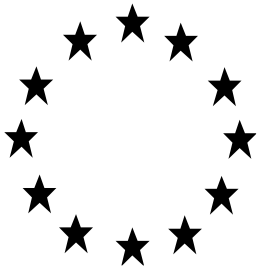
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



Deltamethrin EW 20

Product type 18

Deltamethrin 20 g/L

R4BP Asset No: GR-0002104-0000

Evaluating Competent Authority: EL

Date: September 2020

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# 1 CONCLUSION

Deltamethrin 20 EW is an Emulsion, oil in water (EW) containing 2% w/v deltamethrin.

Its physicochemical properties are considered acceptable. Further data have been requested (see 2.2.2). Acceptable analytical methods have also been submitted.

Primary exposure assessment of professional users, performed for indoor spray application using portable thermal fogger and outdoor spray application using cold (ULV) portable or vehicle-mounted fogging equipment, resulted in acceptable exposure levels only when appropriate personal protective equipment (i.e. gloves & coated coverall during mixing/loading and application and RPE during application) are taken. Secondary exposure of the general public (adults and/or children) re-entering an area where the product has been applied, resulted in acceptable exposure levels. The sprayers should be cleaned in a designated area (e.g. biobeds). The worker involved in the cleaning should be protected using gloves. The wash water should be primarily considered for re-use making sure the maximum dose is not exceeded or should be disposed off as hazardous waste.

The available E-fate and ecotoxicological data are considered adequate to address the ecotoxicological properties of the biocidal product Deltamethrin EW 20.

Based on the environmental risk assessment performed, no unacceptable risks to non-target organisms are expected following the intended indoor use of the product. As regards the intended outdoor applications, unacceptable risks have been identified for surface water and sediment-dwelling organisms. As regards aerial application, no environmental exposure and risk assessment has been performed due to the lack of specific and agreed exposure assessment model/scheme.

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

2.1.1.1 Identifier of the product

| Identifier | Country (if relevant) |
|---|---|
| Deltamethrin EW 20 | Greece |

2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | Bayer Hellas AG |
| | **Address** | 18-20, Sorou Str.<br>Marousi, Athens<br>15125<br>Greece |
| **Authorisation number** | GR-0002104-0000 / ΤΠ18-0244 | |
| **Date of the authorisation** | 6-4-2017 | |
| **Expiry date of the authorisation** | 6-4-2027 | |

2.1.1.3 Manufacturer(s) of the product

| | |
|---|---|
| **Name of manufacturer** | Bayer S.A.S. |
| **Address of manufacturer** | Bayer S.A.S.<br>16 rue Jean-Marie Leclair – CS 90106<br>69266 Lyon Cedex 09<br>France |
| **Location of manufacturing sites** | Bayer S.A.S<br>Bayer CropScience<br>Industrial operation<br>1, Avenue Edouard Herriot<br>F-69400 - Villefranche-Limas<br>France<br><br>or<br><br>SBM Formulation Manufacturing Plant<br>ZI Avenue Jean Foucault<br>CS621<br>34500 Beziers<br>France |

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

| | |
|---|---|
| **Active substance** | Deltamethrin |

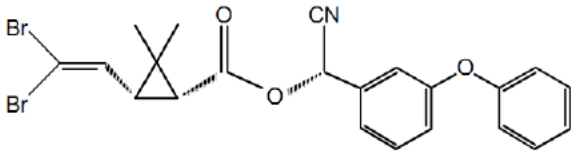
| | |
|---|---|
| **Name of manufacturer** | Bayer CropScience AG |
| **Address of manufacturer** | Alfred-Nobel Strasse 50<br>40789 Monheim am Rhein<br>Germany |
| **Location of manufacturing sites** | Bayer Vapi Private Limited<br>(formerly Bilag Industries Pvt Ltd)<br>306/3, II Phase, GIDC, Vapi-396195 - India |

### 2.1.2 Product composition and formulation

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

Yes ☐
No X

2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|---|---|
| **ISO name** | Deltamethrin |
| **IUPAC or EC name** | (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate |
| **EC number** | 258-256-6 |
| **CAS number** | 52918-63-5 |
| **Index number in Annex VI of CLP** | 607-319-00-X |
| **Minimum purity / content** | 98.5 %w/w |
| **Structural formula** |  |



2.1.2.2 Candidate(s) for substitution

Not relevant.

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|---|---|---|---|
| Deltamethrin | (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate | Active substance | 52918-63-5 | 258-256-6 | 2% w/w |
| Solvesso 200 ND | HSPA Substance Name: Hydrocarbons, C10-C13, aromatics, <1% naphthalene | Solvent | 64742-94-5 | 922-153-0 | [redacted] |
| 1,2-benzisothiazol-3(2H)-one | 1,2-benzisothiazol-3(2H)-one | Preservative | 2634-33-5 | 220-120-9 | [redacted] |
| For more details see 3.6 Confidential Annex. | | | | | |

### 2.1.2.4 Information on technical equivalence

Not relevant.

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

The product contains Solvesso 200 ND (<1% naphthalene) at a concentration of [redacted] w/w.Solvesso 200 ND triggers product classification as Asp Tox 1 (H304). According to the ECHA Guidance on BPR (October, 2015), SoCs which trigger products to be classified as Asp. Tox. 1 (H304), are categorized to Band A of the banding evaluation scheme and the associated evaluation/risk management requirements include the application of H-statements and associated P-statements.
The relevant statements (Asp. Tox. 1 - H304, P301 + P310, P331) are already proposed for product label, and there is no need for further action.
Furthermore, Aqua K-othrine is classified for skin sensitization category 1B with H317. 1,2-benzisothiazol-3(2H)-one, is a skin sensitiser (Skin Sens. 1 – H317; CLP00) is present in Aqua K Othrine at a concentration of [redacted] higher than the elicitation threshold set at 0.005%. According to the ECHA Guidance on BPR (October, 2015), SoCs which trigger products to be classified as Skin sensitizer 1B (H317), are included in Band B of the banding evaluation scheme and the associated evaluation/risk management requirements include (as also with Band A) the qualitative exposure and risk assessment to determine whether Sphrases/P-statements or whether other risk mitigation measures should be applied.
Following this approach the phrase ”H317 May cause an allergic skin reaction. Contains Benzisothiazol-3(2H)-one” will be added in product label, as well as the relevant

precautionary statements (P261, P272, P280, P302+P352, P333+P313, P321, P363, P501).

#### 2.1.2.6 Type of formulation

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

### 2.1.3 Hazard and precautionary statements[1]

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

| **Classification** | |
|---|---|
| Hazard class and category | Acute Tox 4<br>Asp. Tox. 1<br>Skin Sens. 1B<br>Aquatic Acute 1<br>Aquatic Chronic 1 |
| Hazard statement | H302<br>H304<br>H317<br>H400<br>H410 |
| GHS Pictogram |  |
| | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H302 Harmful if swallowed.<br>H304 May be fatal if swallowed and enters airways.<br>H317 May cause an allergic skin reaction. Contains Benzisothiazol-3(2H)-one.<br>H410 Very toxic to aquatic life with long lasting effects.<br>EUH066 Repeated exposure may cause skin dryness or cracking. |

| | |
|---|---|
| Precautionary statements | P261 Avoid breathing spray.<br>P264 Wash hands thoroughly after handling.<br>P270 Do not eat, drink or smoke when using this product.<br>P272 Contaminated work clothing should not be allowed out of the workplace.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing*.<br>P284 Wear respiratory protection**<br>P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.<br>P302 + P352 IF ON SKIN: Wash with plenty of soap and water.<br>P321 Specific treatment (see... on this label).<br>P330 Rinse mouth.<br>P331 Do NOT induce vomiting.<br>P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.<br>P363 Wash contaminated clothing before reuse.<br>P391 Collect spillage<br>P405 Store locked up.<br>P501 Dispose of contents/container in accordance with local regulation |
| | |
| Note | - Shake well before use must be added in the label |

** The use of eye protection is recommended as an additional precautionary measure by the applicant. However, it is not supported by the toxicological properties of the product and/or the human health risk assessment.*
***RPE: 90% protection factor, i.e. A1 for organc gases – EN 14387.*

## 2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Intended use – Ground application (indoor use)

| | |
|---|---|
| **Product Type(s)** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Deltamethrin EW 20 is a deltamethrin based concentrate (20 g/L) for terrestrial application indoors as a space spray with thermal fogging equipment. |
| **Target organism (including development stage)** | Adult mosquitoes (Culicidae)<br><br>When used in tropical areas, consider that efficacy of the product against mosquitoes has been proved against *Aedes sp.* and *Culex sp.* as indoor fogging. |
| **Field of use** | Indoor |

| | |
|---|---|
| **Application method(s)** | Space spray by thermal fogging.<br>The instructions of the chosen equipment must be followed accurately to obtain the optimal droplet size required for best product performance. |
| **Application rate(s) and frequency** | Dose: 0.05 g deltamethrin / 1000$m^3$<br>(2.5 ml product/ 1000$m^3$)<br>Dilution: 1:199 (product: water)<br>Frequency: 1-2 treatments per year<br>Application interval:<br>Infestation dependent |
| **Category(ies) of user(s)** | Trained professional, Professional |
| **Pack sizes and packaging material** | Up to 20 L plastic bottle (CoEX: PE/PA or PE/EV). |

2.1.4.1 Use-specific instructions for use

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| |

2.1.4.2 Use-specific risk mitigation measures

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| |

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

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| |

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

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|---|
| Product: In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.<br><br>Contaminated packaging: Triple rinse empty containers immediately after use. Do not re-use empty containers. Not completely emptied packagings should be disposed of as hazardous waste.<br><br>Waste key for the unused Product: 020108 agrochemical waste containing dangerous substances. |

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

| |
|---|
| The product remains stable for 4 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.<br>Store in a place accessible by authorized persons only.<br>Avoid extremes of temperature and direct sunlight.<br>Store only in the original container. |

## 2.1.5 General directions for use

### 2.1.5.1 Instructions for use

Efficacy

Strategies for avoiding and/or managing the development of resistance are provided as follows:

- where possible, application treatments should be recommended to be combined with non-chemical measures.
- products should always be used in accordance with label recommendations.
- applications should always be made against the most susceptible stages in the pest life cycle.
- where an extended period of control is required, treatments should be alternated with products with different modes of action.
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refuges can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substance with the same mode of action should cease.
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- Do not [use/apply] the product in areas where resistance to the active substance(s) 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.

### 2.1.5.2 Risk mitigation measures

Wear protective gloves, protective clothing during mixing/loading and application.
Wear respiratory protective equipment (*A1 for organc gases – EN 14387)* during application.
The worker involved in the cleaning of the application equipment should wear gloves.

Do no treat areas were food or feed are stored.

Keep away from food, drink and animal feeding stuffs.

The applicator shall inform people living in proximity to the target area of the treatment with Aqua K-Othrine about the following:

| |
|---|
| - Do not apply to agricultural areas after the consumable part of the crop is formed. |

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

| |
|---|
| |

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

| |
|---|
| Product: In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.<br><br>Contaminated packaging: Triple rinse containers. Do not re-use empty containers. Not completely emptied packagings should be disposed of as hazardous waste.<br><br>Waste key for the unused Product: 020108 agrochemical waste containing dangerous substances. |

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

| |
|---|
| The product remains stable for 4 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.<br>Store in a place accessible by authorized persons only.<br>Avoid extremes of temperature and direct sunlight.<br>Store only in the original container. |

### 2.1.6 Other information

| |
|---|
| Application codes |

### 2.1.7 Packaging of the biocidal product

Deltamethrin EW 20 is sold in plastic bottle from 1L up to 20L. The acceptable packaging materials are COEX PE/PA and PE/EVOH.

### 2.1.8 Documentation

#### 2.1.8.1 Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

#### 2.1.8.2 Access to documentation

Not relevant.

## 2.2 Assessment of the biocidal product

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

*(as presented in the SPC submitted by the applicant)*

Table 1. Intended use 1 – Aerial application[2]

| | |
|---|---|
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Deltamethrin EW 20 is a deltamethrin based concentrate (20 g/L) for application as an ultra-low volume aerosol or thermal fog. The product is suitable for vector control use in public health situations. |
| Target organism (including development stage) | Adult mosquitoes (Culicidae)<br>Adult house flies (Muscidae) |
| Field of use | Outdoor |
| Application method(s) | Fogging.<br>AERIAL APPLICATION: helicopter with mounted sprayers (e.g. type Unirot 4, 6 sprayers (3 per boom)) using GPS, on board real-time wind measurement and AGDISP software, or equivalent equipment in order to avoid spray drift in non-target area. |
| Application rate(s) and frequency | Dose: 1g deltamethrin /ha<br>Dilution: 0%<br><br>Application timing:<br>Mosquito: outdoor space spraying is best carried out around dusk at low wind speeds.<br><br>Application interval:<br>Infestation dependent<br><br><u>General directions for use</u><br>Dilution rates vary greatly depending on the selected equipment. Ultra low volume equipment will require a low dilution (e.g. 1:9 or 1:19) or no dilution at all. Other space spray equipment will dispense larger volumes of spray solutions and therefore require a higher dilution of (e.g. 1:99 or 1:199). |
| Category(ies) of user(s) | Trained professional |
| Pack sizes and packaging material | Up to 20 L plastic bottle (CoEX: PE/PA or PE/EV). |

Table 2. Intended use 2 – Ground application

| | |
|---|---|
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |

[2] Copy this section as many times as necessary (one table per use).

| | |
|---|---|
| Where relevant, an exact description of the authorised use | Deltamethrin EW 20 is a deltamethrin based concentrate (20 g/L) for application as an ultra-low volume aerosol or thermal fog. The product is suitable for vector control use in public health situations. |
| Target organism (including development stage) | Adult mosquitoes (Culicidae)<br>Adult house flies (Muscidae) |
| Field of use | Indoor, Outdoor |
| Application method(s) | Fogging.<br>Deltamethrin EW 20 can be used with the two main application techniques, thermal or cold fogging. For thermal fogging equipment, both standard and ULV equipment can be used. The instructions of the chosen equipment must be followed accurately to obtain the optimal droplet size required for best product performance. |
| Application rate(s) and frequency | Dose: 1 g deltamethrin / ha for outdoor application – 0.05 g deltamethrin / 1000$m^3$ for indoor application<br><br>Dilution: 0%<br><br>Application timing:<br>Mosquito: outdoor space spraying is best carried out around dusk at low wind speeds.<br><br>Application interval:<br>Infestation dependent<br><br><u>General directions for use</u><br>Dilution rates vary greatly depending on the selected equipment. Ultra low volume equipment will require a low dilution (e.g. 1:9 or 1:19) or no dilution at all. Other space spray equipment will dispense larger volumes of spray solutions and therefore require a higher dilution of (e.g. 1:99 or 1:199). |
| Category(ies) of user(s) | Trained professional, Professional |
| Pack sizes and packaging material | Up to 20 L plastic bottle (CoEX: PE/PA or PE/EV). |

## 2.2.2 Physical, chemical and technical properties

Deltamethrin EW 20 is an emulsion of oil in water containing 20 g/L deltamethrin. It is an off-white liquid with a xylene-like odour. The product does not burn, does not undergo spontaneous combustion. The pH of a 1% dispersion is 4.32 at 20.5°C. Based on the structural formula of the active, the product has no oxidising and no explosive properties. The product is stable during four years at ambient temperature. Based on the Kinematic Viscosity and the content in hydrocarbons, Deltamethrin EW 20 is classified in Category 1 for aspiration hazard.

**<u>Data requirements:</u>**

- **Homogeneity must be determined according to FEA method 644. Spray diameter must be determined at 30 cm distance. The applicant has stated that the study is ongoing.**

**September 2020:**

- **Explosivity of vapour/air should be addressed. Data can be submitted at the renewal process.**
- **A corrosivity test should be submitted at the renewal process.**

**Label implications:**

- **Classification in Category 1 for aspiration hazard is proposed.**
- **Shake well before.**

**Table 1.3-1 Physico-chemical properties of the biocidal product**

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|
| **Physical state** | Visual | Liquid | Chambers;, 2006 M-274167-01-1 |
| **Colour** | Visual | Off-white | Chambers;, 2006 M-274167-01-1 |
| **Odour** | Olfactory | Xylene-like | Chambers;, 2006 M-274167-01-1 |
| **Acidity/alkalinity pH of undiluted material** | CIPAC MT 75 | pH: 4.47 (1% aqueous dispersion in distilled water at 20.5°C) | Chambers;, 2006 M-274167-01-1 |
| **Relative density** | CIPAC MT 3 | 1.003 g/mL at 20°C | Chambers;, 2006 M-274167-01-1 |

<table>
<tr><th>Physico-chemical property</th><th>Guideline No. and Method used</th><th>Result/Comment</th><th>References in section 3 and 4</th></tr>
<tr><td>Accelerated storage stability</td><td>CIPAC MT 46.3</td><td>No significant deviation from initial concentration is observed after storage during two weeks at 54°C.
<table>
<tr><th rowspan="2">Characteristics<br>Test Method</th><th rowspan="2">Parameter</th><th colspan="2">Results (specification)</th></tr>
<tr><th>Before Accelerated Storage</th><th>After Accelerated Storage</th></tr>
<tr><td>Determination of a.s.<br>CIPAC 333/EC/M/3</td><td>Active substance content</td><td>21.8 g/kg</td><td>21.5 g/L</td></tr>
<tr><td>Appearance<br>Visual</td><td>State<br>Colour<br>Odour</td><td>Liquid<br>Off-white<br>Xylene-like</td><td>Liquid (1)<br>Off-white<br>Xylene-like</td></tr>
<tr><td>Acidity/alkalinity/pH range<br>CIPAC MT 75</td><td>sample pH<br>blank pH</td><td>4.32<br>6.86</td><td>4.47<br>6.86</td></tr>
<tr><td>Persistent foam<br>CIPAC MT 47.2</td><td>After 10 seconds<br>After 1 minute<br>After 3 minutes<br>After 12 minutes</td><td>14 mL foam<br>10 mL foam<br>8 mL foam<br>0 mL foam</td><td>Not required</td></tr>
<tr><td>Surface tension<br>EEC A5</td><td>1 g/L @ 21°C</td><td>38.69 mN/m</td><td>35.58 mN/m</td></tr>
<tr><td>Relative density<br>CIPAC MT 3</td><td>Hydrometer method</td><td>1.003 g/mL @ 20°C</td><td>Not required</td></tr>
<tr><td>Pourability<br>CIPAC MT 148</td><td>Initial residue<br>Rinsed residue</td><td>0.37%<br>0.14%</td><td>0.35%<br>0.12%</td></tr>
<tr><td>Emulsifiability, emulsion stability and re-emulsification<br>CIPAC MT 36.3</td><td>After 30 sec.<br>After 24 hours</td><td>Stable<br>Stable</td><td>Stable<br>Stable</td></tr>
<tr><td>Explosive properties<br>EEC A14</td><td>DSC<br>Structural assessment</td><td>Not explosive</td><td>Not required</td></tr>
<tr><td>Oxidising properties<br>EEC A21</td><td>Structural assessment</td><td>No oxidising properties</td><td>Not required</td></tr>
<tr><td>Flash point<br>EEC A9</td><td>Closed cup, Pensky-Martens up to 110°C</td><td>No flash-point</td><td>Not required</td></tr>
<tr><td>Flammability<br>EEC A15</td><td>Auto-ignition temp.<br>Time-lag</td><td>543°C<br>4 sec.</td><td>Not required</td></tr>
<tr><td rowspan="2">Viscosity<br>OECD Test Guideline 114</td><td rowspan="2">Over range<br>142-1000 (1/s)</td><td>18°C</td><td>non-Newtonian ranging from 64.9 – 21.5 mPa.s</td><td rowspan="2">Not required</td></tr>
<tr><td>38°C</td><td>Newtonian with mean of 1.67 mPa.s</td></tr>
<tr><td>Cold storage stability<br>CIPAC MT 39.3</td><td colspan="2">0-2°C</td><td>Sample remains homogenous</td><td>Not required</td></tr>
</table>
(1) There was a degree of separation of the emulsion after accelerated storage, which after inversion, re-emulsified.<br>
The packaging material is COEX (PE/PA). Based on the raw-data of the accelerated storage stability study for deltamethrin EW 20 g/L , only a slight distortion of the original packaging was observed after removal from the incubator. This distortion disappeared after cooling and neither seepage nor leak was observed.</td><td>Chambers;, 2006 M-274167-01-1</td></tr>
<tr><td>Ambient storage stability</td><td>CIPAC MT 46.3</td><td>No significant loss of active ingredient content after 4 years storage.</td><td>Morgan;, 2009</td></tr>
</table>

<table>
<tr><th>Physico-chemical property</th><th>Guideline No. and Method used</th><th>Result/Comment</th><th>References in section 3 and 4</th></tr>
<tr><td></td><td></td><td>Initial: 21.6% g/kg<br>After storage: 19.8% g/kg<br><br><u>Appearance:</u>
<table>
<tr><th>Sample ref</th><th>Actual storage interval</th><th>Product appearance</th><th>Pack stability</th></tr>
<tr><td>0284-001</td><td>Day 0</td><td>Off-white liquid with a xylene-like odour</td><td>One litre, plastic screw top container</td></tr>
<tr><td>0288-001</td><td>6.0 months at ambient</td><td>White liquid suspension with distinctive odour. No visible separation, some bottom thickening but easily re-homogenised.</td><td>No visible deterioration. No leaks from lid.</td></tr>
<tr><td>0288-002</td><td>12.0 months at ambient</td><td>White liquid with distinctive odour.</td><td>No obvious leaks. Cap seal intact.</td></tr>
<tr><td>0288-003</td><td>18.0 months at ambient</td><td>White liquid with distinctive naphthol odour. Approx 50% separation.</td><td>No damage or leaks.</td></tr>
<tr><td>0288-004</td><td>24.0 months at ambient</td><td>Off-white liquid with aromatic odour. Approx 47% separation with lower viscous layer. No sediment. Homogenises in 7x inversions.</td><td>1 litre PE/EV bottle with 50mm opening. No deformation, swelling, leaking or other visual deterioration of pack. No external odour. Closure integrity good.</td></tr>
<tr><td>0288-005</td><td>36.0 months at ambient</td><td>Off-white liquid with aromatic odour. Approx 53% supernatant. No sediment. Homogenises in 3x inversions.</td><td>1 litre PE/EV bottle with 50mm opening. No deformation, swelling, leaking or other visual deterioration of pack. No external odour. Closure integrity good.</td></tr>
<tr><td>0288-006</td><td>48.2 months at ambient</td><td>Off-white liquid with aromatic odour. Approx 48-53% supernatant. No sediment. Homogenises in 3x inversions.</td><td>1 litre PE/EV bottle with 50mm opening. No deformation, swelling, leaking or other visual deterioration of pack. No external odour. Closure integrity good.</td></tr>
</table>
<u>pH:</u></td><td>M-306193-02-1</td></tr>
</table>

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|

| Sample ref | Actual storage interval | blank pH | sample pH |
|---|---|---|---|
| 0284-001 | Day 0 | 6.9 | 4.3 |
| 0288-001 | 6.0 months at ambient | 6.8 | 4.1 |
| 0288-002 | 12.0 months at ambient | 5.3 | 4.2 |
| 0288-003 | 18.0 months at ambient | 5.0 | 4.4 |
| 0288-004 | 24.0 months at ambient | 6.4 | 5.5 |
| 0288-005 | 36.0 months at ambient | 6.2 | 5.7 |
| 0288-006 | 48.2 months at ambient | 6.1 | 5.8 |

Pourability:

| Sample ref | Actual storage interval | Initial residue (%) | Rinsed residue (%) |
|---|---|---|---|
| 0284-001 | Day 0 | 0.37 | 0.14 |
| 0288-001 | 6.0 months at ambient | 1.67 | 0.23 |
| 0288-002 | 12.0 months at ambient | 0.18 | 0.13 |
| 0288-003 | 18.0 months at ambient | 0.43 | 0.13 |
| 0288-004 | 24.0 months at ambient | 0.79 | 0.11 |
| 0288-005 | 36.0 months at ambient | 0.77 | 0.14 |
| 0288-006 | 48.2 months at ambient | 0.87 | 0.14 |

Persistent foaming:

| Sample ref | Actual storage interval | Volume of foam (ml) | | | |
|---|---|---|---|---|---|
| | | After 10 sec | After 1 min | After 3 min | After 12 min |
| 0284-001 | Day 0 | 14 | 10 | 8 | 0 |
| 0288-001 | 6.0 months at ambient | 20 | 20 | 20 | 20 |
| 0288-002* | 12.0 months at ambient | 3 | 3 | 3 | 3 |
| 0288-003 | 18.0 months at ambient | 20 | 18 | 18 | 18 |
| 0288-004 | 24.0 months at ambient | 2 | <2 | <2 | <1 |
| 0288-005 | 36.0 months at ambient | 5 | 5 | 3 | 3 |
| 0288-006 | 48.2 months at ambient | 5 | 5 | 5 | 3 |

Emulsifiability, emulsion stability and re-emulsification:

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|

| | Sample ref | 0284-001 | 0288-001 | 0288-002 | 0288-003 | 0288-004 | 0288-005 | 0288-006 |
|---|---|---|---|---|---|---|---|---|
| | Actual storage interval (ambient) | Day 0 | 6M | 12M | 18M | 24M | 36M | 48M |
| Test time | | Volume of cream, free oil or sediment (ml) | | | | | | |
| 30 seconds | Emulsion uniformity | Stable | Uniform | Uniform | Uniform | Uniform | Uniform | Uniform |
| 30mins | Free Oil | - | Nil | Nil | Nil | Nil | Nil | Nil |
| | Cream | - | Nil | Nil | Nil | Nil | Nil | Nil |
| 2 hours | Free Oil | - | Nil | Nil | Nil | Nil | Nil | Nil |
| | Cream | - | Nil | Nil | Nil | Trace | Trace | Nil |
| 24 hours | Free Oil | - | Nil | Nil | Nil | Nil | Nil | Nil |
| | Cream/sediment | - | Nil | Nil | Nil | Trace | Trace | Trace |
| Re-emulsification +30 seconds | Emulsion uniformity | Stable | Uniform | NR | NR | Uniform | Uniform | Uniform |
| Re-emulsification +30 minutes | Free Oil | - | Nil | NR | NR | Nil | Nil | Nil |
| | Cream | - | Nil | NR | NR | Nil | Nil | Nil |
| | Solid matter | - | Nil | NR | NR | Trace | Trace | Trace |

Slight increase in pH during storage but this does do not appear to impact chemical stability.
Although there is significant amount of separation on storage, the product is easily homogenised and there is no sediment.
Pour and rinse residues are low.
Dilution properties are good and there are only low levels of persistent foam.
The integrity of the PE/EV packaging was maintained during the course of the storage test and was not affected by the product.

Conclusion: the product is stable during four years at ambient temperature.

**Shake well before use must be added in the label.**

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|
| **Cold storage** | CIPAC MT 39.3 | 0-2°C for 1 week: Sample remains homogenous, no separation was observed. | Chambers;, 2006 M-274167-01-1 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | Stored away from direct sunlight should be added in SPC. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | Not applicable because according to the label instructions the biocidal product has to be kept in original unopened container, stored in a cool, dry and well ventilated place, away from direct sunlight. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | See storage stability studies. | - |

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|
| Wettability | – | Not applicable as the biocidal product is a liquid. | - |
| Suspensibility, spontaneity and dispersion stability | - | Not applicable as the biocidal product is EW. | - |
| Emulsifiability, emulsion stability and re-emulsification | CIPAC MT 36.3 | 5% dilution in CIPAC D water<br>After 30 sec.: Stable<br>After 24 hours: Stable | Chambers;, 2006 M-274167-01-1 |
| | | All homogenous emulsion with no cream and no oil except after 30 sec, at this time a heterogeneous emulsion with flowmarks was observed.<br>Test in CIPAC water D at 0.5%-5% v/v concentrations, initial and after 1 week at 0°C, 2 weeks at 54°C and 24 months at 20°C. | Manka; S., 2019 Study no: Mo5921 |
| Disintegration time | – | Not applicable, the formulation is a liquid. | – |
| Particle size distribution, content of dust/fines, attrition, friability | - | Not applicable as the biocidal product is EW. | - |
| Persistent foam | CIPAC MT 47.2 | 10% dilutions in standard water D<br>After 10 seconds 14 mL foam<br>After 1 minute 10 mL foam<br>After 3 minutes 8 mL foam<br>After 12 minutes 0 mL foam | Chambers;, 2006 M-274167-01-1 |
| **Pourability** | CIPAC MT 148 | Initial residue: 0.37%<br>Rinsed residue: 0.14% | Chambers;, 2006 M-274167-01-1 |
| **Surface tension** | EEC A5 | 5% dilution in distilled water:<br>1 g/L@21°C: 38.69mN/m | Chambers;, 2006 |

| Physico-chemical property | Guideline No. and Method used | Result/Comment | | | References in section 3 and 4 |
|---|---|---|---|---|---|
| | | | | | M-274167-01-1 |
| **Viscosity** | OECD 114 | Over range 142-1000 (1/s) | 18°C | non-Newtonian ranging from 54.9-21.5 mPa.s | Chambers;, 2006 M-274167-01-1 |
| | | | 38°C | Newtonian with mean of 1.87mPa.s<br><br>**The Biocidal product must be classified in Category 1 for aspiration hazard.** | |

| Physico-chemical property | Guideline No. and Method used | Result/Comment | References in section 3 and 4 |
|---|---|---|---|
| Burning rate — smoke generators | – | Not applicable, the formulaton is not a smoke generator. | – |
| Burning completeness — smoke generators | – | Not applicable, the formulaton is not a smoke generator. | – |
| Composition of smoke — smoke generators | – | Not applicable, the formulaton is not a smoke generator. | – |
| Spraying pattern — aerosols | – | Not applicable, the formulation is not an aerosol.<br>The applicant however has stated that Homogeneity according to FEA method 644 and Spray diameter at 30 cm distance study will be submitted. | – |
| Physical compatibility | – | The biocidal product is not intended to be used with other products including other biocidal products. | – |
| Chemical compatibility | – | The biocidal product is not intended to be used with other products including other biocidal products. | – |
| Degree of dissolution and dilution stability | – | Not applicable as the product is EW. | – |

### 2.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Explosives | EEC A. 14 | - | Not Explosive (based on assessment of functional groups) | Chambers;, 2006 M-274167-01-1 |
| Flammable gases | – | – | Not applicable.The biocidal product is not a gas. | – |
| Flammable aerosols | – | – | Not applicable. The biocidal product is not an aerosol. | – |
| Oxidising gases | – | – | Not applicable. The biocidal product is not a gas. | – |
| Gases under pressure | – | – | Not applicable. The biocidal product is not a gas. | – |
| Flammable liquids | EEC A.15 | - | No flash point up to 110°C<br><br>**September 2020: ):** Since the product contains deltamethrin, it falls under "halogenated substance, mixture containing halogenated, volatile or non volatile flammable substance" Explosivity of vapour air should be addressed. Data can be submitted at the renewal process. | Chambers;, 2006 M-274167-01-1 |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Flammable solids | – | – | Not applicable. The biocidal product is liquid. | – |
| Self-reactive substances and mixtures | – | – | There are no chemical groups associated with explosive or self-reactive properties present in the molecule of the active ingredient, or any of other contents. Therefore based on the chemical structures the product is not self-reactive | – |
| Pyrophoric liquids | – | – | The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected | – |
| Pyrophoric solids | – | – | Not applicable. The biocidal product is liquid. | – |
| Self-heating substances and mixtures | – | – | The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-heating | – |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | behaviour if it is not absorbed on a large surface. | |
| Substances and mixtures which in contact with water emit flammable gases | – | – | This product is used in dilution with water and it does contain water itself. Consequently it is concluded that the product is stable and this is demonstrated in the physico-chemical study including the storage stability | – |
| Oxidising liquids | EEC A. 21 | - | No oxidizing properties (based on assessment of functional groups) | Chambers;, 2006 M-274167-01-1 |
| Oxidising solids | – | – | Not applicable. The biocidal product is liquid. | – |
| Organic peroxides | – | – | Not applicable. The biocidal product is not an organic peroxide. | – |
| Corrosive to metals | - | - | The product has been known for many years. It has never been reported any significant corrosion with tank or applicability material which are partially made of metal. Furthermore | - |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | containers made of carbon steel or aluminium are not recommended.<br><br>**September 2020:** According to the "Guidance on the Application of CLP Criteria, version 3.0, November 2012a" a test should also be submitted. Data can be submitted at the renewal process. | |
| Auto-ignition temperatures of products (liquids and gases) | EEC A.15 | - | Auto-ignition temp.: 543°C at 101.8 kPa.<br>Time-lag: 4sec. | Chambers;, 2006 M-274167-01-1 |
| Relative self-ignition temperature for solids | – | – | Not applicable. The biocidal product is liquid. | – |
| Dust explosion hazard | – | – | Not applicable. The biocidal product is liquid unable to produce dust. | – |

### 2.2.4 Methods for detection and identification

The identification and quantification of deltamethrin as manufactured is summarised in the Assessment Report for deltamethrin (PT18).

#### 2.2.4.1 Formulation analysis

Active substance content was determined by HPLC with UV detection following the procedures described in CIPAC 333/EC/M/3.

Prior to determination of the active substance content, method performance was checked with respect to linearity, specificity and precision. For linearity, 5 calibration solutions were

prepared ranging from 1 to 5 mg/mL. A linear response was obtained with a correlation coefficient of 0.9994. Adequate specificity was checked by ensuring that the high performance liquid chromatography (HPLC) conditions resulted in resolution of deltamethrin from its αR, 1R-cis stereo-isomer.

The precision was determined by 5 repeat injections of a 1 mg/mL solution of deltamethrin. The peak areas were integrated and the relative standard deviation was <2%.

Validation data were conducted (precision, linearity) in a different formulation (OD, containing 1% deltamethrin and 10% Thiacloprid). Specificity was conducted in the ND Solvesso formulation version 06477399 (the change in the versions 06477399 to 80234791 is considered minor).

CIPAC 333/SC method (with specificity data) and CIPAC 333/EW method (equivalent to SC method) are also available. These methods were used in the storage stability studies.

None of the components of the formulation are considered to be of toxicological, environmental or eco-toxicological concern and therefore no further methods are required for the formulation.

#### 2.2.4.2 Analytical methods for residues

Analytical methods for determination of deltamethrin residues in relevant environmental matrices (as well as methods for the determination of residues in animal and human body fluids and in/on food or feedstuffs) are already evaluated and accepted for the active substance in the CAR.

### 2.2.5 Efficacy against target organisms

#### 2.2.5.1 Function and field of use

Deltamethrin EW 20 is a deltamethrin based concentrate (20 g/L) intended for space spray applications indoors as fogging by thermal fogging equipment. The product is intended for use indoors in buildings.

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

Target pests: Adult mosquitoes (e.g. *Aedes* spp, *Culex* spp).
The product is an insecticide for the control of adult mosquitoes by terrestrial applications indoor by professionals and trained professionals.

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

According to the applicant, Deltamethrin EW 20 is intended to be sold to the trained Pest Control Operator for use outdoors in rural or urban situation and indoors in domestic buildings. Deltamethrin EW 20 acts on harmful organisms by contact resulting in death. Deltamethrin expresses a knock-down effect.

### 2.2.5.4 Mode of action, including time delay

Deltamethrin is a synthetic pyrethroid which acts on harmful organisms primarily by contact but also by ingestion resulting in death. Deltamethrin expresses a strong knock-down effect.
Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption.
The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability.

