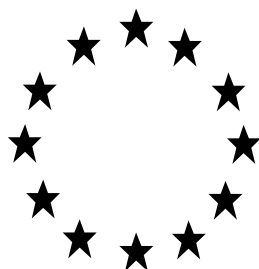


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



[CHIMIGET_CYPER]

Product type(s) [18]

[Cypermethrin]

Case Number in R4BP: [BC-QY059576-88]

Evaluating Competent Authority: [FR CA]

Date: [03/05/2024]

Table of Contents

| | |
|---|-----------|
| TABLE OF CONTENTS | 2 |
| 1 CONCLUSION | 7 |
| 2 ASSESSMENT REPORT | 17 |
| 2.1 SUMMARY OF THE PRODUCT ASSESSMENT | 17 |
| 2.1.1 <i>Administrative information</i> | 17 |
| 2.1.1.1 Identifier of the product family..... | 17 |
| 2.1.1.2 Authorisation holder..... | 17 |
| 2.1.1.3 Manufacturer(s) of the products of the family | 17 |
| 2.1.1.4 Manufacturer(s) of the active substance(s) | 17 |
| 2.1.2 <i>Product family composition and formulation</i> | 18 |
| 2.1.2.1 Identity of the active substance..... | 18 |
| 2.1.2.2 Candidate(s) for substitution | 18 |
| 2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family ² | 18 |
| 2.1.2.4 Information on technical equivalence | 19 |
| 2.1.2.5 Information on the substance(s) of concern..... | 19 |
| 2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family | 19 |
| 2.1.2.7 Type of formulation | 19 |
| 2.1.3 <i>Meta SPC 1 administrative information</i> | 20 |
| 2.1.3.1 Meta SPC identifier | 20 |
| 2.1.3.2 Suffix to the authorisation number..... | 20 |
| 2.1.3.3 Product type(s) | 20 |
| 2.1.4 <i>Meta SPC 1 composition</i> | 20 |
| 2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1..... | 20 |
| 2.1.4.2 Type(s) of formulation of the meta SPC 1..... | 20 |
| 2.1.5 <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1</i> 20 | 20 |
| 2.1.6 <i>Authorised use(s) of the META SPC 1</i> | 21 |
| 2.1.6.1 Use description | 21 |
| 2.1.6.2 Use-specific instructions for use | 22 |
| 2.1.6.3 Use-specific risk mitigation measures..... | 22 |
| 2.1.6.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 22 |
| 2.1.6.5 Where specific to the use, the instructions for safe disposal of the product and its packaging..... | 22 |
| 2.1.6.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 22 | 22 |
| 2.1.7 <i>General directions for use of the meta SPC 1</i> | 23 |
| 2.1.7.1 Instructions for use | 23 |
| 2.1.7.2 Risk mitigation measures | 23 |
| 2.1.7.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 23 |
| 2.1.7.4 Instructions for safe disposal of the product and its packaging..... | 23 |
| 2.1.7.5 Conditions of storage and shelf-life of the product under normal conditions of storage..... | 23 |
| 2.1.8 <i>Other information</i> | 24 |
| 2.1.9 <i>Trade name(s), authorisation number and specific composition of each individual product</i> | 24 |
| 2.1.10 <i>Meta SPC 2 administrative information</i> | 25 |
| 2.1.10.1 Meta SPC identifier..... | 25 |
| 2.1.10.2 Suffix to the authorisation number | 25 |
| 2.1.10.3 Product type(s) | 25 |
| 2.1.11 <i>Meta SPC 2 composition</i> | 25 |
| 2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 2 | 25 |
| 2.1.11.2 Type(s) of formulation of the meta SPC 2 | 25 |
| 2.1.12 <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2</i> 25 | 25 |

| | | |
|----------|--|----|
| 2.1.13 | <i>Authorised use(s) of the META SPC 2</i> | 26 |
| 2.1.13.1 | Use description..... | 26 |
| 2.1.13.2 | Use-specific instructions for use..... | 27 |
| 2.1.13.3 | Use-specific risk mitigation measures | 27 |
| 2.1.13.4 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 27 |
| 2.1.13.5 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 27 |
| 2.1.13.6 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 27 |
| 2.1.14 | <i>General directions for use of the meta SPC 2</i> | 28 |
| 2.1.14.1 | Instructions for use..... | 28 |
| 2.1.14.2 | Risk mitigation measures..... | 28 |
| 2.1.14.3 | Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 28 |
| 2.1.14.4 | Instructions for safe disposal of the product and its packaging | 28 |
| 2.1.14.5 | Conditions of storage and shelf-life of the product under normal conditions of storage | 28 |
| 2.1.15 | <i>Other information</i> | 29 |
| 2.1.16 | <i>Trade name(s), authorisation number and specific composition of each individual product</i> | 29 |
| 2.1.17 | <i>Meta SPC 3 administrative information</i> | 30 |
| 2.1.17.1 | Meta SPC identifier..... | 30 |
| 2.1.17.2 | Suffix to the authorisation number | 30 |
| 2.1.17.3 | Product type(s) | 30 |
| 2.1.18 | <i>Meta SPC 3 composition</i> | 31 |
| 2.1.18.1 | Qualitative and quantitative information on the composition of the meta SPC 3 | 31 |
| 2.1.18.2 | Type(s) of formulation of the meta SPC 3 | 31 |
| 2.1.19 | <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3</i> 31 | 31 |
| 2.1.20 | <i>Authorised use(s) of the META SPC 3</i> | 32 |
| 2.1.20.1 | Use description..... | 32 |
| 2.1.20.2 | Use-specific instructions for use..... | 33 |
| 2.1.20.3 | Use-specific risk mitigation measures | 33 |
| 2.1.20.4 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 33 |
| 2.1.20.5 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 33 |
| 2.1.20.6 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 33 |
| 2.1.21 | <i>General directions for use of the meta SPC 3</i> | 33 |
| 2.1.21.1 | Instructions for use..... | 33 |
| 2.1.21.2 | Risk mitigation measures..... | 33 |
| 2.1.21.3 | Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 34 |
| 2.1.21.4 | Instructions for safe disposal of the product and its packaging | 34 |
| 2.1.21.5 | Conditions of storage and shelf-life of the product under normal conditions of storage | 34 |
| 2.1.22 | <i>Other information</i> | 34 |
| 2.1.23 | <i>Trade name(s), authorisation number and specific composition of each individual product</i> | 35 |
| 2.1.24 | <i>Meta SPC 5 administrative information</i> | 36 |
| 2.1.24.1 | Meta SPC identifier..... | 36 |
| 2.1.24.2 | Suffix to the authorisation number | 36 |
| 2.1.24.3 | Product type(s) | 36 |
| 2.1.25 | <i>Meta SPC 5 composition</i> | 37 |
| 2.1.25.1 | Qualitative and quantitative information on the composition of the meta SPC 5 | 37 |
| 2.1.25.2 | Type(s) of formulation of the meta SPC 5 | 37 |
| 2.1.26 | <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5</i> 37 | 37 |
| 2.1.27 | <i>Authorised use(s) of the META SPC 5</i> | 38 |
| 2.1.27.1 | Use description..... | 38 |
| 2.1.27.2 | Use-specific instructions for use..... | 39 |
| 2.1.27.3 | Use-specific risk mitigation measures | 39 |

| | | |
|-----------|--|----|
| 2.1.27.4 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 39 |
| 2.1.27.5 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 39 |
| 2.1.27.6 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 39 |
| 2.1.28 | <i>General directions for use of the meta SPC 5.....</i> | 40 |
| 2.1.28.1 | Instructions for use..... | 40 |
| 2.1.28.2 | Risk mitigation measures..... | 40 |
| 2.1.28.3 | Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 40 |
| 2.1.28.4 | Instructions for safe disposal of the product and its packaging | 40 |
| 2.1.28.5 | Conditions of storage and shelf-life of the product under normal conditions of storage | 40 |
| 2.1.29 | <i>Other information.....</i> | 41 |
| 2.1.30 | <i>Trade name(s), authorisation number and specific composition of each individual product.....</i> | 41 |
| 2.1.31 | <i>Meta SPC 6 administrative information</i> | 41 |
| 2.1.31.1 | Meta SPC identifier..... | 41 |
| 2.1.31.2 | Suffix to the authorisation number | 42 |
| 2.1.31.3 | Product type(s) | 42 |
| 2.1.32 | <i>Meta SPC 6 composition</i> | 42 |
| 2.1.32.1 | Qualitative and quantitative information on the composition of the meta SPC 6 | 42 |
| 2.1.32.2 | Type(s) of formulation of the meta SPC 6 | 42 |
| 2.1.33 | <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6</i> 42 | 42 |
| 2.1.34 | <i>Authorised use(s) of the META SPC 6.....</i> | 43 |
| 2.1.34.1 | Use description..... | 43 |
| 2.1.34.2 | Use-specific instructions for use..... | 44 |
| 2.1.34.3 | Use-specific risk mitigation measures | 44 |
| 2.1.34.4 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 44 |
| 2.1.34.5 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 44 |
| 2.1.34.6 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 44 |
| 2.1.34.7 | Use description..... | 44 |
| 2.1.34.8 | Use-specific instructions for use..... | 45 |
| 2.1.34.9 | Use-specific risk mitigation measures | 45 |
| 2.1.34.10 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 45 |
| 2.1.34.11 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 45 |
| 2.1.34.12 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 45 |
| 2.1.35 | <i>General directions for use of the meta SPC 6.....</i> | 45 |
| 2.1.35.1 | Instructions for use..... | 45 |
| 2.1.35.2 | Risk mitigation measures..... | 46 |
| 2.1.35.3 | Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 46 |
| 2.1.35.4 | Instructions for safe disposal of the product and its packaging | 46 |
| 2.1.35.5 | Conditions of storage and shelf-life of the product under normal conditions of storage | 46 |
| 2.1.36 | <i>Other information.....</i> | 46 |
| 2.1.37 | <i>Trade name(s), authorisation number and specific composition of each individual product.....</i> | 47 |
| 2.1.38 | <i>Meta SPC 7 administrative information</i> | 47 |
| 2.1.38.1 | Meta SPC identifier..... | 47 |
| 2.1.38.2 | Suffix to the authorisation number | 48 |
| 2.1.38.3 | Product type(s) | 48 |
| 2.1.39 | <i>Meta SPC 7 composition</i> | 48 |
| 2.1.39.1 | Qualitative and quantitative information on the composition of the meta SPC 7 | 48 |
| 2.1.39.2 | Type(s) of formulation of the meta SPC 7 | 48 |
| 2.1.40 | <i>Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7</i> 48 | 48 |

| | | |
|-----------|--|-----|
| 2.1.41 | <i>Authorised use(s) of the META SPC 7</i> | 49 |
| 2.1.41.1 | Use description..... | 49 |
| 2.1.41.2 | Use-specific instructions for use..... | 50 |
| 2.1.41.3 | Use-specific risk mitigation measures | 50 |
| 2.1.41.4 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 50 |
| 2.1.41.5 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 50 |
| 2.1.41.6 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 50 |
| 2.1.41.7 | Use description..... | 50 |
| 2.1.41.8 | Use-specific instructions for use..... | 51 |
| 2.1.41.9 | Use-specific risk mitigation measures | 51 |
| 2.1.41.10 | Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 51 |
| 2.1.41.11 | Where specific to the use, the instructions for safe disposal of the product and its packaging | 51 |
| 2.1.41.12 | Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage..... | 51 |
| 2.1.42 | <i>General directions for use of the meta SPC 7</i> | 52 |
| 2.1.42.1 | Instructions for use..... | 52 |
| 2.1.42.2 | Risk mitigation measures..... | 52 |
| 2.1.42.3 | Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment..... | 52 |
| 2.1.42.4 | Instructions for safe disposal of the product and its packaging | 52 |
| 2.1.42.5 | Conditions of storage and shelf-life of the product under normal conditions of storage | 52 |
| 2.1.43 | <i>Other information</i> | 52 |
| 2.1.44 | <i>Trade name(s), authorisation number and specific composition of each individual product</i> | 53 |
| 2.1.45 | <i>Packaging of the biocidal product</i> | 53 |
| 2.1.46 | <i>Documentation</i> | 54 |
| 2.1.46.1 | Data submitted in relation to product application | 54 |
| 2.1.46.2 | Access to documentation | 54 |
| 2.2 | ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY..... | 55 |
| 2.2.1 | <i>Intended use(s) as applied for by the applicant</i> | 55 |
| 2.2.2 | <i>Physical, chemical and technical properties</i> | 61 |
| 2.2.2.1 | <i>Physical, chemical and technical properties – Meta SPC 1, Meta SPC 2 and Meta SPC6</i> | 61 |
| 2.2.2.2 | <i>Physical, chemical and technical properties – Meta SPC 3</i> | 71 |
| 2.2.2.3 | <i>Physical, chemical and technical properties – Meta SPC 4</i> | 80 |
| 2.2.2.4 | <i>Physical, chemical and technical properties – Meta SPC 5</i> | 81 |
| 2.2.2.5 | <i>Physical, chemical and technical properties – Meta SPC 7</i> | 88 |
| 2.2.3 | <i>Physical hazards and respective characteristics</i> | 98 |
| 2.2.4 | <i>Methods for detection and identification</i> | 108 |
| 2.2.5 | <i>Efficacy against target organisms</i> | 113 |
| 2.2.5.1 | Function and field of use..... | 113 |
| 2.2.5.2 | Organisms to be controlled and products, organisms or objects to be protected | 114 |
| 2.2.5.3 | Effects on target organisms, including unacceptable suffering | 115 |
| 2.2.5.4 | Mode of action, including time delay | 115 |
| 2.2.5.5 | Efficacy data..... | 115 |
| 2.2.5.6 | Occurrence of resistance and resistance management | 129 |
| 2.2.5.7 | Known limitations | 129 |
| 2.2.5.8 | Evaluation of the label claims | 129 |
| 2.2.5.9 | Relevant information if the product is intended to be authorised for use with other biocidal product(s). | 129 |
| 2.2.6 | <i>Risk assessment for human health</i> | 130 |
| 2.2.6.1 | Assessment of effects on Human Health | 130 |
| 2.2.6.2 | Exposure assessment and risk characterisation for Human health | 133 |
| 2.2.7 | <i>Risk assessment for animal health</i> | 162 |
| 2.2.8 | <i>Risk assessment for the environment</i> | 162 |
| 2.2.8.1 | Effects assessment on the environment..... | 163 |
| 2.2.8.2 | Exposure assessment..... | 166 |
| 2.2.8.3 | Risk characterisation..... | 183 |

| | | |
|----------|---|------------|
| 2.2.9 | <i>Measures to protect man, animals and the environment</i> | 192 |
| 2.2.10 | <i>Assessment of a combination of biocidal products</i> | 192 |
| 3 | ANNEXES | 193 |
| 3.1 | LIST OF STUDIES FOR THE BIOCIDAL PRODUCT FAMILY | 193 |
| 3.2 | OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS | 208 |
| 3.3 | CONFIDENTIAL ANNEX..... | 208 |

Changes history table

| Applicati on type | refMS/ eCA | Case number in the refMS | Decision date | Assessment carried out (i.e. first authorisation / amendment / renewal) |
|------------------------------|-----------------------|-------------------------------------|--------------------------|---|
| NA-APP | FR | BC-QY059576-88 | 06.12.2023 | <i>Initial assessment</i> |
| NA-AAT | FR | BC-MS099113-16 | 23.07.2024 | <i>Amendement according to article 48 of the BPR: addition of target organisms species in the SPC</i> |

1 CONCLUSION

The product family CHIMIGET_CYPER is a family of product type 18 (TP18: insecticide) containing between 0.22 and 10.87% w/w technical cypermethrin cis/trans 40/60. Biocidal products are intended to be used by non-professionals, indoor or outdoor, against flying and crawling insects, wasps and hornets.

The family is composed of 7 Meta SPCs:

- Meta SPC 1 product is a ready-to-use aerosol insecticide against wasps and hornets. It is used as direct spraying on insects, outdoor.
- Meta SPC 2 products are ready-to-use aerosol insecticides against crawling and flying insects. They are used as direct spraying on insects outdoor.
- Meta SPC 3 products are ready-to-use one-shot aerosol insecticides against crawling and flying insects. They are used as space treatment, indoor.
- Meta SPC 4 products are ready-to-use trigger spray insecticides against crawling and flying insects. They are used as surface spray under buildings.
- Meta SPC 5 product is a concentrate insecticide against crawling and flying insects. After dilution in water, it is used as surface application, outdoor (under buildings or with a targeted application in cracks and crevices)
- Meta SPC 6 product is a ready-to-use aerosol insecticides against crawling and flying insects. It is used as direct spraying on insects and surface application, indoor and outdoor (by spraying directly on insects or by spraying as target spot in cracks and crevices)
- Meta SPC 7 product is a ready-to-use trigger spray insecticide against crawling and flying insects. It is used as surface application, outdoor (targeted in cracks and crevices or surface spraying under buildings)

Conclusion of the physico-chemical and technical properties

The physico-chemical properties of the family of biocidal products CHIMIGET_CYPER have been described and considered acceptable in the conditions of use detailed in the SPC.

All meta SPCs and products are stable at ambient temperature during 2 years, except for meta SPC 7 for which the shelf-life is set at 1 year due to a leak was observed after 24 months.

All meta SPCs are stable during 8 weeks at 40°C. A mitigation measure: store the product at temperature below 40°C should be added on the label.

For meta SPC 5, as the storage stability at low temperature is not complete, a mitigation measure should be added on the label : protect from frost.

The meta SPCs 1, 2, 3 and 6 are classified Flam, aerosol 1, H222 (extremely flammable aerosol) and H229 (pressurised container: may burst if heated).

The meta SPCs 4, 5 and 7 are not classified for physical hazard properties.

Analytical methods for the determination of the active substance cypermethrin have been developed and validated for this determination in the family of biocidal products CHIMIGET_CYPER.

Conclusion on efficacy

French competent authorities (FR CA) assessed that the family CHIMIGET_CYPER, separated in 7 META-SPC has shown a sufficient efficacy as following:

- **Meta SPC 1:**

The efficacy of the product is demonstrated when used by direct spraying against wasp (*Vespula sp.*, adults), European hornet (*Vespa crabro*, adults) and Asian hornet (*Vespa velutina*, adults) at the application rate of 17.5 g of product (1 second spray) after 1 hour.
- **Meta SPC 2:**

The efficacy of the products is demonstrated when used by direct spraying against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 2.5 g of product (1 second spray) after 1 hour.
- **Meta SPC 3:**

The efficacy of the products is demonstrated when used by fogging against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta Americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 1 mL product / m³ (e.g. a can of 50 mL in a room up to 50 m³) with an exposure time of 4 hours, after 24 hours.
- **Meta SPC 4:**

The efficacy of the products is demonstrated when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m², up to 4 months (time delay: between 24h and 72h).
- **Meta SPC 5:**
 - The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m² (after dilution at 2% v/v), up to 4 months (time delay: between 24h and 72h).
 - The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*), at the application rate of 20 mL product / m² (after dilution between 2% and 8% v/v), up to 4 months (time delay: between 24h and 72h).

- **Meta SPC 6:**

- The efficacy of the products is demonstrated when used by direct spraying against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 2.5 g of product (1 second spray), after 1 hour.
- The efficacy of the products is demonstrated when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*) and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*), at the application rate of 17 mL product / m² (7 seconds spray/m²), up to 4 months (time delay: between 24h and 72h).

- **Meta SPC 7:**

- The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m², up to 4 months.
- The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*) and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella*, *Periplaneta americana*) at the application rate of 20 mL product / m², up to 4 months (time delay: between 24h and 72h).

Conclusion on Human Health

For the family CHIMIGET_CYPER, the risk is considered acceptable for non-professional users and the general public for meta-SPC 1, 2, 3, 4, 5, 6 (outdoor application) and 7, considering a qualitative and quantitative risk assessment, with the application of risk mitigation measures (RMM) listed in the SPC.

For meta-SPC 6 (indoor application in cracks and crevices), the risk is not considered acceptable.

Conclusion risk for consumers via residues in food

Considering the uses, food, or feed contamination is not expected. Therefore, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible, and no dietary risk assessment has been performed. Nevertheless, the following risk mitigation measures are added to prevent any dietary exposure:

For META SPC 1, 2, 4, 5, 6 & 7: Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

For META SPC 3 only:

- Do not use in places where food or feed is stored, prepared or eaten.
- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

Conclusion for Environment

The risk assessment has been conducted for the active substance only. No substance of concern has been identified for the environment.

The conclusions of the risk assessment is presented in the table below :

| Meta-SPC | Use | Indoor/Outdoor | Conclusion | RMM/remarks |
|------------|---|----------------|--|---|
| Meta SPC 1 | Use#1 - AE WH - wasps and hornets aerosol - Direct spraying on insects | Outdoor | Acceptable with RMM | Proposed RMM: Do not use on bare soil |
| Meta SPC 2 | Use#1 - AE FC – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - Direct spraying on insects | Outdoor | Acceptable with RMM | Proposed RMM: Do not use on bare soil |
| Meta SPC 3 | Use # 1 – OS – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - space treatment with a one-shot aerosol | Indoor | Acceptable with RMM (leading to no release to the environment) | Proposed RMMs: - The product is only for indoor use and to be strictly applied in non wet-cleaned premises (cellars, basements, crawl spaces, garages, attics, barns, sheds) - Do not use where the biocidal product is likely to be discharged to a wastewater treatment plant and/or surface water. - Dry clean (broom or vacuum cleaner) treated area and dispose of residues to hazardous solid waste in order to prevent releases to water. |
| Meta SPC 4 | Use # 1 – RTU – crawling insects (adults) including | Outdoor | Not acceptable | Unacceptable risks for the terrestrial compartment |

| | | | | |
|------------|---|---------|--|---|
| | cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - under buildings | | | |
| Meta SPC 5 | Use # 1 – EC – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - Target surface spraying as spots application or in cracks and crevices (Dil 2%) | Outdoor | Not acceptable | A dilution of 2% would require to measure 0.8 ml to dilute the product (considering the targeted application restricted to small surfaces of around 2 m ²) and no device is provided to measure such a quantity. Therefore, it is not feasible for a non-professionnel. |
| | Use # 2 – EC – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - surface spray - under buildings | Outdoor | Not acceptable with dilution of 8% <u>Acceptable with dilution of 2%</u> | Unacceptable risks for the terrestrial compartment with a dilution of 8% |
| Meta SPC 6 | Use # 1 – AE FC1 – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - | Indoor | Not acceptable | Unacceptable risks for the aquatic compartment |
| | | Outdoor | Acceptable | |

| | | | | |
|------------|--|---------|-----------------------|---|
| | direct spraying on insects | | | |
| | Use # 2 – AE FC1 – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - Target surface spraying as spots application or in cracks and crevices | Indoor | Not acceptable | Unacceptable risks for the aquatic compartment |
| | | Outdoor | Acceptable with RMM | Proposed RMM: Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. |
| Meta SPC 7 | Use # 1 – RTU1 – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - Target surface spraying as spots application or in cracks and crevices | Outdoor | Acceptable with RMM | Proposed RMM Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. |
| | Use # 2 – RTU1 – crawling insects (adults) including cockroaches (<i>B. germanica</i> and <i>P. americana</i>) and flying insects (adults) including mosquitoes, (<i>Culex sp.</i>), flies (<i>M. domestica</i>) and wasps (<i>Vespula sp.</i>) - under buildings | Outdoor | Acceptable | |

Overall conclusion

The overall conclusion of the evaluation is that the biocidal product family CHIMIGET_CYPER, does meet the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012, except for some uses, as detailed in the table here below.

