg / min | minimal clothing (long sleeved shirt and trousers, shoes) |
|  |  |  |  |
| Relative penetration of clothing | 50 | % |  |
| Deposit of product on skin | 437 | mg |  |
|  |  |  | no gloves |
| Product on gloves rate | 36,10 | mg / min |  |
| Relative penetration of gloves | 100 | % |  |
| Deposit of product on hands | 3249 | mg |  |
|  |  |  |  |
|  |  |  |  |
| Total deposit of product | 3686 | mg |  |
| Total deposit of active substance | 35,7 | mg |  |
|  |  |  |  |
| Exposure to active substance via the skin | 35,7 | mg / event |  |
| Dermal exposure on contact day | 596 | µg / kg bw |  |
| Year averaged dermal exposure | 37,5 | µg / kg bw / d |  |
| dermal absorption | 5% |  |  |
|  |  |  |  |
| acute systemic dermal | 30,387 | µg / kg bw |  |
| chronic systemic dermal | 1,915 | µg / kg bw / d |  |
|  |  |  |  |
| Inhalatory exposure |  |  |  |
|  |  |  |  |
| Product concentration | 10,5 | mg / m³ |  |
| Respiratory rate | 1,25 | m³ / h | adult |
| Percentage reaching respiratory organs | 100 | % |  |
| Amount product inhaled | 20 | mg |  |
| Amount active substance via inhalation | 0,019 | mg |  |
| Exposure to active substance via inhalation | 0,019 | mg / event |  |
|  |  |  |  |
| Inhalatory exposure on contact day | 0,318 | µg / kg bw |  |
| Year averaged inhalatory exposure | 0,020 | µg / kg bw / d |  |
|  |  |  |  |
| Total systemisch |  |  |  |
| acuut | 30,7 | µg / kg bw |  |
| chronisch | 1,9 | µg / kg bw / d |  |
|  |  |  |  |
| lokaal inhalatoir | 0,102 | mg/m³ |  |

###### Scenario 1 – Tier 2 (30 min/d): Spraying application

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Unit |  |
|  |  |  |  |
| Concentration a.s. in product | 0,97 | % |  |
| Concentration a.s. in used product | 0,97 | % |  |
|  |  |  |  |
| Duration | 30 | min |  |
| Bodyweight | 60 | kg | adult |
| Number of events per day | 1 | / d |  |
| Number of contactdays per year | 23 | / year |  |
|  |  |  |  |
| Dermal exposure |  |  |  |
|  |  |  |  |
| Product on clothing rate | 9,7 | mg / min | minimal clothing (long sleeved shirt and trousers, shoes) |
|  |  |  |  |
| Relative penetration of clothing | 50 | % |  |
| Deposit of product on skin | 146 | mg |  |
|  |  |  | no gloves |
| Product on gloves rate | 36,10 | mg / min |  |
| Relative penetration of gloves | 100 | % |  |
| Deposit of product on hands | 1083 | mg |  |
|  |  |  |  |
|  |  |  |  |
| Total deposit of product | 1229 | mg |  |
| Total deposit of active substance | 11,9 | mg |  |
|  |  |  |  |
| Exposure to active substance via the skin | 11,9 | mg / event |  |
| Dermal exposure on contact day | 199 | µg / kg bw |  |
| Year averaged dermal exposure | 12,5 | µg / kg bw / d |  |
| dermal absorption | 5% |  |  |
|  |  |  |  |
| acute systemic dermal | 10,129 | µg / kg bw |  |
| chronic systemic dermal | 0,638 | µg / kg bw / d |  |
|  |  |  |  |
| Inhalatory exposure |  |  |  |
|  |  |  |  |
| Product concentration | 10,5 | mg / m³ |  |
| Respiratory rate | 1,25 | m³ / h | adult |
| Percentage reaching respiratory organs | 100 | % |  |
| Amount product inhaled | 7 | mg |  |
| Amount active substance via inhalation | 0,006 | mg |  |
| Exposure to active substance via inhalation | 0,006 | mg / event |  |
|  |  |  |  |
| Inhalatory exposure on contact day | 0,106 | µg / kg bw |  |
| Year averaged inhalatory exposure | 0,007 | µg / kg bw / d |  |
|  |  |  |  |
| Total systemisch |  |  |  |
| acuut | 10,2 | µg / kg bw |  |
| chronisch | 0,6 | µg / kg bw / d |  |
|  |  |  |  |
| lokaal inhalatoir | 0,102 | mg/m³ |  |

Scenario 3 – Tier 1 (90 min/d): Application with sponge



Scenario 3 – Tier 2 (30 min/d): Application with sponge



## New information on the active substance

No new information is provided on the active substance.

## Residue behaviour

No new information is provided about residue behaviour.

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

Please refer to the table ***2.2.5.5.1 summary of experimental data.***

## Confidential annex

See annexed document. The confidential annex is for Member State only as it contains information that should not be made available for the applicant.

## Other

Not relevant.

1. The National Academy of Sciences (1997). Committee on Contaminated Marine Sediments, Marine Board, Commission on Engineering and Technical Systems, National Research Council. Contaminated sediments in ports and waterways : clean-up strategies and technologies. [↑](#footnote-ref-1)