## 2.2.5.5 Efficacy data

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | |
|---|---|---|---|---|---|---|
| **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **Indoor application Cold fogging** | Deltamethrin EW 20 | **Mosquitoes** *Aedes aegypti* *Culex quinquefasciatus* *Anopheles gambiae* All adults from susceptible laboratory strains, 3-4 days old. | **Simulated use test.** Biological testing in 20 $m^3$ chambers. Three wire cages per species each containing 20 adult mosquitoes were suspended in the test chambers. Cold fog formulations applied with glass nozzle misting or with turbo sprayer into the room. KT 10, KT 50, KT 95, knock down after 60 minutes and mortality after 24 hours were recoreded. 3-4 replicates per trial. | The formulations were diluted in water and applied per chamber by a cold fog system. The product was applied at different dose and dilution rates (1.2 – 24 mg a.i./20 $m^3$, diluted at 6-20 ml water). | The lowest dose tested (1.2 mg a.i./20 $m^3$ or 0.06 g a.i./1000 $m^3$) was diluted at 1:333 (product:water). This dose was the closest to the label application rate (0.05 g a.i./1000 $m^3$). KD after 1 hour: 100% for *Ae. aegypti* and *An. Gambiae,* 17% for *Cx. quinquefasciatus.* 100% mortality against all three mosquito species. | Nentwig (2006) BES-EH-Mo1947 |
| **Indoor application Space spray** | 2% w/w Deltamethrin EW (formulations for experimental use only) | **Mosquitoes** *Culex quinquefasciatus* **Houseflies** *Musca domestica* W.H.O. strains | **Simulated use test.** Space spray tests in a 42 $m^3$ chamber. 4 cages of 25 female mosquitoes were hung up in the chamber. For houseflies, 100 free flying insects were used. Spraying was carried out with two 2% w/w Deltamethrin EW formulations (one for mosquitoes and one for houseflies) from the center of the room, with a badger air brush. Aqua Reslin Super was used as a | 50 ml diluted formulation/1000 $m^3$ was performed at dilution rates 1+9, 1+19, 1+39 and 1+79 with water (i.e. 0.1. 0.05, 0.025 and 0.0125 gr deltamethrin/1000 $m^3$). | For mosquitoes, dilution rate 1+9 (0.1 g deltamethrin/1000$m^3$) resulted in 85.5% KD in 30 min. At rates 1+9 to 1+79, thus 0.1 to 0.0125 g deltamethrin/1000$m^3$, 94-100% mortality was recorded. For houseflies, dilution rate 1+9 (0.1 g deltamethrin/1000$m^3$) resulted in 75% KD in 15 min. At rates 1+9 and 1+19, thus 0.1 and | Bowron (1994) M-174928-01-1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | commercial standard.<br><br>For mosquitoes, knockdown assessments were carried out at 15 and 30 minutes and 24 hour mortality counts were taken. Two replicates of reference product and one replicate each of deltamethrin EW dilutions were conducted.<br><br>For houseflies, Knockdown counts were carried out at 15 minutes and 48 hour mortality was recorded. Two replicates of each test were conducted. Untreated controls were included for both *Culex* and *Musca*. | | 0.05 g deltamethrin/1000$m^3$, 98 and 99% mortality was recorded, respectively.<br>At the claimed dose rate of 0.05 g deltamethrin/1000$m^3$ (at dilution rate 1:19) the product exerted 99% killing effect against mosquitoes and houseflies.<br>Efficacy of the product was at least equivalent to that of reference product.<br>Untreated controls gave some mortality and results have been corrected using Abbots formula.<br>However, the mortality records in the untreated controls are not provided. | |
| **Indoor application Thermal fogging** | Deltamethrin EW 20 | **Houseflies** *Musca domestica*<br><br>3-5 days old females of C.R.B.A. strains | **Simulated use test.**<br>Space spray tests in a 42 $m^3$ chamber.<br>100 free flying insects were used.<br>Treatment was carried out by thermal fogging through the slightly open doorway with the operator standing outside the room.<br>Knockdown counts were carried out at 30 minutes and 24 and 48 hour mortality was recorded.<br>Control tests (untreated rooms) | The product was diluted with water at a rate of 1+99 to give a dose of 0.1 g deltamethrin/1000 $m^3$ when the dilution was applied at a rate equivalent to 500 ml final spray solution /1000 $m^3$. | The product gave 100% knockdown of free flying houseflies within 30 minutes and 95.5% mortality after 24 hours. | Bowron (1995) M-171592-01-1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | were also conducted. Two replicates of each test were conducted. | | | |
| **Indoor application Thermal fogging** | Deltamethrin EW 20 | **Mosquitoes** *Aedes aegypti, Culex quinquefasciatus* 2-4 day old females | **Small scale field test.** Tests were conducted in four external rooms of a building (with dimensions 38.5 $m^3$ to 48.7 $m^3$). Batches of 25 insects were supplied in two wire cages hugged in each room. Treatment was carried out by thermal fogging through the open doorway with the operator standing outside the room. After spraying the room was sealed and the procedure repeated in the other rooms. After 30 minutes the cages were inspected for knockdown and then insects were transferred to clean cups supplied with food for 24 hour mortality assessments. Control tests (untreated rooms) were also conducted | The product was diluted with water at a rate of 1+199 to give a dose of 0.05 g deltamethrin/1000 $m^3$ when the dilution was applied at a rate equivalent to 500 ml final spray solution /1000 $m^3$. | The product gave 91% and 100% knockdown for *Cx. quinquefasciatus* and *Ae. aegypti,* respectively, after 30 minutes exposure. After 24 hours 100% mortality was recorded for both species. In all control treatments no mortality was recorded. | Bowron (1995) M-171583-01-1 |
| **Outdoor terrestrial application Ultra low volume space spray aerosol** | Deltamethrin EW 20 | **Houseflies** *Musca domestica* **Mosquitoes** *Culex pipiens* | **Field test** (in Turkey). <u>For houseflies:</u> The product was performed once within a village as a ULV space spray, in the morning between 7.40 and 8.10 am, with a vehicle mounted sprayer. Fly numbers were assessed prior and post (30 and 60 min.) to spraying at favoured resting sites (trays of fruits, windows, doors etc.). Any knocked down insects were placed in cups with food and retained for 24 hour mortality | The product was diluted with water at a rate of 1+9 to give a dose of 1 g deltamethrin/ha or 1+19 to give a dose of 0.5 g deltamethrin/ha | <u>For houseflies:</u> The product at a 1+9 dilution rate (1 g deltamethrin/ha) resulted in 87.9% reduction in fly numbers (30+60 min.) compared with pretreatment counts. At 24 hours mean mortality rate was 88.6%. In resistance test, 95% mortality for the field flies was achieved with | Lucas et al., (1995) M-171580-01-1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | assessments.<br>The flies were evaluated at the F0 generation using the topical application technique (reference: SOP 363) against deltamethrin at multiples of the LD95 for the CTB strain of flies<br><br><u>For mosquitoes:</u><br>The product was performed in a rural area with a stagnant lagoon, greenhouses, wells and houses as a ULV space spray, in the evening between 8.30 and 10.00 pm, with a vehicle mounted sprayer. Seven treatments were performed within 8 days. Mosquito numbers were assessed over 3 nights before spraying was initiated and post to each spraying, using 10 CDC light traps positioned both outside and inside houses. Any knocked down insects were placed in cups with food and retained for 24 hour mortality assessments.<br>The field mosquitoes were evaluated at the F0 generation (ie. insects were blood fed) using WHO test kits against deltamethrin. | | x30 LD95 of susceptible CTB fly strain. This fact indicates that field houseflies were resistant to deltamethrin.<br><br><u>For mosquitoes:</u><br>An overall reduction of 27.5% was achieved. Removal of the high catches observed at one house, gave an overall reduction of 60.4%.<br>Comparing the response of susceptible strain C. quinquefasciatus insects with that of the field C. pipiens strain, suggests that the field insects are approximately 5x resistant to deltamethrin.<br>Treatments failed to provide acceptable control of the mosquito population perhaps due to:<br>1. Immigration from outside the treatment block<br>2. Poor road layout which did not permit a traditional 'grid' type application<br>3. Dense foliage and large impenetrable | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | structures hindering droplet penetration<br>4. Duration of treatment: traditional mosquito control programmes continue a nightly spraying regime over a 2-3 week 'attack' phase<br>5. Continued emergence of 'new' adults<br>6. Possible effects of resistance performance | |
| **Outdoor terrestrial application Ultra low volume space spray aerosol** | Deltamethrin EW 20 | **Mosquitoes**<br>*Culex quinquefasciatus*<br>(2-4 day old female non blood fed AEH strain)<br>*Aedes aegypti*<br>(2-3 day old adult female blood fed AEH strain) | **Field test.**<br>The product was performed on the flat level ground that surrounds a cricket pavilion as a ULV space spray with a back carried motorized sprayer against caged mosquitoes. Batches of 25 insects of each species were supplied in wire cages hugged in bamboo poles, 1 m from the ground, that were placed in a 100 x 100 m treatment block. Poles were inserted at 10, 25, 50, 75 and 100 meters from the treatment edge of the block. Treatments were made based on a 50 meter wide swath. 10 minutes after the treatment, the cages were transferred in clean pots with food for 24 hour mortality assessments.<br>Tests were conducted in the early morning on two separate occasions while the air was | The product was diluted with water at a rate of 1+9 to give a dose of 1 g deltamethrin/ha | An overall mean mortality of 72.2% and 88.6% was recorded, for *Culex quinquefasciatus* and *Aedes aegypti,* respectively, at 50 meters distance from the sprayer.<br>Mortality records were 82.2% and 100% against *Ae. aegypti* and 99.3 and 77% against *Cx. quenquefasciatus* at 10 and 25 m from the sprayer, respectively. | Lucas and Bowron (1996) M-171596-01-1 |

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|---|---|---|---|---|---|---|
| | | | relatively still and before the temperature inversion had broken. Two replicates were conducted on the first occasion, 4 on the second, with untreated controls conducted in both instances. | | | |
| **Outdoor terrestrial application Cold fogging** | Deltamethrin EW 20 | **Mosquitoes** *Ochlerotatus caspius, Ochlerotatus detritus Aedes vexans*<br><br>Field collected females | **Field tests** (two trials in France).<br>The first trial consisted of a linear treatment surrounding rural buildings.<br>The second trial was an open field treatment in a humid area previously wetted by irrigation.<br>About ten metallic cages each containing 10 *Oc. caspius* adult females (trial no.1) or *Aedes vexans*, *Oc. caspius* and *Oc. detritus* (trial no.2) were placed 2 to 5 m from the nozzle exit and at variable heights on natural supports (on ground, reeds, tamarisk, etc...).<br><br>Treatments were made with a 4x4 vehicle equipped with a cold fogging system.<br>K-Othrine 15/5 ULV (15 g deltamethrin + 5 g esbiothrin/L) was used as reference product.<br>Knockdown counts of caged mosquitoes at 1 or 2 hours post treatment were recorded. Cages were transferred to the lab where 24 hours mortality was recorded.<br>Control cages were placed away from insecticide treatments but | In the first trial the product was diluted with water at a rate of 1:39 to give a dose of 0.89 g deltamethrin/ha (44 ml product +1730 ml water/ha). K-Othrine 15/5 ULV was mixed with paraffin oil at a rate of 1:28 (60 ml product +1730 ml oil/ha).<br><br>In the second trial the product was diluted with paraffin oil at a rate of 1:39 to give a dose of 0.82 g deltamethrin/ha (41 ml product +1650 ml oil/ha). K-Othrine 15/5 ULV was mixed with paraffin oil | The knockdown effect 1 hr after treatments with both preparations was noticeable in the first trial with a mean of 93% and 98% efficacy for Aqua K-Othrine and K-Othrine 15/5 ULV, respectively.<br>In the second trial knockdown effect after 2 hrs only reached 84% and 63.2%.<br><br>At T+24 hrs, Aqua K-Othrine showed equivalent results to the reference product (100% in the first trial and 96 and 100% in the second trial for Aqua K-Othrine and K-Othrine 15/5 ULV, respectively).<br>No significant mortality was observed in the three control cages.<br><br>In the first trial a reduction of 80.7% of mosquito numbers caught in the first | Lagneau et al., (2006) M-280697-03-1 |

| | | | | | | |
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| | | | experienced the same environmental conditions as the treated cages.<br><br>In the first trial, an evaluation of the pest infestation was carried out just before and 24 hrs after application by human bait in the Aqua K-Othrine treated area. For feasibility reasons, such capture was not possible in the area treated with K-Othrine 15/5 ULV.<br><br>In the second trial, mosquito presence around the experimental area was assessed using Mosquito Magnet trap | at a rate of 1:19 (70 ml product +1410 ml oil/ha). | trial with Aqua K-Othrine was observed based on human bait counts. In the second, such a reduction only reached 23.6% against 33.9% for the reference. However, the effect of experimental treatments not being sufficient to avoid re-introduction of mosquitoes from non-treated adjacent sites, the obtained results are not particularly reliable due to large migration fluxes. | |
| **Outdoor aerial application Ultra Low Volume** | Deltamethrin EW 20 | **Mosquitoes** *Aedes caspius, Culex modestus* and *Anopheles sacharovi*<br><br>Field collected females | **Field tests** (trials in Greece). During 2008, 2 experimental sites were used and one control site. During 2009 an additional treatment site was included and a control site. ULV treatments were conducted in open agricultural areas (rice, cotton, and corn fields) ~ 1,000 ha in size at least 3 km away from any urbanized areas. Control sites located 3–5 km from the treatment areas. Pesguard S102 (10% w/w d-phenothrin) was also used. Aerial ULV treatments were conducted by helicopter equipped with a pair of electric rotary atomizers. The applications were conducted | In 2008, for Aqua-KOthrine, 0.75 and 1 g AI/ha were tested. For Pesguard S102, 7.5 and 10.0 g AI/ha were tested. In 2009, Aqua-K-Othrine was tested at the higher application rate, and Pesguard S102 at the lower rate. For Aqua-KOthrine, the lowest application rate was replicated | The high rate of Aqua-K-Othrine (1 g AI/ha) caused a mean population decrease of 76.5%, and the high application rate of Pesguard resulted in mean mosquito population reduction of 89%. Both rates caused mosquito population reductions that were significantly higher than their respective control area.<br><br>The highest application rate of Aqua-K-Othrine killed an average of 69.2% of the | Chaskopoulou *et al.* (2011) Journal of the American Mosquito Control Association, 27(4):414-422. 2011. |

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| | | | after sunset during high mosquito activity. The helicopter was equipped with a GPS and a real-time meteorology system. The real-time meteorological data were automatically processed by a spray dispersal computer model (AgDISP) to predict the spray movement based on application parameters and meteorological conditions.<br><br>In each spray trial 8–14 sampling stations were deployed overnight. Colocated on each sampling station were 1 adult mosquito cage and 1 droplet sampling device (to record droplet size). Approximately 2 h before each spray application, 30–50 female adult mosquitoes were placed into the cages. Approximately 60 min post-spraying, all cages were returned to the laboratory and mosquito mortality was determined 12 h after the treatment.<br>Five identical sampling stations were placed in the control site. For wild mosquito population evaluation, 2–4 CDC light traps were run 24 h pre- and post-treatment. One to 2 CDC light traps were run in the control areas. | twice and the highest one 5 times. For Pesguard S102, the highest application rate was replicated twice and the lowest one 5 times.<br>Both formulations were applied undiluted. | mosquitoes and the high rate of Pesguard resulted in overall mean mortality of 67.4%.<br><br>The AgDISP dispersal model, coupled with GPS navigation and real-time weather recording, enabled accurate placement of the spray cloud such that the majority of the treatment area received sufficiently high droplet densities to result in uniform caged-mosquito mortality across all sampling sites.<br><br>Caged-mosquito mortality was lower than that of wild mosquitoes, as estimated by trap counts. Cage design and screen size may have affected a fraction of the insecticide from reaching mosquitoes inside the cage. Specifically, the cage design used for this study, when tested in the laboratory, resulted in insecticide concentration reduction in the ranges of 49–59%. Lower | |

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| | | | | | exposure to the insecticide could explain the lower mortality obtained in caged mosquitoes. | |
| **Outdoor aerial application Ultra Low Volume** | Deltamethrin EW 20 | **Mosquitoes** *Aedes aegypti*<br><br>Adults from laboratory strain | **Field tests** (trials in Hungary).<br>**Laboratory tests**<br><br>1) The field trials were carried out on 3 different days in 2009 by a helicopter equipped with 6 spraying nozzles of type UNIROT 4.<br>The products Aqua K-Othrine and K-Othrin 10 ULV were applied.<br><br>2) <u>Spreading of deltamethrin-based products on the ground surface</u><br><br>Across the flying direction water-sensible papers were placed (1 piece/running metre) under a single spraying route of the helicopter (spraying width 50 m). To monitor the relative coverage and the specific droplet number, test papers were also placed in the flying direction on one side in each 5 running meter up to 50 meters.<br>From each monitoring paper 3 samples were chosen and were photographed. The samples were analyzed by a spectrographic analysis software and the values of the relative coverage and those of the | The products Aqua K-Othrine and K-Othrin were applied at 0.5 and 1 g deltamethrin/ha. Also, the product K-Othrin 10 ULV was applied at 0.96 g deltamethrin/ha.<br><br>Aqua K-Othrine was applied at the claimed dose (1 g deltamethrin/ha) on 14th July at a Rowing Club in a 130 ha area, mixing ratio 1:9, 0.5 L/ha spray solution; and at 29th July at a Rowing Club in a 70 ha area, mixing ratio 1:15, applied in 0.8 L/ha spray solution. | 2) <u>Spreading of deltamethrin-based products on the ground surface</u><br>The extent of drifting after treatment with Aqua K-Othrine at 1 g deltamethrin/ ha was considerable up to 25 m and it was still remarkable between 25-50 m.<br>The distribution of the active ingredient in the field improved compared with 0.5 gr a.i./ha. The droplet numbers exceeded the required value of 20-30 droplets/$cm^2$.<br>3) <u>Examination of deltamethrin-based adulticides used in mosquito control by instrumental analytical detection carried out in laboratory</u><br>The distribution of Aqua K-Othrine diluted at 1:9 (1 g deltamethrin/ha) applied in one of the sites was fairly symmetrical, though uneven. 12 % of the | Darvas and Gergely (2009) Mo Es 04848 |

| | | | | | | |
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| | | | specific droplet number (pc/cm2) were determined.<br><br>3) Examination of deltamethrin-based adulticides used in mosquito control by instrumental analytical detection carried out in laboratory<br>Across the flying direction 11 stainless steel trays were placed (1 piece/5 meters) under a single spraying route of the helicopter. 50 meters away from the treated area further control trays were placed to monitor drifting. One hour after the treatment, the mist was left to depose and then it was washed off with hexane. A gas chromatographer was used for measuring detected deltamethrin in ppb.<br><br>4) Laboratory efficacy trial with deltamethrin containing products on test insect *Aedes aegypti*<br>Adult mosquitoes were exposed to sprayed glass plates placed into closed ventilated boxes. The tested spray solution quantity (500 µL and 250 µL equal to 1 and 0.5 g deltamethrin /ha, respectively) was distributed by laboratory spray tower (Potter-tower) on 6 glass plates per treatment/repetition. Untreated control was also included. 10-20 | | active ingredient re-measured from the trays placed 50 meters from the edge of the treated area. 35 % of the quantity applied (1 g deltamethrin/ha) deposed on the ground surface.<br>The distribution picture of Aqua K-Othrine diluted at 1:15 (1 g deltamethrin/ha) applied in the other site was asymmetrical. 7 % of the active ingredient could be measured on the trays placed 50 meters from the edge of the treated area. 23 % of the quantity applied (1 g deltamethrin/ha) deposed on the ground surface.<br><br>4) Laboratory efficacy trial with deltamethrin containing products on test insect *Aedes aegypti*<br>Under laboratory conditions 100% mortality of mosquito adults was recorded 24 hours post treatment with 500 µL spray solution (1g deltamethrin/ha). | |

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| | | | mosquito adults of *Aedes aegipti* aged 3-5 days were placed into the boxes. After the spray solution dried, numb mosquitoes were inserted into the boxes. New mosquitoes we introduced into the boxes 2 and 7 days post treatment. 24 hours mortality was recorded.<br><br>5) Field efficacy trials with deltamethrin containing products on test insect *Aedes aegypti*<br><br>10-15 *Aedes aegypti* adults were placed in netted cages. 8 cages per way of treatment (one cage/5 meters and one in the middle of the treatment strip) were placed on the ground surface. Mortality was measured 30, 60 and 120 minutes post treatment.<br><br>6) Field efficacy trials with deltamethrin containing products by counting bites<br>Before and one day after the treatment 4-8 persons counted bites for a period of 2x5 minutes in the hour of sunset (human bait method).<br>On 14th July mosquito species collected were 100% *Aedes cinereus*<br>On 29th July mosquito species collected were 70% *Culex pipiens* and 30% *Aedes vexans*<br><br>7) Measuring the effects of | | 5) Field efficacy trials with deltamethrin containing products on test insect *Aedes aegypti*<br>Treatment with Aqua K-Othrine at 1 g deltamethrin/ha at mixing ratio 1:9, (0.5 L/ha spray solution) resulted in around 20%, 40% and 90% mortality of caged mosquitoes 30, 60 and 120 minutes post treatment. Treatment with Aqua K-Othrine at 1 g deltamethrin/ha at mixing ratio 1:15 (0.8 L/ha spray solution) resulted in around 60%, 80% and 100% mortality of caged mosquitoes 30, 60 and 120 minutes post treatment.<br><br>6) Field efficacy trials with deltamethrin containing products by counting bites<br>On 14$^{th}$ July treatment with Aqua K-Othrine at 1 g deltamethrin/ha at mixing ratio 1:9 (0.5 L/ha spray solution) resulted in 50% reduction of mosquito bites. On 29$^{th}$ July treatment with Aqua K- | |

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| | | | deltamethrin products used in mosquito control on the fauna<br><br>On 14th and 29th July treatment in the course of the treatment colored paper sheets (6 and 10 per treated area) were set out in the field from which - after one (14th July) to two hours (29th July)-falling out insects were collected in ethanol. Before the treatment the number of insects living on the ground surface was determined.<br>As a control a blue light trap was applied for two hours and a white light trap for 80 min were applied on 14th July and 29th July, respectively.<br><br>On 14th July Aqua K-Othrine applied at 1 g deltamethrin/ha at mixing ratio 1:9 (0.5 L/ha spray solution)<br><br>On 29th July Aqua K-Othrine applied at 1 g deltamethrin/ha at mixing ratio 1:15 (0.8 L/ha spray solution) | | Othrine at 1 g deltamethrin/ha at mixing ratio 1:15 (0.8 L/ha spray solution) resulted in 70% reduction of mosquito bites.<br><br>7) Measuring the effects of deltamethrin products used in mosquito control on the fauna<br><br>The composition of insects falling after the treatment were on 14th July: Hymenoptera 50%, Culicidae 10%, Chironomidae 10%, other Diptera 30%.<br>On 29th July: Cicadelidae 82%, Hymenoptera 6%, Chrysopa sp. 2%, Chironomidae 4%, other Diptera 6%. | |

| **Conclusion on the efficacy of the product** |
|---|
| Based on the results of the submitted efficacy studies, Deltamethrin EW 20 was effective:<br><br>- as an indoor application by thermal fogging at 0.05 g a.i./1000 $m^3$ (diluted with water at 1:199) against mosquito adults.<br><br>- as an outdoor terrestrial application at 1 g a.i./ha by Ultra Low Volume space spray application (diluted with water at 1:9) against housefly adults, and by Ultra Low Volume space spray application (diluted with water at 1:9) and cold fogging application (diluted with water at 1:39) against mosquito adults.<br><br>- as an outdoor Ultra Low Volume aerial application at 1 g a.i./ha (undiluted to 1:9 diluted with water) against mosquito adults using helicopter mounted with sprayers (6 sprayers of type Unirot 4) and equipped with GPS, on board real-time wind measurement and AGDISP software, in order to avoid spray drift in non-target area. |

### 2.2.5.6 Occurrence of resistance and resistance management

Resistance status of Deltamethrin has been reviewed under active substance BPD evaluation and it is presented as follows:
"Deltamethrin is a pyrethroid insecticide. Some resistance to pyrethroids has been found to varying degrees, depending on the pest species and location (Anon, 1987). In Europe the main problems have occurred in some areas with pests of agricultural significance. Laboratory tests on resistant strains have shown, for *Myzus persicae*, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).
A review by the WHO of Vector Resistance to Pesticides (Anon, 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread (Anon, 2000).
Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2004), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).
Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard.
General advice is provided by IRAC (Anon, 1987).
The principles of strategies for managing the development of resistance are similar for deltamethrin as they are for other synthetic pyrethroids:

- where possible, application treatments should be recommended to be combined with non-chemical measures.
- products should always be used in accordance with label recommendations.
- applications should always be made against the most susceptible stages in the pest life cycle.
- where an extended period of control is required, treatments should be alternated with products with different modes of action.

- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refuges can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease."
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- Do not [use/apply] the product in areas where resistance to the active substance(s) 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.
-

eCA points out that according to the Arthropod Pesticide Resistance Database provided by IRAC (http://www.pesticideresistance.org/search.php), many cases of resistance of mosquitoes and houseflies on deltamethrin have been reported in the literature.
Therefore, eCA agrees with the aforementioned proposed resistance management measures for the active substance and suggests that they may apply for the biocidal product as well.
The last resistance management strategy could be slightly revised as follows: "... use of any product containing active substance with the same mode of action should cease".

### 2.2.5.7 Evaluation of the label claims

According to the submitted Doc-I, Doc-IIB and draft label, the applicant proposes the following intended uses including target organisms, dose rates and application methods:
Deltamethrin EW 20 is a deltamethrin based concentrate (20 g/L) for application as an ultra-low volume aerosol or thermal fog. The product is suitable for vector control use in public health situations.
Deltamethrin EW 20 is intended to be sold to the trained Pest Control Operator for use outdoors in rural or urban situation and indoors in domestic buildings. Deltamethrin EW 20 acts on harmful organisms by contact resulting in death. Deltamethrin expresses a knock-down effect.
**Target pests**
Adult mosquitoes (e.g. *Aedes* spp, *Culex* spp)
Adult House flies (*Musca domestica*)
**Dose rates**
- For outdoor uses from the ground (terrestrial) or from airplanes/helicopters (aerial), a dose rate of 1 g Deltamethrin/ha should be used.
- For indoor applications a dose rate of 0.05 g Deltamethrin/1000m³ should be used.

**Suitable application equipment**
Deltamethrin EW 20 can be used with the two main application techniques, thermal or cold fogging. For thermal fogging equipment, both standard and ULV equipment can be used. The instructions of the chosen equipment must be followed accurately to obtain the optimal droplet size required for best product performance.
For AERIAL APPLICATION: helicopter with mounted sprayers (e.g. type Unirot 4, 6 sprayers (3 per boom)) using GPS, on board real-time wind measurement and AGDISP software, or equivalent equipment in order to avoid spray drift in non-target area.
**Dilution and spraying**
Dilution rates vary greatly depending on the selected equipment. Ultra low volume equipment will require a low dilution (e.g. 1:9 or 1:19) or no dilution at all. Other space spray equipment will dispense larger volumes of spray solutions and therefore require a higher dilution (e.g. 1:99 or 1:199).

| Location | Target | Equipment | Dilution | Dose rate |
|---|---|---|---|---|
| Outdoor, aerial | Mosquitos | Airplane/helicopter mounted application equipment | Undiluted to 1:9 Please refer to equipment instructions | 1g DLT/ha |
| Outdoor, terrestrial | Mosquitos | Thermal fogging equipment Cold fogging equipment | 1:9 to 1:99 Please refer to equipment instructions | 1g DLT/ha |
| Outdoor, terrestrial | Flies | Thermal fogging equipment Cold fogging equipment | 1:9 to 1:99 Please refer to equipment instructions | 1g DLT/ha |
| Indoor | Mosquitos Flies | Thermal fogging equipment Cold fogging equipment | 1:99 to 1:199 Please refer to equipment instructions | 0.05g DLT/1000m³ |

**Application timing:**
Mosquito: outdoor space spraying is best carried out around dusk at low wind speeds.

**Application interval:**
Infestation dependent

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

**Indoor applications of Deltamethrin EW 20 against mosquitoes and flies at dose rate of 0.05 g a.i./1000 m³ using thermal or cold fogging (1:99 to 1:199 dilution rates with water).**
According to the results of study BES-EH-Mo1947, Deltamethrin EW 20 was effective against mosquito adults *Aedes aegypti, Culex quinquefasciatus* and *Anopheles gambiae* as an indoor application by cold fogging at 0.06 g a.i./1000 $m^3$, diluted with water at 1:333. However, this study does not support label claims because the lower dose tested was higher than the claimed one.

According to the results of study M-174928-01-1, 2% w/w Deltamethrin EW formulations were effective against mosquito adults *Culex quinquefasciatus* and housefly adults (*Musca domestica*) as indoor space spray applications using a "budger air brush" at 0.05 g a.i./1000 $m^3$, diluted with water at 1:19. Efficacy of the tested formulations (not identical to Deltamethrin EW 20) supports efficacy of Deltamethrin EW 20 since they have the same formulation type (EW) and concentration of deltamethrin (2% w/w). However, this study is rejected and therefore cannot support thermal or cold fogging indoors against houseflies because a) The "Badger air brush" used for space spray treatment in the study, is not a representative equipment for thermal or cold fogging and therefore does not guarantee the generation of the desired droplet size which has a high impact on the efficacy of the product, and b) Mortality records in the untreated control were not provided in the study report and therefore 48 hours mortality in the treatment could not be validated.

According to the results of study M-171592-01-1, Deltamethrin EW 20 was effective against housefly adults (*Musca domestica*) as an indoor application by thermal fogging at 0.1 g a.i./1000 $m^3$, diluted with water at 1:99. However, this study does not support label claims because the dose tested was higher than the claimed one.

According to the results of study M-171583-01-1, Deltamethrin EW 20 was effective against mosquito adults *Aedes aegypti* and *Culex quinquefasciatus* as an indoor application by thermal fogging at 0.05 g a.i./1000 $m^3$, diluted with water at 1:199.

Based on the aforementioned studies, Deltamethrin EW 20 was effective against mosquito adults as an indoor application by thermal fogging at 0.05 g a.i./1000 $m^3$ (diluted with water at 1:199).

**Outdoor terrestrial applications of Deltamethrin EW 20 against mosquitoes and flies at dose rate of 1 g a.i./ha using thermal or cold fogging (1:9 to 1:99 dilution rates with water).**

According to the results of study M-171580-01-1, Deltamethrin EW 20 was effective against housefly (*Musca domestica*) adults as an outdoor terrestrial application by Ultra Low Volume space spray aerosol with a vehicle mounted sprayer at 1 g a.i./ha, diluted with water at 1:9.

According to the results of study M-171596-01-1, Deltamethrin EW 20 was effective against mosquito adults *Culex quinquefasciatus* and *Aedes aegypti* as an outdoor terrestrial application by Ultra Low Volume space spray aerosol with a back carried motorized sprayer at 1 g a.i./ha, diluted with water at 1:9. The results of this study indicate that the product was efficacious at a distance max. 25 meters of the sprayer from the target mosquitoes.

According to the results of study M-280697-03-1, Deltamethrin EW 20 was effective against mosquito adults *Ochlerotatus caspius* as an outdoor terrestrial application by cold fogging with a vehicle mounted sprayer at 0.89 g a.i./ha, diluted with water at 1:39. The product when applied according to the label claims, was not tested against *Culex* sp. (required mosquito species in the TNsG), because the study was performed with field collected mosquitoes and *Culex* mosquitoes did not occur in the area of the field study. However, effectiveness against *Ochlerotatus caspius* is used as supportive data for ground outdoor cold fogging application against mosquitoes.

Based on the aforementioned studies, Deltamethrin EW 20 was effective as an outdoor terrestrial application at 1 g a.i./ha against housefly adults by Ultra Low Volume space spray application (diluted with water at 1:9) and against mosquito adults by Ultra Low Volume space spray application (diluted with water at 1:9) and cold fogging application (diluted with water at 1:39).

**Outdoor aerial Ultra Low Volume application of Deltamethrin EW 20 against mosquitoes at dose rate of 1 g a.i./ha using airplane/helicopter mounted application equipment (undiluted to 1:9 dilution rate with water).**
According to the results of study by Chaskopoulou *et al.* (2011), Deltamethrin EW 20 was effective at 1g/ha Deltamethrin (undiluted) against mosquito adults *Aedes caspius, Culex modestus* and *Anopheles sacharovi* as an outdoor Ultra Low Volume aerial application using helicopter mounted with sprayers and equipped with GPS, on board real-time wind measurement and AGDISP software, in order to avoid spray drift in non-target area.
According to the results of study by Darvas and Gergely (2009), Deltamethrin EW 20 was effective at 1g/ha Deltamethrin (diluted with water at 1:9) against mosquito adults *Aedes aegypti* as an outdoor Ultra Low Volume aerial application using helicopter mounted with 6 spraying nozzles of type UNIROT 4.

Based on the aforementioned studies, Deltamethrin EW 20 was effective at 1g/ha Deltamethrin (undiluted to 1:9 diluted with water) against mosquito adults as an outdoor Ultra Low Volume aerial application using helicopter mounted with sprayers (6 sprayers of type Unirot 4) and equipped with GPS, on board real-time wind measurement and AGDISP software, in order to avoid spray drift in non-target area.

In SPC submitted by the applicant it is postulated that the product is to be applied as an aerial ULV application against flies. However, no efficacy studies have been submitted to prove efficacy of aerial treatment against housefly adults (*Musca domestica*).
The applicant states that "there is no need specified in the TNGs PT18/19 that an aerial application against *Musca* needs to be substantiated in a field trial". Also, the applicant interprets 14.2.2.4 of the guidelines in such way that "a field test should principally show that the product does work via aerial application but that specific tests against all target species are not required. This is especially true as the dose rate for mosquito and *Musca* are identical for outdoor use".
In 13.2 of the TNGs PT18/19 it is stated for claims about flies that "A clear label claim should be submitted. The study results of laboratory and simulated-use tests and field trials should demonstrate the efficacy of the product based on the submitted label claim". Here, a clear link between label claims and submitted field efficacy studies is addressed. eCA suggests that even though no specific dossier requirements are described in the TNGs PT18/19 for aerial application against flies, efficacy of aerial application against mosquitoes cannot be extrapolated to flies.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, eCA concludes into the proposed authorized uses of the product as described in 2.1.4.1 (table 1).

## 2.2.6 Risk assessment for human health

Aqua K-Othrine (Deltamethrin 20 EW) was not one of the representative formulations submitted for EU review according to the biocide Directive 98/8/EC.

With regard to the acute toxicity assessment a full acute toxicity data package with the formulation Aqua K-Othrine has been submitted.

With respect to the exposure assessment, calculations have been performed for indoor spray application using portable thermal fogger and outdoor spray application using cold (ULV) portable or vehicle-mounted fogging equipment. No relevant data have been submitted by the applicant to perform the exposure assessment during airplane/helicopter mounted application which is therefore not covered in this assessment.

### 2.2.6.1 Assessment of effects on Human Health

***Skin corrosion and irritation***

| **Summary table of animal studies on skin corrosion /irritation** | | | | | |
|---|---|---|---|---|---|
| **Method, Guideline,**<br>**GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results**<br>*Average score (24, 48, 72h)/*<br>*observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological*<br>*findings* | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute Dermal Irritation/Corrosion,<br>OECD 404,<br>Prior to GLP<br>Reliability: 1 | 6 female New Zealand White rabbits | Aqua K-Othrine (Code: TF 2628.<br>Batch No. CR21386/01/940601).<br>No vehicle.<br>0.5 ml formulation was applied as a semi-occluded, topical application to the clipped intact skin of six rabbits for | No oedema was observed.<br>The mean scores (24, 48, 72 h) for erythema and eschar formation were 1, 1.33, 2, 2, 2, 2 for each of the animals tested.<br>All skin effects were completely reversible by the end of the 14-day observation period. | None. | [redacted] 1994 |

| | | | | | |
|---|---|---|---|---|---|
| | | 4 hours. | | | |

No human data is available.

| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
|---|---|
| Value/conclusion | Mean erythema score (24-48-72 h) = 1.7<br>Highest oedema score = 0<br>Mild skin irritant. |
| Justification for the value/conclusion | Mild skin effects, completely reversible by the end of the 14-day observation period. |
| Classification of the product according to CLP and DSD | No classification is warranted. |

***Eye irritation***

| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
|---|---|---|---|---|---|
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance,Dose levels, Duration of exposure** | **Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute Eye Irritation,<br>As indicated in the study report, the assay has been carried out in accordance with OECD, EEC and USEPA Guidelines.<br>Prior to GLP.<br>Reliability: | 6 female New Zealand White rabbits | Aqua K-Othrine (Code: TF 2628,<br>Batch No. CR21386/01/940601),<br>No vehicle | In all animals treated with undiluted test material, conjunctival redness (grade 1), chemosis (grade 1) and iritis (grade 1) were noted in all animals 1 hour after instillation.<br>Grade 2 scores (the maximum recorded) for conjunctivl chemosis and/or redness were noted in 5/6 rabbits at either | An additional female NZW rabbit was exposed to 10% test substance in water.<br>No eye irritation was observed. | [redacted] 1994 |

| | | | | | |
|---|---|---|---|---|---|
| 1 | | | 4 or 24 hours after instillation.<br>Corneal opacity (grade 1) was noted in 3 animals 24 hours after instillation. The opacity was present in one animal up to 3 dayes after instillation.<br>Recovery was complete in all animals between 4 and 7 days after instillation. | | |

No human data is available.

| **Conclusion used in Risk Assessment – Eye irritation** | |
|---|---|
| Value/conclusion | Mean scores on 24-48-72 hours after instillation:<br>– Corneal opacity = 0.28<br>– Iritis = 0.72<br>– Conjunctival redness = 1.17<br>– Conjunctival oedema (chemosis) = 1.11<br>Recovery was complete in all animals between 4 and 7 days after instillation.<br>Not an eye irritant. |
| Justification for the value/conclusion | Mild ocular effects; completely reversible within 7 days after instillation. |
| Classification of the product according to CLP and DSD | No classification is warranted.<br>Mean score values for corneal opacity, iritis, conjunctival redness and chemosis were below the generic limit values for classification of the substance for reversible eye effects. |

### *Respiratory tract irritation*

No data available and not required according to Regulation (EU) 284/2013, Part A, Section 7 (Toxicological studies).

### *Skin sensitization*

| Summary table of animal studies on skin sensitisation | | | | | |
|---|---|---|---|---|---|
| **Method, Guideline, GLP status, . Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks** *(e.g. major deviations)* | **Reference** |
| Local Lymph Node Assay in the mouse,<br>OECD 429,<br>GLP<br>Reliability: 1 | 20 female CBA/J Rj mice | Deltamethrin EW 20 g/l.<br>Batch No. 2013-001034<br>Concentrations:<br>50, 25, 10% (w/v) in 1% Pluronic<br>-ve and +ve controls were included | The observed stimulation index values were 6.7, 5.5 and 2.4 at concentrations of 50, 25 and 10 % (w/v) respectively.<br>Based on these data, the calculated EC3 value for this test item is 12.9%.<br>No mortality was observed during the study. Increased activity and twitching was observed in the 50 and 25% (w/v) groups on Days 1-3. No treatment related effects were observed on animal body weights in any test item treated groups. | None. | [redacted] J., 2013 |

| Conclusion used in Risk Assessment – Skin sensitisation | |
|---|---|
| Value/conclusion | The following Stimulation Index (SI) values were obtained: |

| Dose (% w/v) | SI |
|---|---|
| 50 | 6.7 |
| 25 | 5.5 |
| 10 | 2.4 |

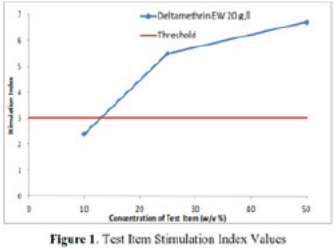


**Figure 1**. Test Item Stimulation Index Values

| | |
|---|---|
| | The calculated EC3 value for this test item is 12.9%.<br>Under the conditions of the present assay Deltamethrin EW 20 g/L was shown to have sensitization potential (sensitizer) in the Local Lymph Node Assay. |
| Justification for the value/conclusion | Since, there was a clear positive effect with a dose response, the test item was clearly a positive sensitizer. |
| Classification of the product according to CLP and DSD | Substances shall be classified as skin sensitisers (Category 1) in case there are positive results from an appropriate animal test.<br>Classification of Deltamethrin EW 20 g/L as Skin Sens. 1B, H317 (may cause an allergic skin reaction) is warranted. |

### *Respiratory sensitization (ADS)*

No data available and not required according to Regulation (EU) 284/2013, Part A, Section 7 (Toxicological studies).