| Meta SPC | Target organisms | Doses | Condition of use | Conclusions |
|-----------------|--|------------------------|--|---|
| 1 | Wasp (<i>Vespula sp.</i>) European hornet (<i>Vespa crabro</i>) Asian hornet (<i>Vespa velutina</i>) Adult | 1 sec spray (17,5g) | Direct spraying Outdoor General public | Acceptable |
| 2 | Crawling insects including cockroaches (<i>Blattella germanica</i> , <i>Periplaneta americana</i>) Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Adult | 1 sec spray (2,5g) | Direct spraying Outdoor General public | Acceptable |
| 3 | Crawling insects Including cockroaches (<i>Blattella germanica</i> , <i>Periplaneta americana</i>) Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Adult | 1 mL/m ³ | One-shot aerosol Indoor General public | Acceptable |
| 4 | Crawling insects including cockroaches (<i>Blattella germanica</i> , | 20 mL/m ² | Spraying surfaces under buildings Outdoor General public | Not acceptable Unacceptable risks for the terrestrial compartment |

| | | | | |
|---|---|--|--|--|
| | <p><i>Periplaneta americana</i></p> <p>Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>)</p> <p>Adult</p> | | | |
| 5 | <p>Crawling insects including cockroaches (<i>Blattella germanica</i>, <i>Periplaneta americana</i>)</p> | 20 mL/m ² ou 4 mL/m after 2 % v/v dilution in water | Target surface spraying as spots application or in cracks and crevices Outdoor General public | Not acceptable The general public cannot dilute the product properly |
| | <p>Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>)</p> <p>Adult</p> | 20 mL/m ² after 2-8% v/v dilution in water | Spraying surfaces under buildings Outdoor General public | Acceptable 2% dilution only |
| 6 | <p>Crawling insects including cockroaches (<i>Blattella germanica</i>, <i>Periplaneta americana</i>)</p> | 1 sec spray (2,5g) | Direct spraying Indoor and Outdoor General public | Not acceptable: - Unacceptable risks for the aquatic compartment with indoor application |
| | <p>Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>)</p> | 1 sec spray (2,5g) | Direct spraying Outdoor General public | Acceptable |
| | <p>Adult</p> | 7 sec spray/m ² (17,5g/m ²) | Target surface spraying as spots application or in cracks and crevices Indoor and Outdoor General public | Not acceptable: - Unacceptable risks for the health of the general public when used indoors in cracks and crevices - Unacceptable risks for the aquatic compartment |

| | | | | |
|---|--|--|---|-------------------------|
| | | | | with indoor application |
| | | 7 sec spray/m ² (17,5g/m ²) | Target surface spraying as spots application or in cracks and crevices Outdoor General public | Acceptable |
| 7 | Crawling insects including cockroaches (<i>Blattella germanica</i> , <i>Periplaneta americana</i>) | 20 mL/m ² | Target surface spraying as spots application or in cracks and crevices Outdoor General public | Acceptable |
| | Flying insects including Mosquitoes (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Adult | 20 mL/m ² | Spraying surfaces under buildings Outdoor General public | Acceptable |

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

| Identifier | Country (if relevant) |
|----------------|-----------------------|
| CHIMIGET_CYPER | |

2.1.1.2 Authorisation holder

| | | |
|---|---------------------|---|
| Name and address of the authorisation holder | Name | Chimiget |
| | Address | Lieu-dit-Sibilot - CD6 13480 Cabriès France |
| Authorisation number | FR-2023-0068 | |
| Date of the authorisation | 06/12/2023 | |
| Expiry date of the authorisation | 05/12/2033 | |

2.1.1.3 Manufacturer(s) of the products of the family

| | |
|--|--|
| Name of manufacturer | BFC |
| Address of manufacturer | 11, rue de l'Huisne 61110 Rémalard-en-Perche, France |
| Location of manufacturing sites | 11, rue de l'Huisne 61110 Rémalard-en-Perche, France |

| | |
|--|---|
| Name of manufacturer | IGET CHIMIE |
| Address of manufacturer | Lieu-dit-Sibilot – CD6 13480 Cabriès France |
| Location of manufacturing sites | Lieu-dit-Sibilot – CD6 13480 Cabriès France |

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

| | |
|-----------------------------|--|
| Active substance | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) |
| Name of manufacturer | Tagros Chemicals India Private Limited |

| | |
|--|--|
| Address of manufacturer | Jhaver Centre, Raja Annamalai Building IVth Floor, 72 Marshall Road, Egmore, 6000 008 Chennai India |
| Location of manufacturing sites | A-4/1&2, Sipcot Industrial Complex, Pachayankuppam, Cuddalore, 607 005 Tamilnadu India |

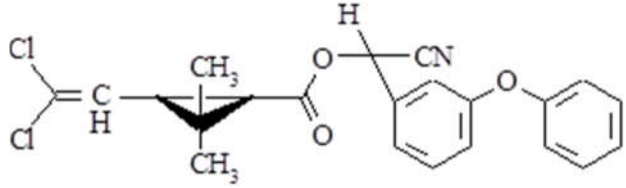
2.1.2 Product family composition and formulation

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

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

Yes
No

2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|--|---|
| ISO name | Cypermethrin, Cypermethrin cis:trans/40:60 |
| IUPAC or EC name | (RS)- α -cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate |
| EC number | 257-842-9 |
| CAS number | 52315-07-8 |
| Index number in Annex VI of CLP | 607-421-00-4 |
| Minimum purity / content | $\geq 92\%$ w/w |
| Structural formula |  |

2.1.2.2 Candidate(s) for substitution

Cypermethrin is not a candidate for substitution in accordance with Article 10 of the BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family²

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|--|---|----------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | (RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.22 | 10.87 |
| Ethanol | | Non-active substance | 64-17-5 | | 0.0 | 29.78 |

2.1.2.4 Information on technical equivalence

A technical equivalence application (BC- MS050669-06) has been submitted at ECHA to demonstrate the equivalence of the source used in this dossier and the source of the original active substance.

2.1.2.5 Information on the substance(s) of concern

The family CHIMIGET_CYPER contains one substance of concern for Human Health.

Please see the confidential annex for further details.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family

The biocidal product contains the active substance cypermethrin which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

Please refer to the Confidential annex for further details.

2.1.2.7 Type of formulation

| |
|---|
| AE - Aerosol dispenser AL - Any other liquid SL - Soluble concentrate |
|---|

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.1.3 Meta SPC 1 administrative information

2.1.3.1 Meta SPC identifier

| | |
|-----------------------|-----------------|
| Identification | Meta SPC1_AE WH |
|-----------------------|-----------------|

2.1.3.2 Suffix to the authorisation number

| | |
|--------|-------------------|
| Number | META_SPC_SUFFIX_1 |
|--------|-------------------|

2.1.3.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.4 Meta SPC 1 composition

2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|--|--|----------------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 | 0.54 |
| Ethanol | | Non-active substance | 64-17-5 | | 29.46 | 29.46 |

2.1.4.2 Type(s) of formulation of the meta SPC 1

| |
|------------------------|
| AE - Aerosol dispenser |
|------------------------|

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

| Classification | |
|--------------------------|--|
| Hazard category | Flammable Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. P273: Avoid release to the environment P391: Collect spillage P403: Store in a well-ventilated place P501: Dispose of contents/container according to local regulation |
| Note | |

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1 – **Wasps and hornets aerosol – non professional users**

| | |
|---|----|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | |

| | |
|---|---|
| Target organism(s) (including development stage) | Wasp (<i>Vespula sp.</i>) European hornet (<i>Vespa crabro</i>) Asian hornet (<i>Vespa velutina</i>) Development stage: adults |
| Field(s) of use | Outdoor |
| Application method(s) | Spraying Direct spraying on insects |
| Application rate(s) and frequency | 17.5 g of product (1 second spraying) |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Aerosol metal can without internal varnish valve type FL 500 to 750 mL |

2.1.6.2 Use-specific instructions for use

-

2.1.6.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- Comply with the instructions for use.
- The user should be aware that a delay of up to 1 hour may be encountered before death.
- Inform the registration holder if the treatment is ineffective.

2.1.7.2 Risk mitigation measures

- Wash hands after use.
- Do not spray towards people and non target animals.
- Do not use on bare soil.
- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

- If medical advice is needed, have product container or label at hand.
- IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.7.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated room.
- Pressurized container: May burst if heated. Do not pierce or burn, even after use. Protect from sunlight.
- Do not store at temperature > 40°C.
- Keep packaging away from sources of heat, sparks and open flame.

- Shelf-life: 24 months.
- Keep out of reach of children and non-target animals/pets.

2.1.8 Other information

- This biocidal product contains cypermethrin which is dangerous to bees.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

2.1.9 Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | AE WH PARASECT TORNADE C IG AEROJET C VESPA TURBO CIT VESPA TURBO L'ELFE INSECTICIDE GUÊPES FRELONS INSECTICIDE ANTI GUÊPES-FRELONS BLASTOR INSECTICIDE GUÊPES & FRELONS F-A97 INS ALGI-INSECT ANTI GUEPES/FRELONS CY CONTROL AEROSOL CY ACTO / MORTIS GUÊPES - FRELONS SUBITO GUEPES ET FRELONS CHOC SUBITO AEROSOL ANTI GUEPES ET FRELONS SUBITO ANTI-GUEPES ET FRELONS LONGUE PORTEE SUBITO ANTI-GUEPES ET FRELONS JET 6 METRES 123 MOUSTIQUES AEROSOL ANTI-GUEPES ET FRELONS 1015VGB INSECTICHOC DP CYP INSECTI-SHOT CYP KAP4HOME TORNADE | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 |

| | | | | | |
|---------|--|-----------|---------|--|-------|
| Ethanol | | Formulant | 64-17-5 | | 29.46 |
|---------|--|-----------|---------|--|-------|

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.1.10 Meta SPC 2 administrative information

2.1.10.1 Meta SPC identifier

| | |
|-----------------------|-----------------|
| Identification | Meta SPC2_AE FC |
|-----------------------|-----------------|

2.1.10.2 Suffix to the authorisation number

| | |
|---------------|-------------------|
| Number | META_SPC_SUFFIX_2 |
|---------------|-------------------|

2.1.10.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.11 Meta SPC 2 composition

2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 2

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|--|---|----------------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 | 0.87 |
| Ethanol | | Formulant | 64-17-5 | | 29.13 | 29.46 |

2.1.11.2 Type(s) of formulation of the meta SPC 2

| |
|------------------------|
| AE - Aerosol dispenser |
|------------------------|

2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

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

| Classification | |
|--------------------------|--|
| Hazard category | Flammable Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after use. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P410+P412: Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. P273: Avoid release to the environment P391: Collect spillage P403: Store in a well-ventilated place P501: Dispose of contents/container according to local regulation |
| Note | |

2.1.13 Authorised use(s) of the META SPC 2

2.1.13.1 Use description

Table 2. Use # 1 –Flying and crawling insects - direct spray – non professional users

| | |
|---------------------|----|
| Product Type | 18 |
|---------------------|----|

| | |
|---|--|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Crawling insects including Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta americana</i>) Flying insects including Common house mosquito (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Development stage: adults |
| Field of use | Outdoor |
| Application method(s) | Spraying Direct spraying on insects |
| Application rate(s) and frequency | 2.5 g of product (1 second spraying) |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | Aerosol metal can without internal varnish valve VP 195 150 to 750 mL |

2.1.13.2 Use-specific instructions for use

-

2.1.13.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.14 General directions for use of the meta SPC 2

2.1.14.1 Instructions for use

- Comply with the instructions for use.
- The user should be aware that a delay of up to 1 hour may be encountered before death.
- Inform the registration holder if the treatment is ineffective.

2.1.14.2 Risk mitigation measures

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Wash hands after use.
- Do not use on bare soil.
- Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

- If medical advice is needed, have product container or label at hand.
- IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.14.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated room.
- Pressurized container: May burst if heated. Do not pierce or burn, even after use. Protect from sunlight .
- Do not store at temperature > 40°C.
- Keep packaging away from sources of heat, sparks and open flame.
- Shelf-life: 24 months.
- Keep out of reach of children and non-target animals/pets.

2.1.15 Other information

| |
|---|
| This biocidal product contains cypermethrin which is dangerous to bees. |
|---|

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**2.1.16** Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | AE FC2 PARASECT AC5 L'ELFE INSECTICIDE SPECIAL RAMPANTS + L'ELFE INSECTICIDE SPECIAL VOLANTS - RAMPANTS + L'ELFE INSECTICIDE SPECIAL VOLANTS + BLASTOR INSECTICIDE SPECIAL RAMPANTS + BLASTOR INSECTICIDE VOLANTS - RAMPANTS + BLASTOR INSECTICIDE SPECIAL VOLANTS + INSECTICIDE ANTI-RAMPANTS + INSECTICIDE ANTI-VOLANTS + F-A87 INS ACTO / MORTIS RAMPANTS ACTO / MORTIS ARAIGNÉES ACTO / MORTIS FOURMIS ACTO / MORTIS MOUCHES SUBITO ANTI INSECTES VOLANTS SUBITO ANTI INSECTES RAMPANTS 1014E KAP4HOME AC5 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 |
| ethanol | | | 64-17-5 | | 29.46 |
| Trade name(s) | AE FC3 PARASECT AC8 ACTO / MORTIS VOLANTS RAMPANTS | | | | |

| | | | | | |
|--|---|----------------------------|-------------------|------------------|--------------------|
| | SUBITO SPECIAL INSECTES RESISTANTS SUBITO AEROSOL SPECIAL INSECTES RESISTANTS SUBITO AEROSOL ANTI CAFARDS 1014C INSECTIHOOC A CYP NETINSECT CYP RAYO-INSECTE PLUS KAP4HOME AC8 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.87 |
| ethanol | | | 64-17-5 | | 29.13 |

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.17 Meta SPC 3 administrative information

2.1.17.1 Meta SPC identifier

| | |
|-----------------------|--------------|
| Identification | Meta SPC3_OS |
|-----------------------|--------------|

2.1.17.2 Suffix to the authorisation number

| | |
|--------|-------------------|
| Number | META_SPC_SUFFIX_3 |
|--------|-------------------|

2.1.17.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.18 Meta SPC 3 composition**2.1.18.1** Qualitative and quantitative information on the composition of the meta SPC 3

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|----------------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 | 0.87 |
| Ethanol | | Formulant | 64-17-5 | | 19.13 | 19.46 |

2.1.18.2 Type(s) of formulation of the meta SPC 3

| |
|------------------------|
| AE - Aerosol dispenser |
|------------------------|

2.1.19 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|-------------------|--|
| Hazard category | Flammable Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H222 Extremely flammable aerosol H229 Pressurised container: May burst if heated H319: Causes serious eye irritation H410: Very toxic to aquatic life with long lasting effects |

| Classification | |
|--------------------------|--|
| Precautionary statements | <p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P211: Do not spray on an open flame or other ignition source.</p> <p>P251: Do not pierce or burn, even after use.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313: If eye irritation persists: Get medical advice/attention.</p> <p>P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.</p> <p>P273: Avoid release to the environment</p> <p>P391: Collect spillage</p> <p>P403: Store in a well-ventilated place</p> <p>P501: Dispose of contents/container according to local regulation</p> |
| Note | |

2.1.20 Authorised use(s) of the META SPC 3

2.1.20.1 Use description

Table 4. Use # 1 –Flying and crawling insects – one-shot aerosol – non professional users

| | |
|---|---|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | <p>One-shot aerosol insecticide against flying and crawling insects</p> <p>Use in cellars, basements, crawl spaces, garages, boxes, attics, barns, sheds or any other premises which are not wet-cleaned.</p> |
| Target organism (including development stage) | <p>Crawling insects including</p> <p>Cockroaches:</p> <p>German cockroaches (<i>Blattella germanica</i>)</p> <p>American cockroaches (<i>Periplaneta americana</i>)</p> <p>Flying insects including</p> <p>Common house mosquito (<i>Culex sp.</i>)</p> <p>House fly (<i>Musca domestica</i>)</p> <p>Wasp (<i>Vespula sp.</i>)</p> <p>Development stage: adults</p> |
| Field of use | Indoor |
| Application method(s) | Fogging with a one-shot aerosol |

| | |
|--|---|
| Application rate(s) and frequency | 1 mL /m ³ (e.g. a can of 50 mL in a room up to 50 m ³) Exposure time: 4 hours |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | Aerosol metal can without internal varnish valve PV 50 to 750 mL |

2.1.20.2 Use-specific instructions for use

-

2.1.20.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.21 General directions for use of the meta SPC 3

2.1.21.1 Instructions for use

- Comply with the instructions for use.
- Apply only on infested area.
- Avoid continuous use of the product.
- Inform the registration holder if the treatment is ineffective.
- Ventilate after re-entering the room.

2.1.21.2 Risk mitigation measures

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Do not use in places where food or feed is stored, prepared or eaten.
- Wash hands after use.
- Leave the room directly after spraying process is triggered.
- Do not enter the room before a waiting time of 4h.
- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.
- The product must be applied at the claimed application rate of 1 ml/m³.

- The product is only for indoor use and to be strictly applied in non wet-cleaned premises (cellars, basements, crawl spaces, garages, boxes, attics, barns, sheds)
- Do not use where release to drains (sewer) and/or surface water cannot be prevented.
- Do not use where the biocidal product can be discharged to municipal sewage treatment plant.
- Dry clean (broom or vacuum cleaner) treated area and dispose of residues to hazardous solid waste in order to prevent releases to water.

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

- If medical advice is needed, have product container or label at hand.
- IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.21.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated room.
- Pressurized container: May burst if heated. Do not pierce or burn, even after use. Protect from sunlight.
- Do not store at temperature > 40°C.
- Keep packaging away from sources of heat, sparks and open flame.
- Shelf-life: 24 months.
- Keep out of reach of children and non-target animals/pets.

2.1.22 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

2.1.23 Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | OS1 ANTISECT C5 IG CYP OS5 L'ELFE INSECTICIDE ONE-SHOT RAMPANTS & VOLANTS BLASTOR INSECTICIDE ONE-SHOT RAMPANTS & VOLANTS INSECTICIDE RAMPANTS ET VOLANTS ONE-SHOT F-A56 INS AEROSOL OS CY INSTANTANE OS CY ACTO / MORTIS VOLANTS - RAMPANTS SUBITO INSECTICIDE CHOC VOLANTS RAMPANTS SUBITO INSECTICIDE CHOC VOLANTS SUBITO INSECTICIDE CHOC RAMPANTS 1014OSP KAP4HOME OS5 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.54 |
| Ethanol | | Formulant | 64-17-5 | | 19.46 |

| | |
|----------------------|--|
| Trade name(s) | OS2 ANTISECT C8 IG CYP OS8 AEROSOL ONE SHOT CY INSTANTANE CHOC CY ACTO / MORTIS SPÉCIAL VOLANTS - RAMPANTS SUBITO INSECTICIDE FLASH VOLANTS SUBITO INSECTICIDE FLASH RAMPANTS SUBITO TOUT INSECTES CHOC 1014OSP2 INSECTICHOC ONE SHOT NETINSECT ONESHOT |
|----------------------|--|

| | | | | | |
|--|---|----------------------------|-------------------|------------------|--------------------|
| | KAP4HOME OS8 CYPER OS | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.87 |
| Ethanol | | Formulant | 64-17-5 | | 19.13 |

PART II - SECOND INFORMATION LEVEL - META SPC 5

2.1.24 Meta SPC 5 administrative information

2.1.24.1 Meta SPC identifier

| | |
|-----------------------|--------------|
| Identification | Meta SPC5_EC |
|-----------------------|--------------|

2.1.24.2 Suffix to the authorisation number

| | |
|---------------|-------------------|
| Number | META_SPC_SUFFIX_5 |
|---------------|-------------------|

2.1.24.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.25 Meta SPC 5 composition**2.1.25.1** Qualitative and quantitative information on the composition of the meta SPC 5

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|----------------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 10.87 | 10.87 |

2.1.25.2 Type(s) of formulation of the meta SPC 5

| |
|--------------------------|
| SL - Soluble concentrate |
|--------------------------|

2.1.26 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|-------------------|--|
| Hazard category | STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H373: May cause damage to organs (nervous system) through prolonged or repeated exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Warning |
| Hazard statements | H373: May cause damage to organs (nervous system) through prolonged or repeated exposure H410: Very toxic to aquatic life with long lasting effects |

| Classification | |
|--------------------------|---|
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P260: Do not breathe spray P314: Get medical advice/attention if you feel unwell. P273: Avoid release to the environment P391: Collect spillage P501: Dispose of contents/container according to local regulation |
| Note | |

2.1.27 Authorised use(s) of the META SPC 5

2.1.27.1 Use description

Table 8. Use # 2 –Flying and crawling insects - surface spray under buildings – non professional users

| | |
|---|--|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Crawling insects including Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta americana</i>) Flying insects including Common house mosquito (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Development stage: adults |
| Field of use | Outdoor (under buildings) |
| Application method(s) | Surface spraying |
| Application rate(s) and frequency | The product should be diluted to 2% in water before use according to the level of infestation. 20 mL of diluted product /m ² Residual effect up to 4 months. |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | Fluorinated HDPE bottle/jerrycan, 0.25, 0.5 and 1L |

2.1.27.2 Use-specific instructions for use

-

2.1.27.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.28 General directions for use of the meta SPC 5**2.1.28.1** Instructions for use

- Spray the product under buildings (i.e. crawlspaces).
- Comply with the instructions for use.
- Avoid continuous use of the product.
- Apply only on infested area.
- Contact time is 24 H to 72H with regards to the kind of surfaces and species.
- Inform the registration holder if the treatment is ineffective.
- The diluted product must be shaken before each use and during application.

2.1.28.2 Risk mitigation measures

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

- If medical advice is needed, have container or label at hand.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.28.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated room.
- Protect from sunlight.
- Protect from frost.
- Do not store at temperature > 40°C.
- Shelf-life: 24 months.
- Keep out of reach of children and non-target animals/pets.

2.1.29 Other information

| |
|---|
| - This biocidal product contains cypermethrin which is dangerous to bees. |
|---|

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**2.1.30** Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | EC PARASECT CYP10 IG SECTICHOC CYP10 INSECTICYP 10 F-28 INS ACTO / MORTIS LIQUIDE CONCENTRÉ VOLANTS - RAMPANTS SUBITO INSECTICIDE CONCENTRE VOLANTS RAMPANTS SUBITO CONCENTRE ANTI-INSECTES 1015C PIPEROCIDE CYP AQUASECT CYP KAP4HOME CYP10 CYPER KILL | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 10.87 |

PART II - SECOND INFORMATION LEVEL - META SPC 6**2.1.31** Meta SPC 6 administrative information**2.1.31.1** Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | Meta SPC 6 |
|-----------------------|------------|

2.1.31.2 Suffix to the authorisation number

| | |
|---------------|-------------------|
| Number | META_SPC_SUFFIX_6 |
|---------------|-------------------|

2.1.31.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.32 Meta SPC 6 composition**2.1.32.1** Qualitative and quantitative information on the composition of the meta SPC 6

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|----------------------------|------------|-----------|-------------|-------|
| | | | | | Min | Max |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.22 | 0.22 |
| ethanol | | Formulant | 64-17-5 | | 29.78 | 29.78 |

2.1.32.2 Type(s) of formulation of the meta SPC 6

| |
|-----------------------|
| AE, aerosol dispenser |
|-----------------------|

2.1.33 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|------------------|--|
| Hazard category | Flammable Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |

| Classification | |
|--------------------------|---|
| Labelling | |
| Signal words | Danger |
| Hazard statements | H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated H319: Causes serious eye irritation H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after use. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. P273: Avoid release to the environment P391: Collect spillage P403: Store in a well-ventilated place. P501: Dispose of contents/container according to local regulation |
| Note | |

2.1.34 Authorised use(s) of the META SPC 6

2.1.34.1 Use description

Table 5. Use # 1 – Flying and crawling insects - direct spray – non professional users

| | |
|---|---|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Crawling insects including Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta americana</i>) Flying insects including Common house mosquito (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) |

| | |
|--|--|
| | Development stage: adults |
| Field of use | Outdoor |
| Application method(s) | Direct spraying |
| Application rate(s) and frequency | 2.5g of product (1 second spraying) |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | Aerosol metal can without internal varnish valve VP 195 150 to 750 mL |

2.1.34.2 Use-specific instructions for use

- The user should be aware that a delay of up to 1 hour may be encountered before death.