### *Acute toxicity*

*Acute toxicity by oral route*

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

| | | | | | | |
|---|---|---|---|---|---|---|
| Acute oral toxicity,<br>OECD 401,<br>GLP,<br>Reliability: 1 | Rat,<br>Sprague-Dawley CD,<br>Males & females,<br>5 rats / sex/group | Aqua K Othrine EW (TF 2628),<br>50, 500, 5000 mg/kg bw,<br>gavage | All males and females treated with 5000 mg/kg bw and nine males and five females dosed with 500 mg/kg bw died within approx. 2.5 hours of dosing.<br>Clinical signs of toxicity were observed in both decendents and survivals of the 500 and 5000 mg/kg bw groups. In surviving animals clinical signs (salivation, hunched posture, reduced activity, soiling and reduced muscle tone) resolved between study day 2 and 3. | ♂: 304 mg/kg<br>♀: 500 mg/kg<br>♂ + ♀: 391 mg/kg | None. | [redacted] 1994 |

| **Value used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Value | The acute oral $LD_{50}$ value of Aqua K Othrine EW (TF 2623) in the rat were:<br>• Males: 304 ( 50-500) mg/kg body weight<br>• Females: 500 (341-733) mg/kg body weight<br>• Males & females : 391 ( 50-500) mg/kg body weight |
| Justification for the selected value | All males and females treated with 5000 mg/kg bw and nine males and five females dosed with 500 mg/kg bw died within approx. 2.5 hours of dosing. |
| Classification of the product according to CLP and DSD | The acute oral $LD_{50}$ values obtained for Aqua K Othrine EW (TF 2623) in the male and female rat fulfil the numeric criteria (300-2000 mg/kg bw) for allocation of the product to Category 4 based on acute toxicity by the oral route.<br>Classification of Aqua K Othrine EW (TF 2623) as Acute Tox. 4 with H302 (harmful if swallowed), is warranted. |

*Acute toxicity by inhalation*

| Summary table of animal studies on acute inhalation toxicity | | | | | | |
|---|---|---|---|---|---|---|
| **Method, Guideline, GLP status , Reliability** | **Species, Strain, Sex, No/group** | **Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD)** **Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LC50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute (4-hour exposure) inhalation toxicity,<br>OECD 403<br>GLP,<br>Reliability: 1 | Rat,<br>Sprague-Dawley CD,<br>Males & females,<br>5 rats / sex/group | Aqua K Othrine EW (TF 2628) aerosol actual concentrations:<br>– 5.24 mg/L<br>(MMAD: 4.9 µm)<br>– 5.80 mg/L<br>(MMAD: 3.7 µm)<br>The nominal concentration was 26.9 and 34.6 mg/L, respectively.<br>Nose (snout) only exposure. | The $LC_{50}$ (4-hour) for Aqua K-Othrine is in excess of 5.80 mg/1 of air.<br>One female rat exposed at 5.80 mg/L died on Day 2 of the observation period. The lungs of this animasl were moderately congested.<br>Hair loss from the head was noted for most male test rats and 1 female test rat. There were no internal abnormalities in the surviving test rats and no abnormalities in the controls. | > 5.80 mg/L air | None. | [redacted] 1995 |

| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
|---|---|
| Value | The acute inhalation $LC_{50}$ (4-hour) of Aqua K-Othrine EW (TF 2628) in rats was in excess of 5.80 mg/L of air and in excess of the highest concentration required by the current regulatory test guidelines. |
| Justification for the selected value | One female rat exposed at 5.80 mg/L died on Day 2 of the observation period. There were no deaths following exposure to Aqua K-Othrine at a concentration of 5.24 mg/L of air.<br>The test material was assessed at the maximum attainable concentration, with a MMAD within the respirable range of 1-4 µm for the highest dose. |
| Classification of the product according to CLP and DSD | Aqua K-Othrine EW (TF 2628) is of low acute inhalation toxicity. No classification is warranted. |

*Acute toxicity by dermal route*

| **Summary table of animal studies on acute dermal toxicity** | | | | | | |
|---|---|---|---|---|---|---|
| **Method, Guideline, GLP status, Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute dermal toxicity,<br>OECD 402<br>GLP,<br>Reliability: 1 | Rat,<br>Sprague-Dawley CD,<br>Males & females,<br>5 rats / sex/group | Aqua K Othrine EW (TF 2628),<br>No vehicle,<br>5000 mg/kg bw (semi-occluded topical application),<br>Skin area treated:<br>6 cm x 10 cm | There were no mortalities.<br>Aggressive behaviour was seen in all males and females 3-5 hrs post-dosing. A swollen head was noted in 2/5 females, 5 hours post-dose. This finding had resolved by day 3 of the study. | > 5000 mg/kg bw | None. | [redacted] P., 1994 |

| Value used in the Risk Assessment – Acute dermal toxicity | |
|---|---|
| Value | The acute dermal $LD_{50}$ value of Aqua K Othrine EW (TF 2628) in both male and female rats was greater than 5000 mg/kg body weight. |
| Justification for the selected value | There were no mortalities at 5000 mg/kg bw |
| Classification of the product according to CLP and DSD | Aqua K-Othrine EW (TF 2628) is of low acute dermal toxicity. No classification is warranted. |

### *Information on dermal absorption*

Aqua K-Othrine EW was not one of the representative formulations submitted for EU review according to the biocide Directive 98/8/EC. However, for the representative formulations submitted for EU review, i.e. K-Othrine WG 250, K-Othrine SC 7.5, K-Othrine SC 26.25 and K-Othrine DP 0.5, a value of 2% dermal absorption was considered appropriate for the concentrate as well as for the in use dilution of the respective products.

Justification for this approach is presented in the CAR, Document IIA, where it is noted that *"dermal penetration studies have been conducted in vitro in rats with deltamethrin as an oil/water emulsion (EW) and as an emulsifiable concentrate (EC) in rat and human skin and in an in vivo study in rats"*. See copy of CAR table 3.1.2-1, below.

*Table 3.1.2-1 (copy from CAR)* – Dermal absorption studies

| Formulation | Study type | Dose levels | Results (absorption rate) | Ref. in Doc III-A section 6 |
|---|---|---|---|---|
| Decis EC25 | *In vivo* - Rat | 25 g/l | 4.82% | [redacted] 2004 (A6.2.2/03) |
| | | 0.118 g/l | 6.79% | |
| | *In vitro* – Rat/human | 25 g/l | Human: 6.75%<br>Rat: 27.30%<br>Rat/human ratio: 4 | [redacted] 2003 (A6.2.2/02) |
| | | 0.118 g/l | Human: 19.22%<br>Rat: 69.08%<br>Rat/human ratio: 3.6 | |
| Decis EW15 | *In vitro* - Rat | 15 g/l | 21.44% | [redacted] 2003 (A6.2.2/01) |
| | | 0.15 g/l | 38.21% | |

As explained in the CAR:

- *"In all studies, deltamethrin showed a very poor absorption through the skin independent of the type of formulation.*
- *The results indicated that rat skin showed a significantly higher absorption than human skin (the total amount of radioactive material absorbed was 4 and 3.6 times greater for rat skin than for human skin at the high and low dose, respectively).*

- *Additionally, the absorption was lower for the EW15 than for the EC25 (1.3 and 1.8 fold lower for high and low dose, respectively).*
- *The extrapolation to an in vivo human scenario from these data is scientifically justified and summarised in the following table."*

Table 3.1.2-2 *(copy from CAR)*

| | High dose | Low dose |
|---|---|---|
| **EC25** | | |
| Rat/human ratio | 4 | 3.6 |
| Dermal absorption | 4.82/4 = 1.2% | 6.79/3.6 = 1.89% |
| **EW15** | | |
| EC25/WE15 ratio | 27.30/21.44=1.3 | 69.08/38.21=1.8 |
| Dermal absorption | 1.2/1.3 = 0.9% | 1.89/1.8=1.05% |

*"Comparison of the in vivo and in vitro data and corrected for a human in vivo scenario, the dermal absorption in humans is estimated to be about 1.2% and 1.89% for the concentrate and the dilution of the EC25 formulation, respectively, and to be about 0.9% and 1.05% for the concentrate and the dilution of the EW15 formulation, respectively. Based on these results it is proposed to use the figure of the EC formulation of 2% for dermal absorption as worst case".*

Further, it is noted that the main difference which is relevant to skin absorption is the solvent (water in K-Othrine SC and Aqua K-Othrine EW formulations versus [redacted] in Decis EC 25). The content of [redacted] is expected to enhance the degree of dermal absorption in comparison with SC and EW K-Othrine formulations.

Taking into account the aforementioned information and considering also that in case of Aqua K-Othrine EW, both the concentrate and the in-use dilutions are covered by the doses tested in the available studies, the value of 2% is considered applicable also for the current evaluation.

For the full evaluation of the dermal absorption studies please refer to deltamethrin CAR.

| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
|---|---|---|
| | **Concentrate** | **Dilution** |
| Value(s) | 2% | 2% |

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

The product contains [redacted] triggers product classification as Asp Tox 1 (H304). According to the ECHA Guidance on BPR (October, 2015), SoCs which trigger products to be classified as Asp. Tox. 1 (H304), are categorized to Band A of the banding evaluation scheme and the associated evaluation/risk management requirements include the application of H-statements and associated P-statements.

The relevant statements (Asp. Tox. 1 - H304, P301 + P310, P331) are already proposed for product label, and there is no need for further action.
Furthermore, Aqua K-othrine is classified for skin sensitization category 1B with H317. 1,2-benzisothiazol-3(2H)-one, is a skin sensitiser (Skin Sens. 1 – H317; CLP00) is present in Aqua K Othrine at a concentration of [redacted] higher than the elicitation threshold set at 0.005%. According to the ECHA Guidance on BPR (October, 2015), SoCs which trigger products to be classified as Skin sensitizer 1B (H317), are included in Band B of the banding evaluation scheme and the associated evaluation/risk management requirements include (as also with Band A) the qualitative exposure and risk assessment to determine whether Sphrases/P-statements or whether other risk mitigation measures should be applied.
Following this approach the phrase "H317 May cause an allergic skin reaction. Contains Benzisothiazol-3(2H)-one" will be added in product label, as well as the relevant precautionary statements (P261, P272, P280, P302+P352, P333+P313, P321, P363, P501).

***Available toxicological data relating to a mixture***
None available.

## 2.2.6.2 Exposure assessment

**Intended uses**

Deltamethrin EW 20 is a deltamethrin-based concentrate for dilution in water. It is recommended for the control of flies and mosquitoes adults in public health situations for professional user only. Deltamethrin EW 20 can be used in refuse tips, transit stations, amenity areas, etc.

**Summary of intended uses of Deltamethrin EW 20**

| PT | Field of uses envisaged | Likely concentrations at which a.s. will be used |
|---|---|---|
| PT18 | Public health<br>Deltamethrin EW 20 is intended for use outdoor or indoor in vector control situation. | Outdoor: 1 g/ha (spray 0.5 to 2 L/ha)<br><br>Indoor: 0.05 g/1000m$^3$ (spray 500mL/1000m$^3$) |

Dose rates
For outdoor uses from the ground (terrestrial) or from airplanes/helicopters (aerial), a dose rate of 1 g Deltamethrin/ha should be used.
For indoor applications a dose rate of 0.05 g Deltamethrin/1000m³ should be used.

Suitable application equipment
Deltamethrin EW 20 can be used on ground applications with the two main application techniques, thermal or cold fogging. For thermal fogging equipment, both standard and ULV equipment can be used. The instructions of the chosen equipment must be followed accurately to obtain the optimal droplet size required for best product performance.

Regarding aerial application, helicopter or airplane with mounted sprayers (e.g. type Unirot 4, 6 sprayers (3 per boom)) using GPS, on board real-time wind measurement and AGDISP software, or equivalent equipment in order to avoid spray drift in non-target area should be used.

Dilution and spraying
Dilution rates vary greatly depending on the selected equipment. Ultra low volume equipment will require a low dilution (e.g. 1:9 or 1:19) or no dilution at all. Other space spray equipment will dispense larger volumes of spray solutions and therefore require a higher dilution of (e.g. 1:99 or 1:199).

**Application parameters for Deltamethrin EW 20**

| Location | Target | Equipment | Dilution | Dose rate |
|---|---|---|---|---|
| Outdoor, aerial | Mosquitos | Airplane/helicopter mounted application equipment | Undiluted to 1:9<br>Please refer to equipment instructions | 1g DLT/ha |
| Outdoor, terrestrial | Mosquitos<br>Flies | Cold fogging equipment | 1:9 to 1:99<br>Please refer to equipment instructions | 1g DLT/ha |
| Indoor | Mosquitos<br>Flies | Thermal fogging equipment | 1:99 to 1:199<br>Please refer to equipment instructions | 0.05g DLT/1000m$^3$ |

Application timing: For mosquitos outdoor space spraying is best carried out around dusk at low wind speeds.

Application interval: Infestation dependent

**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 |
| Inhalation | n.a. | Yes | n.a. | n.a. | No | Yes |
| Dermal | n.a. | Yes | n.a. | n.a. | Yes | Yes |
| Oral | n.a. | No | n.a. | n.a. | No | Yes |

**Exposure during the manufacture of the biocidal product is covered under separate legislation and is subject to national worker protection legislation.*

***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) |
| 1a. | mixing/ loading | Primary exposure during mixing/loading for indoor use - portable receiving vessel | professionals |
| 1b. | mixing/ loading | Primary exposure during mixing/loading for outdoor (terrestrial) use – portable receiving vessel | professionals |
| 1c. | mixing/ loading | Primary exposure during mixing/loading for outdoor (terrestrial) use – fixed receiving vessel | professionals |
| 2a. | application | Primary exposure *via* thermal fogging with hand held fogging equipment (indoor use). | Professionals |
| 2b. | application | Primary exposure *via* cold fogging with hand held or vehicle-mounted fogging equipment (outdoor terrestrial use). | Professionals |
| 3. | application | Primary exposure during airplane/helicopter mounted application. | Professionals |
| | Cleaning | Primary exposure during cleaning of hand-held and vehicle-mounted application equipment | Professionals |
| 4. | Re-entry | Secondary exposure of a person (child or adult) when re-entering an area where Deltamethrin EW 20 has been applied - OUTDOOR | General public - Adults |
| 5. | Re-entry | Secondary exposure of a person (child or adult) when re-entering an area where Deltamethrin EW 20 has been applied - OUTDOOR | General public - Child |
| 6. | Re-entry | Secondary exposure of a person (child or adult) when re-entering an area where Deltamethrin EW 20 has been applied - INDOOR | General public - Toddler |

| | | | |
|---|---|---|---|
| 7. | Laundering | Secondary exposure to persons laundering contaminated work clothing | General public |

*indoor fogging; it also covers for outdoor fogging (see justification below)

## *Professional exposure*

Main routes of operator exposure to Deltamethrin EW 20 during mixing/loading and application are *via* inhalation and by the dermal route. Primary exposure to professional operators may also occur during the post-application phase (cleaning and maintenance).

Hence both situations will be assessed in this evaluation.

*Primary exposure during mixing/loading*

In case of indoor and outdoor hand-held applications, professional exposure during mixing and loading, is estimated considering the scenario of *"Pouring (liquid) formulation from container into portable receiving vessel"* described in the technical notes for guidance (TNsG, 2007). The generic exposure values of 464 mg a.s./kg a.s. (hands), 48.3 mg a.s./kg a.s. (body) and 0.021 mg a.s./kg a.s. (inhalation) are proposed based on the EUROPOEM II database.

In case of outdoor vehicle-mounted applications, professional exposure during mixing and loading is estimated considering the scenario of *"Pouring (liquid) formulation from container into fixed receiving vessel"* described in the technical notes for guidance (TNsG, 2007). The generic exposure values of 8 mg a.s./kg a.s. (hands), 1.95 mg a.s./kg a.s. (body) and 0.003 mg a.s./kg a.s. (inhalation) are proposed based on the EUROPOEM II database.

For indoor use, the area of a house is considered to be 0.04 hectare (400 $m^2$) based on the operational guidelines of WHO (2003[3]). Thus, the space volume is 1200 $m^3$ assuming 3 m height.

For outdoor (terrestrial) use, calculations have been performed considering a treated area of 150 ha/day for vehicle-mounted applications and 5 ha/day for hand-held applications [Operational manual of the application of insecticides for Control of the mosquito vectors of Malaria and other diseases, WHO/CTD/VBC/96.1000, January, (1996), p.98]. The task duration used was 120 min for fogging according to the Biocides Human Health Exposure Methodology (ECHA, October 2015).

No relevant data have been submitted by the applicant to estimate professional primary exposure levels for mixing and loading of an airplane/helicopter mounted equipment, which is therefore not covered in this assessment.

*Primary exposure during application*

Primary exposure during application of the fog is calculated using generic exposure data published in the Technical Notes for Guidance (2002) to the biocide directive 98/8/EC:

- Thermal fogging (applicable for indoor application *via* hand-held fogger, Scenario

[3] WHO (2003). Space spray application of insecticides for vector and public health pest control. A practitioner's guide.

2a): Fogging and misting model 3 TNsG part 2, p 186;

- Cold (ULV) fogging (applicable for outdoor application *via* hand-held or vehicle mounted cold (ULV) fogger, Scenario 2b): Fogging and misting model 2 TNsG part 2, p 185;

It is noted that both models refer to indoor fogging. However, due to the lower ventilation rate indoors than found outside, it is reasonable to assume that the models represent a worst case situation.

No relevant data have been submitted by the applicant to estimate professional primary exposure levels during airplane/helicopter mounted application, which is therefore not covered in this assessment.

Assumptions taken into consideration to assess primary exposure are summarised in the following:

**Assumptions to assess primary exposure – indoor application**

| | |
|---|---|
| **Application scenario:** | Indoor application of Deltamethrin EW 20 by professional operators |
| **Application equipment:** | Hand held application equipment |
| **Product:** | Deltamethrin EW 20 |
| **Deltamethrin content:** | 20 g/L |
| **Application rate:** | 0.05 g a.s./1000 $m^3$ |
| **Spray Volume:** | 500mL/1000$m^3$ |
| **Space to be treated in one day:** | 1200 $m^3$ * |
| **Duration of actual fogging:** | 2 hours/day** |
| **Dermal absorption:** | 2% |
| **Inhalation absorption:** | 100 % for the neat as well as for the dilution |
| **Default values for body weight:** | 60 kg |
| **Personal protective equipment (PPE):** | No PPE: Disregarding the recommendations on the label, no personal protective equipment is used when handling the undiluted product and during application.<br>With PPE: Adequate work clothing (e.g. a coverall) and in addition gloves when handling the undiluted product and during application***. Furthermore respiratory protection is worn during application. |

*: The area of a house is considered to be 0.04 hectare (400 m2) based on the operational guidelines of WHO (2003): Space spray application of insecticides for vector and public health pest control, A practitioner's guide. (Available at: http://whqlibdoc.who.int/hq/2003/WHO_CDS_WHOPES_GCDPP_2003.5.pdf.). The room height is assumed to be 3 m.

**: Biocides Human Health Exposure Methodology (ECHA, October 2015)

***: As proposed in the CAR 80% protection will be taken into account for one layer of adequate work clothing worn by the operator. A value of 90% hand protection is assumed for gloves worn during mixing and loading as well as for a mask worn during application.

**Assumptions to assess primary exposure – outdoor application**

| | |
|---|---|
| **Application scenario:** | Outdoor application of Deltamethrin EW 20 by professional operators |
| **Application equipment:** | Hand held application equipment or vehicle-mounted equipment |
| **Product:** | Deltamethrin EW 20 |
| **Deltamethrin content:** | 20 g/L |
| **Application rate:** | 1 g a.s./ha |
| **Spray Volume:** | 500 mL/ha* |
| **Area to be treated in one day:** | 5 ha/day for hand-held applications or 150 ha/day for vehicle-mounted applications** |
| **Duration of actual fogging:** | 2 hours/day*** |
| **Dermal absorption:** | 2% |
| **Inhalation absorption:** | 100 % for the neat as well as for the dilution |
| **Default values for body weight:** | 60 kg |
| **Personal protective equipment (PPE):** | No PPE: Disregarding the recommendations on the label, no personal protective equipment is used when handling the undiluted product and during application.<br>With PPE: Adequate work clothing (e.g. a coverall) and in addition gloves when handling the undiluted product and during application****. Furthermore respiratory protection is worn during application. |

*: The exposure model considers exposure to the in use spray. Therefore, the application which covers the highest in use spray concentration represents the worst case and is therefore taken into consideration.

**: Operational manual of the application of insecticides for Control of the mosquito vectors of Malaria and other diseases, WHO/CTD/VBC/96.1000, January, (1996), p.98]

***: Biocides Human Health Exposure Methodology (ECHA, October 2015)

****As proposed in the CAR 80% protection will be taken into account for one layer of adequate work clothing worn by the operator. A value of 90% protection is assumed for gloves worn during mixing and loading as well as for a mask worn during application.

The exposure estimations for the identified scenarios are summarised below. Detailed calculations are presented in Annex 3.2.

### Calculations for Scenario [1]

| Summary table: Primary exposure during mixing/loading [mg/kg bw/day] | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1a] | 1/No PPE | 0.000000021 | 0.000010246 | nr | **0.000010267** |
| | 2/PPE* | 0.000000021 | 0.0000011212 | nr | **0.000001142** |
| Scenario [1b] | 1/No PPE | 0.00000175 | 0.000853833 | nr | **0.000855583** |

| | | | | | |
|---|---|---|---|---|---|
| | 2/PPE* | 0.00000175 | 0.000093433 | nr | **0.00009518** |
| Scenario [1c] | 1/No PPE | 0.0000075 | 0.0004975 | nr | **0.000505** |
| | 2/PPE* | 0.0000075 | 0.0000595 | nr | **0.000067** |

** gloves & coated coverall*

### Calculations for Scenario [2]

| **Summary table: Primary exposure *via* fogging [mg/kg bw/day]** | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2a] | 1/No PPE | Negligible | 0.00013652 | nr | **0.00013652** |
| | 2/PPE* | Negligible | 0.0000022 | nr | **0.0000022** |
| Scenario [2b] | 1/No PPE | 0.00585 | 0.002064 | nr | **0.007914** |
| | 2/PPE* | 0.000585 | 0.0003488 | nr | **0.0009338** |

** gloves & coated coverall and RPE (90% protection factor, i.e. A1 for organc gases – EN 14387)*

### Calculations for Scenario [3]

No relevant data have been submitted by the applicant to cover for the Ultra-Low-Volume space spray aerosol scenario.

The applicant proposed that, *"it is assumed that during application, primary exposure of a professional user locked in an helicopter/airplane cabin is expected to be minimal, and in any case lower as compared to a ground application scenario"*.

However, there are no data available to estimate the operator exposure levels during mixing/loading.

Overall, primary exposure assessment during airplane/helicopter mounted application is not concluded due to lack of data. Applicant's proposal is not supported by experimental data or exposure estimates.

*Operator exposure during cleaning of the application equipment*

As outlined in the CAR for K-Othrine WG 250 cleaning is usually performed by filling clean water in the knapsack sprayer and applying the wash water as spray, or disposing as hazardous waste. It is obvious that during this procedure the unavoidable small amount of spray liquid remaining in the sprayer after application gets highly diluted. Therefore, it is reasonable to conclude that exposure during cleaning is negligible as compared to the situation when the spray is applied. One might in addition consider the situation that a blocked nozzle has to be cleaned. However, for the spray formulation of Deltamethrin EW 20 it has to be concluded that under normal conditions this situation does not occur and therefore can be regarded as not relevant. Nevertheless, even if it occurs, it is fair to expect for the professional operator that gloves are worn. For cleaning, the blocked nozzle is rinsed with clean water which removes residues from the nozzle as well as from the

protective gloves. In addition according to good occupational practice the gloves will be rinsed with clean water after the blocked nozzle has been installed again.

No relevant data have been provided by the applicant with regard to cleaning the sprayers attached to the helicopter or airplane used for the aerial application. However, it may assumed that the same principles for cleaning should apply as in the case of a knapsack sprayer. The sprayers should again be cleaned in a designated area (e.g. biobeds). The worker involved in the cleaning should be protected using appropriate personal protective equipment. The wash water should be primarily considered for re-use making sure the maximum dose is not exceeded or should be disposed off as hazardous waste.

Accordingly, in line with the CAR for K-Othrine WG 250, it is concluded that the cleaning practice would not give rise to exposure to Deltamethrin EW 20 higher than already anticipated for the application of the in-use diluted product.

Further to comments received by Member States, primary exposure was assessed during cleaning of the application equipment (both hand-held & vehicle mounted), considering the surrogate values from BEAT model database. Detailed calculations are presented in Annex 3.2.

**Calculations for cleaning**

| Summary table: Cleaning [mg/kg bw/day] | | |
|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated total uptake** |
| Cleaning – hand-held equipment | 1/No PPE | 0.0000368 |
| | 2/PPE* | 0.0000152 |
| Cleaning – vehicle mounted equipment | 1/No PPE | 0.000735 |
| | 2/PPE* | 0.00030489 |

** gloves*

*Combined scenarios*

| Summary table: combined systemic exposure from professional uses [mg/kg bw/day] | | | | | |
|---|---|---|---|---|---|
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios 1a, 2a and cleaning | 1/No PPE | 0.000000021 | 0.0001838 | nr | 0.000183821 |
| | 2/PPE* | 0.000000021 | 0.000018521 | nr | 0.000018542 |
| Scenarios 1b, 2b and cleaning | 1/No PPE | 0.0058518 | 0.00295463 | nr | 0.00880643 |
| | 2/PPE* | 0.0005868 | 0.00045743 | nr | 0.00104423 |
| Scenarios 1c, 2b and cleaning | 1/No PPE | 0.0058575 | 0.0032965 | nr | 0.009154 |
| | 2/PPE* | 0.0005925 | 0.00071319 | nr | 0.00130569 |

** gloves during cleaning, gloves & coated coverall during mixing/loading and application and RPE (90% protection factor, i.e. A1 for organc gases – EN 14387) during application*

### *Non-professional exposure*

Not relevant. The product is intended for professional use only.

### *Exposure of the general public*

It might be assumed that persons (adults and/or children) are secondarily exposed to Deltamethrin EW 20 when re-entering area where the product has been applied.

For K-Othrine WG 250 being a product used by professionals the CAR for deltamethrin in addition considers secondary exposure to persons laundering contaminated work clothing. Hence this scenario will be assessed as well.

In addition, the general public might be exposed to Deltamethrin EW 20 during aerial application. No relevant data have been provided by the applicant. Instead, the applicant has assumed that secondary exposure of the general public in the aerial application scenario, is covered by the assessment provided for ground application considering worst-case assumptions. They also don't expect secondary exposure differences between aerial or ground application scenarios when the fog reach the target application area.

However, the reviewer considers that the exposure of the general public to the fog during application has not been adequately addressed. In the absence of any relevant data to assess this parameter, the exposure assessment of the general public to the Ultra-Low-Volume space spray aerosol has not been assessed and the potential risk has not been identified and characterised.

**A. Exposure of a person (child or adult) when re-entering an area where Deltamethrin EW 20 has been applied.**

In the context of secondary exposure of persons re-entering treated areas potentially two main routes of exposure can be considered, i.e. inhalation exposure due to aerosols present in air and dermal exposure via contact with surfaces containing deltamethrin residues due to deposition of the fog. For the child one might furthermore assume oral exposure via hand to mouth transfer.

Inhalation exposure

With respect to an **indoor** application of Deltamethrin EW 20 it has to be noted that the label clearly instructs the professional user that:

- No bystander should be present during application or re-enter the room during the following 4 hours waiting period
- Ventilate the treated room sufficiently before unprotected people re-enter treated room

Furthermore, the vapour pressure of deltamethrin is very low ($1.24 \times 10^{-8}$ Pa at 25ºC). Thus, the risk for inhalation exposure of persons re-entering a treated room can be regarded as very low. Therefore, with the intended indoor application the dermal route is considered to be the predominant route of exposure.

However, considering the outdoor use of the product one might consider that accidentally a person re-enters a treated area before the fog disappeared. Obviously for this exposure scenario inhalation exposure can be regarded as the most relevant exposure route. As a worst case tier one approach one might assume that shortly after application the fog covers a height of 1 m. Based on this approach an airborne residue concentration of 0.1 mg a.s./$m^3$ is calculated when considering the maximum application rate of 1 g a.s./ha. This concentration is twice as high as the maximum concentration recommended for indoor treatment (= 0.05 g a.s./1000 $m^3$ corresponding to 0.05 mg a.s./$m^3$) which further substantiates the conservatism of this approach. The exposure duration will be assumed to be 15 minutes. This is considered to be a conservative assumption taking into account that the assumed airborne residue concentration is already on the very conservative side. Furthermore, though rapid decline of the airborne concentration can be expected due to dilution *via* air turbulences the worst case initial concentration is considered to remain for the total duration of exposure.

Regarding the breathing rate a value of 1.25 $m^3$/hour will be assumed for the adult (60 kg), i.e. the same breathing rate as considered for the operator. For the child a breathing rate of 0.43 $m^3$/hour is assumed as proposed by ConsExpo 4.1[4] for the 10 kg child performing light exercise activities.

The assumptions to assess inhalation exposure are summarized in the following table.

**Assumptions to assess systemic secondary inhalation exposure when re-entering an area where Deltamethrin EW 20 has been applied.**

| | |
|---|---|
| **Application scenario:** | Outdoor application of Deltamethrin EW 20 by professional operators |
| **Airborne residue concentration (AC):** | 0.1 mg deltamethrin/$m^3$ |
| **Breathing rate (BR):** | |
| - **Adult:** | 1.25 $m^3$/hour |
| - **Child:** | 1.32 $m^3$/hour (HEEG Opinion 17) |
| **Exposure duration (ED):** | 0.25 hours/day |
| **Inhalation absorption:** | 100% |
| **Default values for body weight:** | |
| - **Adult:** | 60 kg |
| - **Child:** | 10 kg |

The corresponding exposure calculations are presented in the following table.

**Estimated systemic secondary inhalation exposure when re-entering an area where Deltamethrin EW 20 has been applied.**

| | Adult | Child |
|---|---|---|
| Inhalation exposure (I) is calculated as follows: | | |

[4] Consumer Exposure model, 4.1 available at: http://www.rivm.nl/en/Topics/Topics/C/ConsExpo

| **I** | **=** | **AC x BR x ED** |
|---|---|---|
| AC (mg a.s./$m^3$): | 0.1 | 0.1 |
| BR ($m^3$/hour): | 1.25 | 1.32 |
| ED (hours/day): | 0.25 | 0.25 |
| **I (mg a.s./person/day):** | **0.031** | **0.033** |
| Taking into account the inhalation absorption of 100% systemic exposure by inhalation ($S_{inhalation}$) is calculated as follows:<br>**$S_{inhalation}$ = I x Inhalation absorption ÷ Body weight** | | |
| I (mg a.s./person/day): | 0.031 | 0.033 |
| Inhalation absorption: | 100% | 100% |
| Body weight (kg bw): | 60 | 10 |
| **$S_{inhalation}$ (mg a.s./kg bw/day):** | **0.000517** | **0.0033** |

Concerning dermal exposure due to transfer of residues from surfaces contaminated *via* deposition of the fog the worst case situation is considered to be the indoor application. This conclusion is based on the following facts:

- Considering the indoor application rate of 0.05 mg/$m^3$ and a room height of 2.5 m the total application rate amounts to 0.125 mg a.s./$m^2$ which is higher than the outdoor application rate of 0.1 mg/$m^2$.
- Due to obviously higher "ventilation" outdoor the risk for deposition of the fog is expected to be lower than for the indoor treatment.

In a theoretical worst case tier one approach a 100% deposition of the fog is assumed resulting in a floor surface loading of 0.125 mg a.s./$m^2$ corresponding to 0.0000125 mg a.s./$cm^2$. The subsequent transfer of residues from surfaces to the skin of re-entering persons (adult or toddler) is calculated following the approach presented in the CAR for deltamethrin[5]. As already indicated for the re-entering toddler one might in addition consider oral exposure *via* subsequent hand to mouth transfer. Hence it is reasonable to conclude that the re-entering toddler represents the worst case and therefore will be considered. This conclusion is substantiated by the exposure results presented in the CAR.

**Assumptions to calculate secondary exposure *via* transfer of residues from surfaces**

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| Scenario: | Secondary exposure to a toddler after indoor treatment. |
|---|---|
| **Maximum application rate:** | 0.05 g deltamethrin/1000 $m^3$ (0.05 mg a.s./$m^3$) |
| **Room height:** | 2.5 m |
| **Deposition rate:** | 100% |
| **Surface residues (SR):** | 0.0000125 mg a.s./$cm^2$ (= 0.05 mg a.s./$m^3$ x 2.5)* |
| **Surface Transferable Residues (TR):** Hard surfaces: | 10% of the residues present on the surface** |
| **Transfer Coefficient (TC):** | 6000 $cm^2$ per day |
| **Dermal absorption:** | 2% |
| **Inhalation absorption:** | 100% |
| **Oral absorption:** | 75% |
| **Body weight of the toddler:** | 10 kg |

* To be consistent with the proposed transfer coefficient, in a conservative approach it is assumed that "virtually" the residues present in the spots are distributed to the whole surface the toddler can play on.

** For deltamethrin a study has been conducted to determine the amount of surface transferable residues when being applied to carpets: "Determination of Dislodgeable Residues of Deltamethrin following a Broadcast Application of Suspend SC Speciality Insecticide, Maxey S.W., Murphey P.G., and Berbrick D.H.; February, 1996". Based on this study the CAR considered a value of 2.5% dislodgeability appropriate for deltamethrin residues present on carpets. A value of 10% dislodgeability was used in the CAR to assess transfer from hard surfaces.

Corresponding exposure calculations are presented in the following table.

**Estimated systemic secondary exposure when re-entering a room where Deltamethrin EW 20 has been applied.**

| | **Toddler** |
|---|---|
| Dermal exposure (D) of the toddler is calculated as follows: **D = SR x TR x TC** | |
| SR (mg a.s./$cm^2$): | 0.0000125 |
| TR: | 0.1 |
| TC ($cm^2$/day): | 6000 |
| **D (mg a.s./toddler/day):** | **0.00750** |
| Taking into account the dermal absorption of 2% systemic exposure by the dermal route ($S_{dermal}$) is calculated as follows: **$S_{dermal}$ = D x Dermal absorption ÷ Body weight** | |
| D (mg a.s./toddler/day): | 0.00750 |
| Dermal absorption: | 0.02 |
| Body weight (kg bw): | 10 |
| **$S_{dermal}$ (mg a.s./kg bw/day):** | **0.0000150** |
| For the toddler one might in addition consider oral exposure via hand to mouth transfer. The TNsG propose to assume in a tier 1 approach that essentially 10% of the total amount of product that ends up on the skin of the toddler is taken in orally by hand to mouth contact (= 20% of | |

| | |
|---|---|
| dermal exposure ends up on the hands and subsequent oral exposure by hand to mouth transfer amounts to 50% of hand exposure).<br>Considering furthermore oral absorption of 75% the systemic exposure by the oral route ($S_{oral}$) is calculated as follows:<br><br>**$S_{oral}$ = D x Fraction on hands x Hand to mouth transfer x Oral absorption ÷ Body weight** | |
| D (mg a.s./toddler/day): | 0.00750 |
| Fraction of D on hands: | 0.2 |
| Hand to mouth transfer: | 0.5 |
| Oral absorption: | 0.75 |
| Body weight (kg bw): | 10 |
| **$S_{oral}$(mg a.s./kg bw/day):** | **0.0000563** |
| Total systemic exposure ($S_{total}$) by the dermal route and hand to mouth transfer is calculated as follows:<br>**$S_{total}$ = $S_{dermal}$+ $S_{oral}$** | |
| $S_{dermal}$ (mg a.s./kg bw/day:) | 0.0000150 |
| $S_{oral}$ (mg a.s./kg bw/day): | 0.0000563 |
| **$S_{total}$ (mg a.s./kg bw/day):** | **0.0000713** |

For the toddler being exposed due to outdoor application as well as due to indoor application the overall exposure is estimated to be **0.003371 mg/kg bw/day** (= 0.0033 mg/kg bw/day + 0.0000713 mg/kg bw/day). With the very conservative approach selected main contribution is by inhalation (= of airborne residues due to accidental re-entry outdoors shortly after the fog has been applied.

### B. Secondary exposure to persons laundering contaminated work clothing

With respect to exposure of persons laundering contaminated work clothing the CAR for deltamethrin used the same approach as proposed by UK-HSE during its evaluation of bendiocarb under the Biocidal Products Directive 98/8/EC.

In general this approach assumes that the laundering is undertaken in a domestic, automatic washing machine. Therefore, exposure will occur the dermal route, *via* hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine. It is considered that laundering is undertaken after a five day work week: hence the total amount of active substance present on the work clothing is assumed to be five times the amount of one work day. For Deltamethrin EW 20 this amounts to 19620 µL in use product (= 5 x 3924 µL in use product/day). Taking into account the in use concentration of 0.002 mg deltamethrin/µL this corresponds to 39.2 mg deltamethrin present on the work clothing. Furthermore UK-HSE considers that the area of a medium-sized coverall is 22700 $cm^2$. Therefore, expressed as mg deltamethrin/$cm^2$, the accumulated residues over 5 days would be 0.00173 mg deltamethrin/$cm^2$.

The total area of the palms and backs of both hands for an adult is 840 $cm^2$, the transfer coefficient for contamination (of dried fluid) from cotton or knitwear to wet hands is 30%

(Technical notes for guidance; Human exposure risk assessment to biocidal products, Guidance on exposure estimation, June 2002") and using the dermal penetration figure of 2%, the systemic dose for a 60 kg adult can be calculated as:

$$\frac{\text{a.s. residues on coverall x surface area of both hands x transfer coefficient x dermal absorption}}{\text{body weight}} = \frac{0.00173 \times 840 \times 30/100 \times 2/100}{60}$$

The systemic dermal dose from laundering the contaminated work clothing is 0.00145 mg deltamethrin / kg bw.

### *Dietary exposure*

Aqua K-Othrine (Deltamethrin EW 20) is proposed by the applicant to be used as to control adult mosquitoes/flies though aerial application or outdoor fogging at a dose rate of 1 g a.s./ha or for indoor fogging at a dose rate of 0.05 g a.s. / 1000m$^3$.

No information was submitted by the applicant regarding the dietary exposure from the proposed uses. The applicant refer ot the dietary risk assessment illustrated in the EFSA reasoned opinion[6] published in 2015. The risk assessment is based on a worst case assumption, which means that it is postulated that all the commodities, for which an use of deltamethrin is registered, eaten by the consumer are treated with deltamethrin at the maximum rate with the shortest PHI. The Aqua K-Othrine fogging outdoor application would correspond to 1g a.s./ha, which is quite low in comparison to the agricultural rate (6-17.5 g a.s./ha), resulting residue would be part of the variability measurement of the deltamethrin residue. Thus for the ground or aerial use of Aqua K-Othrine, a specific dietary risk assessment for consumers exposed via contaminated foodstuffs from vegetable gardens is considered as a less critical case. All the registered crop use patterns of deltamethrin have a minimum PHI of 3 to 7 days in most crops and up to 90 days (Salsify) in some cases, thus it is not posible to set a minimum period based on the agricultural uses. As to assume a worst case the following mitigation measure can be proposed:

"*The applicator shall inform people living in proximity to the target area of the treatment with Aqua K-Othrine about the following:*

- *Do not apply to agricultural areas after the consumable part of the crop is formed.*

In addition, regarding the Indoor use, the following mitigation measures can be used:

- *Do no treat areas were food or feed are stored.*

*Keep away from food, drink and animal feeding stuffs.*

### *Summary of exposure assessment*

| **Scenarios and values to be used in risk assessment** |
|---|

[6] EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(11):4309, 104 pp. doi:10.2903/j.efsa.2015.4309.

| Scenario number | Exposed group (e.g. professionals, non-professionals, bystanders) | Tier/PPE | Estimated total uptake [mg/kg bw/day] |
|---|---|---|---|
| **Primary exposure** | | | |
| 1a, 2a and cleaning | Professionals | 1/No PPE<br>2/PPE* | 0.000183821<br>0.000018542 |
| 1b, 2b and cleaning | Professionals | 1/No PPE<br>2/PPE* | 0.00880643<br>0.00104423 |
| 1c, 2b and cleaning | Professionals | 1/No PPE<br>2/PPE* | 0.009154<br>0.00130569 |
| 3 | Professionals | Not assessed. Pending on relevant data provided by the applicant. | |
| **Secondary exposure** | | | |
| 4 | General public – Adults (re-ntry/outdoor) | No PPE | 0.000517 |
| 5 | General public – Child (re-netry/outdoor) | No PPE | 0.00108 |
| 6 | General public – Toddler (re-entry/indoor) | No PPE | 0.0000713 |
| 7 | General public (laundering) | No PPE | 0.00145 |

** gloves during cleaning, gloves & coated coverall during mixing/loading and application and RPE (90% protection factor, i.e. A1 for organc gases – EN 14387) during application*

### 2.2.6.3 Risk characterisation for human health

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

| Reference | Study | NOAEL (LOAEL) | AF | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| AELshort-term | 13-week dog study | 1 mg/kg bw/day | 100 | 75% | 0.0075 mg/kg bw/day |
| AELmedium-term | 13-week and 1-year dog studies | 1 mg/kg bw/day | 100 | 75% | 0.0075 mg/kg bw/day |
| AELlong-term | 1-year dog studies | 1 mg/kg bw/day | 100 | 75% | 0.0075 mg/kg bw/day |
| ARfD | Not required since no exposure of foodstuffs should occur when product label instructions are followed, and risk of contamination of drinking water is not considered. | | | | |

| | |
|---|---|
| ADI | Not required since no exposure of foodstuffs should occur during and after treatment of food handling areas with deltamethrin when product label instructions are followed. |

### *Risk for professional users*

**Systemic effects / combined scenarios**

| 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) |
|---|---|---|---|---|---|---|
| 1a, 2a and cleaning | 1 | 1 | 0.0075 | 0.000183821 | 2.5 | Yes |
| | 2* | 1 | 0.0075 | 0.000018542 | 0.3 | Yes |
| 1b, 2b and cleaning | 1 | 1 | 0.0075 | 0.00880643 | 117 | No |
| | 2* | 1 | 0.0075 | 0.00104423 | 13.9 | Yes |
| 1c, 2b and cleaning | 1 | 1 | 0.0075 | 0.009154 | 122 | No |
| | 2* | 1 | 0.0075 | 0.00130569 | 17 | Yes |
| Primary exposure during airplane/helicopter mounted application / 3 | The applicant proposed that, *"it is assumed that during application, primary exposure of a professional user locked in an helicopter/airplane cabin is expected to be minimal, and in any case lower as compared to a ground application scenario"*. However, there are no data available to estimate the operator exposure levels during mixing/loading. Overall, primary exposure assessment during airplane/helicopter mounted application is not concluded due to lack of data. Applicant's proposal is not supported by experimental data or exposure estimates. | | | | | |

** gloves during cleaning, gloves & coated coverall during mixing/loading and application and RPE (90% protection factor, i.e. A1 for organc gases – EN 14387) during application*

### *Risk for non-professional users*

Not relevant. The product is intended for professional use only.

### *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) |
|---|---|---|---|---|---|---|
| Adults (re-entry, outdoor) / 4 | 1 | 1 | 0.0075 | 0.000517 | 7 | Yes |
| Child (re-entry, outdoor) / 5 | 1 | 1 | 0.0075 | 0.00108 | 14 | Yes |
| Toddler | 1 | 1 | 0.0075 | 0.0000713 | 1 | Yes |

| | | | | | | |
|---|---|---|---|---|---|---|
| (re-entry, indoor) 6 | | | | | | |
| Adults (laundering ) / 7 | 1 | 1 | 0.0075 | 0.00145 | 19 | Yes |

In the absence of any relevant data, the exposure of the general public to the fog during aerial application of the Ultra-Low-Volume space spray aerosol, has not been assessed and the potential risk has not been identified and characterised.

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

The product must be kept away from food, drink and animal feedstuffs. The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions.

The product does not come into contact with animals when application follows the label instructions. Therefore, exposure to residues in food is not considered relevant.

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

Not relevant.

## 2.2.7 Risk assessment for the environment

Deltamethrin EW 20 is a suspension concentrate formulation which contains the active substance deltamethrin at a concentration of 20 g/L. Deltamethrin EW 20 is intended for i) outdoor aerial applications as an ultra-low volume aerosol (airplane/helicopter mounted application equipment) and ii) outdoor and indoor terrestrial applications as a thermal or cold fog (thermal/cold fogging equipment). Both outdoor and indoor applications of Deltamethrin EW 20 as an insecticide against mosquitos and house flies for human health reasons is for professional use only.

As Deltamethrin EW 20 is not identical to the representative product in the CAR and the intended use and the exposure to the environment is not identical to the respective use and exposure in the CAR, an environmental risk assessment for Deltamethrin EW 20 has been performed.

### 2.2.7.1 Effects assessment on the environment

In order to assess the ecotoxicity of Deltamethrin EW 20, the applicant has provided a number of ecotoxicological studies conducted with either the actual biocidal product under evaluation or deltamethrin-containing alternative formulations. Because of the compositional differences between some of these formulations and the product under evaluation, the submitted data were not always considered relevant for use in the environmental effects and risk assessment. Thus, in principle, the environmental effects assessment for the biocidal product Deltamethrin EW 20 was based on the ecotoxicity data available for the active substance deltamethrin. Deltamethrin has been previously evaluated at EU level as biocidal product in the scope of Biocidal Product Directive 98/8/EC with Sweden as rapporteur member state. It is noted that in addition to the studies with

formulated deltamethrin, ecotoxicity data, not available in the deltamethrin CAR (June 2011), have been also submitted for the technical active substance.

### *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 reliable testing toxicity data on aquatic organisms relevant to the classification of Deltamethrin EW 20 are available. A study on the acute toxicity of Deltamethrin EW 20 to fish has been submitted by the applicant; however the study results were considered unreliabile by the eCA due to the lack of analytical verification of the tested concentrations. The study is described below and is summarized in table 1. As valid data on each of the mixture components are available and synergistic effects between any of the components are not expected, the acute and chronic hazard classification of Deltamethrin EW 20 has been based on the rules laid down in the Regulation (EC) No 1272/2008.

### *Further Ecotoxicological studies*

In order to assess the toxicity of Deltamethrin EW 20 to aquatic organisms, bees, other beneficial arthropods and terrestrial plants, the applicant has provided a number of ecotoxicological studies conducted with either the active substance deltamethrin, the biocidal product under evaluation or deltamethrin-containing alternative formulations. These studies are summarized below.

#### Effects on aquatic organisms

Three new (not available in deltamethrin CAR, June 2011) studies on the effects of deltamethrin (technical or formulated) to aquatic organisms have been submitted by the applicant. These studies investigate (i) the bioaccumulation potential of deltamethrin technical in the Bluegill sunfish [redacted], 1993), (ii) the effects of Deltamethrin EW 15 on rainbow trout in aquatic outdoor microcosm enclosures ([redacted], 2005) and (iii) the acute toxicity of Deltamethrin EW 20 to rainbow trout [redacted], 2008).

The study of [redacted] (1993) was not evaluated by the eCA as the bioaccumulation of deltamethrin technical in bluegill sunfish (*Lepomis macrochirus*) has already been investigated during the EU peer review of the active substance via the fish BCF study of [redacted] (1990, 1992) and no further information is considered necessary. The EU agreed whole body fish BCH of 1400 and the worst-case BMF value of 2 have been considered in the risk assessment of secondary poisoning via the aquatic food chain.

The study of [redacted] (2005) was not evaluated by the eCA because it was considered not relevant for use in the risk assessment of Deltamethrin EW 20. In fact, the test material used was Deltamethrin EW 15 which is chemically not similar and ecotoxicologically not equivalent to Deltamethrin 20 EW (please refer to Section 9 of the Confidential Annex to PAR). Further, based on the EU agreed aquatic toxicity endpoints for deltamethrin, fish are less sensitive than aquatic invertebrates towards the active substance and thus the former taxonomic group is not expected to trigger the aquatic risk assssement for Deltamethrin EW 20. The EU agreed $PNEC_{water}$ of 0.7 ng deltamethrin/L has been used in the aquatic risk assessment for Deltamethrin EW 20.

The acute toxicity study of Deltamethrin EW 20 to rainbow trout ([redacted], 2008) has been evaluated by the eCA and the respective summary is provided in table 1. Five nominal concentrations of Deltamethrin EW 20 were tested: 100, 210, 441, 926 and 1945 µg/L. Forty two fish divided into 6 groups of 7 animals each were exposed to each treatment level and the control for 96 hours under static conditions. Observations of lethal and sublethal effects were made at 3, 6, 24, 48, 72 and 96 hours after the start of the test. Statistical analysis of the study results indicated that the 96-hour $LC_{50}$ of Deltamethrin EW 20 for the rainbow trout *Oncorhynchus mykiss* was 0.422 mg/L.

Although the study was well performed according to the OECD testing guideline 203, no analytical verification of the test substance was consducted during the course of the test. According to the applicant, analysis of the test chemical was not needed as the $DT_{50,\ whole\ system}$ of the active substance is 65 days, it is not readily biodegradable, it is stable in water and its transformation is insignificant. The argumentation provided by the applicant is not considered acceptable by the eCA. According to the ECHA Guidance on the BPR (Volume IV: Environment, Part A: Information Requirements, Version 1.1, November 2014), when carrying out ecotoxicity tests on aquatic organisms, it is required to measure the solubility and stability of the substance in the test medium, as it may differ from the results obtained in the water solubility test. Aquatic toxicity studies performed without any analytical monitoring have to be regarded as invalid and no further be considered in the risk assessment.

**Table 1:** Acute toxicity of Deltamethrin EW 20 to fish

| **Method, Guideline, GLP status, Reliability** | Species/ Inocu-lum | End point | Exposure | | Results | | | Remarks | Refe-rence |
|---|---|---|---|---|---|---|---|---|---|
| | | | Design | Dura-tion | $EC_0$ | $EC_{50}$ | $EC_{100}$ | | |
| OECD 203; GLP study; R.I.: 3 | Rainbow trout *Oncorhynchus mykiss* | Mortality; $LC_{50}$ | Static | 96 h | <100 µg/L | 422 µg/L | 1945 µg/L | The study was assigned a R.I. of 3 as no analytical verification of the test substance was performed | [redacted] (2008) |

**Effects on terrestrial plants**

There is no non-target terrestrial plant study conducted with Deltamethrin EW 20. The effects of deltamethrin to higher terrestrial plants were examined with the product Decis EW 50 in two studies, one on seedling emergence and one on vegetative vigour each testing 6 dicot and 2 monocot plant species under fully controlled conditions. No phytotoxic effects > 50% were found in any of the tested plant species after the application of Decis EW 50 at a maximum single application rate of 12.5 g a.s./ha.

The GLP study on seedling emergence (Gosch & Nguyen, 2006) followed the procedures described in the OECD testing guideline 227 and fulfilled the corresponding validity criteria. Two monocot (*Avena sativa* and *Zea mays*) and six dicot (*Beta vulgaris*, *Cucumis sativus*, *Helianthus annuus*, *Brassica napus*, and *Raphanus sativus* and *Glycine max*) species were sprayed at nominal rate of 12.5 g Deltamethrin/ha. Phytotoxicity was determined 7, 14 and 21 days after application, while effects on plant fresh and dry weight were determined at test termination (21 days after application). Chlorosis was observed for all dicot species, while stunting was observed only for *Cucumis sativus*. No phytotoxicity was observed at the application rate tested, e.g. 12.5 g deltamethrin/ha. Statistical analysis of the study results demonstrated that the per cent inhibition of biomass production compared to the

control was 24% in sugar beet. Biomass increased in corn, oats, oil seed rape, radish and sunflower by 31%, 12%, 3%, 10%, 1%, 4% and 12% respectively. The study results are presented in table 2.

The GLP study on vegetative vigour (Gosch & Nguyen, 2006) followed the procedures described in the OECD testing guideline 208 and fulfilled the corresponding validity criteria. Two monocot (*Avena sativa* and *Zea mays*) and six dicot (*Beta vulgaris*, *Cucumis sativus*, *Helianthus annuus*, *Brassica napus*, *Raphanus sativus* and *Glycine max*) species were sprayed post emergence (BBCH 12-14) at nominal rate of 12.5 g deltamethrin/ha. Phytotoxicity was determined 7, 14 and 21 days after application, while effects on plant fresh and dry weight were determined at test termination (21 days after application). Chlorosis was observed for all dicot species, while stunting was observed only for *Cucumis sativus*. No adverse effects on biomass (dry shoot weight) greater than 50% were observed on any of the monocot and dicot species up to and including the highest application rate tested, e.g. 12.5 g deltamethrin/ha. In fact, statistical analysis of the study results demonstrated that the per cent inhibition of biomass production compared to the control was 1.2% for oats, 3.1% for cucumber, and 12.8% for soybean respectively. Biomass increased in corn, oil seed rape, radish, sugar beet and sunflower by 34.5%, 6.2%, 3.2%, 16.5% and 4.3% respectively. The study results are presented in table 2.

Table 2: Effect of Deltamethrin on higher terrestrial non-target plants

| **Guideline / Test method/ GLP status** | **Species** | **Endpoint / Type of test** | **Exposure** **Design** | **Duration** | **Results** **ER50** | **Reference** |
|---|---|---|---|---|---|---|
| OECD testing guideline 227; GLP | *Avena sativa, Zea mays, Cucumis sativus, Beta vulgaris, Glycine max, Helianthus annuus, Brassica napus, Raphanus sativus* | Phytotoxicity, Fresh and dry weight of shoot / seedling emergence test | Greenhouse test, application closed spray cabin, artificial soil (OC 1.19%) | 21 d | No significant effects at 12.5 g a.s./ha | Gosch & Nguyen (2006) |
| OECD testing guideline 208; GLP | *Avena sativa, Zea mays, Cucumis sativus, Beta vulgaris, Glycine max, Helianthus annuus, Brassica napus, Raphanus sativus* | Phytotoxicity, Fresh and dry weight of shoot / vegetative vigour test | Greenhouse test, application closed spray cabin, artificial soil (OC 1.19%) | 21 d | No significant effects at 12.5 g a.s./ha | Gosch & Nguyen (2006) |

**Effects on non-target arthropods**

Taking into account the intended use pattern of formulated deltamethrin as Deltamethrin EW 20 in outdoor PT18 applications (both aerial and terrestrial), direct exposure of bees and other non-target arthropods cannot be excluded. According to the ECHA Guidance on the BPR (Volume IV: Environment, Part A: Information Requirements, Version 1.1; November, 2014), tests on bees and other non-target arthropods are required for PT18

substances in cases of large scale-outdoor applications like fogging (e.g. products against mosquitos for human health reasons). Furthermore, tests with the corresponding PT18 biocidal product may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In order to address the potential toxicity of Deltamethrin EW 20 to non-target arthropods, various laboratory and field studies with honeybees and other beneficial arthropods were submitted by the applicant. Studies with honeybees were performed with either the active ingredient (deltamethrin) or a range of alternative formulations. Studies with other beneficial arthropods were always performed with formulated test material as recommended by the respective testing guidelines. All studies where formulated deltamethrin was used were performed with formulations other than the biocidal product under evaluation.

It is noted that none of these studies were evaluated during the EU peer review of the active substance deltamethrin in the scope of Biocidal Product Directive 98/8/EC. However, some of the submitted studies were used to support the EU approval of deltamethrin as a Plant Protection Product. In order to limit the workload, these studies have not been re-evaluated by the eCA. It is noted that based on the eCA's evaluation presented in Section 9 of the Confidential Annex to PAR, the following conclusions have been drawn regarding the representativeness of Deltamethrin EW 20 by the alternative deltamethrin-containing formulations used as test materials in the submitted ecotoxicological studies: Deltamethrin EW 50 or DECIS EW 50 (Code AB 0375503) could be considered as ecotoxicologically equivalent to Deltamethrin EW 20 and thus the respective studies have been considered in the environmental risk assessment. Deltamethrin EW 15 (Code AEF032640 00 EW01 B1) is considered not ecotoxicologically equivalent to Deltamethrin EW 20 and thus the respective studies have not been considered in the environmental risk assessment. With respect to Deltamethrin EW 25 (Code 102000020169-01) and Deltamethrin EC 25 (Codes 102000020023, AE F032640 00 EC03 B0), no adequate information is available to enable a definite conclusion on their ecotoxicological equivalence to Deltamethrin EW 20. However, the respective studies have been evaluated and considered by the eCA for completeness reasons. Risk assessment conclusions based on these studies should be regarded as tentative and subject to revision when further data are provided from the applicant to support the ecotoxicological equivalence between the formulations.

Effects to honeybees

Honeybees were exposed to technical and formulated deltamethrin via routes of oral ingestion and topical contact. Acute oral and contact studies with technical deltamethrin were evaluated as part of the EU peer review of the substance as a Plant Protection Product and thus no further evaluation was conducted by the eCA. The technical deltamethrin $LD_{50}$ was 0.079 and 0.0015 µg a.s./bee in the oral and contact toxicity test, respectively, indicating that deltamethrin is inherently toxic to honeybees.

The effects of formulated deltamethrin as Deltamethrin EW 50 and Deltamethrin EC 25 (Code 102000020023) to bees were investigated in two GLP acute toxicity tests by Barth (2006) and Schimitzer (2008), respectively, conducted according to the OECD testing guidelines 213 and 214.

In the study of Barth (2006), thirty adult worker honeybees divided into three replicates of ten animals each were exposed either via oral or topical (contact) application to Deltamethrin EW 50 at nominal rates of 2.5, 5.0, 9.8, 19.5 and 39.4 µg product/bee (oral test) or 0.51, 1.28, 3.2, 8.0 and 20.0 µg product/bee (contact test). Mortality and other treatment related effects (behavioural abnormalities) were assessed 24 and 48 hours after

the test initiation. The treatments were compared to control (negative and solvent) treatments and the toxic standard Dimethoate. Statistical analysis of the study results demonstrated that the oral $LD_{50}$ of Deltamethrin EW 50 to honeybees was 0.79 µg a.s./bee, while the contact $LD_{50}$ was determined to be 0.12 µg a.s./bee. The contact and oral test are considered valid as the control mortality in each case was <10 % and the 24-h $LD_{50}$ values obtained with the reference item (dimethoate) were within the required ranges. The study is summarized in table 3. It is noted that the code number of the product reported in the original study report (i.e. AE F032640 50 EW) is different from the code of the product of which the chemical composition (i.e. AB 0375503 50 EW) was submitted by the applicant.

In the study of Schimitzer (2008), under laboratory conditions, thirty adult worker honeybees were exposed for 48 hours to doses of 67.5, 136, 243, 450 and 1040 ng a.s. per bee for feeding (oral dose response test, value based on the actual intake of the test item) and 30 worker bees per treatment were exposed for 96 hours to doses of 16, 31, 63, 125 and 250 ng a.s. per bee for topical application (contact dose response test). Mortality and other treatment related effects (behavioural abnormalities) were assessed after 4, 24 and 48 hours; and additionally 72 and 96 hours in the contact test. The treatments were compared to control (negative and solvent) treatments and the toxic standard Dimethoate. Statistical analysis of the study results demonstrated that the oral $LD_{50}$ of Deltamethrin EC 25 to honeybees was 143 ng a.s./bee, while the contact $LD_{50}$ was determined to be 110 ng a.s./bee. The contact and oral test are considered valid as the control mortality in each case was <10 % and the 24-h $LD_{50}$ values obtained with the reference item (dimethoate), were within the required ranges. The study is summarized in table 3.

The available data indicate that formulated deltamethrin is less toxic to honeybees than technical deltamethrin following both oral and contact exposure.

**Table 3:** Acute oral and contact toxicity of deltamethrin to honeybees

| **Method, Guideline, GLP status, Reliability** | Species/ Inocu-lum | End point | Exposure | | Results | | | Remarks | Refe-rence |
|---|---|---|---|---|---|---|---|---|---|
| | | | Design | Dura-tion | $LD_0$ | $LD_{50}$ | $LD_{100}$ | | |
| No specific guideline was followed; methodology comparable to the OECD 213; non-GLP study; R.I.: 2 | Honey bees *(Apis mellifera)* | Oral mortality; $LD_{50}$ | Oral exposure | No information available | - | 0.079 µg/bee | - | The study is evaluated in the deltamethrin DAR; no further evaluation was conducted by the eCA; The study was assigned a R.I. of 2 due to the lack of information on the test duration | Stevenson (1978) |
| FIFRA Subdivision L; Subsection 141-1; GLP study; R.I.: | Honey bees *(Apis mellifera)* | Contact mortality; $LD_{50}$ | Contact exposure | 48 h | 0.00063 µg/bee | 0.0015 µg/bee | > 0.01 µg/bee | The study is evaluated in the deltamethrin DAR; no further | Hoxter & Lynn (1991) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | evaluation was conducted by the eCA; | |
| OECD 213 & 214; GLP study; R.I.: 1 | Honey bees *(Apis mellifera)* | Contact and oral mortality; $LD_{50}$ | Oral & contact exposure | 48 h | Oral toxicity <0.124 µg a.s./bee<br><br>Contact toxicity 0.025 µg a.s./bee | Oral toxicity 0.79 µg a.s./bee<br><br>Contact toxicity 0.12 µg a.s./bee | Oral toxicity 1.96 µg a.s./bee<br><br>Contact toxicity 0.994 µg a.s./bee | Test material: Deltamethrin EW 50 | Barth (2006) |
| OECD 213 & 214; GLP study; R.I.: 1 | Honey bees *(Apis mellifera)* | Contact and oral mortality; $LD_{50}$ | Oral & contact exposure | Oral exposure: 48 h<br><br>Contact exposure: 96 h | Oral toxicity 0.0.0675 µg a.s./bee<br><br>Contact toxicity 0.031 µg a.s./bee | Oral toxicity 0.143 µg a.s./bee<br><br>Contact toxicity 0.110 µg a.s./bee | Oral toxicity 0.450 µg a.s./bee<br><br>Contact toxicity >0.25 µg a.s./bee | Test material: Deltamethrin EC 25; Due to increasing mortality between 24 and 72 hours the contact test was prolonged for further 48 hours up to 96 hours | Schimitzer (2008) |

Effects to other beneficial arthropods

The submitted laboratory and field studies on beneficial arthropods were conducted with formulations other than the present biocidal product. These studies were performed at dose levels that were not always comparable with the potential exposure of non-target arthropods via direct spray deposition on treated areas or spray drift to untreated areas. In some cases where the formulation studies were performed with exposure of dried residues, they were considered as relevant for the risk assessment and thus they evaluated by the eCA. As exposure of cultivated crops in treated and untreated areas cannot be excluded based on the intended outdoor use of Deltamethrin EW 20, the available field studies conducted in orchards and winter wheat were also considered relevant and thus evaluated by the eCA. The available laboratory and field studies are described below and summarized in table 4.

*Extended laboratory studies with the paracitic wasp Aphidius rhopalosiphi*

**Barth, 2000**. *Toxicity of AE F032640 00 EC03 BOOS to the cereal aphid parasitoid Aphidius rhopalosiphi (DESTEFANI-PEREZ) (extended laboratory test)*

The study of Barth (2000) was performed according to the extended laboratory testing proposal by Mead-Briggs and Longley (1997). Deltamethrin formulated as Deltamethrin EC 25 (Code AE F032640 00 EC03 B005) was applied to potted wheat plants at rates

equivalent to 0.1, 0.4 and 7.5 g a.s./ha. After the spray deposits had dried, exposure cages were assembled by placing 5 female wasps (maximum 48 h old) into each replicate unit (4 units per treatment). Mortality (number of dead and moribund wasps) was assessed 1, 2, 24 and 48 hours after treatment. To assess any impact on the fecundity of surviving individuals, up to 14 females from each treatment and the control group were taken after 48 h and confined individually over aphid-infested untreated potted wheat plants for a further 24 h period. The wasps were then removed and the number of parasitized aphids (aphid mummies) that developed was recorded after 11 days. The mortality of tested wasps was determined to be 0, 7 and 100 % in the treatment levels of 0.1, 0.4 and 7.5 g a.s./ha, respectively. There were no statistically significant effects of Deltamethrin EC 25 on reproduction (mean number of mummies/female wasp) up to the application rate of 0.4 g a.s./ha. The test is considered as valid as the control and toxic reference mortality as well as the reproductive performance of the control animals were within the required ranges. The study results are presented in table 4.

**Röhlig, 2006**. *Dose-response toxicity (LR50) of Deltamethrin EW 50 to the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) under extended laboratory conditions*

The study of Röhlig (2006) was performed according to the laboratory testing guideline of Mead-Briggs et al. (2000) and the extended laboratory testing proposal by Mead-Briggs and Longley (1997). Deltamethrin formulated as Deltamethrin EW 50 was applied to potted barley plants at rates equivalent to 0.178, 0.355, 0.711, 1.421 and 2.843 g a.s./ha. After the spray deposits had dried, exposure cages were assembled by placing seven female wasps (maximum 48 h old) into each replicate unit (4 units per treatment). Mortality (number of dead and moribund wasps) was assessed 1, 2, 24 and 48 hours after treatment. To assess any impact on the fecundity of surviving individuals, up to 14 females from each treatment and the control group were taken after 48 h and confined individually over aphid-infested untreated barley plants for a further 24 h period. The wasps were then removed and the number of parasitized aphids (aphid mummies) that developed was recorded after 11 days. Statistical analysis of the study results demonstrated that Deltamethrin EW 50 caused no adverse effects on the survival of *A. rhopalosiphi* up to the application rate of 0.711 g a.s./ha. The 48-h $LR_{50}$ of Deltamethrin EW 50 to *A. rhopalosiphi* was calculated be 1.421 g a.s./ha. There were no statistically significant effects of Deltamethrin EW 50 on reproduction (mean number of mummies/female wasp) up to the application rate of 1.421 g a.s./ha. The study results are presented in table 4. The test is considered as valid as the control and toxic reference mortality as well as the reproductive performance of the control animals were within the required ranges. It is noted that the code number of the product reported in the original study report (i.e. AE F032640 50 EW) is different from the code of the product of which the chemical composition (i.e. AB 0375503 50 EW) was submitted by the applicant.

*Extended laboratory studies with the predatory mite Typhlodromus pyri*

**Feije, 2004.** *DELTAMETHRIN EC 25: Extended laboratory study to evaluate the effects on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on bean plants*

The effects of Deltamethrin EC 25 on the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoselidae) (survival and reproduction) were investigated in the extended laboratory study of Feije (2004). The study was performed according to the extended laboratory testing of Blümel et al. (2000) and Candolfi et al. (2001) and fulfilled all the corresponding validity criteria without any deviation. The insecticide Deltamethrin EC 25 was applied to dwarf bean leaves (Phaseolus vulgaris) at 5 nominal concentrations 0.03,

0.05, 0.09, 0.15 and 0.25 g a.i./ha, at spray application volume of 200 L/ha. Mortality was assessed after a 7-day exposure period and on the day of mortality assessment surviving individuals were transferred to open arenas for reproduction assessment. Reproduction for the two lowest treatments was determined during 7 days in total. Statistical analyses allowed the derivation of an $LR_{50}$ of 0.058 g a.s./ha for mortality. The reproduction was statistically significantly reduced compared to the control up to and including the highest application rate tested (0.05 g a.s./ha). The $ER_{50}$ based on reproduction was not calculated, but the tested rate at 0.03 gr a.i./ ha caused a reduction of reproduction of 48%. The results of the study are shown in table 4.

**Loose, 2005.** *An extended laboratory dose-response study to evaluate the effects of DECIS EW 50 on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on cow pea*

The study of Loose (2005) was performed according to the extended laboratory testing guideline of Blümel et al. (2000) and fulfilled the corresponding validity criteria. Deltamethrin formulated as Deltamethrin EW 50 was applied to cow pea leaves (*Phaseolus vulgaris*) at rates equivalent to 12.5, 25, 50, 100 and 200 mg a.s./ha. After the spray deposits had dried, the test units (munger units) were assembled. Ten healthy protonymphs of *Typhlodromus pyri* (maximum 24 hours old) were placed into each replicate unit (10 units for the water control, 8 units per treatment and 6 units for the toxic reference). Mortality were assessed after 7 days in all treatment levels by recording the number of live males/females/juveniles. Reproduction (number of eggs per female produced over a 7-day period) was assessed 3, 5 and 7 days after surviving mites in the treatment levels of 12.5, 25 and 50 mg a.s./ha were transferred to treated leaf discs. Statistical analysis of the study results demonstrated that mortality in the lowest treatment level (12.5 mg a.s./ha) was not statistically significantly increased compared to the control while the 7-day $LR_{50}$ was calculated to be 75.3 mg a.s/ha. The reproduction was not statistically significantly reduced compared to the control up to and including the application rate of 50 mg a.s./ha. The test is considered as valid as the control and toxic reference mortality as well as the reproductive performance of the control animals were within the required ranges. The study results are presented in table 4.

**Aldershof, 2009.** *An extended laboratory dose-response study to evaluate the effects of Deltamethrin EW 25 G on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on apple leaves*

The exended laboratory study of Aldershof (2009) investigated the effects of deltamethrin formulated as Deltamethrin EW 25 on the survival and reproduction of the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoselidae). The insecticide was applied to potted apple trees at five nominal rates from 25 to 503 mg a.s./ha at spray application volume of 200 L/ha. Mortality was assessed after a 7-day exposure period. Reproduction for the three lowest treatments 25, 50 and 112 mg a.s./ha was determined during 7 days in total. The study was performed with the following deviation from the test guidelines (Blummel et al. 2000; Candolfi et al. 2001): initiation of exposure to freshly sprayed apple leaves within 1.5 hrs after application was not feasible for all units; exposure started within 2 hrs after application for all units. The expected impact on the outcome is considered negligible since exposure started within the shortest possible time after drying of residues thus expecting a worst case scenario exposure. The validity criteria were met. The $LR_{50}$ for mortality was estimated to be 77.7 mg a.s./ha. The $ER_{50}$ based on reproduction was not calculated, though the tested rate of 0.05 g a.s./ha caused a reduction of reproduction of 51%. The results are shown in table 4.

*Extended laboratory, aged residue studies with the predatory mite Typhlodromus pyri*

**Feije, 2004.** *DELTAMETHRIN EC 25: Extended laboratory study to evaluate the effects on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on bean plants – aged residue*

In the extended laboratory, aged residue study of Feije (2004), deltamethrin formulated as Deltamethrin EC 25 was applied once to dwarf bean leaves (Phaseolus vulgaris) at a single application rate of 7.5 g a.s./ha based on a carrier volume of 300 L/ha. Bioassays were initiated within one hour after drying of the residues and 2 and 4 weeks later. Ten healthy protonymphs of Typhlodromus pyri (maximum 24 hours old) were placed into each replicate unit (10 units per treatment). Mortality were assessed after 3 and 7 days, while reproduction (number of eggs/juveniles produced) per female was assessed 10, 12 and 14 days after treatment. The study did not meet all the validity criteria and has two deviations from the test guidelines regarding the study plan. In the bioassay 4 weeks after application the relative humidity was slightly below the nominal range (60-90%); this minor deviation is considered to have not significant impact on the study outcome. Control mortality in the bioassay initiated within 1 hour after spraying of the bean plants exceeded the validity criterion of at maximum 20% (57% mortality was observed). This was attributed to malfunction of the climate-controlled cabinet. However, the results of this bioassay will not be further considered and the effect parameters will be determined based on the results of the bioassays two and four weeks after application. Based on the study results, exposure to treated bean leaves aged two weeks caused significant effect on *Typhlodromus pyri* survival (corrected mortality: 58%). When exposed to four weeks aged residues, survival was 34% and significantly different from survival in the control treatment. At this moment in time, reduction in reproduction relative to the control was 27% and not significantly different from reproduction in the control treatment. The results of the study are shown in table 4.

**Bakker, 2004.** DECIS 2.5 EC: *Extended laboratory study to evaluate the effects on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on apple leaves – Aged Residue –*

The study of Bakker (2004) on the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoselidae) was performed according to the extended laboratory testing of Blümel et al. (2000) and Candolfi et al. (2001) and fulfilled the corresponding validity criteria with deviations. Deltamethrin formulated as Deltamethrin EC 25 (Code: AE F032640 00 EC03 B021) was applied three times, with 1-week intervals to potted apple trees at approximately 12.5 g a.s./ha using a carrier volume of 600 L/ha. Ten healthy protonymphs of *Typhlodromus pyri* (maximum 24 hours old) were placed into each replicate unit (10 units per treatment). Mortality were assessed after 3 and 7 days, while reproduction (number of eggs/juveniles produced per female) was assessed 10, 12 and 14 days after treatment. Effects of Deltamethrin EC 25 residues on apple leaves, collected impartially from the treated trees were tested with the predatory mite on the day of the third application (bioassay 1) and after six weeks (bioassay 2). The first deviation occurred in the mortality phase of bioassay 2 where the dark phase started only on day 3. The second deviation occurred in the nominal test concentration of the tested toxic reference item and the mistake was noted before the first spraying thus was not considered to have affected the study outcome. Mortality in mites exposed to the freshly applied test item was 100% (Bioassay 1), i.e. statistically significantly different from the control. After 6 weeks of residue aging (Bioassay 2) mortality was 14 % (or 4%, if two units with relatively many

mites missing are discarded) in the test item group, i.e. not statistically significantly different from the control. Six-week-old residue of Deltamethrin EC 25 resulted in 37% lower reproduction of the mites compared to the control, i.e. effect not statistically significant. The results are presented in table 4.

**Aldershof, 2006.** *DELTAMETHRIN EC 25: Extended laboratory study to evaluate the effects on the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on apple trees – Aged Residue –*

The extended laboratory aged-residue study of Aldershof (2006) was designed to evaluate direct effects and potential for recovery of the predatory mite *Typhlodromus pyri* following exposure to aged residues of Deltamethrin EC 25 on apple elaves. Deltamethrin EC 25 (nominal deltamethrin content 25 g/L) was applied three times to potted apple trees at the rate of 17.5 g a.s./ha using a fourteen-day spray interval. Trees were positioned outdoors under ambient conditions in South-West France. Apple leaves were collected shortly after drying of residues or before initiation of the laboratory bioassays. Each bioassay was initiated at fixed time intervals following the last application. Six bioassays were carried out in munger cages while five bioassays were performed on leaf discs. Test units were assembled immediately after collection of leaves. For each treatment there were 10 units with 10 protonymphs each. Mortality was assessed in all bioassays 7 days after initiation of the exposure. Reproductive performance of surviving mites (number of eggs per female produced over a 7-day period) was assessed in the treatments of bioassays 8-11. It is noted that the in the latter bioassays, the residues in the treated leaves used as test substrates were left to age outdoors for 102 – 146 after the last application. The bioassay procedure followed the design for laboratory studies as in Blümel et al. (2000), with adaptations to accommodate for the detached leaf substrate.

The test item treatment had significant effects (greater than 50%) on juvenile survival of *T.pyri* at least 102 days after the last application. By the end of the study, i.e. 146 days after the last application, the corrected mortality was found to be 28%. From bioassay 8 onwards, i.e. 102 days after last application, surviving animals did not show any statistically significant reductions on reproductive performance compared to the control in any of the assays. Taking into account that (i) the survival of the exposed mites to aged residues of deltamethrin on apple leaves was still adversely affected (statistically significantly reduced compared to the control) 146 days after last application and (ii) the application pattern used in the study (3 applications of 17.5 g a.s./ha with a 14-day interval) was worst-case compared to the intended application pattern of Deltamethrin 20 EW, it is the eCA's opinion that the study of Aldershof (2006) should not be further considered in the risk assessment for non-target arthropods.