2.1.34.3 Use-specific risk mitigation measures

- Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

-

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

-

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

-

2.1.34.7 Use description

Table 6. Use # 2 – Flying and crawling insects – target surface spray – non professional users

| | |
|---|---|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Crawling insects: Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta Americana</i>) Flying insects Common house mosquito (<i>Culex sp.</i>) |

| | |
|--|---|
| | House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Development stage: adults |
| Field of use | Outdoor |
| Application method(s) | Target surface spraying as spots application (flying insects) or in cracks and crevices (crawling insects) |
| Application rate(s) and frequency | Application rate: 17.5 g product/m ² (7 seconds/m ²) or 1.4 seconds/m Residual effect up to 4 months. |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | Aerosol metal can without internal varnish valve VP 195 150 to 750 mL |

2.1.34.8 Use-specific instructions for use

- Contact time is 24 H to 72H with regards to the kind of surfaces and species.
- The product has to be applied only on restricted areas on surfaces not regularly cleaned and protected from the rain.

2.1.34.9 Use-specific risk mitigation measures

- Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.
- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

-

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

-

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

-

2.1.35 General directions for use of the meta SPC 6

2.1.35.1 Instructions for use

- Comply with the instructions for use.
- Avoid continuous use of the product.
- Apply only on infested area.

- Inform the registration holder if the treatment is ineffective.

2.1.35.2 Risk mitigation measures

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Wash hands after use.

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

- If medical advice is needed, have product container or label at hand.
- IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.35.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated room.
- Pressurized container: May burst if heated. Do not pierce or burn, even after use. Protect from sunlight.
- Do not store at temperature > 40°C.
- Keep packaging away from sources of heat, sparks and open flame.
- Shelf-life: 24 months.
- Keep out of reach of children and non-target animals/pets.

2.1.36 Other information

This biocidal product contains cypermethrin which is dangerous to bees.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

2.1.37 Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | AE FC1 PARASECT AC2 L'ELFE INSECTICIDE SPECIAL RAMPANTS L'ELFE INSECTICIDE SPECIAL VOLANTS-RAMPANTS L'ELFE INSECTICIDE SPECIAL VOLANTS BLASTOR INSECTICIDE SPECIAL RAMPANTS BLASTOR INSECTICIDE VOLANTS-RAMPANTS BLASTOR INSECTICIDE SPECIAL VOLANTS INSECTICIDE ANTI-RAMPANTS INSECTICIDE ANTI-VOLANTS ACTO / MORTIS VOLANTS SUBITO AEROSOL ANTI VOLANTS RAMPANTS SUBITO AEROSOL FLASH ANTI VOLANTS SUBITO AEROSOL FLASH ANTI RAMPANTS 123 MOUSTIQUES INSECTICIDES VOLANTS RAMPANTS 1014D RAYO-INSECTE VOLANTS-RAMPANTS KAP4HOME AC2 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.22 |
| ethanol | | Formulant | 64-17-5 | | 29.78 |

PART II - SECOND INFORMATION LEVEL - META SPC 7

2.1.38 Meta SPC 7 administrative information

2.1.38.1 Meta SPC identifier

| | |
|-----------------------|-----------|
| Identification | Meta SPC7 |
|-----------------------|-----------|

2.1.38.2 Suffix to the authorisation number

| | |
|---------------|-------------------|
| Number | META_SPC_SUFFIX_7 |
|---------------|-------------------|

2.1.38.3 Product type(s)

| | |
|------------------------|----|
| Product type(s) | 18 |
|------------------------|----|

2.1.39 Meta SPC 7 composition**2.1.39.1** Qualitative and quantitative information on the composition of the meta SPC 7

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|----------------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.22 | 0.22 |

2.1.39.2 Type(s) of formulation of the meta SPC 7

| |
|----------------------|
| AL- Any other liquid |
|----------------------|

2.1.40 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|-----------------------|--|
| Hazard category | Aquatic Acute 1 Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |

| Classification | |
|--------------------------|---|
| Precautionary statements | P103: Read label before use. P273: Avoid release to the environment P391: Collect spillage P501: Dispose of contents/container according to local regulation |
| Note | |

2.1.41 Authorised use(s) of the META SPC 7

2.1.41.1 Use description

Table 5. Use # 1 –Flying and crawling insects – target surface spray – non professional users

| | |
|---|--|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Crawling insects including Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta americana</i>) Flying insects Common house mosquito (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Development stage: adults |
| Field of use | Outdoor |
| Application method(s) | Spraying Target surface spraying as spots application (flying insects) or in cracks and crevices (crawling insects) |
| Application rate(s) and frequency | 20 mL/m ² (equal to 4 mL/m) Residual effect up to 4 months |
| Category(ies) of users | General public (non professional) |
| Pack sizes and packaging material | HDPE trigger spray (reference: Versaplast EU), 0.5, 0.75 and 1 L. |

2.1.41.2 Use-specific instructions for use

- The product has to be applied only on restricted areas on surfaces not regularly cleaned and protected from the rain.

2.1.41.3 Use-specific risk mitigation measures

- Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.

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

-

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

-

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

-

2.1.41.7 Use description**Table 6. Use # 2 – Flying and crawling insects - surface spray under buildings – non professional users**

| | |
|---|--|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Crawling insects including Cockroaches: German cockroaches (<i>Blattella germanica</i>) American cockroaches (<i>Periplaneta americana</i>) Flying insects Common house mosquito (<i>Culex sp.</i>) House fly (<i>Musca domestica</i>) Wasp (<i>Vespula sp.</i>) Development stage: adults |
| Field of use | Outdoor (under buildings) |
| Application method(s) | Spraying |
| Application rate(s) and frequency | 20 mL of product /m ² Residual effect up to 4 months. |
| Category(ies) of users | General public (non professional) |

| | |
|--|--|
| Pack sizes and packaging material | HDPE trigger spray (reference: Versaplast EU), 0.5, 0.75 and 1 L. 5 L HDPE jerrycan for refill. |
|--|--|

2.1.41.8 Use-specific instructions for use

- Spray the product under buildings (i.e. crawlspaces).

2.1.41.9 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.42 General directions for use of the meta SPC 7

2.1.42.1 Instructions for use

- Comply with the instructions for use.
- Avoid continuous use of the product.
- Apply only on infested area.
- Contact time is 24 H to 72H with regards to the kind of surfaces and species.
- Inform the registration holder if the treatment is ineffective.

2.1.42.2 Risk mitigation measures

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

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

- If medical advice is needed, have product container or label at hand.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.42.4 Instructions for safe disposal of the product and its packaging

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

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

- Keep the container tightly closed in a dry and well-ventilated place.
- Protect from sunlight.
- Do not store at temperature > 40°C.
- Shelf-life: 12 months.
- Keep out of reach of children and non-target animals/pets.

2.1.43 Other information

This biocidal product contains cypermethrin which is dangerous to bees.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

2.1.44 Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|--|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | RTU1 PARACHOC C2 IG SECTISTOP CYP2 L'ELFE INSECTICIDE BLASTOR INSECTICIDE INSECTICIDE ACTO / MORTIS VOLANTS LIQUIDE SUBITO INSECTICIDE PAL VOLANTS RAMPANTS SUBITO INSECTICIDE VOLANTS PRÊT À L'EMPLOI SUBITO INSECTICIDE RAMPANTS PRÊT À L'EMPLOI 1015VGE KAP4HOME CYP2 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) | (RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Technical active substance | 52315-07-8 | 257-842-9 | 0.22 |

2.1.45 Packaging of the biocidal product

| Product | Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---------|-------------------|------------------------------|--------------------------------|---|---|---|
| AE WH | Aerosol can | 500 to 750 mL | Metal without internal varnish | Plastic spray nozzle (valve type FL)+ cap | Non-professional | Yes |

| | | | | | | |
|----------------------------|-------------|-------------------|--------------------------------|--|------------------|-----|
| AE FC1 AE FC2 AE FC3 | Aerosol can | 150 to 750 mL | Metal without internal varnish | Plastic spray nozzle (valve VP 195) + cap | Non-professional | Yes |
| OS1 OS2 | Aerosol can | 50 to 750 mL | Metal without internal varnish | Plastic spray nozzle (valve PV)+ cap | Non-professional | Yes |
| RTU1 RTU2 RTU3 | Bottle | 0.5, 0.75 and 1 L | HDPE | Plastic trigger spray (reference: Versaplast EU) | Non-professional | Yes |
| RTU1 RTU2 RTU3 | Jerrycan | 5 L | HDPE | Plastic screw cap | Non-professional | Yes |
| EC | Bottle | 0.25, 0.5 and 1 L | Fluorinated HDPE | screw cap Plastic | Non-professional | Yes |

Note: the authorisation holder also claimed the following packaging:

| | | | | | | |
|----|----------|-----|------------------|-------------------|------------------|-----|
| EC | Jerrycan | 5 L | Fluorinated HDPE | Plastic screw cap | Non-professional | Yes |
|----|----------|-----|------------------|-------------------|------------------|-----|

However as those packaging for non-professional use may lead to overuse or waste, an unacceptable risk for the environment cannot be excluded, unless the maximum package size for non-professional use are adapted to the claimed use. In the frame of this dossier, those packaging size are thus excluded for meta SPC5.

2.1.46 Documentation

2.1.46.1 Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal products family CHIMIGET_CYPER were provided by Groupe Chimiget.

2.1.46.2 Access to documentation

Groupe Chimiget has access to data on the active substance cypermethrin with a Letter of Access.

2.2 Assessment of the biocidal product family

The biocidal product family is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains between 0.22 and 10.87% w/w technical cypermethrin cis/trans 40/60.

The biocidal product family does not contain PT6 preservative.

The family is composed of 7 Meta SPCs:

- Meta SPC 1 contains the product AE WH, a ready-to-use aerosol.
- Meta SPC 2 contains the products AE FC2 and AE FC3, ready-to-use aerosol.
- Meta SPC 3 contains the products OS1 and OS2, ready-to-use one-shot aerosol.
- Meta SPC 4 contains the products RTU2 and RTU3, ready-to-use trigger spray.
- Meta SPC 5 contains the product EC, concentrate (SL).
- Meta SPC 6 contains the product AE FC1, ready-to-use aerosol.
- Meta SPC 7 contains the product RTU1, ready-to-use trigger spray.

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

Table 2.2.1-1. Use # 1 – Meta SPC 1 – AE WH – wasps and hornets aerosol

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Aerosol insecticide against wasps and hornets |
| Target organism (including development stage) | - <i>Vespula</i> : wasps - <i>Vespa crabro</i> : European hornet - <i>Vespa velutina</i> : Asian hornet Adults |
| Field of use | Outdoor use |
| Application method(s) | Direct spraying on insects |
| Application rate(s) and frequency | Application rate: 1 second spray (= 17.5 g of product) Frequency: as needed. |
| Category(ies) of users | Non-professionals |

| | |
|--|--|
| Pack sizes and packaging material | Aerosol Metal can 500-750 mL See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |
|--|--|

Table 2.2.1-2. Use # 2 – Meta SPC 2 – AE FC – flying and crawling insects_direct spray

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Aerosol insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Direct spraying on insects |
| Application rate(s) and frequency | Application rate: 1 second spray = 2.5 g product Frequency: Avoid continuous use of the product. In case of infestation, use another pest control mean. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Aerosol Metal can 150-750 mL See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-3. Use # 3 – Meta SPC 3 – OS – flying and crawling insects_space treatment

| | |
|---|--|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | One-shot aerosol insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Indoor use |

| | |
|--|---|
| Application method(s) | Space spraying |
| Application rate(s) and frequency | Application rate: 1 mL/m ³ Frequency: as needed. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Aerosol Metal can 50-750 mL See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-4. Use # 4 – Meta SPC 4 – RTU – flying and crawling insects surface_spray_under buildings

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Surface spraying under buildings |
| Application rate(s) and frequency | Application rate: 20 mL/m ² Frequency: residual effect up to 4 months. Reapply in case of new infestation. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | HDPE trigger spray, 0.5, 0.75 and 1 L 5 L HDPE jerrycan for refill See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-5. Use # 5 – Meta SPC 5 – EC – flying and crawling insects_surface spray

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Insecticide against flying and crawling insects |

| | |
|--|--|
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Target surface spraying as spots in cracks and crevices |
| Application rate(s) and frequency | Application rate: 20 mL/m ² or 4 mL/meter, after 2% v/v dilution in water. Frequency: residual effect up to 4 months. Reapply in case of new infestation. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Fluorinated HDPE bottle/jerrycan, 0.25, 0.5, 1 and 5 L See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-6. Use # 6 – Meta SPC 5 – EC – flying and crawling insects_surface spray_under buildings

| | |
|---|--|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Surface spraying under buildings |
| Application rate(s) and frequency | Application rate: 20 mL/m ² after 2% to 8% dilution in water Frequency: residual effect up to 4 months. Reapply in case of new infestation. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Fluorinated HDPE bottle/jerrycan, 0.25, 0.5, 1 and 5 L See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-7. Use # 7 – Meta SPC 6 – AE FC1 – flying and crawling insects_direct spray

| | |
|---|--|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Aerosol insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Indoor and outdoor use |
| Application method(s) | Direct spraying on insects |
| Application rate(s) and frequency | Application rate: 1 second spray = 2.5 g product Frequency: as needed. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Aerosol Metal can 150-750 mL See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-8. Use # 8 – Meta SPC 6 – AE FC1 – flying and crawling insects_surface spray

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Aerosol insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Indoor and outdoor use |
| Application method(s) | Target surface spraying as spots in cracks and crevices |
| Application rate(s) and frequency | Application rate: 7 seconds/m ² = 17.5 g product/m ² Frequency: residual effect up to 4 months. Reapply in case of new infestation. |

| | |
|--|--|
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Aerosol Metal can 150-750 mL See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-9. Use # 9 – Meta SPC 7 – RTU – flying and crawling insects_surface spray

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Target surface spraying as spots in cracks and crevices |
| Application rate(s) and frequency | Application rate: 20 mL/m ² or 4 mL/meter Frequency: residual effect up to 4 months. Reapply in case of new infestation. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | HDPE trigger spray, 0.5, 0.75 and 1 L 5 L HDPE jerrycan for refill See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

Table 2.2.1-10. Use # 10 – Meta SPC 7 – RTU – flying and crawling insects surface_spray_under buildings

| | |
|---|---|
| Product Type | PT18 – insecticide |
| Where relevant, an exact description of the authorised use | Trigger spray insecticide against flying and crawling insects |

| | |
|--|---|
| Target organism (including development stage) | Flying and crawling insects Including - cockroaches - house flies - house mosquitoes - common wasps Adults |
| Field of use | Outdoor use |
| Application method(s) | Surface spraying under buildings |
| Application rate(s) and frequency | Application rate: 20 mL/m ² Frequency: residual effect up to 4 months. Reapply in case of new infestation. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | HDPE trigger spray, 0.5, 0.75 and 1 L 5 L HDPE jerrycan for refill See also paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file. |

2.2.2 Physical, chemical and technical properties

2.2.2.1 Physical, chemical and technical properties – Meta SPC 1, Meta SPC 2 and Meta SPC6

Some studies on physical, chemical and technical properties were performed on the product AE WH, which is the only product of the Meta SPC 1.

Studies on physical, chemical and technical properties were performed on the product AE FC 1 of the Meta-SPC 6, as the product of Meta-SPC 1 (AE WH) has the same composition than the product AE FC 1 of the Meta-SPC 6 (AE FC1) so the bridging between the two products is acceptable.

The detailed compositions of the products are given in Section 2 of the IUCLID file and in the confidential PAR.

Studies on physical, chemical and technical properties were performed on the product AE FC 1, which is the product having the lowest active substance content. As the only difference between the products of Meta SPC 2 and Meta SPC 6 is the active substance content, which varies between 0.20% w/w and 0.80% w/w of pure cypermethrin, this composition change is not expected to have any significant impact on the results obtained on the product AE FC 1.

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | FR Evaluation | Reference |
|---------------------------------------|---------------------------------------|--|--|---------------|--|
| Physical state at 20 °C and 101.3 kPa | Organoleptic and visual observations. | AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin | The liquid formulation without propellant gas of the product AE FC 1 was found to be a homogeneous colourless limpid liquid with characteristic odour before and after an accelerated storage procedure at 40 ± 2°C for 8 weeks in its commercial packaging (210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of test | Acceptable | Halbwachs P., 2020 Study no. 20- ██████████ 3, |
| Colour at 20 °C and 101.3 kPa | No guideline required. | | | | |
| Odour at 20 °C and 101.3 kPa | | | | | |
| Acidity / alkalinity | - | Meta SPC 1, 2 and 6 | The products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products and are not to be applied as aqueous dilutions. Therefore, the pH value is not determined on the products of the Meta SPC 2 and 6. | Acceptable | - |
| Relative density / bulk density | OECD Guideline No.109 (2012) | Liquid formulation without propellant gas of AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) Batch 20/091A01 Containing 0.698% w/w of cypermethrin | The mean relative density of liquid formulation without propellant gas of the product AE FC 1 was 0.794 at 20.0°C. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-001, ██████████ |

| | | | | | | | |
|---|---|---|--|--|--|--|--|
| Storage stability test – accelerated storage | CIPAC MT 46.3 method (storage stability) (2000) Validated analytical method | AE FC 1 (named AÉROSOL VOLANTS/RAMPA NTS in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin 210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation Analytical method, study No. 20-903071-005 validated in analytical part of the PAR | The test item AE FC 1 in its commercial packaging (210 mL multi-shot metal (tinplate) aerosol (valve VP 195) filled with 150 mL of test item) has been tested during an accelerated storage procedure for 8 weeks at 40 ± 2°C. | | Acceptable for the Meta SPC 1, 2 and 6, these products are stable 8 weeks at 40°C. | Halbwachs P., 2020 Study no. 20-903071-003, [REDACTED] | |
| | | | | T0 | | | T 8 weeks at 40°C |
| | | | Test item | Homogeneous colourless limpid liquid with a characteristic odour | | | No change |
| | | | Packaging | White opaque metal (tinplate) aerosol of 150 mL | | | No sign of degradation or leak was observed. |
| | | | AS content with propellant gas | 0.208% | | | 0.210% |
| | | | AS content without propellant gas | 0.698% | | | 0.704% |
| | | | Variation | / | | | +0.9% |
| | | | Ratio cis: trans | 40.1/59.9 | | | 41.1/58.9 |
| | | | Weight (g) | 147.7 | | | 147.2 |
| | | | Variation | / | | | -0.3% |
| Spray diameter and pattern | 21 cm circular | 21 cm circular | | | | | |
| Spray volume | After 5-s spray 20.17 mL Spray rate: 3.17g/s | After 5-s spray 19.30 mL 3.06 g/s | | | | | |

| | | | | Nozzles : no blocking observed | Nozzles : no blocking observed | | |
|--|--|--|--|--|---|---|--|
| | | | | Spray droplet size distribution by laser diffraction | % of the respirable volume fraction less than 10µm = 0 Dv(0.1)=566.4 µm Dv(0.5)=630.4 µm Dv(0.9)=698.9 µm D[3;2]=627.2µm D[4;3]=631.7 µm | / | |

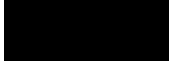
| | | | | | | | | | |
|--|--|--|---|--|--|--|--|---|--|
| Storage stability test – long term storage at ambient temperature | Technical Monograph No.17, 2nd edition, CropLife Validated analytical method | AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin 210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation Analytical method, study No. 20-903071-005 validated in analytical part of the PAR | The long term storage stability study (24 months at 20 ± 2°C) on the test item AE FC 1 in its commercial packaging (210 mL multi-shot metal (tinplate) aerosol (valve VP 195) filled with 150 mL of test item)has been performed. | | | | | Acceptable The Meta SPC 1, 2 and 6 are stable 24 months at ambient temperature.The pH has not been provided. However as the product is not an aqueous solution and as the product is a ready to use, no further data required. | Halbwachs P., 2022 Study no. 20-903071-004, [REDACTED] |
| | | | | T0 | T 6 months | T 12 months | T 24 months | | |
| | | | Test item | Homogeneous colourless limp liquid with a characteristic odour | No change | Homogeneous colourless limp liquid with a characteristic odour | No change | | |
| | | | Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | | |
| | | | AS content with propellant gas | 0.208 | 0.203 | 0.208 | 0.210 | | |
| | | | AS content without propellant gas | 0.698 | 0.681 | 0.697 | 0.704 | | |
| | | | Variation | / | -2.4% | -0.1% | +0.9% | | |
| | | | Ratio cis: trans | 59.94:40.06 | 60.11:39.89 | 59.22:40.78 | 58.51:41.49 | | |
| | | | Variation of weight | / | -0.5% | -1.2% | -2.1% | | |

| | | | | | | | | | | | | | | | |
|--|--|---|---|--|----------------|-------------------------------|----------------|--|--------------|--|--|--|--|--|--|
| | | | <table border="1"> <tr> <td>Spray diameter and pattern</td> <td>21 cm circular</td> <td>20 cm circular</td> <td>19 cm circular</td> <td>24 cm circular</td> </tr> <tr> <td>Spray volume</td> <td>After 5-s spray 19.90 mL Spray rate: 2.98g/s Nozzles : no blocking observed</td> <td>After 5-s spray 19.89 mL Spray rate: 3.11g/s Nozzles : no blocking observed</td> <td>After 5-s spray 19.81 mL Spray rate: 3.10g/s Nozzles : no blocking observed</td> <td>After 5-s spray 19.68 mL Spray rate: 3.02g/s Nozzles : no blocking observed</td> </tr> </table> | Spray diameter and pattern | 21 cm circular | 20 cm circular | 19 cm circular | 24 cm circular | Spray volume | After 5-s spray 19.90 mL Spray rate: 2.98g/s Nozzles : no blocking observed | After 5-s spray 19.89 mL Spray rate: 3.11g/s Nozzles : no blocking observed | After 5-s spray 19.81 mL Spray rate: 3.10g/s Nozzles : no blocking observed | After 5-s spray 19.68 mL Spray rate: 3.02g/s Nozzles : no blocking observed | | |
| Spray diameter and pattern | 21 cm circular | 20 cm circular | 19 cm circular | 24 cm circular | | | | | | | | | | | |
| Spray volume | After 5-s spray 19.90 mL Spray rate: 2.98g/s Nozzles : no blocking observed | After 5-s spray 19.89 mL Spray rate: 3.11g/s Nozzles : no blocking observed | After 5-s spray 19.81 mL Spray rate: 3.10g/s Nozzles : no blocking observed | After 5-s spray 19.68 mL Spray rate: 3.02g/s Nozzles : no blocking observed | | | | | | | | | | | |
| Storage stability test – low temperature stability test for liquids | CIPAC MT 39.3 method (2000) | AE FC 1 (named AÉROSOL VOLANTS/RAMPA NTS in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin 210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of | <p>The test item AE FC 1 and its commercial packaging (210 mL multi-shot metal (tinplate) aerosol (valve VP 195) filled with 150 mL of test item) has been tested during a low storage procedure for 7 days at $0 \pm 2^\circ\text{C}$.</p> <table border="1"> <tr> <td></td> <td>T0</td> <td>T 7 days at 0°C</td> </tr> <tr> <td>Test item</td> <td>Homogeneous colourless limp liquid with a characteristic odour</td> <td>No change</td> </tr> <tr> <td>Packaging</td> <td>White opaque metal (tinplate) aerosol of 150 mL</td> <td>No sign of degradation or leak was observed.</td> </tr> </table> | | T0 | T 7 days at 0°C | Test item | Homogeneous colourless limp liquid with a characteristic odour | No change | Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | Acceptable The meta SPC 2 and 6 are stable 7 days at 0°C . | Halbwachs P., 2020 Study no. 20-903071-002, ██████████ | |
| | T0 | T 7 days at 0°C | | | | | | | | | | | | | |
| Test item | Homogeneous colourless limp liquid with a characteristic odour | No change | | | | | | | | | | | | | |
| Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | | | | | | | | | | | | | |

| | | liquid formulation | Spray diameter and pattern | 23 cm circular | 23 cm circular | | |
|---|---|---------------------|--|--|--|---|---|
| | | | Spray volume | After 5-s spray 20.51 mL Spray rate: 3.09 g/s Nozzles : no blocking observed | After 5-s spray 20.59 mL 3.10 g/s Nozzles : no blocking observed | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | - | Meta SPC 1, 2 and 6 | The study for stability to sunlight is not required as the commercial packaging of the products (210 mL, 650 mL multi-shot metal (tinplate) aerosol), is opaque. | | | Acceptable | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity | - | Meta SPC 1, 2 and 6 | The products of the Meta-SPC 2 (AE FC) in their respective commercial packagings are expected to be stable after an accelerated storage procedure (8 weeks at 40 ± 2°C) according to CIPAC MT 46.3 (Handbook J, 2000) and after a low temperature stability (7 days at 0 ± 2°C) according to CIPAC MT 39.3 (Handbook J, 2000) (please refer to Section 3.4.1). The individual commercial packagings of the products are hermetically sealed, the packagings are leak-tight, and therefore, a study for humidity effects is not required. | | | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | - | - | See the storage stability test - long term storage at ambient temperature | | | - | - |

| | | | | | |
|--|---------------------------------------|--|--|------------------------------------|---|
| Wettability | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Suspensibility, spontaneity and dispersion stability | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Wet sieve analysis and dry sieve test | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Disintegration time | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 187 (2003) ISO 13320-2009 | AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS with (valve VP 195) in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin 210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation | The spray droplet size distribution of the test item AE FC 1 in its commercial packaging (210 mL multi-shot metal (tinplate) aerosol filled with 150 mL of test item) was determined by laser diffraction. The percentage of the respirable volume fraction less than 10 µm is zero. Mean on the three sprays: Dv(0.1) = 566.4 µm Dv(0.5) = 630.4 µm Dv(0.9) = 698.9 µm | Acceptable | Halbwachs P., 2020 Study no. 20-903071-003, [REDACTED] Demangel B., 2021 Study no. 21-903071-001, [REDACTED] |

| | | | | | |
|---|----------------|--|---|------------------------------------|---|
| | | AE WH Batch 20/094B01 Containing 0.461% w/w of cypermethrin 650 mL multi-shot metal (tinplate) aerosol with valve type FL filled with 500 mL of liquid formulation | The spray droplet size distribution of the test item AE WH in its commercial packaging (650 mL multi-shot metal (tinplate) aerosol filled with 500 mL of test item) was determined by laser diffraction. The percentage of the respirable volume fraction less than 10 µm is zero. Mean on the three sprays: Dv(0.1) = 415.9 µm Dv(0.5) = 466.4 µm Dv(0.9) = 523.8 µm | | |
| Persistent foaming | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Flowability/Pourability/Dustability | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Burning rate — smoke generators | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Burning completeness — smoke generators | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Composition of smoke — smoke generators | - | Meta SPC 1, 2 and 6 | Not required as the products of the Meta SPC 1, 2 and 6 are non-aqueous aerosol biocidal products. | Not relevant for an AE formulation | - |
| Spraying pattern — aerosols | FEA 644 (2009) | AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS with (valve VP 195) in the study) Batch 20/091A01 Containing 0.208% w/w of cypermethrin 210 mL multi-shot | At initial time, the mean spray diameter of the 210 mL multi-shot metal (tinplate) aerosol (filled with 150 mL of test item AE FC 1) was 21 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after a 5-s spray of the multi-shot aerosol was 20.17 mL and the mean spray rate was 3.17 g/s. After 8 weeks at 40 ± 2°C, the mean spray diameter of the 210 mL multi-shot metal (tinplate) aerosol (filled with 150 mL of test item) was 21 cm and the shape of the spray on the wetted patch was circular. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-002, [REDACTED] Demangel B., 2021 Study no. 21-903071-001, [REDACTED] |

| | | | | | |
|------------------------|---|--|--|------------|--|
| | | metal (tinplate) aerosol filled with 150 mL of liquid formulation | <p>The mean volume of test item after a 5-s spray of the multi-shot aerosol was 19.30 mL and the mean spray rate was 3.06 g/s. At initial time, the mean spray diameter of the 210 mL multi-shot metal (tinplate) aerosol (filled with 150 mL of test item AE FC 1) was 23 cm and the shape of the spray on the wetted patch was circular.</p> <p>The mean volume of test item after a 5-s spray of the multi-shot aerosol was 20.51 mL and the mean spray rate was 3.09 g/s.</p> <p>After 7 days at $0 \pm 2^\circ\text{C}$, the mean spray diameter of the 210 mL multi-shot metal (tinplate) aerosol (filled with 150 mL of test item) was 23 cm and the shape of the spray on the wetted patch was circular.</p> <p>The mean volume of test item after a 5-s spray of the multi-shot aerosol was 20.59 mL and the mean spray rate was 3.10 g/s.</p> | | Hertz D., 2022 Study n°5561-156-22,  |
| | | AE FC 1 (named Insecticide VOLANTS/RAMPA NTS with (valve VP 195) in the study) Batch 20/091A01 | <p>An additional study has been provided: The mean spray diameter of the 210 mL multi-shot metal (tinplate) aerosol (filled with 150 mL of test item AE FC 1) was 10 cm and the shape of the spray on the wetted patch was circular during 0.3s. The mean spray rate was 3.22 g/s. The packaging and the valve were not specified.</p> | | |
| | | AE WH Batch 20/094B01 Containing 0.461% w/w of cypermethrin 650 mL multi-shot metal (tinplate) aerosol with valve type FL filled with 500 mL of liquid formulation | <p>The mean spray diameter of the 650 mL multi-shot metal (tinplate) aerosol (filled with 500 mL of test item AE WH) was 17 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after a 5-s spray of the multi-shot aerosol was 119 mL and the mean spray rate was 18.4 g/s.</p> | | |
| Physical compatibility | - | Meta SPC 1, 2 and 6 | Not applicable. The products of the Meta SPC 1, 2 and 6 are not intended to be used in conjunction with any other products or active substances. | Acceptable | - |

| | | | | | |
|--|--|--|--|---------------------------------|--|
| Chemical compatibility | - | Meta SPC 1, 2 and 6 | Not applicable. The products of the Meta SPC 1, 2 and 6 are not intended to be used in conjunction with any other products or active substances. | Acceptable | - |
| Degree of dissolution and dilution stability | - | Meta SPC 1, 2 and 6 | Not applicable. The products of the Meta SPC 1, 2 and 6 are not intended to be used in conjunction with any other products or active substances. | Acceptable | - |
| Surface tension | OECD Test Guideline 115 (1995) | Liquid formulation without propellant gas of AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) Batch 20/091A01 Containing 0.698% w/w of cypermethrin | The mean surface tension of liquid formulation without propellant gas of the product AE FC 1 was 22.1 mN/m at 20.3°C. The test item was considered as surface-active in the experimental conditions used. | Acceptable for Meta SPC 2 and 6 | Halbwachs P., 2020 Study no. 20-903071-001, [REDACTED] |
| Viscosity | OECD Test Guideline 114 (2012) ISO 3219 (1993) | Liquid formulation without propellant gas of AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) Batch 20/091A01 Containing 0.698% w/w of cypermethrin | The mean dynamic viscosity of the liquid formulation without propellant gas of the product AE FC 1 was found to be 1.38 mPa.s at 20.0 ± 0.2°C and 0.99 mPa.s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the experimental conditions used. | Acceptable for Meta SPC 2 and 6 | Halbwachs P., 2020 Study no. 20-903071-001, [REDACTED] |

2.2.2.2 Physical, chemical and technical properties – Meta SPC 3

Studies on physical, chemical and technical properties were performed on the product OS 1, which is the product having the lowest active substance content of this Meta SPC. As the only difference between the 2 products of this Meta SPC is the active substance content, which varies between 0.50% w/w and 0.80% w/w of pure cypermethrin, this composition change is not expected to have any significant impact on the results obtained on the product OS 1.

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | FR Evaluation | Reference |
|---------------------------------------|--|--|---|---------------|--|
| Physical state at 20 °C and 101.3 kPa | Organoleptic and visual observations. No guideline required | OS 1 (named ONE SHOT AUTO PERCUTANT with valve PV in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin | The liquid formulation without propellant gas was found to be a homogeneous colourless limp liquid with characteristic odour before and after an accelerated storage procedure at 40 ± 2°C for 8 weeks in its commercial packaging (210 mL one-shot metal (tinplate) aerosol filled with 150 mL of test item) | Acceptable | Halbwachs P., 2020 Study no. 20- ██████████ 8 |
| Colour at 20 °C and 101.3 kPa | | | | | |
| Odour at 20 °C and 101.3 kPa | | | | | |
| Acidity / alkalinity | - | Meta SPC 3 | The products of the Meta SPC 3 are non-aqueous aerosol biocidal products and are not to be applied as aqueous dilutions. Therefore, the pH value is not determined on the products of the Meta SPC 3 | Acceptable | - |
| Relative density / bulk density | ECD Guideline No.109 (2012) | Liquid formulation without propellant gas of OS 1 (named ONE SHOT AUTO PERCUTANT in the study) Batch 20/093A01 Containing 2.56% w/w of cypermethrin | The mean relative density of liquid formulation without propellant gas of the product OS 1 was 0.799 at 20.0°C. | Acceptable | Halbwachs P., 2020 Study no. 20- 903071-006, ██████████ |

| | | | | | | | |
|---|---|---|---|--|--|--|--|
| Storage stability test – accelerated storage | CIPAC MT 46.3 method (storage stability) (2000) Validated analytical method | OS 1 (named ONE SHOT AUTO PERCUTANT with valve PV in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin 210 mL one-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation | The test item OS 1 in its commercial packaging (210 mL one-shot metal (tinplate) aerosol with valve PV filled with 150 mL of test item) has been tested during accelerated storage procedure for 8 weeks at 40 ± 2°C. | | Acceptable The products are stable 8 weeks at 40°C. | Halbwachs P., 2020 Study no. 20-903071-008, [REDACTED] | |
| | | | | T0 | | | T 8 weeks |
| | | | Test item | Homogeneous colourless limpid liquid with a characteristic odour | | | No change |
| | | | Packaging | White opaque metal (tinplate) aerosol of 150 mL | | | No sign of degradation or leak was observed. |
| | | | AS content with propellant gas | 0.516% | | | 0.526% |
| | | | AS content without propellant gas | 2.56% | | | 2.61% |
| | | | Variation | / | | | +2% |
| | | | Ratio cis: trans | 40.1/59.9 | | | 41.1/58.9 |
| | | | Weight (g) | 147.7 | | | 147.2 |
| | | | Variation | / | | | -0.2% |
| | | | Spray diameter and pattern | 11 cm circular | | | 10 cm circular |
| Spray volume | After one-shot 112.35 mL Spray rate: 0.44g/s Nozzles : no blocking observed | After one-shot 111.97 mL 0.47 g/s Nozzles : no blocking observed | | | | | |

| | | | | | | | |
|--|--|--|---|---|---|--|--|
| | | | <p>Spray droplet size distribution by laser diffraction</p> | <p>% of the respirable volume fraction less than 10 μm = 0.</p> <p>Dv(0.1)=636.1 μm Dv(0.5)=678.3 μm Dv(0.9)=718.4 μm D[3;2]=675.8 μm D[4;3]=676.7 μm</p> | / | | |
|--|--|--|---|---|---|--|--|

| | | | | | | | | | |
|--|--|---|--|--|--------------------------------|--------------------------------|--------------------------------|---|--|
| Storage stability test – long term storage at ambient temperature | Technical Monograph No.17, 2nd edition, CropLife Validated analytical method | OS 1 (named ONE SHOT AUTO PERCUTANT in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin 210 mL one-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation Analytical study No.20-903071-005 validated | The long term storage stability study (24 months at 20 ± 2°C) on the test item product OS 1 in its commercial packaging (210 mL one-shot metal (tinplate) aerosol filled with 150 mL of test item) is detailed below. The results related to the appearance of the product and the weight and the appearance of its commercial packaging, the cypermethrin content and its cis-/trans- isomers ratio, the satisfactory operation of the aerosol and the spray volume, the spray diameter and pattern, after storage for 6, 12 and 24 months at 20 ± 2°C will be provided when available. | | | | | Acceptable The meta SPC 3 is stable 24 months at ambient temperature. The pH has not been provided. However as the product is not an aqueous solution and as the product is a ready to use , no further data required | Halbwachs P., 2020 Study no. 20-903071-009, [REDACTED] |
| | | | | T0 | T 6 months | T 12 months | T 24 months | | |
| | | | Test item | Homogeneous colourless limp liquid with a characteristic odour | No sign of degradation or leak | No sign of degradation or leak | No sign of degradation or leak | | |
| | | | Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak | No sign of degradation or leak | No sign of degradation or leak | | |
| | | | AS content with propellant gas | 0.516 | 0.522 | 0.544 | 0.566 | | |
| | | | AS content without propellant gas | 2.56 | 2.59 | 2.70 | 2.81 | | |
| | | | Variation | / | +1.2% | +5.5% | +9.8% | | |
| | | | Spray diameter | 11cm circular | 7cm circular | 7cm circular | 8cm circular | | |

| | | | er and pattern | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|----------------------|-----------------------|-----------------------|-----------------------|----|-------------------------------|-----------|--|-----------|-----------|---|--|----------------------------|----------------|---------------|--------------|--|--|--|---|
| | | | Spray volume | 112.35 mL 0.44g/s | 112.21 mL 0.46 g/s | 111.58 mL 0.45 g/S | 109.17 mL 0.46 g/s | | | | | | | | | | | | | | | | |
| Storage stability test – low temperature stability test for liquids | CIPAC MT 39.3 method (2000) | OS 1 (named ONE SHOT AUTO PERCUTANT with valve PV in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin 210 mL one-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation | <p>The test item OS 1 and its commercial packaging (210 mL one-shot metal (tinplate) aerosol with valve PV filled with 150 mL of test item) were considered to be stable after a low storage procedure for 7 days at $0 \pm 2^\circ\text{C}$; no change in the appearance of the test item and in the appearance of the commercial packaging was observed.</p> <p>The satisfactory operation of the aerosol and the spray volume, the spray diameter and pattern were stable after 7 days at $0 \pm 2^\circ\text{C}$.</p> <p>The detailed results related to the satisfactory operation of the aerosol and the spray volume, the spray diameter and pattern are presented in their respective row of this table.</p> <table border="1"> <thead> <tr> <th></th> <th>T0</th> <th>T 7 days at 0°C</th> </tr> </thead> <tbody> <tr> <td>Test item</td> <td>Homogeneous colourless limpid liquid with a characteristic odour</td> <td>No change</td> </tr> <tr> <td>Packaging</td> <td>White opaque metal (tinplate) aerosol of 150 mL</td> <td>No sign of degradation or leak was observed.</td> </tr> <tr> <td>Spray diameter and pattern</td> <td>11 cm circular</td> <td>9 cm circular</td> </tr> <tr> <td>Spray volume</td> <td>After one-shot 112.35 mL Spray rate: 0.44 g/s Nozzles : no blocking observed</td> <td>After one-shot 111.79 mL 0.47 g/s Nozzles : no blocking observed</td> </tr> </tbody> </table> | | | | | T0 | T 7 days at 0°C | Test item | Homogeneous colourless limpid liquid with a characteristic odour | No change | Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | Spray diameter and pattern | 11 cm circular | 9 cm circular | Spray volume | After one-shot 112.35 mL Spray rate: 0.44 g/s Nozzles : no blocking observed | After one-shot 111.79 mL 0.47 g/s Nozzles : no blocking observed | Acceptable The meta SPC 3 is stable 7 days at 0°C . | Halbwachs P., 2020 Study no. 20-903071-007, ██████████ |
| | T0 | T 7 days at 0°C | | | | | | | | | | | | | | | | | | | | | |
| Test item | Homogeneous colourless limpid liquid with a characteristic odour | No change | | | | | | | | | | | | | | | | | | | | | |
| Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | | | | | | | | | | | | | | | | | | | | | |
| Spray diameter and pattern | 11 cm circular | 9 cm circular | | | | | | | | | | | | | | | | | | | | | |
| Spray volume | After one-shot 112.35 mL Spray rate: 0.44 g/s Nozzles : no blocking observed | After one-shot 111.79 mL 0.47 g/s Nozzles : no blocking observed | | | | | | | | | | | | | | | | | | | | | |
| Effects on content of the active | - | Meta SPC 3 | The study for stability to sunlight is not required as the commercial packagings of the products (210 mL one-shot metal (tinplate) aerosol), are opaque. | | | | - | - | | | | | | | | | | | | | | | |

| | | | | | |
|---|---|------------|--|---|---|
| substance and technical characteristics of the biocidal product - light | | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | - | Meta SPC 3 | The products of the Meta SPC 3 (OS) in their respective commercial packagings are expected to be stable after an accelerated storage procedure (8 weeks at 40 ± 2°C) according to CIPAC MT 46.3 (Handbook J, 2000) and after a low temperature stability (7 days at 0 ± 2°C) according to CIPAC MT 39.3 (Handbook J, 2000) (please refer to Section 3.4.1). The individual commercial packagings of the products are hermetically sealed, the packaging are leak-tight, and therefore, a study for humidity effects is not required. | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | - | - | See the storage stability test – long term storage at ambient temperature | - | - |
| Wettability | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Wet sieve analysis and dry sieve test | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |

| | | | | | |
|--|---------------------------------------|---|---|------------|---|
| Emulsifiability, re-emulsifiability and emulsion stability | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Disintegration time | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 187 (2003) ISO 13320-2009 | OS 1 (named ONE SHOT AUTO PERCUTANT with valve PV in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin 210 mL one-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation | The spray droplet size distribution of the test item OS 1 in its commercial packaging (210 mL one-shot metal (tinplate) aerosol with valve PV filled with 150 mL of test item) was determined by laser diffraction. The percentage of the respirable volume fraction less than 10 µm is zero. Mean on the three sprays: Dv(0.1) = 636.1 µm Dv(0.5) = 678.3 µm Dv(0.9) = 718.4 µm | Acceptable | Halbwachs P., 2020 Study no. 20-903071-008, ██████████ |
| Persistent foaming | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Flowability/Pourability/Dustability | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Burning rate — smoke generators | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Burning completeness — smoke generators | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |
| Composition of smoke — smoke generators | - | Meta SPC 3 | Not required as the products of the Meta SPC 3 are non-aqueous aerosol biocidal products. | - | - |

| | | | | | |
|--|-------------------------------|--|---|------------|--|
| Spraying pattern – aerosols | FEA 644 (2009) | OS 1 (named ONE SHOT AUTO PERCUTANT with valve PV in the study) Batch 20/093A01 Containing 0.516% w/w of cypermethrin 210 mL one-shot metal (tinplate) aerosol filled with 150 mL of liquid formulation | At initial time, the mean spray diameter of the 210 mL one-shot metal (tinplate) aerosol with valve PV (filled with 150 mL of test item OS 1) was 11 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after spraying the one-shot aerosol was 112.35 mL and the mean spray rate was 0.44 g/s. After 8 weeks at 40 ± 2°C, the mean spray diameter of the 210 mL one-shot metal (tinplate) aerosol (filled with 150 mL of test item) was 10 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after spraying the one-shot aerosol was 111.97 mL and the mean spray rate was 0.47 g/s. At initial time, the mean spray diameter of the 210 mL one-shot metal (tinplate) aerosol (filled with 150 mL of test item OS 1) was 11 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after spraying the one-shot aerosol was 112.35 mL and the mean spray rate was 0.44 g/s. After 7 days at 0 ± 2°C, the mean spray diameter of the 210 mL one-shot metal (tinplate) aerosol (filled with 150 mL of test item) was 9 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after spraying the one-shot aerosol was 111.79 mL and the mean spray rate was 0.47 g/s. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-007, [REDACTED] |
| Physical compatibility | - | Meta SPC 3 | Not applicable. The products of the Meta SPC 3 are not intended to be used in conjunction with any other products or active substances. | - | - |
| Chemical compatibility | - | Meta SPC 3 | Not applicable. The products of the Meta SPC 3 are not intended to be used in conjunction with any other products or active substances. | - | - |
| Degree of dissolution and dilution stability | - | Meta SPC 3 | Not applicable. The products of the Meta SPC 3 are not intended to be used in conjunction with any other products or active substances. | - | - |
| Surface tension | OECD Test Guideline115 (1995) | Liquid formulation without propellant gas of OS 1 (named ONE | According to EU Method A.5 and to OECD No.115 methods, the mean surface tension of liquid formulation without propellant gas of the product OS 1 was 22.2 N/m at 20.1°C. | Acceptable | Halbwachs P., 2020 Study no. 20- |

| | | | | | |
|-----------|---|---|---|------------|--|
| | | SHOT AUTO PERCUTANT in the study) Batch 20/093A01 Containing 2.56% w/w of cypermethrin | The test item was considered as surface-active in the experimental conditions used. | | 903071-006, [REDACTED] |
| Viscosity | OECD Test Guideline 114 (2012) ISO 3219 (1993) | Liquid formulation without propellant gas of OS 1 (named ONE SHOT AUTO PERCUTANT in the study) Batch 20/093A01 Containing 2.56% w/w of cypermethrin | According to OECD Test Guideline 114 and to ISO Standard 3219 (rotational viscometer), the mean dynamic viscosity of the liquid formulation without propellant gas of the product OS 1 was found to be 1.41 mPa*s at 20.0 ± 0.2°C and 1.02 mPa*s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the experimental conditions used. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-006, [REDACTED] |

2.2.2.3 Physical, chemical and technical properties – Meta SPC 4

Several studies on physical, chemical and technical properties are performed on the product RTU 1. As the only difference between the products of the two Meta-SPCs 4 and 7 is the active substance content, which varies between 0.20% w/w and 0.80% w/w of pure cypermethrin, this composition variation is not expected to have any significant impact on the results obtained on the Meta-SPC 7 (RTU).

The relative density, the low temperature storage stability, the surface tension and the viscosity of the products of the Meta SPC 4 and 7 are extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC (please refer to the bridging document in the document Excel "Composition" tab "Bridging Meta SPC 4-7" in the confidential PAR).

The only difference between the products of Meta SPC 4 and 7 and the liquid formulation of AÉROSOL GUÊPE/FRELON, is the active substance content, which varies between 0.20% w/w and 0.80% w/w of pure cypermethrin in the products of Meta SPC 4 and is 2.00% w/w of pure cypermethrin in the liquid formulation of AÉROSOL GUÊPE/FRELON. This composition change (maximum of 1.94%) is not expected to have any significant impact on the results obtained on the liquid formulation of AÉROSOL GUÊPE/FRELON. Therefore, the results obtained in these studies on the product AÉROSOL GUÊPE/FRELON can be extrapolated to all products from the Meta SPC 4 and 7.

2.2.2.4 Physical, chemical and technical properties – Meta SPC 5

Studies on physical, chemical and technical properties were performed on the product EC, which is the only product of this Meta SPC.

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | FR Evaluation | Reference |
|--|--|---|---|---------------|---|
| Physical state at 20 °C and 101.3 kPa Colour at 20 °C and 101.3 kPa Odour at 20 °C and 101.3 kPa | Organoleptic and visual observations. No guideline required | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin | The product was found to be a homogeneous yellow limpid liquid with a characteristic odour before and after an accelerated storage procedure at 40 ± 2°C for 8 weeks in its commercial packaging (250 mL fluorinated HDPE bottle). | Acceptable | Halbwachs P., 2020 Study no. 20- ██████████, 8, |
| Acidity / alkalinity | CIPAC MT 75.3 method (2000) | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin | The mean pH of a 1% w/v dilution of the product EC was 6.80 after 1 min at 21.0°C at initial time and 6.87 after 2 min at 21.1°C after an accelerated storage procedure at 40 ± 2°C for 8 weeks in its commercial packaging (250 mL fluorinated HDPE bottle). | Acceptable | Halbwachs P., 2020 Study no.20-903071-018, ██████████ |
| Relative density / bulk density | OECD Guideline No.109 (2012) | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2503 Containing 10.20% w/w of cypermethrin | The mean relative density of the product EC was 0.916 at 20.0°C | Acceptable | Halbwachs P., 2020 Study no.20-903071-017, ██████████ |

| | | | | | | | |
|---|---|--|---|---|---|--|---|
| Storage stability test – accelerated storage | CIPAC MT 46.3 method (storage stability) (2000) Validated analytical method | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin 250 mL fluorinated HDPE bottle | The test item EC in its commercial packaging (250 mL fluorinated HDPE bottle) was tested during an accelerated storage procedure for 8 weeks at 40 ± 2°C. | | Acceptable A mitigation measure should be noted: “the product must be shaken before each use.” | Halbwachs P., 2020 Study no. 20-903071-018, [REDACTED] | |
| | | | | T0 | | | T 8 weeks |
| | | | Test item | Homogeneous orange limpid liquid with a characteristic odour | | | No change |
| | | | Packaging | White opaque fluorinated HDPE flask of 250 mL | | | No change |
| | | | AS content | 10.25 % | | | 10.24% |
| | | | Variation | / | | | -0.1 % |
| | | | %wiegth | / | | | 0% |
| | | | Dilution stability | Two phases were observed after standing for 24 hours at 30 ± 2°C. The test item diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain stable after 30 minutes and 24 hours. | | | Three phases were observed after standing for 24 hours at 30 ± 2°C. The test item diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain stable after 30 minutes and 24 hours. |
| | | | Wet sieve test | At 8%w/v: no residue on 75µm sieve | | | At 8%w/v: no residue on 75µm sieve |
| | | | Persistent foam | At 2% w/v: 15 mL after 1min At 8% w/v: 22 mL after 1min | | | At 2% w/v: 14 mL after 1min At 8% w/v: 23 mL after 1min |
| | | | Ratio cis: trans | Cis/trans 40.45:59.55 | | | Cis/trans 40.49:59.41 |
| pH at 1% | 6.8 at 21°C | 6.93 at 21°C | | | | | |

| | | | | | | | | | |
|--|--|---|--|--|------------|-------------|---|--|---|
| Storage stability test – long term storage at ambient temperature | Technical Monograph No.17, 2nd edition, CropLife Validated analytical method | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin 250 mL fluorinated HDPE bottle | The long term storage stability study (24 months at 20 ± 2°C) on the test item EC in its commercial packaging (250 mL fluorinated HDPE bottle) has been performed. | | | | | Acceptable The meta SPC 5 is stable 24 months at ambient temperature. | Halbwachs P., 2022 Study no. 20-903071-019, ██████████ |
| | | | | T0 | T 6 months | T 12 months | T 24 months | | |
| | | | Test item | Homogeneous orange limp liquid with a characteristic odour | No change | No change | No change | | |
| | | | Packaging | White opaque fluorinated HDPE flask of 250 mL | No change | No change | No change | | |
| | | | AS content %w/w | 10.25 | 9.98 | 10.45 | 10.17 | | |
| | | | Variation | / | -2.6% | +1.9% | -0.8% | | |
| | | | Ratio cis: trans | | | | | | |
| | | | Variation of weight | / | 0.0% | 0.0% | +0.1% | | |
| | | | pH | At 1%w/v 6.8 after 1' | / | / | At 1%w/v 5.31 after 1' | | |
| | | | dilution stability | Two phases were observed after standing | / | / | Two phases were observed after standing | | |

| | | | | | | | | | |
|--|--|--|----------------|--|---|---|--|--|--|
| | | | | for 24 hours at $30 \pm 2^\circ\text{C}$. The test item diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain stable after 30 minutes and 24 hours. | | | for 24 hours at $30 \pm 2^\circ\text{C}$. The test item diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain stable after 30 minutes and 24 hours. | | |
| | | | wet sieve test | No residue on a $75\mu\text{m}$ sieve | / | / | The mean percentage retention of test item held on a $75\text{-}\mu\text{m}$ sieve was 0.04% of the total sieved test item | | |
| | | | Persitent foam | At 2%w/v: 15 mL after 1' | / | / | At 2%w/v: 14 mL after 1' | | |

| | | | | | |
|--|----------------------|---|--|------------|---|
| technical characteristics of the biocidal product - reactivity towards container material | | | | | |
| Wettability | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Wet sieve analysis and dry sieve test | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Disintegration time | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Persistent foaming | CIPAC MT 47.3 (2017) | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin | At 2% w/v: 15 mL after 1min At 8% w/v: 22 mL after 1min | Acceptable | Halbwachs P., 2020 Study no. 20-903071-018, [REDACTED] |

| | | | | | |
|--|------------------------------------|--|--|---|--|
| | | 250 mL fluorinated HDPE bottle | | | |
| Flowability/Pourability/Dustability | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Burning rate — smoke generators | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Burning completeness — smoke generators | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Composition of smoke — smoke generators | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Spraying pattern — aerosols | - | Meta SPC 5 | Not required as the product of the Meta SPC 5 is a soluble concentrate biocidal product. | - | - |
| Physical compatibility | - | Meta SPC 5 | Not applicable. The product of the Meta SPC 5 is not intended to be used in conjunction with any other products or active substances. | - | - |
| Chemical compatibility | - | Meta SPC 5 | Not applicable. The product of the Meta SPC 5 is not intended to be used in conjunction with any other products or active substances. | - | - |
| Degree of dissolution and dilution stability | CIPAC MT 41 (2017) CIPAC MT 185 | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2703 Containing 10.25% w/w of cypermethrin 250 mL fluorinated HDPE bottle | According to CIPAC MT 41.1, before the accelerated storage procedure, the test item EC diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain stable after 30 min and 24h (two phases were observed). As the solution of the test item remained not homogeneous according to CIPAC MT 41.1, a procedure adapted from CIPAC MT 185 test was performed. No residue was measured on the 75µm sieve. After an accelerated storage procedure at 40 ± 2°C for 8 weeks in its commercial packaging (250 mL fluorinated HDPE bottle), the test item solution diluted at 8.0% w/v in standard water D formed a homogeneous dilution at initial time, but did not remain | Acceptable A mitigation measure should be noted : "the product must be shaken before each use and during application." | Halbwachs P., 2020 Study no. 20-903071-018, ██████████ |

| | | | | | |
|-----------------|---|---|--|------------|--|
| | | | homogeneous after 30 min and 24h (three phases were observed). However, the label of the product EC specifies that the trigger spray must be shaken before each use. | | |
| Surface tension | OECD Test Guideline 115 (1995) | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2503 Containing 10.20% w/w of cypermethrin | The mean surface tension of the product EC was 30.4 mN/m at 20.4°C. The test item was considered as surface-active in the experimental conditions used. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-017, [REDACTED] |
| Viscosity | OECD Test Guideline 114 (2012) ISO 3219 (1993) | EC (named LIQUIDE CONCENTRÉ in the study) Batch CRPEC2503 Containing 10.20% w/w of cypermethrin | The mean dynamic viscosity of the product EC was found to be 10.82 mPa.s at 20.0 ± 0.2°C and 6.32 mPa.s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the experimental conditions used. | Acceptable | Halbwachs P., 2020 Study no. 20-903071-017, [REDACTED] |

2.2.2.5 Physical, chemical and technical properties – Meta SPC 7

Several studies on physical, chemical and technical properties were performed on the product RTU 1, which is the only product of this Meta SPC.

The relative density, the low temperature storage stability, the surface tension and the viscosity of the products of the Meta-SPC 7 are extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC (please refer to the bridging document "A3.6_Confidential_bridging_data_Meta SPCs 4 and 7 RTU_20210727" in section 13 of this IUCLID dossier). The only difference between the products of Meta-SPC 7 and the liquid formulation of AÉROSOL GUÊPE/FRELON, is the active substance content, which is 0.20% w/w of pure cypermethrin in the product of Meta-SPC 7 and is 2.00% w/w of pure cypermethrin in the liquid formulation of AÉROSOL GUÊPE/FRELON. This composition change (maximum of 1.94%) is not expected to have any significant impact on the results obtained on the liquid formulation of AÉROSOL GUÊPE/FRELON. Therefore, the results obtained in these studies on the product AÉROSOL GUÊPE/FRELON can be extrapolated to all products from the Meta-SPC 7.

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | FR Evaluation | Reference |
|---------------------------------------|--|--|--|--|---|
| Physical state at 20 °C and 101.3 kPa | Organoleptic and visual observations. No guideline required | RTU 1 (named LIQUIDE PAE in the study) | The product RTU 1 was found to be a homogeneous yellow limp liquid with a characteristic odour. | Acceptable | Padilla P., 2021 Study no. 20-6, [REDACTED] |
| Colour at 20 °C and 101.3 kPa | | | | | |
| Odour at 20 °C and 101.3 kPa | | | | | |
| Acidity / alkalinity | - | Meta SPC 4 and 7 | The products of the Meta SPC 4 and 7 are non-aqueous ready-to-use liquid biocidal products. Therefore, the pH value is not determined on the products of the Meta SPC 4 and 7. | Acceptable | - |
| Relative density / bulk density | OECD Guideline No.109 (2012) | Liquid formulation without propellant gas of AÉROSOL GUÊPE/FRELON Batch 20/094A01 Containing 2.02% w/w of cypermethrin | The mean relative density of liquid formulation without propellant gas of the product AÉROSOL GUÊPE/FRELON was 0.885 at 20.0°C. | Acceptable It was extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC. | Halbwachs P., 2020 Study no. 20-903071-010, [REDACTED] |

| | | | | | | | |
|---|---|---|--|---|---|------------|--|
| Storage stability test – accelerated storage | CIPAC MT 46.3 method (storage stability) (2000) Validated analytical method | RTU 1 (named LIQUIDE PAE with trigger spray Versaplast EU in the study) 500 mL HDPE sprayer | The test item RTU 1 in its commercial packaging (500 mL HDPE sprayer: Versaplast EU) after an accelerated storage procedure for 8 weeks at 40 ± 2°C. | | | Acceptable | Padilla P., 2021 Study no. 20-903071-026, [REDACTED] |
| | | | | T0 | T 8 weeks | | |
| | | | Test item | Homogeneous yellow limpid liquid with a characteristic odour | Homogeneous yellow limpid liquid with a characteristic odour | | |
| | | | Packaging | White opaque HDPE sprayer of 500 mL | White opaque HDPE sprayer of 500 mL slightly curved: no sign of degradation or leak | | |
| | | | AS content | 0.201 | 0.196 | | |
| | | | Variation | / | -2.5% | | |
| | | | Ratio cis: trans | 60.78/39.22 | 60.48% /39.52% | | |
| | | | Weight (g) | 487.55 | 487.4 | | |
| | | | Variation | / | -0.04% | | |
| | | | Spray diameter and pattern | 15 cm circular | 16 cm circular | | |
| | | | Spray volume | Mean volume of 1 pulverisation: 0.592 mL No blocking of the pump | Mean volume of 1 pulverisation: 0.655 mL No blocking of the pump | | |
| | | | Spray droplet size distribution by laser diffraction | % of the respirable volume fraction less than 10µm = 0 Dv(0.1) = 77.1 µm Dv(0.5) = 142.4 µm Dv(0.9) = 295.6 µm D[3;2] = 129.8 µm D[4;3] = 171.6 µm | / | | |

| | | | | | | | | | |
|--|--|---|--|--|---|---|--|--|--|
| Storage stability test – long term storage at ambient temperature | Technical Monograph No.17, 2nd edition, CropLife Validated analytical method | RTU 1 (named LIQUIDE PAE in the study) Batch n° 21090 500 mL HDPE sprayer | 24 months at 20 (15.6 °C and 24.5°C) Test item RTU 1 in its commercial packaging (500 mL HDPE sprayer)the type of sprayer is not indicated in the study... | | | | Acceptable. The product is stable in its packaging during 12 months as leakage has been observed after 12 months. The pH was not measured before and after storage. However, based on the composition of the product and as the product is a ready too use product no further data required. The type of trigger tested was not indicated in th study report, however as only one type is claimed for this meta SPC, we can consider that the commercial packaging tested correspond to the same trigger spray : Versaplast EU. | eDemangel B and Ricau H, 2020 903071-027, XXXXXXXXXX | |
| | | | | T0 | T 6 months | T 12 months | | | T 24 months |
| | | | Test item | Homogeneous yellow limpud liquid with a characterisctic odour | | | | | |
| | | | Packaging (weight = product + packaging) | Weight : / White opaque HDPE sprayer | Difference of weight : 0% White opaque HDPE sprayer slightly curved without leak | Difference of weight : 0% White opaque HDPE sprayer slightly curved without leak | | | Difference of weight : -0.3% White opaque HDPE sprayer with slightly leak on juncture |
| | | | AS content (%w/w) (analytical method is described in the analytical part) | 0.201 (result obtained duri,g study N°20-903071-026, accelerat ed storage stability study) | 0.197 | 0.200 | | | 0.202 |
| | | | Variation (%) | / | -2 | -0.5 | | | +0.5 |
| | | | Ratio cis: trans | 60.78/39.22 | 60.3/39.70 | 60.57/39.43 | | | 60.6/39.4 |
| | | | volume delivered | 0.612 | 0.622 | 0.611 | | | 0.641 |

| | | | (mL)(internal method) | No blockage | No blockage | No blockage | No blockage | | |
|---|-----------------------------|--|--|--|---|---------------------|--|--|--|
| | | | Spray diameter and pattern (adapted FEA 644) | 15 cm Circular form | 16 cm Circular form | 17 cm Circular form | 17 cm Circular form | | |
| Storage stability test - low temperature stability test for liquids | CIPAC MT 39.3 method (2000) | AÉROSOL GUËPE/FRELON Batch 20/094A01 Containing 0.507% w/w of cypermethrin 650 mL multi-shot metal (tinplate) aerosol filled with 500 mL of liquid formulation | The test item AÉROSOL GUËPE/FRELON and its commercial packaging (650 mL multi-shot metal (tinplate) aerosol filled with 500 mL of test item) were considered to be stable after a low storage procedure for 7 days at 0 ± 2°C; no change in the appearance of the test item and in the appearance and the weight of the commercial packaging was observed. | | Acceptable | | The products are stable 7 days at 0°C. | | Halbwachs P., 2020 Study no. 20-903071-011, XXXXXXXXXX |
| | | | | T0 | T 7 days at 0°C | | | | |
| | | | Test item | Homogeneous colourless limp liquid with a characteristic odour | No change | | | | |
| | | | Packaging | White opaque metal (tinplate) aerosol of 150 mL | No sign of degradation or leak was observed. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | - | Meta SPC 4 and 7 | The study for stability to sunlight is not required as the commercial packaging of the products (500 mL HDPE sprayer), is opaque | | As the AS is not light sensitive according to AR. Therefore no further data required. | | | | - |
| Effects on content of the active substance and | - | Meta SPC 4 and 7 | The stability of the product RTU 1 in its commercial packaging (500 mL HDPE sprayer) will be determined after an accelerated storage procedure (8 weeks at 40 ± 2°C) according to CIPAC MT 46.3 (Handbook J, 2000). The results will be provided when available. | | Data on temperature have been provided in the accelerated storage stability | | | | - |

| | | | | | |
|---|---|------------|---|---|---|
| technical characteristics of the biocidal product – temperature and humidity | | | The products of the Meta SPC 4 in their commercial packagings are expected to stable after a low temperature stability procedure (7 days at $0 \pm 2^{\circ}\text{C}$). The individual commercial packagings of the products are hermetically sealed, the packagings are leak-tight, and therefore, a study for humidity effects is not required. | study and in the low temperature stability study. | |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | - | - | See the storage stability test – long term storage at ambient temperature | - | - |
| Wettability | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Wet sieve analysis and dry sieve test | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Disintegration time | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |

| | | | | | |
|--|---------------------------------------|--|---|------------|--|
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 187 (2003) ISO 13320-2009 | RTU 1 (named LIQUIDE PAE with trigger spray Versaplast EU in the study) 500 mL HDPE sprayer | The spray droplet size distribution of the test item RTU 1 in its commercial packaging (500 mL HDPE sprayer: Versaplast EU) will be determined by laser diffraction The percentage of the respirable volume fraction less than 10 µm is zero. Mean on the three sprays: Dv(0.1) = 77.1 µm Dv(0.5) = 142.4 µm Dv(0.9) = 295.6 µm | Acceptable | Padilla P., 2021903071-026, [REDACTED] |
| Persistent foaming | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Flowability/Pourability/Dustability | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Burning rate — smoke generators | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Burning completeness — smoke generators | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Composition of smoke — smoke generators | - | Meta SPC 7 | Not required as the products of the Meta SPC 4 are non-aqueous ready-to-use liquid biocidal products. No data provided. | - | - |
| Spraying pattern — aerosols | FEA 644 (2009) | RTU 1 (named LIQUIDE PAE in the study) 500 mL HDPE sprayer Versaplast EU in the study | At initial time, the mean spray diameter of the RTU 1 sprayer Versaplast EU was 15 cm and the shape of the spray on the wetted patch was circular. The mean volume of test item after one pulverisation of sprayer was 0.592 mL. | Acceptable | Padilla P., 2021Study plan no. 20-903071-026, [REDACTED] |
| Physical compatibility | - | Meta SPC 7 | Not applicable. The products of the Meta SPC 4 are not intended to be used in conjunction with any other products or active substances. | - | - |
| Chemical compatibility | - | Meta SPC 7 | Not applicable. The products of the Meta SPC 4 are not intended to be used in conjunction with any other products or active substances. | - | - |

| | | | | | |
|--|---|--|--|--|---|
| Degree of dissolution and dilution stability | - | Meta SPC 7 | Not applicable. The products of the Meta SPC 4 are not intended to be used in conjunction with any other products or active substances. | - | - |
| Surface tension | OECD Test Guideline 115 (1995) | Liquid formulation without propellant gas of AÉROSOL GUÊPE/FRELON Batch 20/094A01 Containing 2.02% w/w of cypermethrin | According to EU Method A.5 and to OECD No.115 methods (ring method), the mean surface tension of liquid formulation without propellant gas of the product AÉROSOL GUÊPE/FRELON was 26.6 mN/m at 20.2°C. The test item was considered as surface-active in the experimental conditions used. | Acceptable It was extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC. . | Halbwachs P., 2020 Study no. 20-903071-010, [REDACTED] |
| Viscosity | OECD Test Guideline 114 (2012) ISO 3219 (1993) | Liquid formulation without propellant gas of AÉROSOL GUÊPE/FRELON Batch 20/094A01 Containing 2.02% w/w of cypermethrin | According to OECD Test Guideline 114 and to ISO Standard 3219 (rotational viscometer), the mean dynamic viscosity of the liquid formulation without propellant gas of the product AÉROSOL GUÊPE/FRELON was found to be 6.96 mPa*s at 20.0 ± 0.4°C and 4.27 mPa*s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the experimental conditions used. | Acceptable It was extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC. | Halbwachs P., 2020 Study no. 20-903071-010, [REDACTED] |

Conclusion on the physical, chemical and technical properties of the product

AE FC 1 (Meta SPC 6, 1 and 2)

Studies on physical, chemical and technical properties were performed on the product AE FC 1, which is the product having the lowest active substance content of Meta SPC 1, 6 and 2. As the only difference between the 3 products of these Meta-SPC is the active substance content, which

varies between 0.20% w/w and 0.80% w/w of pure cypermethrin, this composition variation is not expected to have any significant impact on the results obtained on the product AE FC 1.

The product **AE FC 1 (Meta SPC 2)** is an aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a homogeneous colourless limpid liquid with characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in metal can packaging material (commercial packaging material).

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Its technical characteristics are acceptable for an AE formulation.

Shelf life : 24 months at ambient temperature

Mitigation measure : store at temperature below 40°C

OS 1 (Meta SPC 3)

Studies on physical, chemical and technical properties were performed on the product OS 1, which is the product having the lowest active substance content of this Meta-SPC. As the only difference between the 2 products of this Meta-SPC is the active substance content, which varies between 0.50% w/w and 0.80% w/w of pure cypermethrin, this composition variation is not expected to have any significant impact on the results obtained on the product OS 1.

The product **OS 1 (Meta SPC 3)** is an aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a homogeneous colourless limpid liquid with characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in metal can packaging material (commercial packaging material).

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Its technical characteristics are acceptable for an AE formulation.

Shelf life : 24 months at ambient temperature

Mitigation measure : store at temperature below 40°C

RTU 1 (Meta SPC 7 and 4)

Several studies on physical, chemical and technical properties were performed on the product RTU 1, which is the product having the lowest active substance content of these Meta-SPC. As the only difference between the 3 products of these Meta-SPC (4 and 7) is the active substance content, which varies between 0.20% w/w and 0.80% w/w of pure cypermethrin, this composition change is not expected to have any significant impact on the results obtained on the product RTU 1.

The relative density, the low temperature storage stability, the surface tension and the viscosity of the products of the Meta SPC 4 are extrapolated from the results obtained on the liquid formulation of the product AÉROSOL GUÊPE/FRELON, which has a similar composition as the products of this Meta SPC (please refer to the bridging document in the document Excel "Composition"). The only difference between the products of Meta SPC 4 and the liquid formulation of AÉROSOL GUÊPE/FRELON, is the active substance content, which varies between 0.20% w/w and 0.80% w/w of pure cypermethrin in the products of Meta SPC 4 and is 2.00% w/w of pure cypermethrin in the liquid formulation of AÉROSOL GUÊPE/FRELON.

The product **RTU 1 (Meta SPC 7)** is an all others liquids (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. However, the study report of the particle size and spray pattern tests should be provided during the commenting phase.

The appearance of the product is a homogeneous yellow limpid liquid with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The long-term storage stability studies was provided and shows that the product is stable in its packaging for 12 months. Indeed, as a leak was observed after 24 months, the product cannot be considered as stable in its commercial packaging.

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Its technical characteristics are acceptable for an AE formulation.

Shelf life : 1 year

Mitigation measure : store at temperature below 40°C

EC (Meta SPC 5)

The product EC (named LIQUIDE CONCENTRÉ in the study) is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a homogeneous yellow limpid liquid with characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in f-HDPE bottle or jerrycan packaging material (commercial packaging material).

After 7 days at 0°C, the appearance has not significantly changed. However, the pH and dilution stability were not provided. Therefore the data available are not sufficient to conclude on the stability at 0°C. A mitigation measure should be added on the label.

Its technical characteristics are acceptable for an SL formulation.

Shelf life : 24 months at ambient temperature

Mitigation measures :

Store at temperature below 40°C.

Shake the product before and during use.

Protect from frost.