*Field studies*

**Aldershof, 2001.** *Evaluating effects of AE F032640 00 EC03 B007 applications on predatory mites (Acari: Phytoseiidae) and other non-target arthropod species in the field (apple orchards, Portugal)*

The GLP field study of Aldershof (2001) aimed at evaluating the effects of Deltamethrin EC 25 (Code: AE F032640 00 EC03 B007) on the key plant-dwelling, non-target arthropods under field conditions. The study was conducted in an apple orchard in Portugal. Off-crop exposure was simulated using drift rates of 0.8%, 4.8% and 16% of the full rate (Gonzalez-Valero et al., 1999). Effects of these rates were evaluated against the test item applied at the full rate and against a water control. Plant-dwelling arthropod populations

(comprising pests and non-target arthropods) were monitored throughout the growing season. The start of the trial was postponed for 2 weeks to enable non-target populations (in particular phytoseiid mites) to develop. The timing chosen aimed at ensuring a maximum exposure for most taxonomic groups found.

Predatory mite populations and non-target arthropod species were exposed to 4 rates of the test product: the highest recommended field rate of 12.5 g a.s./ha (positive reference), and a 16%, 4.8%, and 0.8% drift rate of 2 g, 0.6 g and 0.1 g a.s./ha, respectively. Application volumes were 600 L/ha. Exposure of arthropod species was achieved by applying the test products to trees in an apple orchard with motorized air assisted tractor mounted sprayers. Test solutions and a water control were applied 3 times with 15-day spray intervals, approximately 3 weeks after flowering (BBCH stage 73). Abundance of predatory mites and other non-target arthropod species and densities were estimated. Organisms were identified to family level. Endpoints were (1) immediate effects of applications on density (predatory mites and abundant other non-target arthropod species) relative to densities observed in water control plots; (2) recovery during the season and duration of effects; (3) indirect effects of abundant predator species or parasites through direct effects on abundant prey species or host species. The experimental design was semi-randomized complete blocks with 4 replicates, tested into 4 blocks. The experimental unit was the entire orchard. Each block was divided into 5 plots: 1 for each treatment (i.e. water control, test compound at 3 drift rates and at the highest recommended field rate serving as positive reference treatment). Each plot was considered as a replicate. Treatments were applied to the entire plot. Sampling units were individual trees. For each sampling occasion, 4 trees were selected in each plot.

At the full rate (12.5 g a.s./ha) in all taxa, except in the Collembola and non-predatory mites, immediate effects were observed. In 27 of 43 groups reductions in numbers per tree exceeded 50%. More mobile species as parasitoids and flies showed rapid recovery, but long term effects were observed in certain groups of phytoseiids, spiders, beetles and Juveniles of Orfws species as well as in ants and booklice (Psocoptera). Certain Phytoseiidae and Coieoptera groups did not recover within the growing season. The target pest groups in the Homoptera and the Curcuiionidae had no or late recovery. Persistent and significant increases in numbers of pest mites were observed. In the 16% drift rate (2 g a.s./ha), 16 groups were not affected and 14 taxa had effects of 50% and higher. In general recovery periods were of the same order of magnitude as observed in the full rate, but, with the exception of the target group Curcuiionidae, all groups recovered within the growing season. In the 4.8% drift rate (0.6 g a.s./ha), 23 groups were not affected and 6 taxa had effects of 50% and higher. In general recovery periods were of the same order of magnitude as observed in the 16% drift rate. In the 0.8% drift rate (0.1 g a.s./ha), 34 groups were not affected and 2 taxa had effects of 50% and higher. Of these two groups, the Corylophidae had an immediate recovery. Recovery for larvae of Syrphtdae could not be established due to low numbers found after the application period. The study is summarized in table 4.

**Bakker, 2005.** *Effects on Non-Target Arthropod fauna Insecticide treatments in cereal fields Deltamethrin EC 25*

The objective of the study of Bakker (2005) was to evaluate the within and between season effects of Deltamethrin EC 25 (code: AE F032640 00 EC03 B021) applications on the key plant- and soil-dwelling, non-target arthropods (NTAs) under arable field conditions. For this reason NTA populations were monitored over three cropping cycles, viz. winter wheat, oil seed rape, winter wheat. The study had three main endpoints: (1) the range of NTA taxa affected by the treatment; (2) the magnitude of treatment effects

on non-target arthropods and (3) the duration of treatment effects and the time period until populations recovered.

The test item was applied according to GAP in a representative worst-case use pattern to winter wheat in North-Western France. The first application was applied in the 2-3 leaf stage in autumn on 18 November 2003. The second and third applications were performed in spring on 3 May 2004 in the stem elongation stage and on 28 May 2004 in the flowering stage, respectively. The nominal test rate was 6.25 g a.i./ha on the first occasion and 12.5 g a.i./ha on the second and third occasion. A negative control and a reference item treatment (lambda-cyhalothrin formulated as Karate Zeon) were also included in the study. Four replicate plots were set up for the test item and the water control treatments and three replicates for the reference item.

To account for differences in biology/ecology of non-target arthropod fauna three different sampling techniques were used. Pitfall samples were taken to collect active ground dwelling arthropods (e.g. carabids, springtails and spiders). Photo-eclector samples were used to obtain information about species inhabiting the vegetation and species emerging from the soil. Yellow pan trap samples were used to monitor the in-crop flight activity (i.e. migration) of potential prey items (e.g. aphids) and predators (e.g. ballooning spiders). These migration patterns helped to interpret population dynamics and relations to treatment observed in data obtained with the other two sample types. In the centre of each plot a total of 12 pitfall traps, 4 photoeclectors and 4 yellow pan traps were established inside a sampling area of 30m x 30m.

Statistical analyses were done for the entire arthropod community, but in addition also separately for different functional groups and for different taxonomic groups. Functional groups examined were: predators, parasitoids, herbivorous taxa and other taxa (mainly saprophagous, fungivorous and detritivorous taxa). Taxonomic groups analysed sepatately were: Coleoptera, Araneae, Diptera, Hymenoptera and others (e.g. Thysanoptera, Heteroptera, Collembola, Diplopoda). Pitfall samples and photo-eclector samples were analysed separately. Pan trap samples only contained information about highly mobile species.

Catches from pitfall traps and photo-eclectors showed that the non-target arthropod fauna in the field crop was abundant and typical for arable fields. The final data sets used for evaluation of community effects contained 77 taxa from pitfall samples and 50 taxa from photo-eclector samples. In general, pitfall samples contained higher numbers and more taxa than photo-eclector samples. The most numerous taxon in both sample types were Collembola (Arthropleona and Symphypleona).

Analysis of community responses indicated that non-target arthropods (NTAs) recovered from pitfall traps and photo-eclectors exhibited an overall additive negative community response to multiple test item applications, i.e. each application resulted in a subsequent increase of the deviation from the water treatment. However, for pitfall traps in the test item treatment the lowest sample score was already observed shortly before the third application. For both sample types the period of adverse community effects was followed by an upward pattern indicating recovery. Sample scores obtained from the pitfall trap data for the reference item treatment remained significantly different from the water control until the end of the study, illustrating the sensitivity of the test system and the applied methods. The same analysis of pitfall data for the test item treatment on the other hand showed non-significant or positive responses from September 2004 onwards, indicating that full recovery of the ground dwelling NTA community had occurred before the start of the next growing season. Likewise, in the photo-eclector samples recovery had occurred before the start of the next cropping cycle. It is noted that two important groups of NTAs did not match the overall response pattern. First, carabid beetle species obtained from pitfall traps only of the test item treatment did not follow the overall negative pattern

caused by the test item. Second, the Arthropleona (springtails) displayed positive responses in this case both to test and reference item and in both sample types.

Analysis of responses of functional groups indicated that herbivores, being target organisms, were strongly affected by the test item treatment. Significant treatment related effects on the phytophagous community, attributed to the taxon Thysanoptera were still apparent at the last photo-eclector sample in spring 2005. Saprophages, mainly consisting of dipteran and coleopteran species, were not statistically significantly affected by the test item treatment. Predators showed an overall negative response to test and reference item treatments, followed by recovery in the test item treatment. Compared to other functional groups the winter application had a large impact on the predator community. Both predatory beetles and spiders were present at relatively high densities in this period. Recovery was observed before the next growing season in September 2004 for the predator community as a whole, when population densities were high. However, in early spring 2005 a statistically significant adverse effect for the predator community sampled with photo-eclectors was observed. Detailed analysis showed that this effect could be attributed to the linyphiid spider subfamily Erigoninae (mainly *Oedothorax apicatus)*. For pitfall traps densities at this point in time were too low for robust statistical analysis. Two weeks later, Erigoninae populations sampled with both methods had increased and statistical testing did not show differences among water control plots and test item treated plots, implying that recovery had occurred. Parasitoids showed a negative response to test and reference item treatments, followed by recovery. Effects of the second and third application were additive, i.e. they led to an increase of the deviation with the water control. The winter application had no impact on the parasitoid community. Inferential testing showed statistically significant differences with the water control for most sampling dates in the period following the last application until September 2004. Densities remained very low during winter 2004. In spring 2005 taxa that were caught at sufficiently high numbers did not show any effects, hence it can be inferred that recovery had occurred. The study is summarized in table 4.

**Table 4:** Effects of deltamethrin on beneficial arthropods (*T.pyri, A.rhipalosiphi*)

| **Method, Guideline, GLP status, Reliability** | Species/ Inocu-lum | End point | Exposure | | Results | Remarks | Refe-rence |
|---|---|---|---|---|---|---|---|
| | | | Design | Duration | | | |
| **Extended laboratory studies with the paracitic wasp *Aphidius rhopalosiphi*** | | | | | | | |
| Mead-briggs & Longley (1997); GLP study; R.I.: 1 | Parasitic wasp *Aphidius rhopalosiphi* | Mortality; Reproduction | Extended laboratory test; Natural substrate used: potted wheat plants | Total test duration: 14 d; Mortality assessment: 48 d; Reproduction assessment: 12 d | Mortality: 0, 7 and 100 % at 0.1, 0.4 and 7.5 g a.s./ha respectively; Reproduction: Not significantly affected up to 0.4 g a.s./ha | Test material: Deltamethrin EC 25 | Barth (2000) |
| Mead-briggs et al. (2000), Mead-briggs & | Parasitic wasp *Aphidius rhopalosiphi* | Mortality; Reproduction | Extended laboratory test; Natural substrate | Total test duration: 14 d; Mortality assessment: | Mortality: Not significantly affected at 0.711 g | Test material: Deltamethrin EW 50 [1] | Röhlig (2006) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Longley (1997); GLP study; R.I.: 1 | | | used: potted barley plants | 48 d; Reproduction assessment: 12 d | a.s./ha; 48-d $LR_{50}$=1.421 g a.s/ha<br>Reproduction:<br>Not significantly affected up to 1.421 g a.s./ha | | |
| **Extended laboratory studies with the predatory mite *Typhlodromus pyri*** | | | | | | | |
| Blümel et al. (2000); Candolfi et al. (2001); GLP study; R.I.: 1 | Predatory mite *Typhlodromus pyri* | Mortality; Reproduction | Extended laboratory test; Natural substrate used: bean leaves | Total test duration: 14 d; Mortality assessment: 7 d; Reproduction assessment: 7 d | Mortality:<br>Statistically significantly affected at 0.03-0.25 g a.s./ha; 7-d $LR_{50}$=0.058 gr a.s./ ha<br>Reproduction:<br>Statistically significantly affected at 0.03 and 0.05 g a.s./ha (48% reduction at 0.03 g a.s./ ha) | Test material: Deltamethrin 25 EC | Feije (2004) |
| Blümel et al. (2000); Candolfi et al. (2001); GLP study; R.I.: 1 | Predatory mite *Typhlodromus pyri* | Mortality; Reproduction | Extended laboratory test; Natural substrate used: cow pea leaves | Total test duration: 14 d; Mortality assessment: 7 d; Reproduction assessment: 7 d | Mortality:<br>Not significantly affected at 12.5 mg a.s./ha; 7-d $LR_{50}$=75.3 mg a.s/ha<br>Reproduction:<br>Not significantly affected up to 50 mg a.s./ha | Test material: Deltamethrin EW 50 [1] | Loose (2005) |
| Blümel et al. (2000); Candolfi et al. (2001); GLP study; R.I.: 1 | Predatory mite *Typhlodromus pyri* | Mortality; Reproduction | Extended laboratory test; Natural substrate used: apple leaves | Total test duration: 14 d; Mortality assessment: 7 d; Reproduction assessment: 7 d | Mortality:<br>Not significantly affected at 0.025 g a.s./ ha; 7-d $LR_{50}$=77.7 mg a.s/ha<br>Reproduction:<br>Not significantly affected up to 0.025 g a.s./ ha | Test material: Deltamethrin EW 25 G | Aldershof (2009) |
| **Extended laboratory, aged residue studies with the predatory mite *Typhlodromus pyri*** | | | | | | | |
| Blümel et | Predatory | Mortality; | Extended | Total test | Mortality: | Test | Feije |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| al. (2000); Candolfi et al. (2001); GLP study; R.I.: 2 | mite *Typhlodromus pyri* | Reproduction | laboratory test; Natural substrate used: bean leaves application pattern: 1 x 7.5 g a.s./ha | duration: 14 d; Mortality assessment: 7 d; Reproduction assessment: 7 d | Statistically significant effects following exposure to treated bean leaves (at 7.5 g a.s./ha) aged 2 (58% mortality) and 4 (34% mortality) weeks<br><u>Reproduction:</u><br>Not significantly affected following exposure to treated bean leaves (at 7.5 g a.s./ha) aged 4 weeks | material: Deltamethrin 25 EC | (2004) |
| Blümel et al. (2000); Candolfi et al. (2001); GLP study; R.I.: 2 | Predatory mite *Typhlodromus pyri* | Mortality; Reproduction | Extended laboratory test; Natural substrate used: apple leaves application pattern: 3 x 12.5 g a.s./ha, 17-d interval | Total test duration: 14 d; Mortality assessment: 7 d; Reproduction assessment: 7 d | <u>Mortality & Reproduction:</u><br>Not statistically significant effects following exposure to treated apple leaves (3 x 12.5 g a.s./ha; 7-d interval) aged 6 weeks | Test material: DECIS 2.5 EC | Bakker (2004) |
| Blümel et al. (2000); Candolfi et al. (2001); GLP study; R.I.: 2 | Predatory mite *Typhlodromus pyri* | Mortality; Reproduction | Extended lab, aged residue test; Natural substrate used: apple leaves application pattern: 3 x 17.5 g a.s./ha, 14-d interval | Total test duration: 174 d; (application: 28 d; observation: 146 d) Mortality assessment: 7 d; Reproduction assessment: 7 d | <u>Mortality:</u><br>Statistically significant effects following exposure to treated apple leaves (3 x 17.5 g a.s./ha; 14-d interval) aged 130 days<br><u>Reproduction:</u><br>No statistically significant effects following exposure to treated apple leaves (3 x 17.5 g a.s./ha; 14-d | Test material: Deltamethrin EC 25 [2] | Aldershof (2006) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | interval) aged 130 days | | |
| **Field studies** | | | | | | | |
| Angelli et al. (2000); Blümel et al. (2000); GLP study; R.I.: 2 | NTA-fauna in apple orchards | Immediate effects of applications on density relative to densities observed in water control plots; recovery during the season and duration of effects; indirect effects of abundant predator species or parasites through direct effects on abundant prey species or host species | Field study; exposure to spray deposits on orchards trees | Total test duration: 17 weeks | <u>At 0.1 g a.a./ha:</u> effects on few taxa for a short period of time <u>At 0.6 and 2 g a.s./ha:</u> reduced populations of increasing number of taxa but mainly recovery within the season <u>At 12.5 g a.s./ha:</u> reduced populations of most taxa; in some toxa no recovery during the season | Test material: Deltamethrin EC 25 (Code: AE F032640 00 EC03 B007) | Aldershof (2001) |
| IOBC (Hassan, 1992), Anonymous (1992), ESCORT (Barrett et al, 1994), Brown (1998) and IOBC, BART and EPPO Joint Initiative (Candolfl et al, 2000) | Non-target arthropod fauna in winter wheat fields | Range of NTA taxa affected by the treatment; magnitude of treatment effects on non-target arthropods; duration of treatment effects and the time period until populations recovered | Field study; exposure to spray deposits on winter wheat fields; <u>Application pattern:</u> 1st treatment: 6.25 g a.s./ha (18/11/2003), 2nd treatment: 3/5/2004 (12.5 g a.s./ha), 3rd treatment: 28/5/2004 (12.5 g a.s./ha) | Total test duration: approx. 18 months Start of field phase (first biological sample): 2/11/2003 Start of test item application: 18/11/2003 End of field phase (last biological sample): 4/4/2005 | <u>Community repsonses:</u> Statistically significant advesrse effects following multiple test item applications; full recovery of the NTA community had occurred before the start of the next growing season | Test material: Deltamethrin EC 25 (code: AE F032640 00 EC03 B021) | Bakker (2005) |

[1] the applicant is requested to confirm that the test formulation Delatmetrhin EW 50 is identical to the formulation Deltametrhin EW 50 for which the chemical composition is available

[2] the applicant is requested to clarify which of the deltamethrin-containing alternative formulations, for which the chemical composition is available, corresponds to the formulation used in the study

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

Please refer to the section *"Further Ecotoxicological studies"* above.

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

Please refer to the section *"Further Ecotoxicological studies"* above.

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

No studies on acceptance by ingestion of the biocidal product by any non-target organisms are required as Deltamethrin EW 20 is not in the form of bait or granules.

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

No higher tier field studies for the identification of secondary ecological effects in a specific habitat type have been submitted.

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

According to the intended uses (see the following table), AQUA K-OTHRINE 20 EC is applied outdoors (aerial application with helicopter and ground application with thermal or cold fogging equipment) and indoors (application with thermal or cold fogging equipment) in vector control situation.

| **Location** | **Target** | **Equipment** | **Application rate** |
|---|---|---|---|
| Outdoor, aerial | Mosquitos | Airplane/helicopter mounted application equipment | 1 g a.s./ha |
| Outdoor, terrestrial | Mosquitos | Thermal fogging equipment<br>Cold fogging equipment | 1 g a.s./ha |
| Outdoor, terrestrial | Flies | Thermal fogging equipment<br>Cold fogging equipment | 1 g a.s./ha |
| Indoor | Mosquitos<br>Flies | Thermal fogging equipment<br>Cold fogging equipment | 0.05 g a.s./1000 $m^3$ |

The relevant environmental compartments considered in the present Environmental Exposure Assessment are presented in the following table.

| | **Environmental Compartments** | | | | |
|---|---|---|---|---|---|
| | Air | STP | Soil | Surface water | Groundwater |
| Rural application (aerial) | **(+)** | | **++** | **++** | **+** |

| | | | | | |
|---|---|---|---|---|---|
| Rural application (ground) | **(+)** | | **++** | **+** | **+** |
| Urban application (ground) | **(+)** | **++** | **+** | **+** | **+** |
| Indoor applications | **(+)** | **++** | **+** | **+** | **+** |

++ Primarly exposed
+ Secondarily exposed
(+) Potentially exposed

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

No further studies on environmental fate and behaviour with the biocidal product or its any of its components have been submitted. The fate and behaviour of the biocidal product Deltamethrin EC 20 is adequately covered by the EU peer reviewed data for the active substance deltamethrin.

### *Leaching behaviour (ADS)*

No further studies on environmental fate and behaviour with the biocidal product or its any of its components have been submitted.

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

No further studies on environmental fate and behaviour with the biocidal product or its any of its components have been submitted.

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

No further studies on environmental fate and behaviour with the biocidal product or its any of its components have been submitted.

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

No further studies on environmental fate and behaviour with the biocidal product or its any of its components have been submitted.

### *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)*

Not relevant based on the intended use pattern of the biodical product Deltamethrin EW 20.

### *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)*

Please refer to the section *"Further Ecotoxicological studies"* above.

### 2.2.7.2 Exposure assessment

**General information**

| | |
|---|---|
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor application by professionals using thermal or cold fogging equipment.<br>Scenario 2: Outdoor application (around buildings) by professionals using thermal or cold fogging equipment.<br>Scenario 3: Outdoor aerial application with helicopter equipped with mounted application. |
| ESD(s) used | Emission Scenario Document for Product insecticides, acaricides and products to control other arthropods for household and professional uses (OECD No 18, 2008). |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on TGD 2003 and according to OECD ESD no 18 for PT 18. |
| Groundwater simulation | FOCUS PEARL 2.2.2 for both Deltamethrin and its metabolite $Br_2CA$. |
| Confidential Annexes | NO |
| Life cycle steps assessed | Scenario 1 and 2:<br>Production: No<br>Formulation No<br>Use: Yes<br>Service life: Yes |
| Remarks | For aerial applications (Scenario 3) using a specific helicopter type, Applicant was asked to perform the exposure assessment using AgDrift and AgDisp models, as proposed in OECD ESD PT 18 (2008) (Point 2.1.5, p.19) for outdoor large scale spraying applications. Applicant response was that AgDISP and AgDrift results are specific to the model aircraft however, aerial application will be carried out with AgDISP software. According to eCA the performed by the Applicant exposure assessment does not fulfil the data gap and a new exposure assessment regarding aerial application should be performed and submitted by the Applicant. In conclusion there are no adequate data to conclude on the exposure assessment following aerial application of DELTAMETHRIN 20 EW. |

***Emission estimation***

In the following environmental exposure assessment for the product Aqua K-othrine, exclusively the active substance Deltamethrin and its metabolite $Br_2CA$ are taken into consideration.

***Emissions to the environment***

An exposure assessment has been submitted by the applicant. A number of data gaps have been identified and the Applicant was notified to fulfill the requirements (21.04.2016). An updated exposure assessment has been submitted, however, according to eCA the determined open points have not been addressed adequately. Therefore, Exposure Risk Assessment has been prepared by the eCA for the intended uses. More specifically, for indoor treatment Applicant stated that *"AQUA K-OTHRINE is applied as an air space treatment to treat indoor domestic area. Typically, injection will be carried out from outside of the premises (e.g. entry of the product from door, window). In some*

*instances, while outdoor injection is carried out, recommendation will be given to leave windows and doors open to allow for indoor treatment. In order to prevent emissions reaching the wet-cleaned areas (bathroom and kitchens) to be released to STP, it is requested in the direction for use that all doors and windows of wet cleaned areas are closed during treatment."* This statement does not reflect the common practice for fogging application for indoor areas. Moreover, Applicant erroneously refers to *"injection"* application. Therefore, emissions calculated and presented below according to ESD PT 18 (2008) following the common approach for all the relevant active substances with the same application method. For outdoor ground application with thermal and cold fogging equipment, emission calculations have been performed by the Applicant [redacted]. For these reasons new PEC calculations have been released by eCA for rural and urban areas following the guidance as given in OECD ESD PT 18 (2008) and TGD (2003). Moreover, for aerial applications using a specific helicopter type, Applicant was asked to perform the exposure assessment using AgDrift and AgDisp models, as proposed in OECD ESD PT 18 (2008) (Point 2.1.5, p.19) for outdoor large scale spraying applications. Applicant's response was that AgDISP and AgDrift results are specific to the model aircraft however, aerial application will be carried out with AgDISP software. This is contradictory and according to eCA does not fulfil the data gap for a new exposure assessment. In conclusion there are no adequate data to conclude for the PECs following aerial application of DELTAMETHRIN 20 EW.

The following calculations for indoor and outdoor application with cold and thermal fogging have been performed by the eCA. No calculations have been presented for aerial application since Applicant's approach has not considered acceptable. Moreover, in the corresponding SPC the following phrase will be added: "*Do not use on agricultural areas or areas that are adjacent to crops*", in order to prevent any potential risk on non-target organisms from direct exposure of the product.

The environmental exposure has been assessed using all the valid submitted studies and the Organisation for Economic Co-operation and Development (OECD) Task Force documents; Emission Scenario Document (ESD) for 'Insecticides, acaricides and products to control arthropods (PT 18) for household and professional use' (July 17, 2008), Part II of the Technical Guidance Document on Risk Assessment (TGD; EC, 2003), guidance from MOTA (Manual of Technical Agreements, Vs. 4, 2010) and TAB (September 2015) were also included to derive the PEC values.

Deltamethrin 20 EW is intended for professional outdoor and indoor use. More information regarding the intended uses and the application rates is presented in the following table.

| **Location** | **Target** | **Equipment** | **Application rate** |
|---|---|---|---|
| Outdoor, aerial | Mosquitos | Airplane/helicopter mounted application equipment | 1 g a.s./ha |
| Outdoor, terrestrial | Mosquitos | Thermal fogging equipment<br>Cold fogging equipment | 1 g a.s./ha |
| Outdoor, terrestrial | Flies | Thermal fogging equipment<br>Cold fogging equipment | 1 g a.s./ha |
| Indoor | Mosquitos<br>Flies | Thermal fogging equipment<br>Cold fogging equipment | 0.05 g a.s./1000 $m^3$ |

Releases into the environment can take place from processes at any stage of the life-cycle of a substance. However, the local scale environmental emissions associated with the outdoor and indoor use for Deltamethrin 20 EW, are considered for PECs calculations.
The following environmental compartments might be exposed from the use of Deltamethrin within Aqua K-othrine:

- **Sewage treatment plants (STP)**
  Sewage water treatment plants are regarded as the only pathway of Deltamethrin emissions after use as indoor insecticide. Possible entry pathways of wastewater during normal use of the product are via wet cleaning operations of treated surfaces, which will result in very low rates of active substance, which might be washed from treated surfaces. The consecutive cleaning of the fogging equipment can also be a possible source for Deltamethrin to the sewer system.
- **Surface water and sediment**
  Due to the intended uses, there are no direct emissions of Deltamethrin to surface water and sediments. The exposure to surface water and sediment is indirect via STP effluents.
- **Soil, groundwater and air**
  For indoor use of Aquapy potential direct contamination of the environment via the pathways air, soil or groundwater is considered negligible. However, STP sludge might be applied to soils. Therefore the STP sludge concentration and the concentrations in soil after one year and ten years of sludge application are calculated.

**Relevant Environmental compartments for each application method.**

| | **Environmental Compartments** | | | | |
|---|---|---|---|---|---|
| | Air | STP | Soil | Surface water | Groundwater |
| Rural application (aerial) | **(+)** | | **++** | **++** | **+** |
| Rural application (ground) | **(+)** | | **++** | **+** | **+** |
| Urban application (ground) | **(+)** | **++** | **+** | **+** | **+** |
| Indoor applications | **(+)** | **++** | **+** | **+** | **+** |

++ Primarly exposed , + Secondarily exposed, (+) Potentially exposed

**Emission rates**
Emission rates have been calculated based upon eCA's proposal for the intended uses of Aquapy:

Outdoor: 1g a.s./ ha

Indoor: 0.05 g a.s./1000 $m^3$

The concentration of DELTAMETHRIN in the biocidal product is considered to be 20% w/w.

Please notice that Applicant's calculations for all the intended uses are presented in the attached document in Annex I.

**1. Indoor uses.**

For indoor uses the estimations of environmental emissions are based air space application:

For emission calculations the following formulas (ESD for PT18 products, July 17, 2008) were used to calculate daily local emission to STP (as STP is regarded as the only pathway of direct Deltamethrin emissions after indoor use of Aqua K-othrine):

(1) $E_{prep,air} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,air} \times 10^{-3}$

(2) $E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,applicator} \times 10^{-3}$

(3) $E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,floor} \times 10^{-3}$

(4) $E_{applicat\ on,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times VOLUME$

(5) $E_{applicat\ on,appl\ cator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times VOLUME$

(6) $E_{applicat\ on,floor} = N_{appl,building} \times F_{appl\ cation,floor} \times Q_{prod} \times F_{AI} \times VOLUME$

(7) $E_{applicator,ww} = (E_{prep,applicator} + E_{appl\ cation,applicator}) \times F_{applicator,ww}$

(8) $E_{treated,ww} = (E_{prep,floor} + E_{appl\ cation,floor}) \times F_{ww} \times F_{CE}$

(9) $Elocal_{\ waste\ water} = E_{applicator,ww} + E_{treated,ww}$

(10) $Elocal_{waste\ water,total} = ((Elocal_{waste\ water,\ houses} \times N_{houses}) + (Elocal_{waste\ water,\ larger\ buildings} \times N_{larger\ buildings})) \times F_{simultaneity}$

Each approach warrants new input values, as described in each section below.

### 1.1 Indoor air spray application

Air space treatment scenario has been considered for indoor uses. A volume of 325 $m^3$ (130$m^2$ x 2.5m) with a wet cleaned zone of 96.25 $m^3$ for private houses and a volume of 1827 $m^3$ (540 $m^3$ wet cleaned zone) for larger buildings have been used. In the case of large buildings the volume treated has been calculated by multiplying 609 $m^2$ by the room height (3m). The values are in line with TAB version 2.1. $Q_{prod,prep}$ calculation (e.g. for indoor uses private house scenario: 2.51 x $10^{-3}$ g product/$m^3$ x 325 $m^3$ = 0.82 g product). Taking into consideration that product's relative density is 1.003 g/mL.

For exposure assessment purposes a number of total 4000 houses ($N_{houses}$) and 300 larger buildings ($N_{larger\ buildings}$) are considered to be connected to one STP according TAB (September 2015).

The formulas (1) to (10) as described above were used to calculate daily local emission to STP.Fraction emitted to waste waters by the applicator during the cleaning step: $\boldsymbol{F_{applicator\ ww}}$. In the present case, $\boldsymbol{F_{applicator\ ww}}$ is equal to 1 as 100% of the coveralls are washable;

- Fraction emitted to waste waters during the cleaning step: $\boldsymbol{F_{ww}}$. In the present case, $\boldsymbol{F_{ww}}$ is equal to 1 as 100% of the treated surfaces are washed with water;
- Cleaning efficiency for the total surface application: $\boldsymbol{F_{CE}}$ = 1 for spray applications (ESD PT 18, Table 3.3-8, p.64);
- Simultaneity factor, $\boldsymbol{F_{simultaneity}}$, represents the percentage of houses/buildings which are treated simultaneously (ESD PT18, p. 38-40). Calculations were made with the default $\boldsymbol{F_{sim}}$ of 0.00204, as a worst case scenario, considering one to two applications per year.
- A container volume of 5L has been assumed for Aqua K-Othrine, however, this will need to be checked at product authorisation stage to see if the proposed container matches with what was selected for modelling.

All the values that used for local emission to STP after total surface treatment calculations are presented in Table 1.1-1 below.

**Table 1:** Calculation of the local emissions to waste water - total surface spraying

| Parameter | Symbol | Unit | Houses | Larger buildings | S/D/O[1] |
|---|---|---|---|---|---|
| Area treated | $AREA_{treated}$ | $m^2$ | 130 | 609 | D |
| Total volume treated with product | VOLUME | $m^3$ | 325 | 1827 | D |
| Wet cleaned area volume | VOLUME | $m^3$ | 96.25 | 540 | |
| Fraction of active substance in the commercial product | $F_{AI}$ | - | 0.02 | 0.02 | S |
| **PREPARATION** | | | | | |
| Container volume | | L | 5 | 5 | S |
| Fraction emitted to air during preparation step (Liquid) | $F_{prep,air}$ | - | 0 | 0 | D |
| Fraction emitted to applicator during preparation step (Liquid) | $F_{prep,applicator}$ | - | 0.0012 | 0.0012 | D |
| Fraction emitted to floor during preparation step | $F_{prep,floor}$ | - | $4x10^{-4}$ | $4x10^{-4}$ | D |
| Quantity of commercial product used for the preparation per building | $Q_{prod,prep}$ | g | 0.82 | 4.6 | S |
| Quantity of commercial product applied in air space treatment | $Q_{prod}^{*}$ | $Kg.m^{-3}$ | $2.5x10^{-6}$ | $2.5x10^{-6}$ | S |
| Number of preparations per day | $N_{prep,building}$ | $d^{-1}$ | 1 | 3 | S |
| **Emission to the air during preparation step (1)** | **$E_{prep,air}$** | **kg/d** | **0** | **0** | **O** |
| **Emission to the applicator during preparation step (2)** | **$E_{prep,applicator}$** | **kg/d** | **$1.97x10^{-08}$** | **3.30175E-07** | **O** |
| **Emission to floor during preparation step (3)** | **$E_{prep,floor}$** | **kg/d** | **$1.64x10^{-09}$** | **$2.75x10^{-08}$** | **O** |
| **APPLICATION** | | | | | |
| Fraction emitted to air during application | $F_{appl\ cat\ on,air}$ | - | 0.02 | 0.02 | D |
| Fraction emitted to applicator during application (air-space) | $F_{applicat\ on,appl\ cator}$ | - | 0.024 | 0.024 | D |
| Fraction emitted to floor during application (air-space) | $F_{applicat\ on,floor}$ | - | 0.956 | 0.956 | D |
| Number of application per day per building | $N_{appl\ cation,building}$ | $d^{-1}$ | 1 | 1 | D |
| Quantity of commercial product applied | $Q_{prod}$ | $Kg/m^3$ | $2.5x10^{-6}$ | $2.5x10^{-6}$ | S |
| **Emission to the air during application step (air-space)** | **$E_{application,air}$** | **kg/d** | **$9.6 \times 10^{-8}$** | **$5.4 \times 10^{-7}$** | **O** |
| **Emission to the applicator during application step (air-space)** | **$E_{application,applicator}$** | **kg/d** | **$1.15 \times 10^{-7}$** | **$6.5 \times 10^{-7}$** | **O** |

| | | | | | |
|---|---|---|---|---|---|
| **Emission to floor during application step (air-space)** | **$E_{application,floor}$** | **kg/d** | **$4.6 \times 10^{-6}$** | **$2.6 \times 10^{-5}$** | **O** |
| **PREPARATION AND APPLICATION** | | | | | |
| Emission to waste water from applicator (air-space) | $E_{applicator,ww}$ | kg/d | $1.35 \times 10^{-7}$ | $9.8 \times 10^{-7}$ | O |
| Cleaning efficiency for floor and treated surfaces | $F_{CE}$ | - | 1 | 1 | D |
| Emission to waste water from floor and treated surfaces (air-space) | $E_{treated,ww}$ | kg/d | $4.6 \times 10^{-6}$ | $2.6 \times 10^{-5}$ | O |
| **Local emission to STP/building (air space)** | **$Elocal_{ww}$** | **kg/d** | **$4.7 \times 10^{-6}$** | **$2.7 \times 10^{-5}$** | **O** |
| Simultaneity factor (1 time per year) | $F_{simultaneity}$ | - | 0.00204 | 0.00204 | D |
| **Total local emissions to STP (air-space)** | **$Elocal_{waste\ water,\ total}$** | **[kg/d]** | **$5.5 \times 10^{-5}$** | | |

[1] O/S/D: Output/Set/Default value
[2] Worst cases, hand-held trigger spray (air spray treatment)
[3]considering "Surface treatment of a with trigger spray" scenario
* considering a density of 1.003 g/mL at 20°C

## Fate and distribution in the environment

### Soil $DT_{50}$ values for Deltamethrin

| | **$DT_{50}$ at 12°C (days)** |
|---|---|
| Geometric mean (n=4) | 48.2 |

| | |
|---|---|
| Molecular weight | 505.2 |
| Solubility in water | 0.005 mg/L |
| Partition coefficient (log $K_{ow}$) | 4.6 |
| Vapour pressure | $1.24 \times 10^{-8}$ Pa(25°C) |
| Henry's law constant (H) | $1.25 \times 10^{-3}$ Pa $m^3$/mole (25°C) |
| Koc | 408250 mL/g |
| DT50soil | 48.2 days (geometric mean n=4) |
| DT50 w/s | 267 days (max. n=2) |

## PEC calculations

In the following, Predicted Environmental Concentrations for the active substance DELTAMETHRIN are calculated for the influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$ = $PEC_{STP}$) of a sewage treatment plant and for the environmental compartments surface water

($PEC_{surface\ water}$) and sediment ($PEC_{sediment}$). In addition to that the concentrations in STP sludge ($C_{sludge}$) and the Predicted Environmental Concentrations for the active substance in soil after one year and ten years of sludge application ($PEC_{soil}$) are calculated. Furthermore the Predicted Environmental Concentration (PEC) for oral uptake of contaminated food (secondary poisoning of top predators via the aquatic and terrestrial food chain) is calculated in section.
Local emission rates to waste water ($Elocal_{water}$) for total surface application, air-space were calculated in section 0 above. The public sewage treatment plant effluent discharge rate ($EFFLUENT_{stp}$) based on an averaged wastewater flow of 200 L per capita per day for a population of 10 000 inhabitants is 2 000 000 L/d ($EFFLUENT_{stp}$) corresponding to the guidance document (TGD, Part II, Chapter 3, section 2.3.7.1, Table 9). For the risk assessment a population of 10 000 inhabitants per public STP is taken as a typical example for rural populations where sewage water treatment plants are located.
The influent concentration in a sewage treatment plant is calculated with equation 32 of TGD (Part II, Chapter 3, p.62):
$Clocal_{inf} = Elocal_{water} \times 10^6 / EFFLUENT_{STP}$

**Table 2:** Calculation of the STP influent concentrations

| Parameter | Symbol | Value |
|---|---|---|
| Local emission rate to waste water [kg/d] | $Elocal_{water}$ | **$5.5x10^{-5}$** |
| Sewage treatment plant effluent discharge rate [L/d] | $EFFLUENT_{STP}$ | 2 000 000 |
| **Influent concentration in untreated waste water [mg/L]** | **$Clocal_{inf}$** | **$2.75x10^{-5}$** |

**Table 3: Distribution of deltamethrin in the STP, as calculated by SimpleTreat 3.1**

| | |
|---|---|
| to air (%) | 0.00 |
| to water (%) | 9.6 |
| via sludge (%) | 90.4 |
| Degraded (%) | 0.00 |
| Total (%) | 100.00 |

With $Clocal_{inf}$, we are able to calculate the STP effluent concentrations ($Clocal_{eff}$). To calculate this concentration, the fraction of the emission to wastewater directed to effluent ($Fstp_{water}$) was estimated at **9.6 %** with Simple Treat 3.1. Assuming no biodegradability. No active substance is expected to be directed to air ($Fstp_{air}$) while **90.4** % would be directed to the sludge phase (Sum of emissions to primary and secondary sludge, $Fstp_{sludge}$).
The parameter $Clocal_{eff}$ can also be regarded as the $PEC_{STP}$ of Deltemethrin (TGD for risk assessment, equation n° 38), which represents the worst-case concentration the micro-

organisms in the sewage treatment plant are exposed to. The $Clocal_{eff}$ is calculated in Table 3.3-9 with the following equation n° 33:
$PEC_{STP} = Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$

**Table 4:** Calculation of the STP effluent concentration ($Clocal_{eff}$)

| Parameter | Symbol | Value |
|---|---|---|
| Influent concentration in untreated waste water [mg/L] | **$Clocal_{inf}$** | **$2.75x10^{-5}$** |
| Fraction of emission directed to water by STP [-] | $Fstp_{water}$ | 0.096 |
| **Effluent concentration in untreated waste water [mg/L]** | **Clocaleff = $PEC_{STP}$** | **$2.6x10^{-6}$** |

1.3.1 PEC for Surface Water (PECsurface water)

The indoor use of Aqua K-othrine does not allow direct exposure to surface waters, only indirect exposure via an effluent of the sewage treatment plant. In the calculations presented below, complete mixing of the effluent in surface water is assumed and volatilisation, degradation and sedimentation are ignored beCAuse of the short distance between the point of effluent discharge and the exposure location.
The solid-water partition coefficient in suspended matter ($Kp_{susp}$) can be calculated from the Koc value and the fraction of organic carbon in the compartment ($Foc_{susp}$), according to equation 23 of TGD Part II, Chapter 3, p. 47. The fraction of organic carbon in suspended soils is set as default value at 0.1 kg/kg following the Table 5 of the TGD for Risk Assessment.
Calculation of partition coefficient solid-water in suspended matter

**Table 5. Partition coefficient solid-water in suspended matter calculation**

| Parameter | Symbol | | Value |
|---|---|---|---|
| Weight fraction organic carbon in suspended soils [$kg_{organic\ carbon}/kg_{solid}$] | $Foc_{susp}$ | | 0.1 |
| Partition coefficient organic carbon-water [L/kg] | $K_{oc}$ | Deltamethrin | 408250 |
| | $K_{oc}$ | $Br_2CA$ | 25.6 |
| Partition coefficient solid-water in suspended matter [L/kg] | **$Kp_{susp}$ = $Foc_{susp}$ × $K_{oc}$** | Deltamethrin | **40825** |
| | | $Br_2CA$ | **2.56** |

The resulting $Kp_{susp}$ of 40825 L/kg is used to calculate the local concentration in surface water ($Clocal_{water}$) with the equation n° 45 of TGD (TGD for Risk Assessment, Part II, Chapter 3, p.76):
$PEClocal_{water} = Clocal_{water} = Clocal_{eff} / (1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION$
Where $SUSP_{water}$ and DILUTION are default values, according to the TGD for Risk Assessment (Part II, Chapter 3, p.43).
$Clocal_{water}$ can be regarded as the $PEClocal_{water}$ (Table 1.1.2-2).