2.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | FR evaluation | Reference |
|-----------------|----------------------|--|---|---------------|-----------|
| Explosives | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | The products formulated as aerosol dispenser (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) are not concerned by the physical hazard Unstable explosives or explosives of Divisions 1.1 to 1.6 as they are already classified as Flam. Aerosol 1, H222 and Flam. Aerosol 1, H229. | Acceptable | IUCLID |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | The products of the Chimiget_Cyper family contain maximum 10.87% w/w of technical cypermethrin cis/trans 40/60 (technical) (CAS No. 52315-07-8), which has no potential for explosion according to its Assessment Report (Product-Type 18, February 2017). Moreover maximum more than 99% w/w of the composition of the products RTU1, RTU2, RTU3 and EC are fatty acids. These components have no chemical group associated with explosive properties and are not classified for explosive properties according to its safety data sheet. The other components, maximum of 5% w/w of the formulations, doesn't contain reactive groups and due to its low content in the products, it is not considered as being able to lead to a classification of the products of the family. Therefore, the products RTU 1, RTU 2, RTU 3 and EC of the Chimiget_Cyper family are not expected to have explosive properties and test is considered unnecessary. | | |
| Flammable gases | - | Chimiget_Cyper family | Not required as the family products are liquid products or formulated as aerosol dispenser. | - | - |

| | | | | | |
|----------------------|-----------|--|--|---|--------|
| Flammable aerosols | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | As the products of the Chimiget_Cyper family formulated as aerosol dispensers (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) contain 19% to 30% w/w of a solvent mixture, which is classified Flam. Liq. 2, H225, , they are classified as Flam. Aerosol cat 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated). | Acceptable | IUCLID |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | The products of the Chimiget_Cyper family RTU 1, RTU 2, RTU 3 and EC are not concerned by the physical hazard "Flammable aerosol" as they are liquid products. | | |
| Oxidising gases | - | Chimiget_Cyper family | Not required as the family products are liquid products or formulated as aerosol dispenser. | - | - |
| Gases under pressure | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | The products formulated as aerosol dispensers (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) are not concerned by the physical hazard "gases under pressure" according to Regulation (EC) No.1272/2008, 2.3.2.1, Note 2: "Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids)". | Not relevant as the product is not a gas under pressure | - |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | The products of the Chimiget_Cyper family are not concerned by the physical hazard "gases under pressure" as they are liquid products (RTU 1, RTU 2, RTU 3 and EC). | | |
| Flammable liquids | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | The products formulated as aerosol dispensers (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) are not concerned by the physical hazard "flammable liquids" according to Regulation (EC) No.1272/2008, 2.3.2.1, Note 2: "Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids)". | Acceptable | IUCLID |

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|---------------------------------------|--|--|--|---|--|
| | ISO Standard 3679 EC A.9 method (when available) | Meta SPC 4 Meta SPC 5 Meta SPC 7 | <p>A flash point has been performed on the products EC (Meta SPC 5) and RTU1 (Meta SPC 7, with 0.22% w/w technical cypermethrin) and no flash point was observed up to 100°C for both products. As the product RTU2 (Meta SPC 4) contains 0.54% w/w technical cypermethrin, its flash point is expected to be between RTU1 and RTU3 flash point.</p> <p>A flash point has been measured on the product RTU 3 at 172°C</p> | Acceptable The meta SPC 4, 5 and 7 are no flammable liquids. | Yaverian J-M, 2021 Padilla P, 2022, 22-903071-001 |
| Flammable solids | - | - | Chimiget_Cyper family are not concerned by the physical hazard "Flammable solids" as they are liquid products. | Not relevant as the products are not solid. | - |
| Self-reactive substances and mixtures | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | The products formulated as aerosol dispensers (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) are not concerned by the physical hazard "Self-reactive substances and mixtures" as they are already classified as Flam. Aerosol 1, H222 and Flam. Aerosol 1, H229. Tests are considered unnecessary. | Acceptable | IUCLID |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | <p>The products of the Chimiget_Cyper family contain maximum 10.87% w/w of technical cypermethrin cis:trans 40:60 (technical) (CAS No. 52315-07-8), which is not classified for self-reactive properties according to its Assessment Report (Product-Type 18, February 2017). Moreover maximum more than 99% w/w of the composition of the products RTU 1, RTU 2, RTU 3 and EC are fatty acids. These components are not classified for self-reactive properties</p> <p>The other component, maximum of 5% w/w of the formulations, is not classified for self reactive properties, and due to its low content in the products, it is not considered as being able to lead to a classification of the products of the family.</p> <p>Therefore, the products RTU 1, RTU 2, RTU 3 and EC of the Chimiget_Cyper family are not expected to have self-reactive properties and tests are considered unnecessary.</p> | | |

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|--|-----------|-----------------------|---|---|--------|
| Pyrophoric liquids | Statement | Chimiget_Cyper family | Tests are not required as the products of the Chimiget_Cyper family do not contain any components classified as pyrophoric. Moreover, experience in manufacture and handling shows that the products of the Chimiget_Cyper family do not ignite spontaneously on coming into contact with air at normal temperature. The products of the Chimiget_Cyper family are not expected to be pyrophoric liquids and and test is considered unnecessary. | Acceptable | IUCLID |
| Pyrophoric solids | - | Chimiget_Cyper family | The products of the Chimiget_Cyper family are not concerned by the physical hazard "pyrophoric solids" as they are aerosols dispensers and liquid products. | Not relevant as the products are a solid | IUCLID |
| Self-heating substances and mixtures | Statement | Chimiget_Cyper family | Tests are not required as experience in manufacture and handling shows that the products of the Chimiget_Cyper family do not ignite spontaneously on coming into contact with air at normal temperature. The products of the Chimiget_Cyper family are not expected to be self-heating mixtures and tests are not required. Moreover, the products of the Chimiget_Cyper family are not expected to present a significant hazard for auto-flammability. | Acceptable all product is under liquid form therefore no self-heating properties is expected. | IUCLID |
| Substances and mixtures which in contact with water emit flammable gases | Statement | Chimiget_Cyper family | Tests are not required as the products of the Chimiget_Cyper family do not contain any components classified as substances which in contact with water emit flammable gases. Therefore the products of the Chimiget_Cyper family are not expected to emit flammable gases in contact with water and and tests are considered unnecessary. | Acceptable | IUCLID |

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|-------------------|-----------|--|--|------------|--------|
| Oxidising liquids | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | <p>The products of Meta-SPCs 1, 2, 3 and 6 contain between 0.22% and 0.87% w/w of technical Cypermethrin cis:trans 40:60 (CAS No. 52315-07-8), which is not oxidising according to its Assessment Report (Product-Type 18, February 2017).</p> <p>The aerosol dispensers (i.e. AE WH, AE FC1, AE FC2, AE FC3, OS1 and OS2) contain between 70% and 80% w/w of a propellant gas which is not classified for oxidising properties according to Regulation (EC) No.1272/2008. Moreover between 19% and 30% w/w of the composition of the products is a component with no chemical group associated with oxidising properties (no compound contains oxygen, fluorine or chlorine bonded to atom different as carbon and hydrogen) and which is not classified for oxidising properties according to Regulation (EC) No.1272/2008.</p> <p>Therefore, the products AE WH, AE FC 1, AE FC2, AE FC 3, OS 1 and OS 2 of the Chimiget_Cyper family are not expected to have oxidising properties and test is considered unnecessary.</p> | Acceptable | IUCLID |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | <p>The products of Meta-SPCs 4 and 5 contain between 0.22% and 10.87% w/w of technical Cypermethrin cis:trans 40:60 (CAS No. 52315-07-8), which is not oxidising according to its Assessment Report (Product-Type 18, February 2017).</p> <p>Moreover maximum more than 99% w/w of the composition of the products RTU 1, RTU 2, RTU 3 and EC are fatty acids. This component has no chemical group associated with oxidising properties (no compound contains oxygen, fluorine or chlorine bonded to atom different as carbon and hydrogen) and is not classified for oxidising properties according to its SDS.</p> <p>The other component, maximum of 5% w/w of the formulations, is not classified for its oxidising properties according to its safety datasheet, and due to its low content in the products, it is not considered as being able to lead to a classification of the products of the family.</p> <p>Therefore, the products RTU1, RTU2, RTU3 and EC of the Chimiget_Cyper family are not expected to have oxidising properties and test is considered unnecessary.</p> | | |

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|-------------------|---|-----------------------|---|---|--------|
| Oxidising solids | - | Chimiget_Cyper family | The products of the Chimiget_Cyper family are not concerned by the physical hazard "oxidising solids" as they are liquid products. | Not relevant as the product is a liquid | IUCLID |
| Organic peroxides | - | Chimiget_Cyper family | The products of the Chimiget_Cyper family are not concerned by the physical hazard "organic peroxides" as their components are not expected to form or contain organic peroxides. | Acceptable | IUCLID |

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|---------------------|------------|--|--|---|--------|
| Corrosive to metals | Method C.1 | <p>Meta SPC 3 : OS2 product Batch 20/093A03</p> <p>Meta SPC 5 : EC product batch Cyp2507</p> | <p>Size : 2mm thick plates, 50 mm lenght, 20 mm width Aluminium , non clad type 7075-T6 Steel-type S235JR+CR</p> <p>Immersed 7 days at 55°C Steel : -0.6% Aluminium : -0.01%</p> <p>Half immersed Steel : -0.6% I Aluminium : -0.04%</p> <p>In gaseous phase Steel : / Aluminium : /</p> <p>No localised corrosion was observed on steel and aluminium</p> <p>Size : 2mm thick plates, 50 mm lenght, 20 mm width Aluminium , non clad type 7075-T6 Steel-type S235JR+CR</p> <p>Immersed 7 days at 55°C Steel : -0.004% Aluminium : -0.004%</p> <p>Half immersed Steel : -0.003% I Aluminium : -0.005%</p> <p>In gaseous phase Steel : -0.003% Aluminium : 0.002%</p> <p>No localised corrosion was observed on steel and aluminium</p> | <p>The results show that the product OS2 is not classified corrosive to metal. Based on the compositions, the result covers the meta SPC 1, 2, 3 and 6</p> <p>The results show that the product EC is not classified corrosive to metal. Based on the compositions, the result covers the meta SPC 4, 5 and 7</p> | IUCLID |
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|--|-----------|--|--|---|--------|
| Auto-ignition temperatures of products (liquids and gases) | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | The products of Meta-SPCs 1, 2, 3 and 6 contain between 0.22% and 0.87% w/w of technical Cypermethrin cis:trans 40:60 (CAS No. 52315-07-8), which is not auto-flammable (auto ignition temperature = 400°C) according to its Assessment Report (Product-Type 18, February 2017). The aerosol dispensers (i.e. AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2) contain between 70% and 80% w/w of a propellant gas which is not auto-flammable. Data is lacking on the self-ignition temperature of the other components, although they are not expected to present a significant hazard for auto-flammability. Therefore, the products AE WH, AE FC 1, AE FC 2, AE FC 3, OS 1 and OS 2 of the Chimiget_Cyper family are not expected to have auto-ignition properties and test is considered unnecessary. | Acceptable for meta SPC 1, 2, 3 and 6 as they are covered by AE classification. Based on the result obtained for meta SPC 5, it can be considered that meta SPC 4 and 7 are cover by meta SPC 5. | IUCLID |
| | | Meta SPC 4 Meta SPC 5 Meta SPC 7 | The products of the Meta-SPCs 4, 5 and 7 contain maximum 10.87% w/w of technical cypermethrin cis:trans 40:60 (technical) (CAS No. 52315-07-8), which is not auto flammable (auto-ignition temperature = 400°C) according to its Assessment Report (Product-Type 18, February 2017). Data is lacking on the self-ignition temperature of the other components, although they are not expected to present a significant hazard for auto-flammability. An auto-ignition test is performed according to EC A15 on the product EC (Meta SPC 5) +The auto-ignition was 251°C. | | |
| Relative self-ignition temperature for solids | Statement | Meta SPC 1 Meta SPC 2 Meta SPC 3 Meta SPC 6 | Tests for relative self-ignition temperature of the products AE WH, AE FC1, AE FC2, AE FC3, OS1 and OS2 of the Chimiget_Cyper family are not required as they are aerosol dispensers and not solid products. | Acceptable Not relevant as the product is not a solid | IUCLID |
| | | Meta-SPC 4 Meta-SPC 5 Meta SPC 7 | Tests for relative self-ignition temperature of the products RTU1, RTU2, RTU3 and EC of the Chimiget_Cyper family are not required as they are liquid products. | | |

| | | | | | |
|-----------------------|-----------|-----------------------|--|--|--------|
| Dust explosion hazard | Statement | Chimiget_Cyper family | The products of the Chimiget_Cyper family are not concerned by the physical hazard "dust explosion" as they are liquid products. | Acceptable Not relevant as the product is not a solid | IUCLID |
|-----------------------|-----------|-----------------------|--|--|--------|

Conclusion on the physical hazards and respective characteristics of the product

The products of the Chimiget_Cyper family are not expected to present a significant hazard for explosive properties, pyrophoric properties, oxidising properties. They do not emit flammable gases in contact with water.
The products of the Meta SPCs 1, 2, 3 and 6, formulated as aerosol dispensers, are classified as Flam. Aerosol 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated).
The products of Meta SPCs 4, 5 and 7 are not classified.

Implication concerning labelling:

Meta SPCs 1, 2, 3 and 6: Flam. Aerosol 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated).

2.2.4 Methods for detection and identification

The products family CHIMIGET_CYPER consists of 7 Meta-SPC having similar compositions

- AÉROSOL GUÊPE/FRELON (formulation not claimed in this dossier) and Meta SPC 4 and 7 RTU for which the liquid formulations contain the same ingredients,
- Meta SPC 1 (AE WH), Meta SPC 2 and 6 AE FC and Meta SPC 3 OS for which the liquid formulations contain the same ingredients.
- Meta SPC 5 (EC) which contains the same ingredients as the liquid formulations of AÉROSOL GUÊPE/FRELON and as Meta-SPCs 4 and 7 (RTU), with only an additional component.

In order to determine the cypermethrin cis/trans 40/60 content in the products family CHIMIGET_CYPER, three analytical methods were performed.

An analytical method for the determination of cypermethrin contents in the products of AÉROSOL GUÊPE/FRELON and Meta SPC 4 and 7 RTU was fully validated on the product AÉROSOL GUÊPE/FRELON (formulation not claimed in this dossier) (study no. 20-903071-014), as only the content of active substance changes in the liquid formulations of these products.

An additional study was performed and the specificity, the precision and the reproducibility of this method was performed on the product EC (Meta SPC 5 EC) (study no. 20-903071-20), as this product contains an additional component.

The linearity was tested within the concentration range of cypermethrin cis/trans 40/60 in the liquid formulation without the propellant gas in the test item. In order to be covered by the validated linearity range, the quantity of each product (RTU 1, RTU 2, RTU 3 or EC) weighed for the determination of cypermethrin cis/trans 40/60 content was adjusted according to the active substance content in the products.

An analytical method for the determination of cypermethrin contents in the products of Meta SPC 2 and 6 AE FC and Meta SPC 3 OS was performed on the product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS) (study no. 20-903071-005), as only the content of active substance changes in the liquid formulations of the products of these two Meta-SPCs.

Product AÉROSOL GUÊPE/FRELON and Meta SPC 4 RTU

Report: Ricau H. 2020. Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product In compliance with SANCO/3030/99 rev.5 from 22/03/2019

Report no 20-903071-014

Test facilities: [REDACTED] (Brindas, France)

Principle of the method: (see Conf PAR)

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

| Specificity | <p>To demonstrate the specificity of the method, several solution are analyzed:</p> <ul style="list-style-type: none"> - the solvent blank (acetonitrile), - the matrix without any active, substance (blank formulation), - the cypermethrin reference item, - the test item (liquid formulation of the product AÉROSOL GUÊPE/FRELON) <p>No peak appears in the solvent blank and in the blank formulation. In the solutions of cypermethrin reference item and test item, the peaks at the retention times around 9.684 min and 10.282 min represent respectively trans-cypermethrin and cis-cypermethrin. An unknown peak appears in the test item near the peak of trans- cypermethrin. As the unknown area peak was less than 3% of the cypermethrin area peak, the unknown peak was not considered to be interfering peak for the analysis. All chromatograms (and mass spectra) were available.</p> | | | | | | | | | | |
|---------------------|--|---------------------|---------------------|------------------|---|----------|---------|---------|---|----------|---------|
| Linearity | <p>Linearity was studied by carrying out five concentrations (in duplicate) between 50% and 150% (from 117.3 mg/L to 348.3 mg/L) of the reference item. Calibration curve has been provided with a r higher than 0.99.</p> <table border="1" data-bbox="564 925 1415 1099"> <thead> <tr> <th data-bbox="564 925 879 965">Compound</th> <th data-bbox="879 925 1415 965">Linearity %</th> </tr> </thead> <tbody> <tr> <td data-bbox="564 965 879 1099">Active substance</td> <td data-bbox="879 965 1415 1099"> 50% to 150% $Y = 1.17 * 10^5 * x + 7.35 * 10^4$ $r = 0.9999$ $n=2$ for 5 levels of concentration </td> </tr> </tbody> </table> | Compound | Linearity % | Active substance | 50% to 150% $Y = 1.17 * 10^5 * x + 7.35 * 10^4$ $r = 0.9999$ $n=2$ for 5 levels of concentration | | | | | | |
| Compound | Linearity % | | | | | | | | | | |
| Active substance | 50% to 150% $Y = 1.17 * 10^5 * x + 7.35 * 10^4$ $r = 0.9999$ $n=2$ for 5 levels of concentration | | | | | | | | | | |
| Precision | <p>Repeatability was evaluated by analyzing twice five test item solutions. Mean content : 2.09%w/w corresponding to 0.522% w/w in to aerosol with the propellant gas</p> <table border="1" data-bbox="564 1200 1415 1294"> <thead> <tr> <th data-bbox="564 1200 879 1240">Compound</th> <th data-bbox="879 1200 1415 1240">Repeatability (RSD)</th> </tr> </thead> <tbody> <tr> <td data-bbox="564 1240 879 1294">Active substance</td> <td data-bbox="879 1240 1415 1294">RSD = 0.57%</td> </tr> </tbody> </table> | Compound | Repeatability (RSD) | Active substance | RSD = 0.57% | | | | | | |
| Compound | Repeatability (RSD) | | | | | | | | | | |
| Active substance | RSD = 0.57% | | | | | | | | | | |
| Accuracy | <p>Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.</p> <table border="1" data-bbox="564 1429 1415 1576"> <thead> <tr> <th data-bbox="564 1429 879 1498">Fortification level</th> <th data-bbox="879 1429 1083 1498">Recovery rate</th> <th data-bbox="1083 1429 1275 1498">Mean recovery</th> <th data-bbox="1275 1429 1415 1498">n</th> </tr> </thead> <tbody> <tr> <td data-bbox="564 1498 879 1538">230 mg/L</td> <td data-bbox="879 1498 1083 1538">100.9 %</td> <td data-bbox="1083 1498 1275 1538" rowspan="2">100.9 %</td> <td data-bbox="1275 1498 1415 1538" rowspan="2">2</td> </tr> <tr> <td data-bbox="564 1538 879 1576">230 mg/L</td> <td data-bbox="879 1538 1083 1576">100.8 %</td> </tr> </tbody> </table> | Fortification level | Recovery rate | Mean recovery | n | 230 mg/L | 100.9 % | 100.9 % | 2 | 230 mg/L | 100.8 % |
| Fortification level | Recovery rate | Mean recovery | n | | | | | | | | |
| 230 mg/L | 100.9 % | 100.9 % | 2 | | | | | | | | |
| 230 mg/L | 100.8 % | | | | | | | | | | |
| Ratio of isomers | <p>The ratio between cis- and trans-cypermethrin was studied during the precision and reproducibility analysis. The percent area (%) of cis- and trans-cypermethrin was calculated: 60.1% of trans-cypermethrin and 39.9% of cis-cypermethrin.</p> | | | | | | | | | | |

The analytical method is fully validated for the determination of the active substance Cypermethrin in the product.

Meta SPC 1, Meta SPC 2 and 6 AE FC and Meta SPC 3 OS

Report: Ricau H. 2020. Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product AÉROSOL VOLANTS/RAMPANTS In compliance with SANCO/3030/99 rev.5 from 22/03/2019

Report no 20-903071-005

Test facilities: ██████████ (Brindas, France)

Principle of the method:

Cypermethrin cis/trans 40/60 is analysed after extraction from the liquid formulation of product AE FC 1 (named AÉROSOL VOLANTS/RAMPANTS in the study) and quantified by liquid chromatography using a reverse phase column and a UV detector.

About 0.3750 g of the liquid formulation of product AE FC 1 is accurately weighed (to the nearest 0.01 mg) into a 10-mL volumetric flask and the volume is made up with acetonitrile. The solution is homogenised then diluted 10 times with acetonitrile before analysis.

Cypermethrin cis/trans 40/60 is analysed by Liquid Chromatography with UV detection (225 nm) by external standard calibration, at retention time of about 7.7 min for cis-cypermethrin peak and 7.3 min for trans-cypermethrin peak.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

| | | |
|-------------|--|--|
| Specificity | <p>To demonstrate the specificity of the method, several solution are analyzed:</p> <ul style="list-style-type: none"> - the solvent blank (acetonitrile), - the matrix without any active, substance (blank formulation), - the cypermethrin reference item, - the test item (liquid formulation of the product AE FC 1) <p>No peak appears in the solvent blank and in the blank formulation. In the solutions of cypermethrin reference item and test item, the peaks at the retention times around 7.3 min and 7.7 min represent respectively trans-cypermethrin and cis-cypermethrin. No additional peak appears near the retention times of the two cypermethrin peaks in the reference item and in the test item.</p> <p>All chromatograms (and mass spectra) were available.</p> | |
| Linearity | <p>Linearity was studied by carrying out five concentrations (in duplicate) between 50% and 150% (from 117 mg/L to 346.8 mg/L) of the reference item.</p> <p>Calibration curve has been provided with a r higher than 0.99.</p> | |
| | Compound | Linearity % |
| | Active substance | <p>50% to 150%</p> $Y = 1.15 * 10^5 * x + 2.34 * 10^5$ <p>r = 1.0000 n=2 for 5 levels of concentration</p> |
| Precision | <p>Repeatability was evaluated by analyzing twice five test item solutions. Mean content : 0.704 %w/w corresponding to 0.210% w/w in to aerosol with the propellant gas</p> | |
| | Compound | Repeatability (RSD) |
| | Active substance | RSD = 0.41% |

| | | | | |
|------------------|---|---------------|---------------|---|
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate. | | | |
| | Fortification level | Recovery rate | Mean recovery | n |
| | 230 mg/L | 99.2 % | 99.1% | 2 |
| | 230 mg/L | 99.1 % | | |
| Ratio of isomers | The ratio between cis- and trans-cypermethrin was studied during the precision and reproducibility analysis. The percent area (%) of cis- and trans-cypermethrin was calculated: 59.9% of trans-cypermethrin and 40.1% of cis-cypermethrin. | | | |

The analytical method is fully validated for the determination of the active substance Cypermethrin in the product.

Meta SPC 5 EC

Following SANCO/3030/99 rev.5 from 22/03/2019, an analytical method for the determination of cypermethrin cis/trans 40/60 content in the liquid formulation of product AÉROSOL GUÊPE/FRELON (formulation not claimed in this dossier) was validated during the study N°20-903071-014 by definition of the specificity, the linearity, the accuracy, the precision and the reproducibility of the method.

Furthermore, this method allows determining the ratio of cis- and trans-cypermethrin isomers. This analytical method for the determination of cypermethrin cis/trans 40/60 was validated during this study by definition of the specificity, the precision and the reproducibility of the method for the product EC (named LIQUIDE CONCENTRÉ in the study).

Report: Ricau H. 2020. Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product LIQUIDE CONCENTRÉ In compliance with SANCO/3030/99 rev.5 from 22/03/2019

Report no 20-903071-020

Test facilities: [REDACTED] (Brindas, France)

Principle of the method:

Cypermethrin cis/trans 40/60 is analysed after extraction from the liquid formulation of product EC and quantified by liquid chromatography using a reverse phase column and a UV detector.

About 1.25 g of the liquid formulation of product EC is accurately weighed (to the nearest 0.01 mg) into a 10-mL volumetric flask and the volume is made up with acetonitrile. The solution is homogenised then diluted 10 times with acetonitrile before analysis.

Cypermethrin cis/trans 40/60 is analysed by Liquid Chromatography with UV detection (225 nm) by external standard calibration, at retention time of about 10.6 min for cis-cypermethrin peak and 10.0 min for trans-cypermethrin peak.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

| | | | |
|---|---|---|---------------|
| Specificity | <p>To demonstrate the specificity of the method, several solution are analyzed:</p> <ul style="list-style-type: none"> - the solvent blank (acetonitrile), - the matrix without any active, substance (blank formulation), - the cypermethrin reference item, - the test item (liquid formulation of the product EC) <p>No peak appears in the solvent blank and in the blank formulation. In the solutions of cypermethrin reference item and test item, the peaks at the retention times around 9.980 min and 10.602 min represent respectively trans-cypermethrin and cis-cypermethrin. No additional peak appears near the retention times of the two cypermethrin peaks in the reference item and in the test item. All chromatograms (and mass spectra) were available.</p> | | |
| Linearity (Result from the study 20-903071-014) | <p>Linearity was studied by carrying out five concentrations (in duplicate) between 50% and 150% (from 117.3 mg/L to 348.3 mg/L) of the reference item. Calibration curve has been provided with a r higher than 0.99.</p> | | |
| | Compound | Linearity % | |
| | Active substance | <p>50% to 150% $Y = 1.17 * 10^5 * x + 7.35 * 10^4$ $r = 0.9999$ $n=2$ for 5 levels of concentration</p> | |
| Precision | <p>Repeatability was evaluated by analyzing twice five test item solutions. Mean content : 10.31% w/w</p> | | |
| | Compound | Repeatability (RSD) | |
| | Active substance | RSD = 1.70 % | |
| Accuracy (Result from the study 20-903071-014) | <p>Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.</p> | | |
| | Fortification level | Recovery rate | Mean recovery |
| | 230 mg/L | 100.9 | 100.9 |
| | 230 mg/L | 100.8 | 2 |
| Ratio of isomers | <p>The ratio between cis- and trans-cypermethrin was studied during the precision and reproducibility analysis. The percent area (%) of cis- and trans-cypermethrin was calculated: 56.7% of trans-cypermethrin and 43.3% of cis-cypermethrin.</p> | | |

The analytical method is fully validated for the determination of the active substance Cypermethrin in the product.

Analytical methods for Cypermethrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report of Cypermethrin Product-type 18, February 2017. The applicant CHIMIGET has a Letter of Access from LIMARU NV (Acting for Tagros Chemicals India Private Limited) for these data.

As the active substance Cypermethrin is not classified Toxic or Very Toxic, an analytical method for the determination of Cypermethrin residue in human body fluids and tissues is unnecessary.

As the products Family CHIMIGET_CYPER is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of Cypermethrin residue in food/feed of plant and animal origin is unnecessary. However, analytical methods for the determination of cypermethrin residues in Food/feed of plant and animal origin are available in Document I, Evaluation Report of Cypermethrin, Product-type 18 (Insecticides), February 2017.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes):

LOD = 0.05 mg/kg (oilseed rape),
0.025 mg/kg (wheat).

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes):

LOQ = 0.05 mg/kg (bovine tissue),
0.005 mg/kg (bovine milk),
0.01 mg/kg (hen eggs)

Conclusion on the methods for detection and identification of the product

The analytical method is fully validated for the determination of the active substance Cypermethrin in the products for all meta-SPCs.

Analytical methods were provided at EU level for the determination of Cypermethrin residue in soil, air and water with respectively LOQ = 0.05 mg/kg, 0.375 µg/m³ and 0.01 µg/L.

Cypermethrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.

As the products Family CHIMIGET_CYPER is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of Cypermethrin in food/feed of plant and animal origin is not required. However, analytical methods for the determination of cypermethrin residues in Food/feed of plant and animal origin are available in Document I, Evaluation Report of Cypermethrin, Product-type 18 (Insecticides), February 2017.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main Group 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

The products family CHIMIGET_CYPER are insecticide products containing between 0.22 and 10.87% w/w cypermethrin. They are intended to be used by non-professionals, indoor or outdoor.

The family is composed of 7 Meta SPCs:

- Meta SPC 1 contains a ready-to-use aerosol product (0.54% w/w cypermethrin) against wasps and hornets. It is intended to be used as direct spraying on insects, outdoor.
- Meta SPC 2 contains ready-to-use aerosol products (0.54%-0.87% w/w cypermethrin) against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*). They are intended to be used as direct spraying on insects outdoor.
- Meta SPC 3 contains ready-to-use one-shot aerosol products (0.54%-0.87% w/w cypermethrin) against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*). They are intended to be used as space treatment, indoor.
- Meta SPC 4 contains ready-to-use trigger spray products (0.54%-0.87% w/w cypermethrin) against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*). They are intended to be used as surface application, under buildings (i.e. crawlspaces).
- Meta SPC 5 contains concentrate insecticide product (10.87% w/w cypermethrin) against crawling and flying insects. After dilution in water, it is intended to be used as surface application, outdoor.
 - Use 1 of Meta SPC 5: outdoor spray as target spot spraying against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*), and in cracks and crevices against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*)
 - Use 2 of Meta SPC 5: outdoor surface spray under buildings (i.e. crawlspaces).
- Meta SPC 6 contains ready-to-use aerosol product (0.22% w/w cypermethrin) against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*). It is intended to be used as direct spraying on insects and surface application, indoor and outdoor.
 - Use 1 of Meta SPC 6: indoor and outdoor direct spray on insects
 - Use 2 of Meta SPC 6: indoor and outdoor spray as target spot (flying insects) and in cracks and crevices (crawling insects)
- Meta SPC 7 contains ready-to-use trigger spray product (0.22% w/w cypermethrin) against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*M. domestica*) and wasps (*Vespula sp.*). It is intended to be used as surface application.
 - Use 1 of Meta SPC 7: outdoor spray as target spot spraying (flying insects) and in cracks and crevices (crawling insects)
 - Use 2 of Meta SPC 7: surface spray under buildings (i.e. crawlspaces).

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

According to the uses claimed by the applicant, the products of the family CHIMIGET_CYPER are used by non-professional users for the control of crawling and flying insects, indoor and outdoor.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products family CHIMIGET_CYPER is insecticide. The target organisms are killed after contact with/ingestion of the active substance cypermethrin.

2.2.5.4 Mode of action, including time delay

According to the Assessment Report of the Cypermethrin (February 2017), this active substance is a synthetic pyrethroid insecticide with contact and stomach action.

It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid "knockdown". The affected insect shows uncoordinated movements and finally dies.

According to the efficacy tests provided with the products, complete mortality of the insects is achieved within hours or days, depending on the species and the type of application.

2.2.5.5 Efficacy data

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|--|---|--|--|--------------------|--|--|---|
| Function | Field of use envisaged | Test substance | Test organism(s) | Test method | Test system / concentrations applied / exposure time | Test results: effects | Reference |
| Insecticide | Outdoor Meta SPC 1 Use#1 - Direct spraying on insects (not on nest) | AE WH (Cypermethrin 0.54% w/w) - Meta SPC 1 | Wasp <i>Vespula germanica</i> Hornet <i>Vespa crabro</i> <i>Vespa velutina</i> 18 adults (trapped in the field) per replicate | Laboratory test | Direct spraying on the insects, which are then immediately transferred in a clean jar Application rate: 17.5 g per jar (17.0 to 18.1 g applied) Assessments: after 5, 10, 15, 30 and 45 minutes and 1 hour. Mortality validated after 24 hours. Replicates: 3 replicates per test species (3 replicates of 6 jars of 3 insects) Non-treated controls: same number of insects in the same conditions (0% mortality for all untreated controls at the end of the tests (24 hours)) Efficacy criteria: - $\geq 90\%$ knockdown 15 minutes after direct after spray. - Mortality $>90\%$ after 1 hour. Temperature: $22 \pm 1^\circ\text{C}$ Humidity: $58\% \pm 5\%$ | <u>Time to achieve more than 90% knock-down:</u> - <i>V. germanica</i> : 15 min (94.4%) - <i>V. crabro</i> : 15 min (100%) - <i>V. velutina</i> : 15 min (100%) <u>Time to achieve more than 90% mortality:</u> - <i>V. germanica</i> : 1 h (100%) - <i>V. crabro</i> : 45 min (100%) - <i>V. velutina</i> : 45 min (94.4%), 1h (100%) The efficacy requirement is fulfilled for the 3 tested species, with a mean application rate of 17.5 g per spray. | Guicherd A., 2020 S6.7_01 20STALab006 R.I.: 1 |
| Insecticide | Outdoor Meta SPC 2 Use#1 - Direct | AE FC1 (Cypermethrin 0.22% w/w) - Meta SPC 6 | Cockroaches <i>Blatella germanica</i> <i>Periplaneta americana</i> | Laboratory test | Insects in plastic boxes or jars, 6 boxes with 5 insects for each replicate (except <i>Vespula</i> 6 jars with 3 insects) | <u>Time to achieve more than 90% mortality:</u> - <i>B. germanica</i> : 15 min (100% mortality in 1 hour) - <i>P. americana</i> : 45 min | Guicherd A., 2020 S6.7_02 |

| | | | | | | | |
|--|---|--|---|--|---|---|-----------------------------------|
| | <p>spraying on insects (not on nest)</p> <p>Meta SPC 6 Use#1 - Direct spraying on insects (not on nest)</p> | | <p>Mosquito <i>Culex pipiens</i></p> <p>House fly <i>Musca domestica</i></p> <p>Wasp <i>Vespula germanica</i></p> <p>30 adults per replicate (except <i>V. germanica</i>: 18 adults per replicate)</p> | | <p>Treatment: direct spraying on the insects, which are then immediately transferred in clean Petri dishes or plastic jars</p> <p>Application rate: 2.5 g per box (2.1 to 2.7 g applied)</p> <p>Assessments: after 5, 10, 15, 30 and 45 minutes. Mortality validated after 1 hour and 24 hours.</p> <p>Replicates: 5 replicates per test species, except wasps, 3 replicates</p> <p>Non-treated controls: same number of insects in the same conditions (0% mortality for all untreated controls at the end of the tests (24 hours))</p> <p>Efficacy criteria for cockroaches: - ≥90% KD within few minutes - Mortality ≥ 90 % in 24 hours</p> <p>Efficacy criteria for mosquitoes and flies: - >80% KD - Mortality >90% after 24 hours</p> <p>Efficacy criteria for wasp: - ≥ 90% knockdown within a 5-10 minutes after direct after spray. - Mortality preferably 90% in 1 hour.</p> <p>Temperature: 24±1°C Humidity: 60% ±5%</p> | <p>(100% mortality in 1 hour) - <i>C. pipiens</i>: 10 min (100%) - <i>M. domestica</i>: 15 min (100%) - <i>V. germanica</i>: 15 min (100%)</p> <p>In addition, all the individuals were knocked-down or dead at the first assessment, 5 minutes after treatment.</p> <p>The efficacy requirement is fulfilled for the 5 tested species, with a mean application rate of 2.5 g per spray</p> | <p>20STALab001</p> <p>R.I.: 1</p> |
|--|---|--|---|--|---|---|-----------------------------------|

| | | | | | | | |
|-------------|---|---|--|--------------------|---|--|--|
| Insecticide | Outdoor Meta SPC 6 Use#2 – surface treatment – spot (flying insects) and cracks and crevices (crawling insects) | AE FC1 (Cypermethrin 0.22% w/w) - Meta SPC 6 | <p>Cockroaches <i>Blatella germanica</i> <i>Periplaneta americana</i></p> <p>Mosquito <i>Culex pipiens</i></p> <p>House fly <i>Musca domestica</i></p> <p>Wasp <i>Vespula germanica</i></p> <p>Per replicate: 30 cockroaches 20 mosquitoes or flies 10 wasps</p> | Simulated-use test | <p><u>For crawling insects:</u> Arenas (25x40x30 cm) with a "nest" on one side, and a water source and a food source on the other side. In between, test device made from porous (wood) or non-porous (ceramic tile) surfaces and mimicking cracks and crevices. Choice tests: device only partially treated, the insects can reach food and water from their nest without being in contact with the product.</p> <p><u>For flying insects:</u> Cages (30x30x30 cm) with a treated frame made from porous (wood) or non-porous (vinyl tape) surfaces on one side. The treated surface is $4 \times 0.05 \times 0.3 = 0.06 \text{ m}^2$ in a total of $6 \times 0.3 \times 0.3 = 0.54 \text{ m}^2$, therefore 10% of the total surface. Food and water on the floor, accessible to the insects. Choice tests: the insects can reach food and water without being in contact with treated surfaces.</p> <p>Temperature: $24 \pm 1^\circ\text{C}$ Humidity: $60\% \pm 5\%$</p> <p>Application rate: 17.5 g (equivalent to 7 seconds spraying)/m^2, so 3.5 g (equivalent to 1.4 seconds) to treat 1 linear meter (width 20cm). Exposure during 3 days</p> <p>Residual efficacy: test done after drying of the product on the treated surfaces, and then after 2 and 4 months of storage of the treated surfaces (at ambient temperature</p> | <p><u>Time to achieve more than 90% mortality (mean of 5 replicates):</u> T0 - <i>B. germanica</i>: 48 hours on non-porous surface (100%), 72 hours on porous surface (100%) - <i>P. americana</i>: 24 hours on non-porous surface (100%), 48 hours on porous surface (100%) - <i>C. pipiens</i>: 24 hours on non-porous and porous surfaces (97% and 92%) - <i>M. domestica</i>: 24 hours on non-porous and porous surfaces (100% and 93%) - <i>V. germanica</i>: 24 hours (100%)</p> <p>Mortality complete within 24 to 72 hours, depending on insect' species and type of surface.</p> <p>T0+2 months - <i>B. germanica</i>: 24 hours on non-porous surface (100%), 48 hours on porous surface (100%) - <i>P. americana</i>: 24 hours on non-porous surface (100%), 48 hours on porous surface (100%) - <i>C. pipiens</i>: 24 hours on non-porous surface (97%), 48 hours on porous surface (100%) - <i>M. domestica</i>: 6 hours on non-porous surface (90%), 24 hours on porous surface (94%) - <i>V. germanica</i>: 48 hours on non-porous and porous surfaces (100%)</p> <p>Mortality complete within 24 to</p> | Guicherd A., 2020 S6.7_03 20STALab004 R.I.: 2 |
|-------------|---|---|--|--------------------|---|--|--|

| | | | | | | | |
|--|--|--|--|--|---|---|--|
| | | | | | <p>and away from the light and rain).</p> <p>Assessments: after 3 and 6 hours, and then 24, 48 and 72 hours. Counting of KD/dead insects and calculation of mortality percentage.</p> <p>Replicates: 5 replicates per test species</p> <p>Non-treated controls: 5 replicates per species, surfaces treated with water (0% mortality for all untreated controls at the end of the tests)</p> | <p>72 hours, depending on insect' species and type of surface.</p> <p>T0+4 months</p> <ul style="list-style-type: none"> - <i>B. germanica</i>: 72 hours on non-porous and porous surfaces (100% and 95%) - <i>P. americana</i>: 72 hours on non-porous and porous surfaces (94.7% and 92%) - <i>C. pipiens</i>: 24 hours on non-porous and porous surfaces (98% and 90%) - <i>M. domestica</i>: 48 hours on non-porous and porous surfaces (100% and 99%) - <i>V. germanica</i>: 48 hours on non-porous and porous surfaces (100%) <p>Mortality complete within 48 to 72 hours, except for cockroaches, depending on insect' species and type of surface.</p> <p>Efficacy threshold in the BPR Efficacy guidance (simulated-use test): knock-down of insects and mortality according to the claim, preferably more than 90% after 24 hours.</p> <p>The efficacy requirement is fulfilled for the 5 tested species, on both porous and non-porous surfaces, with an application rate of 17.5 g/m². Residual effect up to 4 months after treatment.</p> | |
|--|--|--|--|--|---|---|--|

| | | | | | | | |
|-------------|---|--|--|--|--|--|---|
| Insecticide | Indoor Meta SPC 3 Use#1 – space treatment | AE OS1 (Cypermethrin 0.54% w/w) - Meta SPC 3 | Cockroaches <i>Blatella germanica Periplaneta americana</i> Mosquito <i>Culex pipiens</i> House fly <i>Musca domestica</i> Wasp <i>Vespula germanica</i> 100 adults per replicate (except for wasp, 40 adults per replicate) | Simulated- use test | Insects in boxes with shelters, 4 boxes per test species (25 insects inside, or 10 wasps). Boxes disposed in a 54.8 m ³ test room, at 2 heights (0.5 and 2 m), and at the corners of two opposite walls. Treatment: one-shot aerosol applied (50 mL) in the center of the closed test room, then 4 hours exposure. Application rate: 0.912 mL/m ³ Assessments: at the end of the 4 hours exposure, and then 12 and 24 hours after exposure, and transfer in clean boxes with food and water, in a clean room. Replicates: 3 replicates of treatment Non-treated controls: 3 replicates (0% mortality for all untreated controls at the end of the tests), and also controls to check no contamination of the test room between replicates Temperature: 24±1°C Humidity: 63% ±5% | <u>Time to achieve more than 90% mortality (mean of 3 replicates):</u> - <i>B. germanica</i> : 24 hours (100% mortality) - <i>P. americana</i> : 24 hours (98% mortality) - <i>C. pipiens</i> : 12 hours (100% mortality) - <i>M. domestica</i> : 4 hours (90% mortality) 12 hours (100% mortality) - <i>V. germanica</i> : 12 hours (100% mortality) In addition, all the insects already affected (knock-down or dead) at the first assessment, right after the 4 hours exposure. | Guicherd A., 2020 S6.7_04 20STALab005 R.I.: 1 |
| Insecticide | Outdoor Meta SPC 5 and 7 Use#1 and use#2– surface treatment | RTU1 (Cypermethrin 0.22% w/w) - Meta SPC 7 | Cockroaches <i>Blatella germanica Periplaneta americana</i> Mosquito <i>Culex pipiens</i> | Laboratory test – no choice test | Insects exposed with forced contact in trays containing treated/control surfaces Treatment: spraying on ceramic surfaces (25 cm*25 cm) Application rate: 20 mL/m ² , so 1.25 mL/surface (1.2 to 1.4 g | <u>Time to achieve more than 90% mortality (mean of 5 replicates):</u> - <i>B. germanica</i> : 10 min (100% mortality in 15 min) - <i>P. americana</i> : 10 min (100% mortality in 15 min) - <i>C. pipiens</i> : 10 min (100%) - <i>M. domestica</i> : 10 min (100% mortality in 15 min) | Guicherd A., 2020 S6.7_05 20STALab002 R.I.: 1 |

| | | | | | | | |
|-------------|--|---|--|--------------------|--|---|--|
| | | | <p>House fly <i>Musca domestica</i></p> <p>Wasp <i>Vespula germanica</i></p> <p>30 adults per replicate (except <i>V. germanica</i>: 10 adults per replicate)</p> | | <p>applied)</p> <p>Assessments: knock-down and mortality after 5, 10, 15, 30 and 45 minutes. Mortality validated after 1 hour and 24 hours.</p> <p>Replicates: 5 replicates per test species</p> <p>Non-treated controls: same number of insects in the same conditions, but surfaces treated with water (0% mortality for all untreated controls at the end of the tests)</p> <p>Temperature: 24±1°C Humidity: 60% ±5%</p> | <p>- <i>V. germanica</i>: 10 min (100% mortality in 15 min)</p> <p>More than 95% of all the individuals (90% for wasps) were knocked- down or dead at the first assessment, 5 minutes after treatment.</p> | |
| Insecticide | Outdoor Meta SPC 5 and 7 Use#1 and use#2– surface treatment - spot (flying insects) and cracks and crevices (crawling insects) | RTU1 (Cypermethrin 0.22% w/w) - Meta SPC 7 | <p>Cockroaches <i>Blatella germanica</i> <i>Periplaneta americana</i></p> <p>Mosquito <i>Culex pipiens</i></p> <p>House fly <i>Musca domestica</i></p> <p>Wasp <i>Vespula germanica</i></p> <p>Per replicate: 30 cockroaches 20 mosquitoes or flies 10 wasps</p> | Simulated-use test | <p><u>For crawling insects:</u> Arenas (25x40x30 cm) with a nest on one side, and a water source and a food source on the other side. In between, test device made from porous (wood) or non-porous (ceramic tile) surfaces and mimicking cracks and crevices. Choice tests: device only partially treated, the insects can reach food and water from their nest without being in contact with the product.</p> <p><u>For flying insects:</u> Cages (30*30*30 cm) with a treated frame made from porous (wood) or non- porous (vinyl tape) surfaces on one side. The treated surface is 4*0.05*0.3 = 0.06 m² in a total of 6*0.3*0.3=0.54 m², therefore 10% of the total surface. Food and water on the floor,</p> | <p><u>Time to achieve more than 90% mortality (mean of 5 replicates):</u> TO</p> <p>- <i>B. germanica</i>: 24 hours on non-porous surfaces (97.3%), 48 hours on porous surfaces (100%) - <i>P. americana</i>: 24 hours on non-porous and porous surfaces (100% and 93.3%) - <i>C. pipiens</i>: 24 hours on non-porous and porous surfaces (100%) - <i>M. domestica</i>: 24 hours on non-porous and porous surfaces (100%) - <i>V. germanica</i>: 24 hours on non-porous and porous surfaces (100% and 94%)</p> <p>Mortality complete within 24 to 48 hours, depending on insect'</p> | Guicherd A., 2020 S6.7_06 20STALab003 R.I.: 2 |

| | | | | | | |
|--|--|--|--|---|--|--|
| | | | | <p>accessible to the insects. Choice tests: the insects can reach food and water without being in contact with treated surfaces.</p> <p>Temperature: 24±1°C Humidity: 60% ±5%</p> <p>Application rate: 20 mL/m² (16 sprays) equivalent to 4 mL/m (width 20cm). Exposure during 3 days</p> <p>Residual efficacy: test done after drying of the product on the treated surfaces, and then after 2 and 4 months of storage of the treated surfaces (at ambient temperature and away from the light and rain).</p> <p>Assessments: after 3 and 6 hours, and then 24, 48 and 72 hours. Counting of KD/dead insects and calculation of mortality percentage.</p> <p>Replicates: 5 replicates per test species</p> <p>Non-treated controls: 5 replicates per species, surfaces treated with water (0% mortality for all untreated controls at the end of the tests)</p> | <p>species and type of surface.</p> <p>T0+2 months</p> <ul style="list-style-type: none"> - <i>B. germanica</i>: 24 hours on non-porous surface (92%), 48 hours on porous surface (100%) - <i>P. americana</i>: 24 hours on non-porous surface (97.3%), 48 hours on porous surface (100%) - <i>C. pipiens</i>: 24 hours on non-porous and porous surfaces (90%) - <i>M. domestica</i>: 6 hours on non-porous surface (92%), 24 hours on porous surface (96%) - <i>V. germanica</i>: 24 hours on non-porous surface (90%), 48 hours on porous surface (100%) <p>Mortality complete within 48 hours for all insects and surfaces.</p> <p>T0+4 months</p> <ul style="list-style-type: none"> - <i>B. germanica</i>: 48 hours on non-porous surface (98.7%), 72 hours on porous surface (100%) - <i>P. americana</i>: 72 hours on non-porous and porous surfaces (98% and 95%) - <i>C. pipiens</i>: 24 hours on non-porous and porous surfaces (95% and 90%) - <i>M. domestica</i>: 48 hours on non-porous surface (90%), 72 hours on porous surface (100%) - <i>V. germanica</i>: 24 hours on non-porous surface (92%), 48 hours on porous surface (100%) | |
|--|--|--|--|---|--|--|

| | | | | | | | |
|--|--|--|--|--|--|---|--|
| | | | | | | <p>Mortality complete within 48 to 72 hours, except for American cockroaches, depending on insect' species and type of surface.</p> <p>Efficacy threshold in the BPR Efficacy guidance (simulated-use test): knock-down of insects and mortality according to the claim, preferably more than 90% after 24 hours.</p> <p>The efficacy requirement is fulfilled for the 5 tested species, on both porous and non-porous surfaces, with an application rate of 20 mL/m². Residual effect up to 4 months after treatment.</p> | |
|--|--|--|--|--|--|---|--|

Please note that according to the requirements of the BPR Efficacy guidance Volume II part B/C (version 3.0, April 2018), section 5.6.4.2.2.1 for products against crawling and flying insects, the requirements are:

- for a claim of "killing crawling insects", sufficient efficacy against cockroaches has to be demonstrated
- for a "flying insects" claim, sufficient efficacy against flies (tests with *Musca domestica*), mosquitoes (tests with *Culex spp.*) and wasps (tests with *Vespula spp.*) has to be demonstrated

Meta SPC 1

The tests have been performed with the product AE WH (0.54% w/w Cypermethrin, Meta SPC1) which correspond to the product claimed for this Meta SPC.

The use claimed for the Meta SPC 1 is "Aerosol against wasps and hornets, for non-professional users. Spray 1 second (17.5 g) directly on the insect".

According to the requirements of the BPR Efficacy guidance Volume II part B/C (version 3.0, April 2018), for products intended for the control of flying wasps (and hornets), the requirements and efficacy criteria are:

- a product against wasps should be tested on workers of *Vespula spp.* or *Dolichovespula spp.*
- a laboratory or simulated-use test, with more than 90% knock-down within 5-10 minutes after spray (or according to the claim); and mortality, preferably at least 90%, within 1 hour

Since the product claims efficacy not only against wasps, but also against hornets, including Asian hornets, laboratory tests against *Vespula germanica* (common wasp), *Vespa crabro* (European hornet) and *Vespa velutina* (Asian hornet) were provided by the applicant.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product AE WH (Meta SPC1) according to the use and the application rate claimed:

- Regarding the efficacy claim against wasp (*Vespula germanica*), European hornet (*Vespa crabro*) and Asian hornet (*Vespa velutina*) - adults:
 - The product is efficient by direct spray (1 second spray= 17.5 g of product) with a Kd 90 of 15 minutes and a mortality of 100% 1 hour after the treatment in laboratory tests.