**Table 6. Calculation of $Clocal_{water}$ concentration for Deltamethrin**

| Parameter | Symbol | Value |
|---|---|---|
| Concentration of Deltamethrin in the STP influent [mg/L] | **$Clocal_{eff}$** | **$2.6x10^{-6}$** |
| Solids-water partitioning coefficient of suspended matter [L/kg] | $Kp_{susp}$ | 40825 |
| Concentration of suspended matter in the river [mg/L] | $SUSP_{water}$ | 15 |
| Dilution factor [-] | DILUTION | 10 |
| **Local concentration of Deltamethrin in surface water during emission episode [mg/L]** | **$Clocal_{water}$ = PEC surface water** | **1.6E-7** |

Furthermore, Deltamethrin is degraded to its major metabolite $Br_2CA$. No data are available for the formation of $Br_2CA$ in the STP. In addition, it is difficult to predict the actual quantity of metabolite $Br_2CA$ present in wastewater after areas treated with Aqua K-Othrine
have been cleaned, since the parent will potentially have been subject to transformation either
in situ or in the STP itself under very different environmental conditions. Therefore, in order to estimate potential environmental exposure to the major metabolite $Br_2CA$ associated with losses to the wastewater compartment during the service life of Aqua K-Othrine it has been assumed that the metabolite is formed at the point of emission (from Clocaleff of Deltamethrin) at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds) and diluted by the default factor of 10 as proposed in Deltamethrin's CAR (June 2011). The parent compound has a molecular mass of 505.2 g/mol, whilst the metabolite $Br_2CA$ has a molecular mass of 298.0 $g.mol^{-1}$.

Therefore, the estimate of $PEC_{STP}$ presented above has been adjusted by a factor of 0.59 (i.e. 298.0 / 505.2) **$PEC_{STP}$ $Br_2CA$**=2.64x$10^{-6}$x 0.59/10 = **1.56E-7 mg/L**.

**Table 7. Calculation of $Clocal_{water}$ concentration for $Br_2CA$**

| Parameter | Symbol | Value |
|---|---|---|
| Concentration of $Br_2CA$ in the STP influent [mg/L] | **$Clocal_{eff}$** | 1.56E-7 |
| Solids-water partitioning coefficient of suspended matter [L/kg] | $Kp_{susp}$ | 2.56 |
| Concentration of suspended matter in the river [mg/L] | $SUSP_{water}$ | 15 |
| Dilution factor [-] | DILUTION | 10 |
| **Local concentration of Deltamethrin in surface water during emission episode [mg/L]** | **$Clocal_{water}$ = PEC surface water** | **1.3E-8** |

### *1.3.2 PEC for Sediment*

To assess the Predicted Environmental Concentration in sediment ($PEClocal_{sed}$), wet bulk density of suspended matter ($RHO_{susp}$) and the suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) are calculated below.
The wet bulk density of suspended matter ($RHO_{susp}$) is calculated in Table 3.3-12 according to TGD for Risk Assessment (Part II, Chapter 3, equation 18, p. 43). $Fsolid_{susp}$ (0.1 $m^3/m^3$), $RHO_{solid}$ (2500 $kg/m^3$), $Fwater_{susp}$ (0.9 $m^3/m^3$) and $RHO_{water}$ (1000 $kg/m^3$) are default values of TGD (Part II, Chapter 3, Table 5, p.43).
$RHO_{susp}$ = $Fsolid_{susp}$ × $RHO_{sol\ d}$ + $Fwater_{susp}$ × $RHO_{water}$ = 1150 $kg/m^3$

**Table 8.** Calculation of $RHO_{susp}$

| Parameter | Symbol | Value |
|---|---|---|
| Fraction solids in suspended matter [$m^3/m^3$] | $Fsolid_{susp}$ | 0.1 |
| Bulk density of the solid phase [$kg/m^3$] | $RHO_{solid}$ | 2500 |

| | | |
|---|---|---|
| Fraction water in suspended matter [kg/m³] | $Fwater_{susp}$ | 0.9 |
| Density of the water phase [kg/m³] | $RHO_{water}$ | 1000 |
| Bulk density of wet suspended matter [kg/m³] | $RHO_{susp}$ | 1150 |

As a result, a wet bulk density of suspended matter ($RHO_{susp}$) of 1150 kg/m³ was calculated.
The suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) is calculated following equation 24 of TGD for Risk Assessment (Part II, Chapter 3, p. 47). The concentration in freshly deposited sediment is taken as the PEC for sediment, therefore, the properties of suspended matter are used. According to the TGD for Risk Assessment (Part II, Chapter 3, Table 5, p.43), default values of 0.9 $m^3/m^3$ for $Fwater_{susp}$, 0.1 $m^3/m^3$ for $Fsolid_{susp}$ and 2500 $kg/m^3$ for $RHO_{solid}$ are used for the calculation in Table 1.1.2-2 and $Kp_{susp}$ has been calculated in Table 1.1.2.2-1.

**Table 9.** Calculation of $K_{susp\text{-}water}$

| Parameter | Symbol | | Value |
|---|---|---|---|
| Fraction water in suspended matter [m³/m³] | $Fwater_{susp}$ | | 0.9 |
| Fraction solids in suspended matter [m³/m³] | $Fsolid_{susp}$ | | 0.1 |
| Partition coefficient solid-water in suspended matter [L/kg] | $Kp_{susp}$ | Deltamethrin | 40825 |
| | | $Br_2CA$ | 2.56 |
| Density of the solid phase [kg/m³] | $RHO_{solid}$ | | 2500 |
| Suspended matter-water partitioning coefficient [m³/m³] | $\mathbf{K_{susp\text{-}water} = Fwater_{susp} + Fsolid_{susp} \times Kp_{susp}/1000 \times RHO_{solid}}$ | Deltamethrin | **10207.2** |
| | | $Br_2CA$ | **1.54** |

As a result, a suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) of 10207.2 m³/m³ was calculated. Therefore, the PEClocal for sediment is calculated (Table 1.1.2-3) with the aid results obtained above and with the equation 50 of the TGD for Risk Assessment (Part II, Chapter 3, p.78):
$PEClocal_{sed} = (K_{susp\text{-}water} / RHO_{susp}) \times PEClocal_{water} \times 1000$

**Table 10.** Calculation of PEClocalsed for Deltamethrin

| Parameter | Symbol | Value |
|---|---|---|
| Concentration in surface water during emission episode (mg/L) | $PEClocal_{water}$ | **1.6E-7** |

| | | |
|---|---|---|
| Suspended matter-water partitioning coefficient ($m^3/m^3$) | $K_{susp\text{-}water}$ | 10207.2 |
| Bulk density of suspended matter ($kg/m^3$) | $RHO_{susp}$ | 1150 |
| **Predicted Environmental Concentration in sediment (mg/kg)** | **$PECloca l_{sed}$** | **$1.4x10^{-3}$** |

Using the same approach PECsed for the major metabolite Br2CA has been calculated taking into consideration the PECsw as calculated above. In the calculation a Koc value of 25.61 L/kg has been considered for $Br_2CA$ (arithmetic mean).

**Table 11.** Calculation of PEClocalsed for $Br_2CA$

| Parameter | Symbol | Value |
|---|---|---|
| Concentration in surface water during emission episode (mg/L) | $PECloca l_{water}$ | **1.3E-8** |
| Suspended matter-water partitioning coefficient ($m^3/m^3$) | $K_{susp\text{-}water}$ | 1.54 |
| Bulk density of suspended matter ($kg/m^3$) | $RHO_{susp}$ | 1150 |
| **Predicted Environmental Concentration in sediment (mg/kg)** | **$PECloca l_{sed}$** | **$1.7x10^{-8}$** |

### 1.3.3 PEC soil

Concentration of Deltamethrin in the STP sludge and its concentration in soil during the first year and after ten years of sludge application were calculated for the assessment of the soil compartment. The rate of sludge application is calculated without considering anaerobic degradation in the STP. According to the TGD for Risk Assessment (Part II, Chapter 3, Table 9), default values of 0.45 $kg/m^3$ for $SUSPCONC_{inf}$, 0.011 kg/d for $SURPLUS_{sludge}$ and 10000 for $CAPACITY_{stp}$ are used for the calculation (Table 1.1.2.3-1).

**Table 12.** Calculation of the rate of sewage sludge production in the STP

| Parameter | Symbol | Value |
|---|---|---|
| Concentration of suspended matter in STP influent [kg/m³] | $SUSPCONC_{inf}$ | 0.45 |
| Effluent discharge rate of STP [m³/d] | $EFFLUENT_{stp}$ | 2000 |
| Surplus sludge per inhabitant equivalent [kg/d × eq] | $SURPLUS_{sludge}$ | 0.011 |
| Capacity of the STP [eq] | $CAPACITY_{stp}$ | 10 000 |
| Rate of sewage sludge production [kg/d] | **SLUDGERATE** | **710** |

$SLUDGERATE = 2/3 \times SUSPCONC_{inf} \times EFFLUENT_{stp} + SURPLUS_{sludge} \times CAPACITY_{stp}$ (equation 37)
For calculating the concentration in dry sewage sludge ($C_{sludge}$), the fraction of the emission directed to sludge by STP ($Fstp_{sludge}$) is set to 0.284 (28.4 %), according to the SimpleTreat 4.0.
$Csludge = Fstp_{sludge} \times Elocal_{water} \times 10^6$ / SLUDGERATE (equation 36)
The resulting sludgerate amounts to 710 kg/d and is used for the calculation in Table 1.1.2.3-2 below.

**Table 13.** Calculation of the STP sludge concentration

| Parameter | Symbol | Value |
|---|---|---|
| Local emission rate to waste water during episode [kg/d] | $Elocal_{water}$ | **$5.5x10^{-5}$** |
| Fraction of emission directed to sludge by STP [-] | $Fstp_{sludge}$ | 0.904 |
| Rate of sewage sludge production [kg/d] | SLUDGERATE | 710 |
| **Concentration in dry sewage sludge [mg/kg]** | **$C_{sludge}$** | 0.07 |

The concentration in soil just after the first sludge application and the fraction accumulation in one year are calculated, Table 1.1.1.2.3-4 and Table 1.1.1.2.3-7, respectively. The initial soil concentration after ten applications of sludge is also assessed (Table 1.1.1.2.3.8).
According to TGD for Risk Assessment (Part II, Chapter 3, Table 11), three default values of $APPL_{sludge}$ and for $DEPTH_{soil}$ are used for the calculation in Table 3.3-17. A bulk density of

soil ($RHO_{soil}$) of 1700 kg/m³ is taken for the calculation (TGD for Risk Assessment, Part II, Chapter 3, Equation 18).
$PEC_{soil}$ = Csludge soil (0) = $C_{sludge} \times APPL_{sludge} / DEPTH_{soil} \times RHO_{soil}$ (equation 60)

| Soil | Depth of soil (m) | Averaging time (days) | $APPL_{sludge}$ ($kg_{dwt} \times m^2 \times yr^{-1}$) |
|---|---|---|---|
| Local soil | 0.20 | 30 | 0.50 |
| Agricultural soil | 0.20 | 180 | 0.50 |
| Grassland soil | 0.10 | 180 | 0.10 |

Calculations of the concentration in soil due to sludge in first year:
$C_{sludge\ soil}(0)$ (terrestrial ecosystem)= $1.03 \times 10^{-4}$ mg/kg
$C_{sludge\ soil}(0)$ (agricultural soil)= $1.03 \times 10^{-4}$mg/kg
$C_{sludge\ soil}(0)$ (grassland soil)= $4.1 \times 10^{-5}$ mg/kg
These values can also be regarded as the $PEC_{soil}$ values of Deltamethrin which represent the concentration soil organisms are exposed to just after the first year of sludge application. The fraction of the substance that remains in the topsoil layer (20 cm) at the end of a year is given by Table 1.1.1.2.3-7. For the calculation of the k-rate (taking biodegradation in soil into account), a geometric mean $DT_{50}$ value in soil of 48.2 days (at $12^0$C) is considered.
Equation 56: $\mathbf{k = k_{volat} + k_{leach} + k_{bio\ soil} = K_{biosoil} = 0.0144}$
$\mathbf{k_{volat}}$ = $1.11 \times 10^{-8}$ (eq. 57)
$K_{air\text{-}water}$ = $5.28 \times 10^{-7}$ (eq. 22)

**Table 14.** Air-water pertitioning coefficient

| Parameter | Symbol | Value |
|---|---|---|
| Henry's law constant [Pa × m³/mol] | HENRY | $1.252 \times 10^{-3}$ |
| Gas constant [Pa × m³/mol × k] | R | 8.314 |
| Temperature at the air water interface [K] | TEMP | 285 |
| **Air-water partitioning coefficient [-]** | **$K_{air\text{-}water}$ = HENRY/(R × TEMP)** | **$5.28 \times 10^{-7}$** |

$K_{soil\text{-}water}$ = 12247.7 (eq. 24) ($K_{psoil}$=8165)

**Table 15.** Soil-water partitioning coefficient calculation

| Parameter | Symbol | Value |
|---|---|---|
| Weight fraction organic carbon in soil [kg/kg] | $Foc_{soil}$ | 0.02 |
| Partition coefficient organic carbon-water [L/kg] | Koc | 408250 |
| **Partition coefficient solid-water in soil [L/kg]** | **$Kp_{soil} = Foc_{soil} \times Koc$ (equation 23)** | **8165** |
| Fraction air in soil [m³/m³] | $Fair_{soil}$ | 0.2 |
| Air-water partitioning coefficient [-] | $K_{air\text{-}water}$ | $5.28 \times 10^{-7}$ |
| Fraction water in soil [m³/m³] | $Fwater_{soil}$ | 0.2 |

| | | |
|---|---|---|
| Fraction solids in soil [m³/m³] | $Fsolid_{soil}$ | 0.6 |
| Density of the solid phase [kg/m³] | $RHO_{solid}$ | 2500 |
| Soil-water partitioning coefficient [m³/m³] | $\mathbf{K_{soil\text{-}water} = Fair_{soil} \times K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} \times Kp_{soil} / 1000 \times RHO_{solid}}$ | **12247.7** |

$\mathbf{K_{leach}}$ = 1.96 x $10^{-7}$ (eq.58)
$\mathbf{K_{biosoil}}$= 0.0144 = ln 2/$DT_{50\ biosoil}$ (eq.29), where $DT_{50\ bio\ soil}$ is set to 48.2 days.

**Table 16.** Calculation of the fraction accumulation in one year (equation 61)

| Parameter | Symbol | Value |
|---|---|---|
| First order rate constant for removal from top soil [$d^{-1}$] | k | 0.0144 |
| Fraction accumulation in one year [-] | Facc = $e^{-365\ k}$ | 5.2E-3 |

The results obtained in Table 3.3-17 and Table 3.3-18 are used for the calculations in Table 3.3-19 to ascertain the concentrations after ten years of sludge application (immediately after the tenth application) with the following equation (equation 62):
$Csludge_{soil\ 10}$ (0) = $Csludge_{soil}$ (0) × [1+$\sum^{9}{}_{n=1}$ $Facc^{n}$]

**Table 17.** Calculation of initial concentration after ten applications of sludge

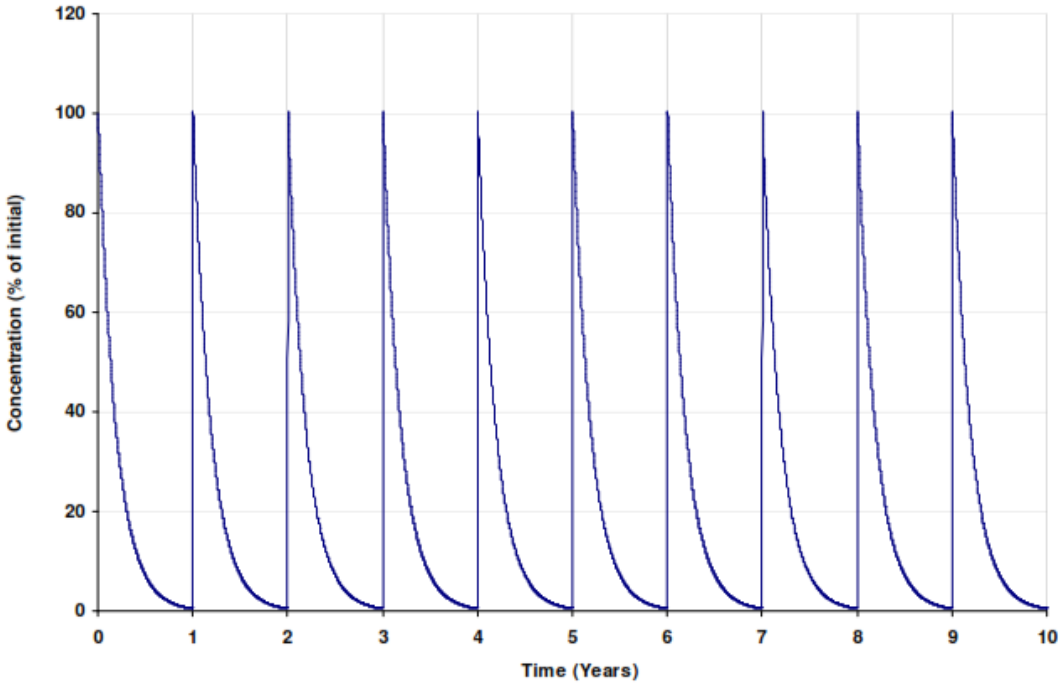
| Parameter | Symbol | | Value |
|---|---|---|---|
| **Concentration in soil due to sludge after ten applications (mg/kg)** | **$Csludge_{soil\ 10}$ (0) = $PEC_{soil\ 10}$** | Local and Agricultural soil | **$1.03x10^{-4}$** |
| | | Grassland | **$4.1x10^{-5}$** |

The parameter $Csludge_{soil\ 10}$ (0) (= $C_{soil\ 10}$ (0)), deposition via air can be excluded) can also be regarded as the $PEC_{soil\ 10}$ of Deltamethrin which represents the concentration soil organisms are exposed to after ten applications of sludge (immediately after the tenth application). A PEC time-weight average soil ($PEC_{twa\ soil}$) was also calculated after the tenth application of sludge over 30 and 180 days. Results are summarized in Table 1.1.2.3-9.
$PEC_{soil}$ (TWA 30 d) = ($C_{soil\ sludge,10years}$ (0) * (1 - $e^{-kt}$)) / (k * t)
$PEC_{soil}$ (TWA 180 d) = ($C_{soil\ sludge,10years}$ (0) * (1 - $e^{-kt}$)) / (k * t)
Where:
t = 30 d, 180 d
k = 0.0144 $d^{-1}$

**$C_{sludgesoil}$ (30-d TWA terrestrial ecosystem) = $8.4x10^{-4}$ mg/kg**
**$C_{sludgesoil}$ (180-d TWA agricultural ecosystem) = 1.5 x $10^{-5}$ mg/kg**
**$C_{sludgesoil}$ (180-d TWA grassland soil) = $3.7x10^{-5}$ mg/kg**

In Deltamethrin's Draft final CAR (eCA Sweden, September, 2010) calculations for dissipation of residues applied in successive applications were also carried out, assuming a one-year application interval in each case. The calculations were carried out for daily time-steps. The total concentration present in soil at any one time as calculated as the sum of the residue in soil remaining from each of the annual sludge application events. The

resulting pattern of deltamethrin dissipation in soil over a ten year period is summarised below:




From this figure it can be seen that Deltamethrin has a very low carry-over potential.
Furthermore, it is foreseen that the degradation of Deltamethrin will lead to $Br_2CA$ formation which is regarded as a major metabolite. However, it is difficult to predict the actual concentration of $Br_2CA$ in soil after the sludge application since parent compound will likely be subject to transformation either in soil or in the sludge itself depending on the different environmental conditions. In order to overlap this problem, it is assumed that the metabolite is formed in the sludge at a quantity equivalent of 100% of the parent (multiplied to a molar weight fraction of 0.59). This is a worst-case assumption for the estimation of the exposure to the metabolite $Br_2CA$.
$C_{sludge\ soil}(0)$ (terrestrial ecosystem)= $6.1x10^{-5}$ mg/kg
$C_{sludge\ soil}(0)$ (agricultural soil)= $6.1x10^{-5}$ mg/kg
$C_{sludge\ soil}(0)$ (grassland soil)= $2.4x10^{-5}$mg/kg
The persistency potential between successive sludge applications is not necessary to be calculated, since it is quite clear that $Br_2CA$ is far less persistent than the parent. The time-weighted average concentration in soil regarding $Br_2CA$ calculated as above for the parent. In the case of terrestrial ecosystem 30 days have been considered, whilst for agricultural and grassland soils the time is 180 days. These calculations have been carried out using the geometric mean $DT_{50}$ for the metabolite $Br_2CA$ of 5.6 days (normalised to $12^0C$ and pF2). Taking into consideration that $Br_2CA$ is formed at a maximum of 23% from the parent after 14 days the considered assumptions are considered that consist a worst-case scenario regarding $Br_2CA$.
Based on these assumptions the calculated concentrations are:
**$C_{sludgesoil}$ (30-d TWA terrestrial ecosystem) = $3.7 \times 10^{-6}$ mg/kg**
**$C_{sludgesoil}$ (180-d TWA agricultural ecosystem) = $6.3 \times 10^{-7}$ mg/kg**
**$C_{sludgesoil}$ (180-d TWA grassland soil) = $2.5 \times 10^{-7}$ mg/kg**
The above mentioned concentrations have been calculated following the same approach as for parent compound.

### 1.3.3 PEClocal$_{soil,porewater}$

$PEC_{groundwater}$ can be regarded as the concentration in soil porewater following sludge application. The concentration of Deltamethrin in soil porewater ($PEClocal_{soil,porewater}$) is calculated in Table 1.1.2.4-1, taking the $Csludge_{soil}$ (0) concentrations calculated in the Table 1.1.1.2.3-4, the soil-water partitioning coefficient of 112.55 m³/m³ obtained above and the bulk density of soil of 1700 kg/m³ (TGD, Part II, Chapter 3, equation 18) into account.
$PEClocal_{soil,porewater} = PEClocal_{soil} \times RHO_{soil} / K_{soil\text{-}water} \times 1000$ (equation 67).

**Table 18.** Calculation of the concentration in soil porewater for Deltamethrin

| Parameter | Symbol | Value |
|---|---|---|
| Predicted Environmental Concentration in soil [mg/kg] | **$PEClocal_{soil}$ = $Csludge_{soil}$ (0)** | $1.03x10^{-4}$ |
| Soil-water partitioning coefficient [m³/m³] | $K_{soil\text{-}water}$ | 12247.7 |
| Bulk density of soil [kg/m³] | $RHO_{soil}$ | 1700 |
| **Predicted Environmental Concentration in porewater [mg/L]** | **PEC local $_{soil,porewater}$** | 1.43E-8 |

No unacceptable risk is expected for groundwater from the exposure of Deltamethrin since it is well below the drinking water trigger value of 0.1 µg/L.
In order to assess the leaching potential of the major metabolite **$Br_2CA$**, pore water calculations have been calculated as well.

| Parameter (unit) | Value | Source |
|---|---|---|
| Vapour pressure (Pa) | $8.2 \times 10^{-4}$ | Input |
| Solubility (mgL) | 60.5 | Input |
| Molecular weight (g/mol) | 298 | Input |
| Henry's law constant ($Pa.m^3/mol$) | $40.4 \times 10^{-3}$ | Calculated in accordance with TGD 2003. |

The rest of the calculation was carried out according to the approach presented for Deltamethrin above.

$K_{air\text{-}water} = 1.71 \times 10^{-5}$
$K_{psoil} = 0.512$ L/kg
$K_{soil\text{-}water} = 0.97$

Based on the aforementioned inputs and assumptions, the calculated $PECloca l_{soil,\ porew}$ are presented below.
$PECloca l_{grw}$ = $PECloca l_{soil,porew}$ (agricultural soil) = (6.1 x $10^{-5}$x 1700)/(0.97 x 1000) = **$6.5x10^{-6}$mg/L**
$PECloca l_{grw}$ = $PECloca l_{soil,porew}$ (grassland) = (2.4 x $10^{-5}$ x 1700)/(0.97 x 1000) = **4.2 x $10^{-5}$ mg/L**
No unacceptable risk regarding groundwater is identified, following application of Aqua K-othrine.

### 1.3.5 PEC in atmosphere compartment ($PEC_{air}$)

Based on the vapour pressure (1.24 x $10^{-8}$ Pa at 25 °C), volatilisation of deltamethrin is negligible. The calculation of $PECA_{ir}$ is therefore of no relevance.

## 2. Outdoor use (ground application with thermal or cold fogging equipment)

Deltamethrin EW 20 is intended to be applied around buildings in vector control situation. Application can be performed using two main application techniques, thermal or cold fogging. For thermal fogging equipment both standard and ULV equipment can be used. Dilution rates vary greatly depending on the selected equipment. Ultra-low volume equipment will require a low dilution (e.g. 1:9 or 1:19) or no dilution at all. Other space spray equipment will dispense larger volumes of spray solutions and therefore require a higher dilution of (e.g. 1:99 or 1:199).
The application rate is 1g of deltamethrin/ha per treatment, considering 1application per year.
In the scenario for the outdoor control, entire wall application for flying insects, up to 2.5 m has been considered ($AREA_{wall}$ 625 $m^2$).

### 2.1 Emission to air

According to the OECD Series on Emission Scenario Documents No 18 for Insecticides, acaricides and products to control other arthropods for household and professional uses (ESD PT18), release to air will not be further taken into account because of instant dilution and turbulence in air.

### 2.2 Emission to soil/rainwater:

**Table 19.** PECs during mixing/loading step

| Variable/parameter (units) | Symbol | | Unit | Value |
|---|---|---|---|---|
| Quantity of product used for one preparation event | $Q_{prod,prep}$ | House | g | 0.001 |
| | | Large building | | 0.005 |
| Fraction of active substance in the commercial product | $F_{AI}$ | | - | 0.02 |
| Number of preparations per day | $N_{prep}$ | | $d^{-1}$ | 1 (for both house and large building) |
| Fraction emitted to soil during preparation step | $F_{prep,soil}$ | | - | $4x10^{-4(a)}$ |

| | | | | |
|---|---|---|---|---|
| Soil volume for the mixing loading step | $V_{prep,soil}$ | | $m^3$ | 0.40 |
| Bulk density of wet soil | *RHO* | | $Kg.m^{-3}$ | 1700 |
| Emission to soil during preparation | $E_{prep,soil}$ | Large building | $Kg.d^{-1}$ | **$4x10^{-11}$** |
| | | House | | **$8x10^{-12}$** |
| Local concentration of active substance in soil during mixing/loading | $C_{prep,soil}$ | Large building | $Kg.kgww^{-1}$ | **$5.88x10^{-14}$** |
| | | House | | **$1.18x10^{-14}$** |
| Local concentration of active substance in soil following mixing/loading step | $PEC_{prep}$ | Large building | mg x $kg_{ww}^{-1}$ | **$5.88 \times 10^{-8}$** |
| | | House | | **$1.18 \times 10^{-8}$** |

[a] Considering 5L container

The potential emission to the soil/rainwater and the local concentration in soil during the mixing/loading step is calculated using equations 39 and 40 (ESD, PT 18).
$E_{prep,soil} = Q_{prod,prep} \times FAI \times N_{prep} \times F_{prep,soil} \times 10^{-3}$ (eq. 39)
$C_{prep,soil} = E_{prep,soil} / (V_{prep,soil} \times RHO_{soil})$ (eq. 40)
In urban areas the emissions from the preparation step ($E_{prepsoil}$ ) should be assumed to be washed up by rainwater and therefore added to the emissions from the application step to give a total "per application" loading to waste water. Hence, the ECA has calculated also the local emissions to ground from the preparation step, and finally added these to the emissions from the application step and the emission from the wash-off.

**2.2.1 Environmental exposure during application. Treatment around buildings.**
Local emissions due to the deposition related to the outdoor application of insecticide on the entire wall for **flying insect treatment** are derived from equation 41 (ESD, PT 18):
$E_{spraying,wall,appl,soil} = Q_{prod} \times FAI \times AREA_{wall} \times F_{spray,wall}$

**Table 20.** Local emissions from outdoor spray application due to deposition

| **Variable/parameter (units)** | **Symbol** | | **Unit** | **Value** | |
|---|---|---|---|---|---|
| Quantity of product applied | $Q_{prod}$ | | $kg.m^2$ | $10^{-7}$ | |
| Fraction of active substance in the commercial product | $F_{AI}$ | | - | 0.02 | |
| Area of exterior wall treated per day | $AREA_{wall}$ | House | $m^2.d^{-1}$ | 125 | |
| | | Large building | | 625 | |
| Fraction emitted to soil during preparation step | $F_{spray,wall}$ | | - | 0.3 | |

| | | | | | |
|---|---|---|---|---|---|
| Local emission from outdoor spray application on wall due to deposition on large building. | $E_{spraying,wall,soil}$ | House | Kg.d$^{-1}$ | **3.75x10$^{-6}$** | eq. 41, ESD PT18 |
| | | Large building | | **1.875x10$^{-5}$** | |

Local emissions related to the washing by rainwater of the entire wall are derived from equation 42 (ESD, PT18)

$E_{spray,wall,wash\text{-}off} = Q_{prod} \times FAI \times AREA_{wall} \times F_{spray,wash\text{-}off}$

In urban areas, releases to hard surfaces are directed to the rainwater/sewage system. Rainfall will then wash-off both quantities emitted to soil during application and from wall from wash-off. Emissions are calculated by equation 43 (ESD, PT18).

$E_{spray,flying} = E_{spraying,wall,soil} + E_{spray,wall,wash\ off\ soil}$

**Table 21.** Local emissions from outdoor spray application due to wall application and wash-off

| **Variable/parameter (units)** | **Symbol** | | **Unit** | **Value** | |
|---|---|---|---|---|---|
| Quantity of product applied | $Q_{prod}$ | | kg.m$^2$ | 10$^{-7}$ | |
| Fraction of active substance in the commercial product | $F_{AI}$ | | - | 0.02 | |
| Area of exterior wall treated per day. | $AREA_{wall}$ | House | m$^2$.d$^{-1}$ | 125 | |
| | | Large building | | 625 | |
| Fraction emitted to soil due to wash-off by rainfall | $F_{spray,wash\text{-}off}$ | | - | 0.5 | |
| Local emissions from outdoor spray application on wall due to wash-off by rainfall on. | $E_{spray,wall,wash\text{-}off}$ | House | Kg.d$^{-1}$ | **6.25 x10$^{-6}$** | eq. 42, ESD PT18 |
| | | Large building | | **3.125x10$^{-5}$** | |
| Local emissions from outdoor spray application on wall due to wall application and wash-off by rainfall on. | $E_{spray,flying}$ | House | Kg.d$^{-1}$ | **1x10$^{-5}$** | eq. 43, ESD PT18 |
| | | Large building | | **5x10$^{-5}$** | |

Total daily emission ($E_{total,spray,flying}$) of Deltamethrin EW 20 to local STP from large building has been calculated adding the emissions from preparation step, deposition and run-off during application step.
House:
$E_{total,spray,flying} = E_{prep,soil} + E_{spraying,wall,soil} + E_{spray,wall,wash-off} = 8x10^{-12} + 3.75x10^{-6} + 6.25x10^{-6}$ = **$1x10^{-5}$ kg/d**
Large building:
$E_{total,spray,flying} = E_{prep,soil} + E_{spraying,wall,soil} + E_{spray,wall,wash-off} = 4x10^{-11} + 1.875x10^{-5} + 3.125x10^{-5}$ = **$5x10^{-5}$ kg/d.** These values will be further considered in the environmental assessment.

The local concentration of the active substance in soil in the **countryside** due to wall application and to wash-off by rainfall can be calculated using equations 44, 45 and 46 (ESD, PT 18).
$C_{spray,wall,soil} = E_{spraying,wall,soil} / (V_{spray,soil} \times RHO_{soil})$ (eq.44)

$C_{spray,wall,wash-off,soil} = E_{spraying,wall,wash-off,soil} / (V_{spray,soil} \times RHO_{soil})$ (eq.45)

$C_{spray,flying,soil} = (E_{spraying,wall,soil} + E_{spraying,wall,wash-off,soil}) / (V_{spray,soil} \times RHO_{soil})$ (eq.46)

**Table 22.** Local concentration of active substance in soil following application

| **Variable/parameter (units)** | **Symbol** | | **Unit** | **Value** | |
|---|---|---|---|---|---|
| Local emissions from outdoor spray application on wall due to deposition. | $E_{spraying,wall,soil}$ | House | $Kg.d^{-1}$ | **$3.75x10^{-6}$** | |
| | | Large building. | | **$1.875x10^{-5}$** | |
| Local emissions from outdoor spray application on wall due to wash-off by rainfall. | $E_{spray,wall,wash-off,soil}$ | House | $Kg.d^{-1}$ | **$6.25x10^{-6}$** | |
| | | Large building. | | **$3.125x10^{-5}$** | |
| Soil volume around the building. | $V_{spray,soil}$ | | $m^3$ | 13 | |
| | | | | 63 | |
| Bulk density of wet soil | *RHO* | | $Kg.ww.m^{-3}$ | 1700 | |
| ***Output*** | | | | | |
| **Local concentration of active substance in soil adjacent to the building due to wall application against flying insects.** | $C_{sprayingwall,soil}$ | **House** | $Kg.kgww^{-1}$ | **$1.7x10^{-10}$** | eq. 44, ESD PT18 |
| | | **Large building** | | **$1.75x10^{-10}$** | |
| **Local concentration of active substance in soil adjacent to the building due to wash-off by rainfall.** | $C_{spray,wall,wash-off,soil}$ | **House** | $Kg.kgww^{-1}$ | **$2.8\ x10^{-10}$** | eq. 45, ESD PT18 |
| | | **Large building** | | **$2.9x10^{-10}$** | |
| **Local concentration** | $C_{spray,flying,,soil}$ | **House** | $Kg.kgww^{-1}$ | **$4.5x10^{-10}$** | eq. 46, |

| | | | | | |
|---|---|---|---|---|---|
| **of active ingredient in soil adjacent to the building due to washing and wall application for flying insects.** | | **Large building** | | **$4.7x10^{-10}$** | ESD PT18 |
| **Local concentration of active substance in soil following application** | $PEC_{spray,flying,soil}$ | **House** | mg x $kg_{ww}^{-1}$ | **$4.5x10^{-7}$** | |
| | | **Large building** | | **$4.7x10^{-7}$** | |

### 2.2.3 Total emissions in waste water entering STP

The local emissions to STP and the concentrations in the influent of the STP from outdoor treatments are estimated below.

$E_{localwater,outdoor} = E_{spray,flying} \times N_{building} \times F_{simultaneity}$

$Clocal_{inf} = Elocal_{water} \times 10^6/EFFLUENT_{STP}$

**Table 23.** STP influent

| **Variable/parameter (units)** | **Symbol** | | **Unit** | **Value** |
|---|---|---|---|---|
| Local emissions from outdoor spray application on wall due to wall application and wash-off by rainfall. | $E_{spray,flying}$ | House | $Kg.d^{-1}$ | **$1x10^{-5}$** |
| | | Large building | | **$5x10^{-5}$** |
| Capacity of the local STP | $CAPACITY_{STP}$ | | eq | 10000 |
| Number of inhabitants per STP. | $N_{house}$ | | - | 2500 |
| | $N_{building}$ | | - | 300 |
| Simultaneity factor | $F_{sim}$ | | - | 0.0275 |
| ***Output*** | | | | |
| Urban scenario emissions into STP per day from outdoor use. | $E_{localwater,outdoor}$ | | $Kg.d^{-1}$ | **$1.1x10^{-3}$** |
| Concentration in STP influent | Clocal inf | | mg/L | **$5.5x10^{-4}$** |

Following the same approach as for the PEC calculations for indoor use, PECs in all the relevant compartments are presented under the following points. For default input values, specific values for Deltamethrin and its metabolite $Br_2CA$ and for all the relevant used equations please refer to the corresponding section in the exposure assessment regarding indoor use of Aqua K-othrine.

#### 2.2.3.1 $PEC_{STP}$

**Table 24.** Calculation of the STP effluent concentration ($Clocal_{eff}$)

| **Parameter** | **Symbol** | **Value** |
|---|---|---|
| | | |

| | | |
|---|---|---|
| Influent concentration in untreated waste water [mg/L] | **$Clocal_{inf}$** | **$5.5x10^{-4}$** |
| Fraction of emission directed to water by STP [-] | $Fstp_{water}$ | 0.096 |
| **Effluent concentration in untreated waste water [mg/L]** | **Clocaleff = $PEC_{STP}$** | **5.3E-5** |

#### 2.2.3.2 PECsw

**Table 25.** Calculation of $Clocal_{water}$ concentration for Deltamethrin

| Parameter | Symbol | Value |
|---|---|---|
| Concentration of Deltamethrin in the STP influent [mg/L] | **$Clocal_{eff}$** | **5.3E-5** |
| Solids-water partitioning coefficient of suspended matter [L/kg] | $Kp_{susp}$ | 40825 |
| Concentration of suspended matter in the river [mg/L] | $SUSP_{water}$ | 15 |
| Dilution factor [-] | DILUTION | 10 |
| **Local concentration of Deltamethrin in surface water during emission episode [mg/L]** | **$Clocal_{water}$ = $PEC_{surface\ water}$** | **3.3E-6** |

**Table 26.** Calculation of $Clocal_{water}$ concentration for $Br_2CA$

| Parameter | Symbol | Value |
|---|---|---|

| | | |
|---|---|---|
| Concentration of Deltamethrin in the STP influent [mg/L] | **$Clocal_{eff}$** | **5.3E-5** |
| Concentration of $Br_2CA$ in the STP influent [mg/L] | **$Clocal_{eff}$** | **3.1E-6** |
| Solids-water partitioning coefficient of suspended matter [L/kg] | $Kp_{susp}$ | 2.56 |
| Concentration of suspended matter in the river [mg/L] | $SUSP_{water}$ | 15 |
| Dilution factor [-] | DILUTION | 10 |
| **Local concentration of Deltamethrin in surface water during emission episode [mg/L]** | **$Clocal_{water}$ = PEC surface water** | **3.1E-7** |

### 2.2.3.3 PECsed

**Table 27.** Calculation of $PEClocal_{sed}$ for Deltamethrin

| **Parameter** | **Symbol** | **Value** |
|---|---|---|
| Concentration in surface water during emission episode (mg/L) | $PEClocal_{water}$ | **3.3E-6** |
| Suspended matter-water partitioning coefficient ($m^3/m^3$) | $K_{susp\text{-}water}$ | 10207.2 |
| Bulk density of suspended matter ($kg/m^3$) | $RHO_{susp}$ | 1150 |

| | | |
|---|---|---|
| Predicted Environmental Concentration in sediment (mg/kg) | $PECloca l_{sed}$ | 0.03 |

**Table 28.** Calculation of $PECloca l_{sed}$ for $Br_2CA$

| **Parameter** | **Symbol** | **Value** |
|---|---|---|
| Concentration in surface water during emission episode (mg/L) | $PECloca l_{water}$ | **3.1E-7** |
| Suspended matter-water partitioning coefficient ($m^3/m^3$) | $K_{susp-water}$ | 1.54 |
| Bulk density of suspended matter ($kg/m^3$) | $RHO_{susp}$ | 1150 |
| Predicted Environmental Concentration in sediment (mg/kg) | $PECloca l_{sed}$ | 4.2E-7 |

**$C_{sludge}$**
According to SimpleTreat 3.1 a 90.4% of Deltamethrin will be partitioned into sludge. Therefore an estimation of environmental exposure following application of sewage sludge to land should be presented. No atmospheric deposition has been considered, since emissions to air are considered as negligible.
The STP sludge concentration and the concentration in soil just after the first year of sludge application are calculated following using the relevant equations (eq. 36 and 60, TGD, Part II).

Three different PECs for soils are estimated, according to TGD:
- PEC in local soil for comparison against terrestrial ecosystem endpoints,
- PEC in agricultural soil for comparison against crop endpoints for human consumption and
- PEC in grassland soil for comparison against endpoints in grass for cattle.
For this aim different values for mixing depth of soil and dry sludge application rate are used, depending upon the endpoint being considered.

**$C_{sludge}$ and $C_{sludgesoil\ 1\ yr\ (time\ 0)}$ for the general use:**
Total concentration in dry sewage sludge (Csludge) after spraying application of the Deltamethrin EW 20 and concentration in soil due to sludge in first year at t=0 (Csludgesoil 1yr (time 0).

**Table 29.** $C_{sludge}$

| Parameter | Symbol | Value |
|---|---|---|
| Local emission rate to waste water during episode [kg/d] | $Elocal_{water}$ | **$1.1x10^{-3}$** |
| Fraction of emission directed to sludge by STP [-] | $Fstp_{sludge}$ | 0.904 |
| Rate of sewage sludge production [kg/d] | SLUDGERATE | 710 |
| **Concentration in dry sewage sludge [mg/kg]** | **$C_{sludge}$** | 1.4 |

**2.2.3.4 $PEC_{soil}$**

According to TGD for Risk Assessment (Part II, Chapter 3, Table 11), three default values of $APPL_{sludge}$ and for $DEPTH_{soil}$ are used for the calculation. A bulk density of soil ($RHO_{soil}$) of 1700 kg/m³ is taken for the calculation (TGD for Risk Assessment, Part II, Chapter 3, Equation 18).

$PEC_{soil}$ = Csludge soil (0) = $C_{sludge} \times APPL_{sludge} / DEPTH_{soil} \times RHO_{soil}$ (equation 60)

| Soil | Depth of soil (m) | Averaging time (days) | $APPL_{sludge}$ ($kg_{dwt} \times m^2 \times yr^{-1}$) |
|---|---|---|---|
| Local soil | 0.20 | 30 | 0.50 |
| Agricultural soil | 0.20 | 180 | 0.50 |
| Grassland soil | 0.10 | 180 | 0.10 |

Calculations of the concentration in soil due to sludge in first year:

$C_{sludge\ soil}(0)$ (terrestrial ecosystem)= $2 \times 10^{-3}$ mg/kg

$C_{sludge\ soil}(0)$ (agricultural soil)= $2 \times 10^{-3}$ mg/kg

$C_{sludge\ soil}(0)$ (grassland soil)= $8.2 \times 10^{-4}$ mg/kg

**$PEC_{soil}$ after 10 years**

The above presented values can also be regarded as the PECsoil values of the active substance following the application of Deltamethrin EW 20 around buildings after the first year of application.

In the following section, Csludge is calculated after ten years of sludge application.

The k-rate has been calculated to be 0.0144, taking into consideration that Deltamethrin biodegradates with a geometric mean DT50 of 48.2 days at $12^0$C (please refer to the section for indoor application. In addition Facc is calculated to be $5.2x10^{-3}$.

**$Csludge_{soil\ 10}$ (0)** has been calculated according to TGD equation 62:

$Csludge_{soil\ 10}(0) = Csludge_{soil}(0) \times [1+\sum^{9}_{n=1} Facc^n]$

**Table 30.** Calculation of initial concentration after ten applications of sludge

| Parameter | Symbol | | Value |
|---|---|---|---|
| **Concentration in soil due to sludge after ten applications (mg/kg)** | **$Csludge_{soil\ 10}$ (0) = $PEC_{soil\ 10}$** | Local and Agricultural soil | **$2x10^{-3}$** |
| | | Grassland | **$8.2\ x10^{-4}$** |

The parameter $Csludge_{soil\ 10}$ (0) (= $C_{soil\ 10}$ (0)), deposition via air can be excluded) can also be regarded as the $PEC_{soil\ 10}$ of Deltamethrin which represents the concentration soil organisms are exposed to after ten applications of sludge (immediately after the tenth application). A PEC time-weight average soil ($PEC_{twa\ soil}$) was also calculated after the tenth application of sludge over 30 and 180 days.
$PEC_{soil}$ (TWA 30 d) = ($C_{soil\ sludge,10years}$ (0) * (1 - $e^{-kt}$)) / (k * t)
$PEC_{soil}$ (TWA 180 d) = ($C_{soil\ sludge,10years}$ (0) * (1 - $e^{-kt}$)) / (k * t)
Where:
t = 30 d, 180 d
k = 0.0144 $d^{-1}$
**$C_{sludgesoil}$** (30-d TWA terrestrial ecosystem) **= $1.6x10^{-3}$ mg/kg**
**$C_{sludgesoil}$** (180-d TWA agricultural ecosystem) **= $7.1\ x\ 10^{-4}$ mg/kg**
**$C_{sludgesoil}$** (180-d TWA grassland soil) **= $2.9\ x\ 10^{-4}$ mg/kg**

### 2.2.3.6 PECsoil for metabolite $Br_2CA$

The concentrations of the metabolite $Br_2CA$ are calculated following the approach as described in the section for indoor applications.
Deltamethrin's concentrations in sludge ($C_{sludge\ soil}$) are multiplied to 0.59 (100% formation is assumed) and to 0.23 (maximum occurrence) in order to calculate PECs for metabolite $Br_2CA$. Consequentively:
$C_{sludge\ soil}$(0) (terrestrial ecosystem)= 2.7 x $10^{-4}$ mg/kg
$C_{sludge\ soil}$(0) (agricultural soil)= 2.7 x $10^{-4}$ mg/kg
$C_{sludge\ soil}$(0) (grassland soil)= 1.1 x $10^{-4}$ mg/kg
**$C_{sludgesoil}$** (30-d TWA terrestrial ecosystem) **= $7.1x10^{-5}$ mg/kg**
**$C_{sludgesoil}$** (180-d TWA agricultural ecosystem) **= $1.21\ x\ 10^{-5}$ mg/kg**
**$C_{sludgesoil}$** (180-d TWA grassland soil) **= $4.9\ x\ 10^{-6}$ mg/kg**

### 2.2.3.7 $PEClocal_{soil,porewater}$

Following the same approach as presented in the section for indoor applications, $PEClocal_{soil,porewater}$ has been calculated following sludge application. Deltamethrin's concentration in porewater is regarded as PECgroundwater.
Calculations have been performed according to equation:
$PEClocal_{soil,porewater}$ = $PEClocal_{soil}$ × $RHO_{soil}$ / $K_{soil\text{-}water}$ × 1000 (equation 67).

**Table 31.** Calculation of the concentration in soil porewater for Deltamethrin

| Parameter | Symbol | | Value |
|---|---|---|---|
| Predicted Environmental Concentration in soil [mg/kg] | **$Csludge_{soil}$ (0)** | Terrestrial/agricultural | 2 x $10^{-3}$ |
| | | Grassland | 8.2 x $10^{-4}$ |

| | | | |
|---|---|---|---|
| Soil-water partitioning coefficient [m³/m³] | **$K_{soil-water}$** | | 12247.7 |
| Bulk density of soil [kg/m³] | **$RHO_{soil}$** | | 1700 |
| **Predicted Environmental Concentration in porewater [mg/L]** | **PEC local $_{soil,porewater}$** | Terrestrial/agricultural | 2.8 x $10^{-7}$ |
| | | Grassland | 1.14 x $10^{-7}$ |

No unacceptable risk is expected for groundwater from the exposure of Deltamethrin since it is well below the drinking water trigger value of 0.1µg/L.

**$PEClocal_{soil,porewater}$ for metabolite $Br_2CA$**

In order to assess the leaching potential of the major metabolite $Br_2CA$, pore water calculations have been calculated as well.

| Parameter (unit) | Value | Source |
|---|---|---|
| Vapour pressure (Pa) | 8.2 x $10^{-4}$ | Input |
| Solubility (mgL) | 60.5 | Input |
| Molecular weight (g/mol) | 298 | Input |
| Henry's law constant ($Pa.m^3/mol$) | 40.4 x $10^{-3}$ | Calculated in accordance with TGD 2003. |

The rest of the calculation was carried out according to the approach presented for Deltamethrin in the section for indoor application.

$K_{air-water}$ = 1.71 x $10^{-5}$
$K_{psoil}$ = 0.512 L/kg
$K_{soil-water}$ = 0.97
Kbiosoil=0.124 (ln2/5.6)

Based on the aforementioned inputs and assumptions, the calculated $PEClocal_{soil,\ porew}$ are presented below.

$PEClocal_{grw}$ = $PEClocal_{soil,porew}$ (terrestrial soil) = (1.25 x $10^{-5}$ x 1700)/(0.97 x 1000) = **2.2 x $10^{-5}$ mg/L**

$PEClocal_{grw}$ = $PEClocal_{soil,porew}$ (agricultural soil) = (4.9 x $10^{-6}$ x 1700)/(0.97 x 1000) = **8.6 x $10^{-6}$ mg/L**

Higher concentrations predicted for the metabolite compared to those for Deltamethrin, which is expected since $Br_2CA$ has a higher mobility. No unacceptable risk is expected for groundwater for terrestrial soil and grassland.

**$PEC_{soil}$ due to spray drift-untreated area.**

The PECsoil values calculated for the application and wash-off steps in accordance with the ESD No 18 are representative for the 0.5 m wide zone along the treated house. Since the spray is directly oriented to the wall it is expected that the distance travelled by droplets is low (section 4.3.1.3 of the ESD). However, the ESD also recognizes that the potential for recovery/recolonization of non-target populations from the untreated area may need to be

considered. The eCA has therefore tried here to supplement the scenarios provided by the applicant with an exposure assessment for the untreated area.
It should be noted that the ESD proposes that F spray, untreated soil = 0.0042 could be used to calculate emissions during *direct spray application on ground* (section 4.3.1.5). However, Deltamethrin EW 20 is not applied directly to soil. In the absence of any other value for the F spray,untreated soil the value of 0.0042 is used but it may be that this is an overly conservative worst-case emission when used to calculate spray drift from application *to wall*.

The following equations have been used for the calculations:
$E_{spray,wall,spray\ drift} = Q_{prod} * F_{AI} * AREA_{wall} * F_{spray,untreated\ soil}$

$C_{spray\ drift,untreated\ area} = E_{spray,wall,spray\ drift} / V_{spray,untreated\ soil} * RHO_{soil}$

$E_{spray,wall,spray\ drift\ to\ soil} = E_{spray,wall,spray\ drift}$ x $(1\text{-}Interception_{plant})$

**Table 32.** Local concentration of active substance in soil following application

| **Variable/parameter (units)** | **Symbol** | | **Unit** | **Value** | |
|---|---|---|---|---|---|
| Quantity of product applied | $Q_{prod}$ | | $kg.m^2$ | $10^{-7}$ | |
| Fraction of active substance in the commercial product | $F_{AI}$ | | - | 0.02 | |
| Area of exterior wall treated per day | $AREA_{wall}$ | House | $m^2.d^{-1}$ | 125 | |
| | | Large building | | 625 | |
| Fraction emitted due to spray drift. | $F_{spray,untreated\ soil}$ | | - | 0.0042 | Default value |
| Soil volume in untreated zone | $V_{spray,untreated\ soil}$ | | $m^3$ | 5 | Default value |
| Bulk density of wet soil | $RHO_{soil}$ | | $Kg_{ww}$ x $m^{-3}$ | 1700 | Default value |
| Emission from outdoor spray application on wall due to spray drift | $E_{spray,wall,spray\ drift}$ | House | Kg | **5.3E-8** | |
| | | Large building | | **2.6E-7** | |
| Relative crop interception | $Interception_{plant}$ | - | | 0.40 | |
| Emission from outdoor spray application on the wall that reaches the soil | $E_{spray\ wall,drift\ to\ soil,}$ | House | Kg | **3.15E-8** | |
| | | Large building | | **1.6E-7** | |
| Local concentration of a.s. in untreated soil due to spray drift | $C_{spray\ drift,untreated\ area}$ | House | Kg x $kg_{ww}^{-1}$ | **6.2E-12** | |
| | | Large building | | **3.1E-11** | |
| **Local concentration** | $PEC_{soil,untreated}$ | House | mg x $kg_{ww}^{-1}$ | **6.2E-6** | |

| | | | | | |
|---|---|---|---|---|---|
| **of active substance in soil following application** | *area* | *Large building* | | **3.1E-5** | |

**Table 33.** Summary of soil PECs - direct exposure from outdoor use (rural areas) for Deltamethrin

| | | | |
|---|---|---|---|
| $PEC_{soil,prep}$ | Mixing/loading step | House | $5.88 \times 10^{-8}$ |
| | | Large building | $1.18 \times 10^{-8}$ |
| $PEC_{soil,untreated}$ | Due to spray drift | House | 6.20E-06 |
| | | Large building | 3.10E-05 |
| $PEC_{spray,flying,soil}$ | Application | House | 4.50E-07 |
| | | Large building | 4.70E-07 |
| **$PEC_{total}$ (mg/kg)** | Total | House | 6.71E-06 |
| | | Large building | 3.15E-05 |

**Summary of soil PECs - direct exposure from outdoor use (rural areas) for $Br_2CA$.**
$PEC_{soil}$ for Deltamethrin's metabolite $Br_2CA$ is calculated taking into account active substance's concentrations multiplied to a molar weight fraction of 0.59 (please refer to section for indoor applications).

**Table 34.** $PEC_{total}$ (mg/kg)

| | | |
|---|---|---|
| **$PEC_{total}$ (mg/kg)** | House | $4 \times 10^{-6}$ |
| | Large building | $1.9 \times 10^{-5}$ |

**PEC in groundwater for direct exposure from outdoor use in rural areas.**
Although the application of Deltamethrin EW 20 regarding outdoor applications is not carried out near to aquatic environments, nevertheless, a worst-case conservative assessment of the concentration of the active substance in surface water for the potential exposure via soil run-off. A simple Tier 1 assessment of the potential predicted concentration in groundwater (PECgw) was carried out by calculating the pore water concentration of the active substance in soil according to the general TGD (section 2.3.8.6). The safe assumption is that the concentration in groundwater will not exceed the maximum soil pore water concentration.
$PEC_{soil,porewater} = (PEC_{soil} \times RHO_{soil})/(K_{soil\text{-}water} \times 1000)$

**Table 35.** PEC local $_{soil,porewater}$ for Deltamethrin

| | | |
|---|---|---|
| Soil-water | $K_{soil\text{-}water}$ | 12247.7 |

| | | | |
|---|---|---|---|
| partitioning coefficient [m³/m³] | | | |
| Bulk density of soil [kg/m³] | $RHO_{soil}$ | | 1700 |
| **Predicted Environmental Concentration in porewater [mg/L]** | **PEC local soil,porewater** | **House** | 9.3 E-10 |
| | | **Large building** | 4.4E-9 |

The corresponding $PEClocal_{soil,porewater}$ for $Br_2CA$ are calculated as well.

**Table 36.** PEC local $_{soil,porewater}$ for $Br_2CA$.

| | | | |
|---|---|---|---|
| Soil-water partitioning coefficient [m³/m³] | $K_{soil\text{-}water}$ | | 0.97 |
| Bulk density of soil [kg/m³] | $RHO_{soil}$ | | 1700 |
| **Predicted Environmental Concentration in porewater [mg/L]** | **PEC local soil,porewater** | **House** | 7E-6 |
| | | **Large building** | 3.2E-5 |
| **Predicted Environmental Concentration in surface water [mg/L]** | **$PEC_{sw,\ ground\ run\text{-}off}$** | **House** | 7E-7 |
| | | **Large building** | 3.2E-6 |

**PEC in surface water and sediment from ground run-off in rural areas**

The maximum potential concentration in soil pore water was used and a default dilution factor to an adjacent surface water body of 10 applied. The concentration in surface water is given in the table below.

**Table 37.** PEC local $_{sw,\ ground\ run\text{-}off}$ for Deltamethrin

| | | | |
|---|---|---|---|
| **Predicted Environmental Concentration in porewater [mg/L]** | **PEC local soil,porewater** | **House** | 9.3E-10 |
| | | **Large building** | 4.4E-9 |
| **Predicted Environmental** | **$PEC_{sw,\ ground\ run\text{-}off}$** | **House** | 9.3E-11 |

| | | | |
|---|---|---|---|
| **Concentration in surface water [mg/L]** | | **Large building** | 4.4E-10 |

The corresponding $PEC_{sed,ground\ run\text{-}off}$ was calculated using eq. (50) in the TGD:
$PEC_{sed} = (K_{susp\text{-}water} / RHO_{susp}) * PEC_{localwater} * 1000$
Where $K_{susp\text{-}water}$ = 10207.2
$RHO_{susp}$ = 1150 (default). Hence, $PEC_{sed,ground\ run\text{-}off}$ **= 8.25 E-7 mg/kg (house)**

**= 3.9 E-6 mg/kg (large building)**

For $Br_2CA$ $PEC_{sw}$ and $PEC_{sed}$ due to run-off are calculated as:

**Table 38.** PEC local $_{sw,\ ground\ run\text{-}off}$ for $Br_2CA$

| | | | |
|---|---|---|---|
| **Predicted Environmental Concentration in surface water [mg/L]** | **$PEC_{sw,\ ground\ run\text{-}off}$** | **House** | 7E-7 |
| | | **Large building** | 3.2E-6 |

The corresponding $PEC_{sed,ground\ run\text{-}off}$ was calculated using eq. (50) in the TGD:
$PEC_{sed} = (K_{susp\text{-}water} / RHO_{susp}) * PEC_{localwater} * 1000$
Where $K_{susp\text{-}water}$ = 1.54
$RHO_{susp}$ = 1150 (default). Hence, $PEC_{sed,ground\ run\text{-}off}$ **= 9.4E-7 mg/kg (house)**

**= 4.3E-6 mg/kg (large building)**

### *Calculated PEC values*

#### Indoor application

PECs for Deltamethrin:

| | |
|---|---|
| **$PEC_{STP}$ (mg/L)** | $2.6x10^{-6}$ |
| **$PEC_{surface\ water}$ (mg/L)** | $1.6x10^{-7}$ |
| **$PEC_{sediment}$ (mg/kg ww)** | $1.4x10^{-3}$ |
| **$PEC_{local\ soil}$ (mg/kg ww)** | $1.03x10^{-4}$ (terrestrial ecosystem) |
| | $1.03x10^{-4}$(agricultural soil) |
| | $4.1x10^{-5}$ (grassland soil) |
| **$PEClocal_{soil,porewater}$ (mg/L)** | $1.43x10^{-8}$ |
| **$PEC_{gw}$ (µg/L) (FOCUS PEARL)** | <0.1 |

PECs for $Br_2CA$:

| | |
|---|---|
| **$PEC_{surface\ water}$ (mg/L)** | $1.3x10^{-8}$ |
| **$PEC_{sediment}$ (mg/kg ww)** | $1.7x10^{-8}$ |
| **$PEC_{local\ soil}$ (mg/kg ww)** | $6.1x10^{-5}$ (terrestrial ecosystem) |
| | $6.1x10^{-5}$ (agricultural soil) |

| | |
|---|---|
| | 2.4x10$^{-5}$ (grassland soil) |
| **PEClocal$_{soil,porewater}$ (mg/L)** | 6.5x10$^{-6}$ |
| **PEC$_{gw}$ (µg/L) (FOCUS PEARL)** | <0.1 |

**Outdoor application (thermal or cold fogging)**

PECs for Deltamethrin (urban area):

| | |
|---|---|
| **PEC$_{STP}$ (mg/L)** | 5.3x10$^{-5}$ |
| **PEC$_{surface\ water}$ (mg/L)** | 3.3x10$^{-6}$ |
| **PEC$_{sediment}$ (mg/kg ww)** | 0.03 |
| **PEC$_{local\ soil}$ (mg/kg ww)** | 2x10$^{-3}$ (terrestrial ecosystem) |
| | 2x10$^{-3}$ (agricultural soil) |
| | 8.2x10$^{-4}$ (grassland soil) |
| **PEClocal$_{soil,porewater}$ (mg/L)** | 2.8x10$^{-7}$ (terrestrial/agricultural) |
| | 1.14x10$^{-7}$ (grassland soil) |

PECs for $Br_2CA$ (urban area):

| | |
|---|---|
| **PEC$_{surface\ water}$ (mg/L)** | 3.1x10$^{-7}$ |
| **PEC$_{sediment}$ (mg/kg ww)** | 4.2x10$^{-7}$ |
| **PEC$_{local\ soil}$ (mg/kg ww)** | 2.7x10$^{-4}$ (terrestrial ecosystem) |
| | 2.7x10$^{-4}$ (agricultural soil) |
| | 1.1x10$^{-4}$ (grassland soil) |
| **PEClocal$_{soil,porewater}$ (mg/L)** | 2.2x 10$^{-5}$ (max for grassland) |

PECs for Deltamethrin (rural area):

| | |
|---|---|
| **PEC$_{soil,total}$ (mg/kg)** | 6.7 x 10$^{-6}$ (house) |
| | 3.2x10$^{-5}$ (large building) |
| **PEC$_{local,porewater}$ (mg/L)** | 9.3x10$^{-10}$ (house) |
| | 4.4x10$^{-9}$ (large building) |
| **PEC$_{surface\ water}$ (mg/L)** | 9.3x10$^{-11}$ (house) |
| | 4.4x10$^{-10}$ (large building) |
| **PEC$_{sed}$ (mg/kg)** | 8.25x10$^{-7}$ (house) |
| | 3.9x10$^{-6}$ (large building) |

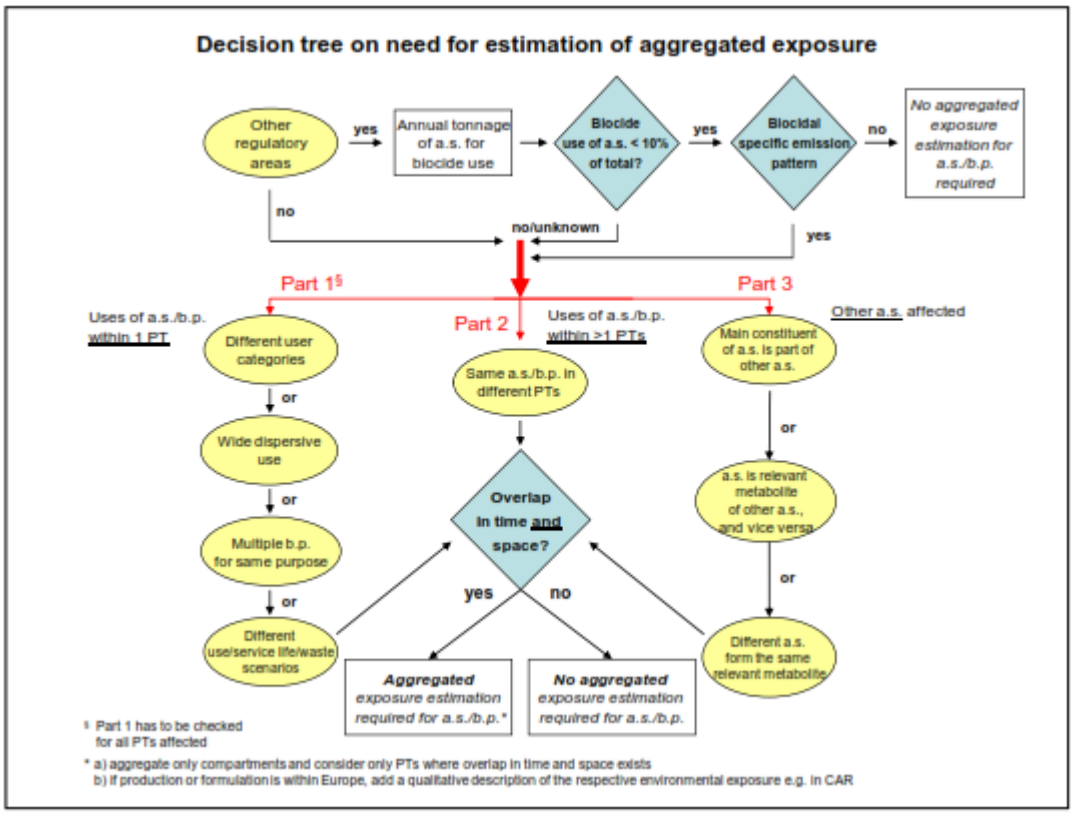
PECs for $Br_2CA$ (rural area):

| | |
|---|---|
| **PEC$_{soil,total}$ (mg/kg)** | 4x10$^{-6}$ (house) |
| | 1.9x10$^{-5}$ (large building) |
| **PEC$_{local,porewater}$ (mg/L)** | 7x10$^{-6}$ (house) |
| | 3.2x10$^{-5}$ (large building) |
| **PEC$_{surface\ water}$ (mg/L)** | 7x10$^{-7}$ (house) |
| | 3.2x10$^{-6}$ (large building) |

| | |
|---|---|
| **$PEC_{sed}$ (mg/kg)** | $9.4x10^{-7}$ (house) |
| | $4.3x10^{-6}$ (large building) |

2.2.7.3 Aggregated Environmental Exposure Assessment (PEClocal_agg)

Biocidal active substances (a.s.) are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentrations of a.s. to be found in the environment. Article 19(2) of the Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." This is further elaborated in Annex VI (common principles for the evaluation of biocidal products) which states that the risks associated with the relevant individual components of the biocidal product shall be assessed, taking into account any cumulative and synergistic effects. This refers to environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs. Moreover, according to the latest version of Technical Agreements for Biocides-ENV v. 2.0, an evaluation on the need to conduct an aggregated exposue assessment should be performed as a first step. The need whether this type of assessment is required it is checked according to the "Decision tree on the need for estimation of aggregated exposure" (refer to Guidance on the BPR: Volume IV Part B Risk Assessment (active substances) Version 2.0 October 2017).




Annual tonnage for biocide uses is unknown, therefore only the consumption approach is considered. Part 2 and 3 of the decision tree seems to be not applicable for deltamethrin.

Part 1:
The application of Aqua K-Othrine is authorised for the control of mosquitoes. It is not possible to have overlapping in time and space, regarding different user categories since Aqua K-othrine is foreseen only by trained professional users for mosquitoes.
A wide dispersive use of the biocidal product seems not to be possible since Aqua K-othrine, however, the use in wide dispersion should be specified in details in future to have a clear outcome. Furthermore, only one additional b.p. against mosquitoes containing deltamethrin is authorised in Europe.
Furthermore, the b.p. is authorised to be used in private houses and larger buildings as well. Hence, there is a possibility that an overlapping application in time and space of deltamethrin containing b.p. with subsequent release into the same sewer system cannot be excluded. For this reason, the exposure estimation for Aqua K-Othrine already considers a simultaneous release of the product. This has been implemented into the calculations by the simultaneity factor ($F_{sim}$), which represents the fraction of households and larger buildings within one STP catchment, in which the b.p. is considered to be applied simultaneously. These simultaneous releases are subsequently being collected in one STP.
Based on the abovementioned reasons, there is a need for a qualitative aggregated assessment, for future authorisations and for the product renewal, when a specific, EU-wide harmonised guidance is developed

## *Primary and secondary poisoning*

Primary poisoning

Primary poisoning is concerned with toxic effects in the higher members of the food chain (predatory birds and mammals) which result from direct exposure to the formulated active substance. Deltamethrin EW 20 is intended for i) outdoor aerial applications as an ultra-low volume aerosol (airplane/helicopter mounted application equipment) and ii) outdoor and indoor terrestrial applications as a thermal or cold fog (thermal/cold fogging equipment). Primary exposure of predatory birds and mammals via these application techniques is considered unlikely and thus no risk assessment of primary poisoning is required.

Secondary poisoning

Based on its log $K_{OW}$ value (i.e. 4.6), deltamethrin has a potential for bioaccumulation in aquatic and terrestrial biota. Thus, an estimation of the theroretical exposure of top predators via the aquatic and terrestrial food chain has been performed and is presented in the following tables. In accordance with the ECHA Guidance on the BPR (Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0, April 2015), the predicted environmental concentration in fish- and earthworm-eating top predators has been estimated according to the following relationships:

$$PEC_{oral,\ fish\text{-}eating\ predator} = PEC_{water} \times BCF_{fish} \times BMF$$

Where:

| Variable/parameter (unit) | Symbol | Unit | Value | Source |
|---|---|---|---|---|
| Predicted Environmental Concentration in | $PEC_{oral,\ fish\text{-}}$ | [$mg.kg_{wet}$ | - | Output |

| | | | | |
|---|---|---|---|---|
| fish-eating predators | *eating predator* | $fish^{-1}$] | | |
| Predicted Environmental Concentration in water | $PEC_{water}$ | [$mg.L^{-1}$] | [1] | Input |
| Bioconcentration Factor for fish on wet weight basis | $BCF_{fish}$ | [$L.kg_{wet\ fish}^{-1}$] | 1400 [2] | Input |
| Biomagnification factor in fish | *BMF* | [-] | 2 [3] | Default |

[1] $PEC_{water}$ = 1.6E-07 $mg.L^{-1}$ (indoor use); 3.3E-06 $mg.L^{-1}$ (outdoor urban use); 9.3E-11 $mg.L^{-1}$ (outdoor rural use; house scenario); 4.4E-10 $mg.L^{-1}$ (outdoor rural use; large buidling scenario)
[2] EU agreed fish BCF (whole fish) for deltamethrin
[3] worst-case BMF value agreed for deltamethrin during the EU peer review based on the TGD (Part II, 2003) recommendations and the log $K_{OW}$ of 4.6 for the active substance

$PEC_{oral,\ earthworm\text{-}eating\ predator}=$

$C_{earthworm}=(BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}) / (1 + F_{gut} \times CONV_{soil})$

Where:

| **Variable/parameter (unit)** | **Symbol** | **Unit** | **Value** | **Source** |
|---|---|---|---|---|
| Predicted Environmental Concentration in earthworm-eating predators | $PEC_{oral,\ earthworm\text{-}eating\ predator}$ | [$mg.kg_{wet\ earthworm}^{-1}$] | - | Output |
| Concentration in earthworm on wet weight basis | $C_{earthworm}$ | [$mg.kg_{wet\ earthworm}^{-1}$] | - | Output |
| Bioconcentration Factor for earthworms on wet weight basis | $BCF_{earthworm}$ | [$mg.kg_{wet\ earthworm}^{-1}$] | 483 [1] | Input |
| Concentration in porewater | $C_{porewater}$ | [$mg.L^{-1}$] | [2] | Input |
| Concentration in soil | $C_{soil}$ | [$mg.kg_{wwt}^{-1}$] | [3] | Input |
| Fraction of gut loading in worm | $F_{gut}$ | [$kg_{dwt}.kg_{wwt}^{-1}$] | 0.1 [4] | Default |
| Conversion factor for soil concentration wet-dry weight soil | $CONV_{soil}$ | [$kg_{wwt}.kg_{dwt}^{-1}$] | 1.13 [4] | Default |

[1] EU agreed earthworm BCF for deltamethrin; estimated according to the equation of Jager (1998)

[2] $PEC_{soil}$ = 1.50E-05 $mg.kg_{wwt}^{-1}$ (indoor use, agricultural soil; averaged over a period of 180 days), 3.70E-05 $mg.kg_{wwt}^{-1}$ (indoor use, grassland, averaged over a period of 180 days), 7.10E-04 $mg.kg_{wwt}^{-1}$ (outdoor urban use, agricultural soil; averaged over a period of 180 days), 2.90E-04 $mg.kg_{wwt}^{-1}$ (outdoor urban use, grassland; averaged over a period of 180 days), 6.70E-06 $mg.kg_{wwt}^{-1}$ (outdoor rural use, house scenario), 3.20E-05 $mg.kg_{wwt}^{-1}$ (outdoor rural use, large building scenario)

[3] $PEC_{poreawtaer}$ = 1.43E-08 $mg.L^{-1}$ (indoor use), 2.8E-07 $mg.L^{-1}$ (outdoor urban use, agricultural soil), 1.14E-07 $mg.L^{-1}$ (outdoor urban use, grassland), 9.3E-10 $mg.L^{-1}$ (outdoor rural use, house scenario), 4.4E-09 $mg.L^{-1}$ (outdoor rural use, large building scenario)

[4] Deafult values were obtained from ECHA Guidance on the BPR (April 2015)

It is noted that (i) a worst-case scenario of 100% of the diet coming from $PEC_{local}$ was considered for both the aquatic and terrestrial food chain and (ii) the 180-d time-weighted average PEC values for soil have been used, where available, in line with the recommendations of the ECHA Guidance on the BPR (April, 2015).

| Summary table on estimated theoretical exposition (ETE) of fish-eating top predators | |
|---|---|
| **Scenario** | **ETE** [mg/kg*d$^{-1}$] |
| Indoor use | 4.48E-04 |
| Outdoor urban use | 9.24E-03 |
| Outdoor rural use (house scenario) | 2.60E-07 |
| Outdoor rural use (large building scenario) | 1.23E-06 |
| **Summary table on estimated theoretical exposition (ETE) of earthworm-eating top predators** | |
| **Scenario** | **ETE** [mg/kg*d$^{-1}$] |
| Indoor use (180d averaged period, agricultural soil) | 7.73E-06 |
| Indoor use (180d averaged period, grassland) | 9.96E-06 |
| Outdoor urban use (180d averaged period, agricultural soil) | 1.94E-04 |
| Outdoor urban use (180d averaged period, grassland) | 7.89E-05 |
| Outdoor rural use (house scenario) | 1.08E-06 |
| Outdoor rural use (large building scenario) | 5.16E-06 |

### 2.2.7.4 Risk characterisation

#### *Atmosphere*

Due to its low vapour pressure (1.24E-08 Pa at 25°C), it is not expected that any significant volatile losses of deltamethrin to the air compartment would occur either during or after the application. If however present in air, the chemical lifetime of deltamethrin in the air of 16.4 hours as estimated according to the incremental method of Atkinson and AOPWIN program indicates rapid degradation of volatilised deltamethrin by photo-oxidation (i.e. reaction with hydroxyl radicals). Furthermore, deltamethrin is not expected to evaporise to air from bare soil and plant surfaces at significant levels as confirmed by a wind-tunnel study where the volatilisation of deltamethrin from soil and plants was estimated to be 0.2% and 0.6% of applied amount, respectively (deltamethrin CAR, June 2011).

Conclusion: No unacceptable risk to the air compartment is expected following application of Deltamethrin EW 20 according to the proposed use pattern.

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

Deltamethrin and its major metabolite $Br_2CA$ can reach Sewage Treatment Plants during the indoor and outdoor urban uses of Deltamethrin EW 20. The EU agreed $PNEC_{STP}$ value of 30 µg/L for both the active substance deltamethrin and its metabolite $Br_2CA$ has been considered in the risk assessment for STP presented in the table below.

| Summary table on calculated PEC/PNEC values for the active substance deltamethrin | |
|---|---|
| **Scenario** | **PEC/PNEC$_{STP}$** |
| Indoor use | 8.67E-05 |
| Outdoor urban use | 1.77E-03 |
| **Summary table on calculated PEC/PNEC values for the major metabolite $Br_2CA$** | |
| **Scenario** | **PEC/PNEC$_{STP}$** |
| Indoor use | 5.20E-06 |

Conclusion: No unacceptable risk to STP microorganisms is anticipated following application of Deltamethrin EW 20 according to the proposed use pattern.

### *Aquatic compartment*

Deltamethrin and its major metabolite $Br_2CA$ can reach the aquatic environment indirectly via STP effluent discharge (indoor and outdoor urban uses) or surface run-off (outdoor rural use). The EU agreed PNEC$_{water}$ values of 0.7 ng/L and 10.4 µg/L as well as the EU agreed PNEC$_{sediment}$ values of 6.2 µg/kg ww sediment and 13.9 µg/kg ww sediment for the parent compound deltamethrin and its metabolite $Br_2CA$, respectively, have been considered in the risk assessment for surface water and sediment presented in the table below.

According to deltamethrin CAR (June, 2011), the PNEC$_{water}$ for the active substance has been based on the lowest chronic toxicity endpoint (NOEC) of 0.0035 µg/L derived from the 28-day water spiked *Chironomous riparius* study of Heusel et al. (1998).

Due to the observed effects at the lowest test concentrations and the uncertainties regarding the exposure pattern compared to the biocidal use of deltamethrin, the available mesocosm study of Heimbach et al. (2005) was considered inappropriate to form the basis for the PNEC$_{water}$ derivation. More specifically, it was agreed that the potential for recovery observed in the mesocosm study should not be taken into account in the PNEC calculation when exposure of aquatic organisms occurs via STP since it is in contrast with the concept of continuous exposure via this route. Therefore, only effect endpoints representing No Observed Effect Concentrations were considered relevant for use in the aquatic risk assessment. However, adverse effects on one species (i.e. *Chaoborus crystallinus*) were observed at the lowest treatment level (4.8 ng/L) and thus no reliable NOEC could be derived from the mesocosm study. Nevertheless, it was agreed that the large number of species tested in the mesocosm study could support a lower assessment factor. Thus, an assessment factor of 5 (instead of 10) was applied to the 28-day NOEC of 0.0035 µg/L for *Chironomus riparius* resulting to a PNEC$_{water}$ of 0.7 ng/L.

It is noted that PEC/PNEC ratios have been calculated only for the indoor and outdoor (rural, urban) terrestrial applications. No aquatic risk assessment has been performed for the aerial application as no respective exposure assessment has been provided by the applicant.

| Summary table on calculated PEC/PNEC values for the active substance deltamethrin | | |
|---|---|---|
| **Scenario** | **PEC/PNEC$_{water}$** | **PEC/PNEC$_{sed}$** |
| Indoor use | 2.29E-01 | 2.26E-01 |

| | | |
|---|---|---|
| Outdoor urban use | **4.71E+00** | **4.84E+00** |
| Outdoor rural use (house scenario) | 1.33E-04 | 1.33E-04 |
| Outdoor rural use (large building scenario) | 6.29E-04 | 6.29E-04 |
| **Summary table on calculated PEC/PNEC values for the major metabolite $Br_2CA$** | | |
| **Scenario** | **$PEC/PNEC_{water}$** | **$PEC/PNEC_{sed}$** |
| Indoor use | 1.25E-06 | 1.22E-06 |
| Outdoor urban use | 2.98E-05 | 3.02E-05 |
| Outdoor rural use (house scenario) | 6.73E-05 | 6.76E-05 |
| Outdoor rural use (large building scenario) | 3.08E-04 | 3.09E-04 |

Conclusion: Based on the calculated PEC/PNEC ratios:

- No unacceptable risk to surface water organisms from the parent compound are expected following indoor use of Deltamethrin EW 20 according to the proposed use pattern. The risk to surface water organisms for outdoor use around buildings, has been found to be unacceptable.
- No unacceptable risk to sediment-dwelling organisms from the parent compound are expected following the indoor and outdoor rural uses of Deltamethrin EW 20 according to the proposed use pattern. The risk to sediment-dwelling organisms for outdoor use around buildings has been found to be unacceptable.
- The risk to surface water and sediment-dwelling organisms from metabolite $Br_2CA$ has been calculated to be acceptable for all exposure scenarios under consideration.

Following the release of the first draft PAR, the applicant has provided a position paper (Annex II) through which a refined $PNEC_{aquat\ c}$ of 23 ng/L is proposed in order to address the risk identified for the aquatic environment. The eCA has evaluated the respective information and the following has been concluded:

- For risk assessment harmonization reasons, the eCA EL does not consider appropriate to re-evaluated studies and data already available during the EU peer review of the active substance under concern. The endpoints agreed and conclusions reached from the EU evaluation of the data on the active substance should be maintained in the evaluation of the biocidal products. Thus the aquatic risk assessment should be based on the EU agreed PNEC of 0.7 ng/L.
- No amendment of the above presented risk assessment approach followed by the eCA EL is required on the basis of the new information provided by the applicant.

## *Terrestrial compartment*

### *Risk assessment for soil*

Deltamethrin and its major metabolite $Br_2CA$ can reach the terrestrial environment directly. The EU agreed $PNEC_{soil}$ values of 0.075 mg/kg ww soil (based on reproduction endpoint in springtails and applying an assessment factor of 10) and 0.14 mg/kg ww soil (based on mortality endpoint in predatory mites and applying an assessment factor of

100) for the parent compound deltamethrin and its metabolite $Br_2CA$, respectively, have been considered in the terrestrial risk assessment presented in the table below.

It is noted that the PEC/PNEC calculations for the indoor and outdoor urban exposure scenarios have been based on the concentration in soil averaged over a period of 30 days (relevant for the terrestrial ecosystem) while the PEC/PNEC calculations for the outdoor rural exposure scenarios has been based on the total concentration in soil following application of Deltamethrin EW 20.

| **Summary table on calculated PEC/PNEC values for the active substance deltamethrin** | |
|---|---|
| **Scenario** | **$PEC/PNEC_{soil}$** |
| Indoor use | 1.12E-02 |
| Outdoor urban use | 2.13E-02 |
| Outdoor rural use (house scenario) | 8.93E-05 |
| Outdoor rural use (large building scenario) | 4.27E-04 |
| **Summary table on calculated PEC/PNEC values for the major metabolite $Br_2CA$** | |
| **Scenario** | **$PEC/PNEC_{soil}$** |
| Indoor use | 2.64E-05 |
| Outdoor urban use | 5.07E-04 |
| Outdoor rural use (house scenario) | 2.86E-05 |
| Outdoor rural use (large building scenario) | 1.36E-04 |

Terrestrial plant studies' results: two toxicity studies were submitted, one seedling emergence and one study on vegetative vigour, testing one treatment level. No significant phytotoxic effects were reported in either study at the tested treatment level of 12.5 g a.s./ha. eCA proposes not to consider these studies since only one treatment level was tested; therefore the NOEC derived cannot be concluded as reliable.

According to Deltamethrin CAR (2011), *"Chronic toxicity data is available for earthworms, springtail, predatory mite and terrestrial microorganisms, representing two trophic levels. However, since deltamethrin is an insecticide used for crop protection and is not phytotoxic, plants are not expected to be more sensitive than terrestrial invertebrates. It could therefore be considered that three trophic levels are covered by the available data, and that an assessment factor of 10 can be used to derive the PNEC."*

Conclusion: No unacceptable risk to the soil compartment is anticipated following application of Deltamethrin 20 EW according to the proposed use pattern.

### *Risk assessment for groundwater*

Deltamethrin and its major metabolite $Br_2CA$ can reach the groundwater via leaching from soil surface. The predicted environmental concentrations of both substances in groundwater as calculated according to the ESD (OECD, 2006) and, if required (e.g. for the metabolite following indoor use) the simulation model FOCUS-PEARL 2.2.2 (Schafer, 2004b) were below the limit value of 0.1 µg a.s./L fixed as the maximum permissible concentration of pollutants in groundwater (Directive 98/83/EC).

Conclusion: Groundwater used for drinking water is not expected to contain unacceptable levels of deltamethrin and its metabolite $Br_2CA$ resulting from the intended use pattern of Deltamethrin EW 20.

### *Risk assessment for bees and other non-target organisms*

According to the ECHA GD on the BPR (Volume IV Environment; April, 2015), at the moment no method is available for biocides on how to perform the risk assessment for bees and non-target arthropods while the methods applied under the pesticides EU framework are not directly applicable. Therefore, the tests available for bees and other beneficial arthropods with technical and formulated deltamethrin should be used in a qualitative or semi-quantitative risk assessment if exposure pattern is comparable.

### *Risk assessment for bees*

The available toxicity data (table 1) indicate that both the technical and formulated deltamethrin is highly toxic to honeybees.

Table 1: Summary of acute toxicity of deltamethrin to honeybees

| Test substance | Ecotoxicological endpoints | | Reference |
|---|---|---|---|
| Deltamethrin technical | oral $LD_{50}$ | 0.079 µg a.s./bee | Stevenson (1978) |
| | 48 h contact $LD_{50}$ | 0.0015 µg a.s./bee | Hoxter & Lynn (1991) |
| Deltamethrin EW 50 | 48 h oral $LD_{50}$ | 0.79 µg a.s./bee | Barth (2006) |
| | 48 h contact $LD_{50}$ | 0.12 µg a.s./bee | |
| Deltamethrin EC 25 (Code 102000020023) | 48 h oral $LD_{50}$ | 0.143 µg a.s./bee | Schimitzer (2008) |
| | 96 h contact $LD_{50}$ | 0.110 µg a.s./bee | |

A qualitative or semi-quantitative risk assessment for bees cannot be performed as the effect endpoints (dose levels) for acute oral and contact toxicity (µg a.s./bee) are not directly comparable to the potential exposure of bees in treated areas (i.e. intended application rate of deltamethrin in outdoor applications: 1 g a.s./ha). Nevertheless, for reason of precaution and in case of outdoor applications, the following statements should be included on the product label:

*"Do not use on agricultural areas or areas that are adjacent to crops."*

*"Do not allow direct spray to fall within 50 m of bee hives. Beekeepers must be informed of the intended application at least 24 hours in advance. Bee colony must be in the hive and it is recommended that the hives are covered at the time of application."*

As deltamethrin is a non-systemic insecticide, there is no potential of indirect exposure of bees via STP sludge application to soil (indoor and outdoor urban use) or atmospheric deposition on soil (outdoor rural and aerial use) and subsequent uptake in plants.

### *Risk assessment for other non-target organisms*

The available toxicity data on other no-target arthropods are summarized in table 4 in effect assessment section and table 2 below.

For the parasitic wasp *Aphidius rhopalosiphi*, two extended laboratory studies using natural substrates (Barth, 2000; Röhlig, 2006) are available. Based on the studies' findings, deltamethrin is not expected to have any unacceptable (statistically significant) effects on the survival and reproductive performance of *Aphidius rhopalosiphi* at application rates of 0.711 g/ha and 1.421 g/ha, respectively.

For the predatory mite *Typhlodromus pyri*, three extended laboratory (Feije, 2004; Loose, 2005; Aldershof, 2009) and three extended laboratory, aged residue studies (Feije, 2004; Bakker, 2004; Aldershof, 2006) are available.

In the extended laboratory study of Feije (2004), the survival and reproduction of *Typhlodromus pyri* were statistically significantly reduced at the lowest treatment level, i.e. 0.03 g a.s./ha. In the extended laboratory study of Loose (2005), the survival of *T. pyri* was not statistically significantly reduced at the lowest treatment level of 0.0125 g a.s./ha (but statistically significantly reduced at 0.025 and 0.050 g a.s./ha), while reproduction was not statistically significantly reduced up to and including the application rate of 0.050 g a.s./ha. In the extended laboratory study of Aldershof (2009), the survival of *T. pyri* was not statistically significantly reduced at the lowest treatment level of 0.025 g a.s./ha, while reproduction was not statistically significantly reduced up to and including the application rate of 0.025 g a.s./ha (but statistically significantly reduced at 0.025 and 0.050 g a.s./ha). Overall, based on the findings of the three extended laboratory studies, deltamethrin is not expected to have any unacceptable (statistically significant) effects on the survival and reproductive performance of *Typhlodromus pyri* at application rates of 0.0125 g/ha and 0.025 g/ha, respectively.

In the extended laboratory, aged residue study of Feije (2004), the survival of *Typhlodromus pyri* was statistically significantly reduced following exposure to bean leaves treated with deltamethrin at 1 x 7.5 g/ha and aged two (58% mortality) and four (34% mortality) weeks after application. Reproduction was not significantly affected following exposure to treated bean leaves (1 x 7.5 g a.s./ha) aged four weeks after application. In the extended laboratory, aged residue study of Bakker (2004), the survival and reproduction of *Typhlodromus pyri* were not statistically significantly affected following exposure to apple leaves treated with deltamethrin at 3 x 12.5 g/ha (7-d application interval) and aged six weeks after application. In the extended laboratory, aged residue study of Aldershof (2006), the survival of *Typhlodromus pyri* was statistically significantly affected while reproduction was not statistically significantly affected following exposure to apple leaves treated with deltamethrin at 3 x 17.5 g/ha (14-d application interval) and aged 130 days after application. It is noted that the available aged residue studies were conducted at rates higher than the application rate under the proposed use (1 x 1 g a.a./ha). However, they can still provide useful information with respect to the risk assessment.

In addition to the laboratory tests with *Aphidius rhopalosiphi* and *Typhlodromus pyri*, two field studies on the effects of formulated deltamethrin to non-target arthropod fauna in apple orchards (Aldershof, 2001) and winter wheat (Bakker, 2005) are available. In the field study of Aldershof (2001), application of deltamethrin at 3 x 2.0 g a.s./ha (15-d interval) resulted in reduced populations of an increased number of taxa but full recovery was observed for almost all taxa within the growing season. In the field study of Bakker (2005), multiple applications of deltamethrin at 6.25 g a.s./ha, 12.5 g a.s./ha and 12.5 g a.s./ha according to a worst-case GAP scenario resulted in statistically significant adverse effects at community and functional group level but full recovery was observed before the start of the next growing season.

The results of the laboratory and field studies on other non-target arthropods are summarized in the following table.

**Table 2:** Summary of effects of deltamethrin on non-target arthropods under laboratory and field conditions

| Test species | Type of test | Maximum outdoor application rate | Ecotoxicological endpoints |
|---|---|---|---|
| *Aphidius rhopalosiphi* | Extended laboratory tests | 1 g a.s./ha | Survival: 0.711 g a.s./ha *; 48-h $LR_{50}$ = 1.421 g a.s./ha<br>Reproduction: 1.421 g a.s./ha * |
| *Typhlodromus pyri* | Extended laboratory tests | | Survival: 0.0125 g a.s./ha *<br>Reproduction: 0.025 g a.s./ha * |
| | Extended laboratory, aged residue tests | | Exposure to 4-week aged residues of deltamethrin at the application rate of 1 x 7.5 g/ha:<br>Statistically significant effects on survival & not statistically significant effects on reproduction<br>Exposure to 6-week aged residues of deltamethrin at application rates of 3 x 12.5 g/ha (7-d application interval):<br>No statistically significant effects on survival and reproduction<br>Exposure to 130-day (approx. 18 week) aged residues of deltamethrin at application rates of 3 x 17.5 g/ha (14-d application interval):<br>Statistically significant effects on survival & not statistically significant effects on reproduction |
| NTA-fauna in apple orchards | Field study | | At 0.1 g a.a./ha: effects on few taxa for a short period of time<br>At 0.6 and 2 g a.s./ha: reduced populations of increasing number of taxa but mainly recovery within the season<br>At 12.5 g a.s./ha: reduced populations of most taxa; in some toxa no recovery during the season |
| NTA-fauna in winter wheat | Field study | | Following multiple test item applications (1st treatment: 6.25 g a.s./ha (18/11/2003), 2nd treatment: 3/5/2004 (12.5 g a.s./ha), 3rd treatment: 28/5/2004 (12.5 g a.s./ha), any statistically significant adverse reponses of NTA community and functional groups recovered before the start of the next growing season |

* concentrations at which no statistically significant effects on survival and reproduction were observed

A semi-quantitative risk assessment for non-target arthropods is applicable by comparing the outdoor application rate of deltamethrin (1 g/ha) with the ecotoxicological endpoints (in g/ha) derived from the available studies (table 2). The available laboratory toxicity data indicate that deltamethrin is highly toxic to the two representative species of foliage dwelling non-target arthropods, i.e. *Aphidius rhopalosiphi* and *Typhlodromus pyri*. In fact, the extended laboratory studies indicate that unacceptable effects on the survival and

reproductive performance of *Aphidius rhopalosiphi* and *Typhlodromus pyri* cannot be excluded following application on Deltamethrin EW 20 according to the proposed use pattern. However, the available field studies indicate that no adverse prolonged (persistent) effects to non-target arthropod fauna under real field conditions are to be expected following application of Deltamethrin EW 20 at rates up to 2 g a.s./ha. Therefore, it can be concluded that application of Deltamethrin EW 20 according to the proposed use pattern will not adversely affect beneficial arthropods.

## *Primary and secondary poisoning*

Primary poisoning

No primary poisoning of predatory birds and mammals is expected following application of Deltamethrin EW 20 according to the proposed use pattern. Thus, a respective risk assessment has not been performed.

Secondary poisoning

The risk of secondary poisoning via the terrestrial and aquatic food chain has been calculated as the ratio between the concentration in the food of fish- and earthworm eating predators ($PEC_{oral,\ predator}$) and the predicted no effect concentration of top predators, i.e. birds and mammals, for oral intake ($PNEC_{oral}$). The $PEC_{oral}$ for fish- and earthworm eating predators has been estimated on the basis of the recommendations provided in the ECHA Guidance on the BPR (April 2015) and is thoroughly described in the sections above. The $PNEC_{oral}$ for birds and mammals were agreed during the EU peer review of the active substance deltamethrin and corresponds to 15 mg/kg food and 2.67 mg/kg food respectively. It is noted that PEC/PNEC ratios have been calculated only for the indoor and outdoor (rural, urban, agricultural) terrestrial applications. No risk assessment of secondary poisoning has been performed for the aerial application as no respective exposure assessment has been provided by the applicant.

| **Summary table on secondary poisoning via the aquatic food chain** | | | |
|---|---|---|---|
| **Scenario** | **$PEC_{oral}$ predator** | **PEC/PNEC birds** | **PEC/PNEC mammals** |
| Indoor use | 4.48E-04 | 2.99E-05 | 1.68E-04 |
| Outdoor urban use | 9.24E-03 | 6.16E-04 | 3.46E-03 |
| Outdoor rural use (house scenario) | 2.60E-07 | 1.74E-08 | 9.75E-08 |
| Outdoor rural use (large building scenario) | 1.23E-06 | 8.21E-08 | 4.61E-07 |
| **Summary table on secondary poisoning via the terrestrial food chain** | | | |
| **Scenario** | **$PEC_{oral}$ predator** | **PEC/PNEC birds** | **PEC/PNEC mammals** |
| Indoor use (180d averaged period, agricultural soil) | 7.73E-06 | 5.15E-07 | 2.89E-06 |
| Indoor use (180d averaged period, grassland) | 9.96E-06 | 6.64E-07 | 3.73E-06 |

| | | | |
|---|---|---|---|
| Outdoor urban use (180d averaged period, agricultural soil) | 1.94E-04 | 1.29E-05 | 7.25E-05 |
| Outdoor urban use (180d averaged period, grassland) | 7.89E-05 | 5.26E-06 | 2.96E-05 |
| Outdoor rural use (house scenario) | 1.08E-06 | 7.23E-08 | 4.06E-07 |
| Outdoor rural use (large building scenario) | 5.16E-06 | 3.44E-07 | 1.93E-06 |

Conclusion: No unacceptable risk of primary and secondary poisoning is expected following application of Deltamethrin EW 20 according to the proposed use pattern.

### *Mixture toxicity*

According to the ECHA Guidance on the BPR (Volume IV: Environment, Part A: Information Requirements; Version 1.1, November 201), *where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP)… further studies chosen from among the endpoints referred to in section 9 of Annex II for the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.*

No ecotoxicological effects assessment for the whole mixture has been conducted. The ecotoxicological properties of Deltamethrin 20 EW have been assessed on the basis of the available data for the active substance deltamethrin and the submitted studies with deltamethrin-containing alternative formulations.

Although two co-formulants are considered to be ecotoxicologically relevant as they are classified as Aquatic Chronic 2 and Aquatic Acute 1, respectively, they do not raise any further ecotoxicological concern for the biocidal product. Considering the ecotoxicological properties of deltamethrin and more specifically its hazard characterization as Aquatic Acute 1 with an M-factor of $10^4$ and Aquatic Chronic 1 with an M-factor of $10^4$, it can be reasonably assumed that the ecotoxicity of the product is driven by the active ingredient while other components have a negligible impact. Further, no synergestic interactions between the product components are expected and thus considered necessary for the assessment of the mixture toxicity.

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

- Keep away from food, drink and animal feedingstuffs.

## 2.2.9 Assessment of a combination of biocidal products

Not relevant.

# 3 ANNEXES

## 3.1 List of studies for the biocidal product

The applicant is requested to submitted the list of studies used for the assessment of the biocidal product Deltametrhin EW 20.

## 3.2 Output tables from exposure assessment tools

**PROFESSIONAL EXPOSURE ASSESSMENT**

**Scenario 1a: Exposure during mixing and loading Deltamethrin EW 20 into the spray tank of hand held fogging equipment (portable) for indoor use**

Amount a.s. handled per day = space x use rate = 1200$m^3$/day x 0.05 mg a.s./$m^3$.
= 60 mg a.s./day = 0.00006 kg a.s./day

Abbreviations: I = estimated inhalation exposure; D = estimated dermal exposure

***No PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [$m^3$/day] x use rate [kg a.s./$m^3$] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.021 | x | 0.00006 | | | = | **0.00000126** |
| $D_{hands}$ | 464 | x | 0.00006 | | | = | **0.02784** |
| $D_{body}$ | 48.3 | x | 0.00006 | | | = | **0.002898** |

***With PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [ha/day] x use rate [kg a.s./ha] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.021 | x | 0.00006 | | | = | **0.00000126** |
| $D_{hands}$ | 464 | x | 0.00006 | x | 0.1 | = | **0.002784** |
| $D_{body}$ | 48.3 | x | 0.00006 | x | 0.2 | = | **0.0005796** |

**Conversion of exposure estimates to systemic exposures**

Considering 100% inhalation absorption and 2% dermal absorption the exposure estimates [in mg/person/day] are converted to systemic exposures [in mg/kg bw/day considering the 60 kg adult].

The results are summarised in the following table.

**Estimated primary systemic operator exposure to deltamethrin [mg/kg bw/day] during mixing and loading Deltamethrin EW 20 in the spray tank of hand held (portable) fogging equipment for indoor use/no PPE and with PPE**

| **Systemic exposure in mg/kg bw/day** resulting from | **Mixing and loading** | |
|---|---|---|
| | **no PPE** | **with PPE** |
| Dermal exposure | 0.000010246 | 0.0000011212 |
| Inhalation exposure | 0.000000021 | 0.000000021 |
| **Total systemic exposure [mg/kg bw/day]** | **0.000010267** | **0.0000011422** |

**Scenario 1b: Exposure during mixing and loading Deltamethrin EW 20 into the spray tank of hand held fogging equipment (portable) for outdoor (terrestrial) use**

Amount a.s. handled per day = treated area x use rate = 5 ha/day x 1 g a.s./ha
= 5 g a.s./day = 0.005 kg a.s./day

Abbreviations: I = estimated inhalation exposure; D = estimated dermal exposure

***No PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [$m^2$/day] x use rate [kg a.s./$m^2$] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.021 | x | 0.005 | | | = | **0.000105** |
| $D_{hands}$ | 464 | x | 0.005 | | | = | **2.32** |
| $D_{body}$ | 48.3 | x | 0.005 | | | = | **0.2415** |

***With PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [ha/day] x use rate [kg a.s./ha] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.021 | x | 0.005 | | | = | **0.000105** |
| $D_{hands}$ | 464 | x | 0.005 | x | 0.1 | = | **0.232** |
| $D_{body}$ | 48.3 | x | 0.005 | x | 0.2 | = | **0.0483** |

**Conversion of exposure estimates to systemic exposures**

Considering 100% inhalation absorption and 2% dermal absorption the exposure estimates [in mg/person/day] are converted to systemic exposures [in mg/kg bw/day considering the 60 kg adult].

The results are summarised in the following table.

**Estimated primary systemic operator exposure to deltamethrin [mg/kg bw/day] during mixing and loading Deltamethrin EW 20 in the spray tank of hand held fogging equipment/no PPE and with PPE**

| **Systemic exposure in mg/kg bw/day** resulting from | **Mixing and loading** | |
|---|---|---|
| | **no PPE** | **with PPE** |
| Dermal exposure | 0.000853833 | 0.000093433 |
| Inhalation exposure | 0.00000175 | 0.00000175 |
| **Total systemic exposure [mg/kg bw/day]** | **0.000855583** | **0.00009518** |

**Scenario 1c: Exposure during mixing and loading Deltamethrin EW 20 into the spray tank of vehicle-mounted fogging equipment (fixed receiving vessel) for outdoor (terrestrial) use**

Amount a.s. handled per day = treated area x use rate = 150 ha/day x 1 g a.s./ha
= 150 g a.s./day = 0.150 kg a.s./day

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Abbreviations: I = estimated inhalation exposure; D = estimated dermal exposure

***No PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [$m^2$/day] x use rate [kg a.s./$m^2$] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.003 | x | 0.150 | | | = | **0.00045** |
| $D_{hands}$ | 8.0 | x | 0.150 | | | = | **1.2** |
| $D_{body}$ | 1.95 | x | 0.150 | | | = | **0.2925** |

***With PPE***

| Route of exposure | Specific exposure [mg/person x kg a.s.] | | Treated area [ha/day] x use rate [kg a.s./ha] | | Reduction coefficient | | **Result [mg/person/day]** |
|---|---|---|---|---|---|---|---|
| I | 0.003 | x | 0.150 | | | = | **0.00045** |
| $D_{hands}$ | 8.0 | x | 0.150 | x | 0.1 | = | **0.12** |
| $D_{body}$ | 1.95 | x | 0.150 | x | 0.2 | = | **0.0585** |

**Conversion of exposure estimates to systemic exposures**

Considering 100% inhalation absorption and 2% dermal absorption the exposure estimates [in mg/person/day] are converted to systemic exposures [in mg/kg bw/day considering the 60 kg adult].

The results are summarised in the following table.

**Estimated primary systemic operator exposure to deltamethrin [mg/kg bw/day] during mixing and loading Deltamethrin EW 20 in the spray tank of hand held fogging equipment/no PPE and with PPE**

| **Systemic exposure in mg/kg bw/day** resulting from | **Mixing and loading** | |
|---|---|---|
| | **no PPE** | **with PPE** |
| Dermal exposure | 0.0004975 | 0.0000595 |
| Inhalation exposure | 0.0000075 | 0.0000075 |
| **Total systemic exposure [mg/kg bw/day]** | **0.000505** | **0.000067** |

**Scenario 2a: Exposure during application of Deltamethrin EW 20 *via* thermal fogging with hand held fogging equipment**

**Professional thermal fogging with hand held application equipment /no PPE**

| Exposure Description | 75th percentile |
|---|---|
| **Potential hand dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 33* |
| task duration (default value = 120 min/day) | 120 |
| potential amount of product on rest of body (µL /day) | 3960 |
| clothing penetration (default value = 100%) | 100% |
| actual dermal deposit of product on rest of body (µL /day) | **3960** |
| **Potential body dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 1.13 |
| task duration (default value = 120 min/day) | 120 |
| potential amount of product on rest of body (µL /day) | 135.6 |
| clothing penetration (default value = 100%) | 100% |
| actual dermal deposit of product on rest of body (µL /day) | **135.6** |
| **Total dermal exposure to a.s. (mg)** *[in-use product contains 0.05 mg a.s./500 µL]* | 0.40956 |
| **Total systemic exposure to a.s. via dermal exposure** (mg a.s./person/day) [skin penetration (2%)] | **0.00819** |
| **Inhalation exposure** | **NEGLIGIBLE** |
| **Total systemic exposure to a.s. for a 60 kg adult** (mg a.s./kg bw/day) | **0.00013652** |

**according to HEEG opinion 2, the actual (in-glove) hand dermal exposure value is divided by 100 to estimate the potential dermal exposure.*

**Professional thermal fogging with hand held application equipment /with PPE**

| Exposure Description | 75th percentile |
|---|---|
| **Hand (in-glove) dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 0.33 |
| task duration (default value = 120 min/day) | 120 |
| product on hands (µL /day) | 39.6 |
| **Rest of body dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 1.13 |
| task duration (default value = 120 min/day) | 120 |
| potential amount of product on rest of body (µL /day) | 135.6 |
| clothing penetration (default value = 20%) | 20% |
| actual dermal deposit of product on rest of body (µL /day) | **27.12** |
| **Total dermal exposure to a.s. (mg)** *[in-use product contains 0.05 mg a.s./500 µL]* | 0.006672 |
| **Total systemic exposure to a.s. via dermal exposure** (mg a.s./person/day) [skin penetration (2%)] | **0.000133** |
| **Inhalation exposure** | **NEGLIGIBLE** |
| **Total systemic exposure to a.s. for a 60 kg adult** (mg a.s./kg bw/day) | **0.0000022** |

**Scenario 2b: Exposure during application of Deltamethrin EW 20 *via* thermal fogging with hand held or vehicle-mounted fogging equipment**

**Professional fogging with hand held or vehicle-mounted application equipment (ULV application)/no PPE**

| Exposure Description | 75th percentile |
|---|---|
| **Potential hand dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 4 * |
| task duration (default value = 120 min/day) | 120 |
| potential amount of product on rest of body (µL /day) | 480 |
| clothing penetration (default value = 100%) | 100% |
| actual dermal deposit of product on rest of body (µL /day) | **480** |
| **Potential body dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 21.8 |
| task duration (default value = 120 min/day) | 120 |
| potential amount of product on rest of body (µL /day) | 2616.0 |
| clothing penetration (default value = 100%) | 100% |
| actual dermal deposit of product on rest of body (µL /day) | **2616.0** |
| **Total dermal exposure to a.s. (mg)** *[in-use product contains 1 mg a.s./500 µL]* | 6.192 |
| **Total systemic exposure to a.s. via dermal exposure** (mg a.s./person/day) *[skin penetration (2%)]* | **0.12384** |
| **Inhalation exposure** | |
| indicative value (exposure to product *via* inhalation : µL in-use product/$m^3$) | 70.2 |
| breathing rate (default value = 1.25 $m^3$/h) | 1.25 |
| task duration (default value = 120 min/day) | 120 |
| volume of air inhaled over task duration ($m^3$) | 2.5 |
| amount of product inhaled during task (µL) | 175.5 |
| reduction factor for respiratory protection | 1 |
| actual inhalation exposure (µL) | 175.5 |
| **Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled** (mg a.s./person/day) *[in-use product contains 1 mg a.s./500 µL]* | **0.351** |
| **Total systemic exposure *via* skin and inhalation to a.s.** (mg a.s./person/day) | **0.47484** |
| **Total systemic exposure to a.s. for a 60 kg adult** (mg a.s./kg bw/day) | **0.007914** |

**according to HEEG opinion 2, the actual (in-glove) hand dermal exposure value is divided by 100 to estimate the potential dermal exposure.*

**Professional fogging with hand held or vehicle-mounted application equipment (ULV application) /with PPE**

| Exposure Description | 75th percentile |
|---|---|
| **Hand (in-glove) dermal exposure** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 0.04 |
| task duration (default value = 120 min/day) | 120 |
| product on hands (µL /day) | 4.8 |
| **Feet exposure inside shoes** | |
| indicative value (rate of deposition of product : µL in-use product/min) | 0.04 |
| task duration (default value = 180 min/day) | 120 |
| product on feet (µL /day) | 4.8 |
| **Rest of body dermal exposure** | |

| | |
|---|---|
| indicative value (rate of deposition of product : µL in-use product/min)<br>task duration (default value = 120 min/day)<br>potential amount of product on rest of body (µL /day)<br>clothing penetration (default value = 20%)<br>actual dermal deposit of product on rest of body (µL /day) | 21.8<br>120<br>2616<br>20%<br>523.2 |
| **Total dermal exposure to a.s. *via* hands, feet and body (mg)** *[in-use product contains 1 mg a.s./500 µL]* | 1.0464 |
| **Total systemic exposure to a.s. via dermal exposure** (mg a.s./person/day) *[skin penetration (2%)]* | **0.020928** |
| **Inhalation exposure** | |
| indicative value (exposure to product *via* inhalation : µL in-use product/$m^3$)<br>breathing rate (default value = 1.25 $m^3$/h):<br>task duration (default value = 120 min/day)<br>volume of air inhaled over task duration ($m^3$)<br>amount of product inhaled during task (µL)<br>reduction factor for respiratory protection (90% protection factor, i.e. A1 for organc gases – EN 14387)<br>actual inhalation exposure (µL) | 70.2<br>1.25<br>120<br>2.5<br>175.5<br>10%<br>17.55 |
| **Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled** (mg a.s./person/day) *[in-use product contains 1 mg a.s./500 µL]* | **0.0351** |
| Total systemic exposure *via* skin and inhalation to a.s. (mg a.s./person/day)<br>**Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)** | 0.056028<br>**0.0009338** |

**Primary exposure during cleaning of application equipment**

For assessing exposure during cleaning of the application equipment (both hand-held & vehicle mounted), the surrogate values from BEAT model database have been used.

**Cleaning of application equipment (either hand held and vehicle mounted fogger) / no PPE**

| Exposure Description | |
|---|---|
| **Hand** | |
| indicative value (rate of deposition of product : µL in-use product/min)<br>task duration (default value = 20 min/day)<br>product on hands (µL /day) | 35.87<br>20<br>717.4 |
| **Body** | |
| indicative value (rate of deposition of product : µL in-use product/min)<br>task duration (default value = 20 min/day)<br>potential amount of product on rest of body (µL /day)<br>clothing penetration (default value = 100%)<br>actual dermal deposit of product on rest of body (µL /day) | 19.28<br>20<br>385.6<br>100%<br>385.6 |
| **Total actual dermal exposure to product (µL /day)** | **1103** |
| **A) Hand-Held Equipment** | |
| Total dermal exposure to a.s. (mg) *[in-use product contains 0.05 mg a.s./500 µL]* | 0.1103 |
| Total systemic exposure to a.s. via dermal exposure (mg a.s./person/day) [skin penetration (2%)] | 0.002206 |
| Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day) | 0.0000368 |
| **B) Vehicle-mounted Equipment** | |
| Total dermal exposure to a.s. (mg) *[in-use product contains 1 mg a.s./500 µL]* | 2.206 |
| Total systemic exposure to a.s. via dermal exposure (mg a.s./person/day) [skin penetration (2%)] | 0.04412 |
| Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day) | 0.000735 |

**Cleaning of application equipment (either hand held and vehicle mounted fogger) / with PPE**

| **Exposure Description** | |
|---|---|
| Hand | |
| indicative value (rate of deposition of product : µL in-use product/min)<br>task duration (default value = 20 min/day)<br>product on hands (µL /day)<br>Gloves penetration (default value = 10%)<br>actual dermal deposit of product on hands (µL /day) | 35.87<br>20<br>717.4<br>10%<br>71.74 |
| Body | |
| indicative value (rate of deposition of product : µL in-use product/min)<br>task duration (default value = 20 min/day)<br>potential amount of product on rest of body (µL /day)<br>clothing penetration (default value = 100%)<br>actual dermal deposit of product on rest of body (µL /day) | 19.28<br>20<br>385.6<br>100%<br>385.6 |
| Total actual dermal exposure to product (µL /day) | 457.34 |
| **A) Hand-Held Equipment** | |
| Total dermal exposure to a.s. (mg) *[in-use product contains 0.05 mg a.s./500 µL]* | 0.045734 |
| Total systemic exposure to a.s. via dermal exposure (mg a.s./person/day) [skin penetration (2%)] | 0.00091468 |

| | |
|---|---|
| Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day) | 0.0000152 |
| **B) Vehicle-mounted Equipment** | |
| Total dermal exposure to a.s. (mg) *[in-use product contains 1 mg a.s./500 µL]* | 0.91468 |
| Total systemic exposure to a.s. via dermal exposure (mg a.s./person/day) [skin penetration (2%)] | 0.018294 |
| Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day) | 0.00030489 |

## 3.3 New information on the active substance

Any new information on the active substance deltametrhin considered in the assessment of the biocidal product Deltamethrin EW 20 is thoroughly presented in the sections above.

## 3.4 Residue behaviour

The intended use descriptions of the Deltamethrin-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions. No further data are required concerning the residue behaviour.

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

Summaries of efficacy studies are provided in tabular form in 2.2.5.5.

## 3.6 Confidential annex

See attached file.