Meta SPC 2

The tests have been performed with the product AE FC1 (0.22% w/w Cypermethrin, Meta SPC 6).

As this product contains less active substance than that claimed for the Meta SPC 2 (0.54-0.87% w/w Cypermethrin) and only the % of solvent is slightly different between both, the cross reading is considered as acceptable. Therefore, the efficacy data provided with the product AE FC1 are used to support the efficacy for Meta SPC2 products.

The use claimed for the Meta SPC 2 is "Aerosol against flying and crawling insects, for non-professional users. Spray 1 second (2.5 g) directly on the insects. For outdoor use".

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the Meta SPC 2 products (0.54-0.87% w/w Cypermethrin) according to the use and the application rates claimed:

- Regarding the efficacy against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes (*C. pipiens*), flies (*M. domestica*) and wasps (*V. germanica*):
 - The product is efficient by direct spray (1 second spray= 2.5 g of product) with a Kd100 of 5 minutes and a mortality of 100% 1 hour after the treatment in laboratory tests.

Meta SPC 3

The tests have been performed with the product OS1 (0.54% w/w Cypermethrin, Meta SPC 3) which correspond to the product with the minimum active substance claimed for this Meta SPC (0.54-0.87% w/w Cypermethrin).

The use claimed for the Meta SPC 3 is "One shot aerosol against flying and crawling insects, for non-professional users. Use the correct packaging to have 1 mL/m³. For indoor use, only in rooms inaccessible to children and pets and not wet cleaned". No residual efficacy is claimed for this use.

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the Meta SPC 3 products according to the use (exposure time: 4 hours) and the application rate claimed:

- Regarding the efficacy against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes (*C. pipiens*), flies (*M. domestica*) and wasps (*V. germanica*):
 - The products are efficient by fogging at the application rate of 50 mL product /50 m³ with a Kd100 of 4 hours and a mortality of 100% (98% for *P. Americana*) 24 hours after the treatment in simulated use tests.

Meta SPC 4

The tests have been performed with the product RTU1 (0.22% w/w Cypermethrin, Meta SPC 7).

As this product contains less active substance than that claimed for the Meta SPC 4 (0.54-0.87% w/w Cypermethrin) and only the % of solvent is slightly different between both, the cross reading is considered as acceptable.

Therefore, we consider that the efficacy data provided with the product RTU1 is acceptable to support the efficacy for Meta SPC 4 products.

The use claimed for the Meta SPC 4 is "Trigger spray against flying and crawling insects, for non-professional users. Apply on surfaces under buildings, at an application rate of 20 mL/m². For outdoor use. Residual efficacy up to 4 months after treatment".

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the Meta SPC 4 products (0.54-0.87% w/w Cypermethrin) according to the use and the application rate claimed:

- Regarding the efficacy against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes (*C. pipiens*), flies (*M. domestica*) and wasps (*V. germanica*):
 - The product is efficient by spraying at the application rate of 20 mL product / m² with a Kd90 of 10 minutes and a mortality of 100% 15 minutes after the treatment in laboratory no choice tests on non-porous surfaces.
 - In the semi-field tests, a mortality of 100% is observed after 72 hours on porous and non-porous surfaces (protected from rainfall) until 4 months for spot applications (flying insects) and cracks and crevices application (crawling insects) at the application rate of 20 mL product / m².

Please note that the SU tests provided are considered sufficient to support the spot application (flying insects) and application in cracks and crevices (crawling insects) but are also accepted to support a general surface treatment claim (as a worst case). The claimed application rate of the product on the surfaces to be treated is the same.

Meta SPC 5 and Meta SPC 7

The tests have been performed with the product RTU1 (0.22% w/w Cypermethrin, Meta SPC 7).

As the amount of active substance applied is the same between the product RTU1 (Meta SPC 7) and Meta SPC 5 product (at the claimed application rate, i.e. after the worst case dilution claimed for Meta SPC 5 (2% v/v)), the cross reading is considered as acceptable between both.

Therefore, we consider that the efficacy data provided with the product RTU1 is acceptable to support the efficacy for Meta SPC 5 and Meta SPC 7.

The uses claimed for the Meta SPC 5 and 7 are:

- "Trigger spray against flying and crawling insects, for non-professional users. Apply as target spot treatment (for flying insects) and in cracks and crevices (for crawling insects), at an application rate of 20 mL/m² (4 mL/m). For outdoor use. Residual efficacy up to 4 months after treatment".
- "Trigger spray against flying and crawling insects, for non-professional users. Apply on surfaces under buildings, at an application rate of 20 mL/m². For outdoor use. Residual efficacy up to 4 months after treatment".

Please note that a specific instruction for use is added in the SPC to clarify that "The product has to be applied only on restricted areas on surfaces not regularly cleaned and protected from the rain." regarding the outdoor surfaces.

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the Meta SPC 5 (after dilution at 2% v/v) and 7 according to the uses and the application rate claimed:

- Regarding the efficacy claim against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes (*C. pipiens*), flies (*M. domestica*) and wasps (*V. germanica*):
 - The product is efficient by spraying at the application rate of 20 mL product / m² with a Kd90 of 10 minutes and a mortality of 100% 15 minutes after the treatment in laboratory no choice tests on non-porous surfaces.
 - In the semi-field tests, a mortality of 100% is observed after 72 hours on porous and non-porous surfaces (protected from rainfall) until 4 months for spot applications (flying insects) and cracks and crevices application (crawling insects).

Please note that the SU tests provided are considered sufficient to support the spot application (flying insects) and application in cracks and crevices (crawling insects) but are also accepted to support a general surface treatment claim (as a worst case). The claimed application rate of the product on the surfaces to be treated is the same.

Meta SPC 6, AE FC1

The tests have been performed with the product AE FC1 (0.22% w/w Cypermethrin, Meta SPC 6).

The uses claimed for Meta SPC 6 are:

- "Aerosol against flying and crawling insects, for non-professional users. Spray 1 second (2.5 g) directly on the insects. For indoor and outdoor use".
- "Aerosol against flying and crawling insects, for non-professional users. Apply as target spot treatment in cracks and crevices, at an application rate of 17.5 g/m² (7 seconds/m²). For indoor and outdoor use. Residual efficacy up to 4 months after treatment".

Please note that a specific instruction for use is added in the SPC to clarify that "The product has to be applied only on restricted areas on surfaces not regularly cleaned and protected from the rain." regarding the outdoor surfaces.

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the Meta SPC 6 according to the uses and the application rate claimed:

- Regarding the efficacy against crawling insects (adults) including cockroaches (*B. germanica* and *P. americana*) and flying insects (adults) including mosquitoes (*C. pipiens*), flies (*M. domestica*) and wasps (*V. germanica*)- adults:
 - The product is efficient by direct spray (1 second spray= 2.5 g of product) with a Kd100 of 5 minutes and a mortality of 100% 1 hour after the treatment in laboratory tests.
 - In the semi-field tests, the product is efficient at the application rate of 17.5 g (equivalent to 7 seconds spraying)/m², with a mortality of 100% after 72 hours on porous and non-porous surfaces (protected from rainfall) until 4 months for spot applications (flying insects) and cracks and crevices application (crawling insects).

Conclusion on the efficacy of the product

French competent authorities (FR CA) assessed that the family CHIMIGET_CYPER, separated in 7 META-SPC has shown a sufficient efficacy as following:

- **Meta SPC 1:**

The efficacy of the product is demonstrated when used by direct spraying against wasp (*Vespula sp.*, adults), European hornet (*Vespa crabro*, adults) and Asian hornet (*Vespa velutina*, adults) at the application rate of 17.5 g of product (1 second spray) after 1 hour.
- **Meta SPC 2:**

The efficacy of the products is demonstrated when used by direct spraying against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes, (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 2.5 g of product (1 second spray) after 1 hour.
- **Meta SPC 3:**

The efficacy of the products is demonstrated when used by fogging against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 1 mL / m³ (e.g. a can of 50 mL in a room up to 50 m³) with an exposure time of 4 hours, after 24 hours.
- **Meta SPC 4:**

The efficacy of the products is demonstrated when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m², up to 4 months (time delay: between 24h and 72h).
- **Meta SPC 5:**
 - The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica*, *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m² (after dilution at 2% v/v), up to 4 months (time delay: between 24h and 72h).
 - The efficacy of the product is demonstrated when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*) and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*), at the application rate of 20 mL product / m² (after dilution between 2% and 8% v/v), up to 4 months (time delay: between 24h and 72h).
- **Meta SPC 6:**
 - The efficacy of the products is demonstrated when used by direct spraying against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex*

sp.), flies (*Musca domestica*) and wasps (*Vespula sp.*) at the application rate of 2.5 g of product (1 second spray), after 1 hour.

- The efficacy of the products is demonstrated when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*) and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*), at the application rate of 17.5 g product / m² (7 seconds spray/m²), up to 4 months (time delay: between 24h and 72h).

- **Meta SPC 7:**

- The efficacy of the product when used by spraying on surfaces (porous and non-porous) against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*) and flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*), at the application rate of 20 mL product / m², up to 4 months.
- The efficacy of the product when used by spraying on surfaces (porous and non-porous) by spot application against flying insects (adults) including mosquitoes (*Culex sp.*), flies (*Musca domestica*) and wasps (*Vespula sp.*) and in cracks and crevices against crawling insects (adults) including cockroaches (*Blattella germanica* and *Periplaneta americana*) at the application rate of 20 mL product / m², up to 4 months (time delay: between 24h and 72h).

2.2.5.6 Occurrence of resistance and resistance management

According to the Assessment Report of Cypermethrin cis/trans 40/60 (February 2017), resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

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

Not relevant.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No toxicological studies have been submitted for the biocidal product family CHIMIGET_CYPER. The classification of each meta-SPC has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

According to the CLP regulation, "an aerosol form of a mixture shall be classified in the same hazard category as the non-aerolised form of the mixture". Therefore, the classification of the meta-SPC 1, 2, 3 and 6 has been made following the composition of each meta-SPC without propellant and with the content of the other co-formulants recalculated accordingly.

Please refer to the Confidential annex for further informations.

Skin corrosion and irritation

| Conclusion used in Risk Assessment – Skin corrosion and irritation | |
|---|---|
| Value/conclusion | Not corrosive to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification is required |

Eye irritation

Meta-SPC 1, 2, 3 and 6

| Conclusion used in Risk Assessment – Eye irritation | |
|--|---|
| Value/conclusion | Causes eye irritation |
| Justification for the value/conclusion | The concentration of one of the co-formulant (ethanol) is above the threshold value of 10% for classification as Category 2 Eye Irritant. |
| Classification of the product according to CLP | The meta-SPC 1, 2, 3 and 6 of the BPF CHIMIGET_CYPER are classified as Eye Irrit. 2; H319, according to the CLP criteria. |

Meta-SPC 4, 5 and 7

| Conclusion used in Risk Assessment – Eye irritation | |
|--|---|
| Value/conclusion | Not irritant to the eye |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification required |

Respiratory tract irritation

| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
|--|---|
| Value/ conclusion | Not irritating for the respiratory tract |
| Justification for the conclusion | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification is required. |

Skin sensitization

| Conclusion used in Risk Assessment – Skin sensitisation | |
|--|---|
| Value/conclusion | Not sensitising to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification is required. |

Respiratory sensitization (ADS)

| Conclusion used in Risk Assessment – Respiratory sensitisation | |
|---|---|
| Value/conclusion | Not sensitising for the respiratory tract |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification required. |

Acute toxicity**Acute toxicity by oral route**

| Value used in the Risk Assessment – Acute oral toxicity | |
|--|---|
| Value | Not acutely toxic via inhalation route |
| Justification for the selected value | Based on intrinsic properties of individual components or their concentration in the meta-SPCs. |
| Classification of the product according to CLP | No classification required |

Acute toxicity by inhalation

| Value used in the Risk Assessment – Acute inhalation toxicity | |
|--|---|
| Value | Not acutely toxic via inhalation route. |
| Justification for the selected value | Based on intrinsic properties of individual components and their concentrations in the meta-SPCs. Please, see confidential PAR. |
| Classification of the product according to CLP | No classification required. |

Acute toxicity by dermal route

| Value used in the Risk Assessment – Acute dermal toxicity | |
|--|---|
| Value | Not acutely toxic via dermal route |
| Justification for the selected value | Based on intrinsic properties of individual components of the meta-SPC. |
| Classification of the product according to CLP | No classification required. |

Information on dermal absorption

| Value(s) used in the Risk Assessment – Dermal absorption | | |
|---|--|--|
| Substance | Cypermethrin | |
| Value(s) | 70% Meta-SPC 1, 2, 3, 4, 5 (in-use dilution), 6 and 7 | 25% Meta-SPC 5 (concentrate) |
| Justification for the selected value(s) | Default dermal absorption value for solvent-based products with a concentration in active substance below 5%, based on the EFSA guidance on dermal absorption (2017) | Default dermal absorption value for solvent-based products with a concentration in active substance above 5%, based on the EFSA guidance on dermal absorption (2017) |

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

According to the definition of Substance of Concern (SoC) laid down in the Guidance on the BPR for Human Health Assessment & Evaluation, volume III Part B+C (2017), the meta-SPC 1, 2, 3 and 6 of the BPF CHIMIGET_CYPER contains one SoC.

Indeed, ethanol is considered a SoC, as it is present in the meta-SPC in sufficient concentration to trigger the classification as Eye Irritant Cat. 2 – H319 by itself. Taking into account this classification, a Band A is assigned, leading to the application of P-statements normally associated with the concerned H-statements. A qualitative risk assessment for local effect is performed for the meta-SPC 1, 2, 3 and 6.

Please refer to the Confidential annex for further information.

Available toxicological data relating to a mixture

Not relevant.

2.2.6.2 Exposure assessment and risk characterisation for Human health

The CHIMIGET_CYPER biocidal product family is composed of 7 meta-SPCs with ready-to-use products insecticides containing 0.22% to 4.35% w/w cypermethrin (Meta-SPC 1 to 4, 6 and 7) and a concentrate product (Meta-SPC 5) containing 10.87% w/w cypermethrin to dilute prior the application. These products are intended to be used by **non-professional users** against crawling and flying insects.

The different uses and meta-SPC concerned are resumed in the table below.

According to the Assessment Report of Cypermethrin (Belgium, 2017), this active substance is characterised by systemic effects observed in toxicity studies. Consequently, a quantitative risk assessment for systemic effects is performed for dermal, inhalation and oral routes when relevant.

As the products of meta-SPC 1, 2, 3 and 6 are classified as Eye Irritant Cat 2 (H319), a qualitative risk assessment for local effects is performed.

Secondary exposure is considered for adults and children re-entering the room after the air space application (meta-SPC 3), adults in contact with treated surfaces and infants crawling in the treated floor and having hand-to-mouth transfer.

| Meta SPC | Direct spray on insect | | | Air space treatment | Crack and crevices | | | Treatment under building | | |
|---|------------------------|-------------|-------------------|----------------------|--------------------|--------------------------------------|-------------------|--------------------------|---|-------------------|
| | 1 | 2 | 6 | 3 | 6 | 5 | 7 | 4 | 5 | 7 |
| Type of products | RTU aerosol | RTU aerosol | RTU aerosol | RTU one-shot aerosol | RTU aerosol | Concentrate to dilute, trigger spray | RTU trigger spray | RTU trigger spray | Concentrate to dilute, trigger spray | RTU trigger spray |
| Indoor/ outdoor | outdoor | outdoor | indoor outdoor | indoor | indoor outdoor | outdoor | outdoor | outdoor | | |
| Max a.s. content without propellant | 1.8% | 2.9% | 0.73% | 4.35% | 0.73% | 10.87% 0.20% after dilution | 0.22% | 0.87% | 10.87% 0.20% to 0.80% after dilution | 0.22% |
| Mass generation rate | 17.5 g/s | 2.98 g/s | 2.98 g/s | 0.44 g/s | 2.98 g/s | - | - | - | - | - |
| Density | - | 0.794 | 0.794 | 0.799 | 0.794 | 0.916 | 0.885 | 0.885 | 0.916 | 0.885 |

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

| Summary table: main paths of human exposure | | | | | |
|--|--|-------------------------------|--|--|-----------------|
| Exposure path | Primary (direct) exposure | | Secondary (indirect) exposure | | |
| | Professional users (including industrial users and trained professional users) | Non-professional users | Professional users (including industrial users and trained professional users) | Non-professional bystanders/ General public | Via food |
| Oral | n/a | No | n/a | Yes | No |
| Dermal | n/a | yes | n/a | Yes | |
| Inhalation | n/a | yes | n/a | Yes | |

List of scenarios

| Summary table: exposure scenarios | | |
|--|---|---------------------------------------|
| Scenario and task number | Description of scenario and tasks | Exposed group |
| Primary exposure | | |
| [Scenario 1] | <i>Direct application on insets (meta-SPC 1, 2 and 6)</i> | Non-professionals |
| [Scenario 2] | <i>Air space treatment (meta-SPC 3)</i> | Non-professionals |
| [Scenario 3] | <i>Treatment under building (meta-SPC 4, 5 and 7)</i> | Non-professionals |
| Task [3.1] | <i>Mixing and loading (meta-SPC 5)</i> | Non-professionals |
| Task [3.2] | <i>Application by spraying</i> | Non-professionals |
| Task [3.3] | <i>Post-application – Cleaning of the spray equipment (meta-SPC 5)</i> | Non-professionals |
| [Scenario 4] | <i>Crack and crevices</i> | Non-professionals |
| Secondary exposure | | |
| [Scenario 5] | <i>Re-entry in the treated room – inhalation (meta-SPC 3)</i> | Non-professionals / General public |
| [Scenario 6] | <i>Contact with the treated surface</i> | General public (adult) |
| [Scenario 7] | <i>Infant crawling on the treated surface and hand-to-mouth transfer</i> | General public (infant) |

Reference values to be used in Risk Characterisation - Cypermethrin

| Reference | Study | NOAEL (LOAEL) | AF | Correction for oral absorption | Value |
|----------------|--|---------------|-----|--------------------------------|------------------|
| AELshort-term | Rat, acute delayed neurotoxicity, oral behavioural effects | 20 mg/kg/d | 100 | 44% | 0.088 mg/kg bw/d |
| AELmedium-term | Dog, 90-days, oral | 12.5 mg/kg/d | 100 | 44% | 0.055 mg/kg bw/d |
| AELlong-term | Rat, y-years, oral | 5 mg/kg/d | 100 | 44% | 0.022 mg/kg bw/d |
| ARfD | AR (BE, 2019): At WG-IV-2016, the following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005) | | | | 0.2 mg/kg bw/d |
| ADI | | | | | 0.05 mg/kg bw/d |

Industrial exposure

Not relevant.

Professional exposure

Not relevant.

Non-professional exposure

Scenario [1] – Direct application on insects (Meta-SPC 1, 2 and 6)

| Description of Scenario [1] – Direct application on insects | | | |
|--|------------|-------|---------------|
| <p>Products of meta-SPC 1, 2 and 6 are RTU aerosols to be used by non-professional users by direct spraying on insects, outdoor (and indoor for meta-SPC 6).</p> <p>To assess the dermal and inhalation exposure expected during the application, the air space application model from ConsExpo Pest Control Products Fact Sheet – Exposure to spray - Spraying (inhalation) and Constant rate (dermal) is used. Default values from the Consexpo model are used for the modelisation, with parameters for an indoor application, as there is no specific model for outdoor application. The mass generation rates of 17.5 g/s for Meta-SPC 1 and 2.98 g/s for Meta-SPC 2 and 6 used for the modelisation have been determined in the ACP section.</p> <p>In a Tier 2 for Meta-SPC 1 and 2, a reverse scenario is done to determine the maximum duration the user has to stay in the room before reaching the AEL medium-term.</p> <p>A qualitative local risk assessment is also performed.</p> | | | |
| | Parameters | Value | Justification |

| Description of Scenario [1] – Direct application on insects | | | |
|--|--|--|---|
| Tier 1 | Concentration of Cypermethrin (Meta-SPC 1) | 1.8% w/w | Applicant's data |
| | Concentration of Cypermethrin (Meta-SPC 2) | 2.9% w/w | Applicant's data |
| | Concentration of Cypermethrin (Meta-SPC 6) | 0.73% w/w | Applicant's data |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |
| | Spray duration | 0.33 min | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Exposure duration | 240 min | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Room volume | 20 m ³ | Default value from General Consexpo Factsheet |
| | Room height | 2.5 m | Standard room height |
| | Ventilation rate | 0.6/h | Default value from General Consexpo Factsheet for unspecified room |
| | Inhalation rate | 1.25 m ³ /h | Ad hoc Recommendation 14 |
| | Mass generation rate | 17.5 g/s (meta-SPC 1) 2.98 g/s (meta-SPC 2 and 6) | Applicant's data (APCP section) |
| | Airborne fraction | 0.3 | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Density non volatile | 1.8 g/cm ³ | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Inhalation cut off diameter | 15 µm | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Median diameter | 28.2 µm | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Arithmetic coefficient of variation | 1.6 | Default value for air space application model from Consexpo Pest Control Products Factsheet |

| Description of Scenario [1] – Direct application on insects | | | |
|--|-----------------------|---|---|
| | Maximum diameter | 50 µm | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Inhalation absorption | 100% | Default value |
| | Dermal contact rate | 269 mg/min | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| Tier 2 | Exposure duration | 5 min (meta-SPC 1) 20 min (meta-SPC 2) | See explanation above |

Calculations for Scenario [1]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|--------------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenario [1] – Meta-SPC 1 | 1/ No PPE | 1.66×10^{-1} | 1.86×10^{-2} | nr | 1.84×10^{-1} |
| Scenario [1] – Meta-SPC 1 | 2/ No PPE (5 min) | 3.56×10^{-2} | 1.86×10^{-2} | nr | 5.43×10^{-2} |
| Scenario [1] – Meta-SPC 2 | 1/ No PPE | 4.54×10^{-2} | 3.00×10^{-2} | nr | 7.55×10^{-2} |
| Scenario [1] – Meta-SPC 2 | 2/ No PPE (20 min) | 2.45×10^{-2} | 3.00×10^{-2} | nr | 5.46×10^{-2} |
| Scenario [1] – Meta-SPC 6 | 1/ No PPE | 1.14×10^{-2} | 7.56×10^{-3} | nr | 1.90×10^{-2} |

Scenario [2] – Air space treatment (meta-SPC 3)

| Description of Scenario [2] – Air space treatment (meta-SPC 3) |
|---|
| <p>Products of meta-SPC 3 are ready-to-use one-shot aerosol insecticides used as space treatment in cellars, basement, crawl space, garages, boxes, attics, barns, sheds or any other premises which are not wet-cleaned. As the product is to be used at an application rate of 1 ml/m³, the non-professional user has to choose the appropriate packaging (from 50 to 750 ml) depending on the volume of the room to treat.</p> <p>The aerosol is placed vertically, slightly elevated, in the center of the room and is activated by pressing the trigger of the diffuser. The entirety of the packaging (50 to 750 ml) is released into the room, i.e. 39.95 g to 599.25g of product with a density of 0.799, and containing 4.35% w/w cypermethrin.</p> |

Description of Scenario [2] – Air space treatment (meta-SPC 3)

To assess exposure during the application, the **air space application model from ConsExpo Pest Control Products Fact Sheet – Exposure to spray - Spraying** (inhalation route) and **Constant rate** (dermal route) is used.

The spray duration is the net spraying time between start and finish of spraying. With a spray rate of 0.44 g/s and an amount of product of 39.95 g (50 ml), it takes 91 seconds (39.95/0.44), or 1.5 min, to empty the aerosol.

Since the user is expected to leave the room directly after the activation of the one-shot aerosol, it is considered that the user is only exposed during the time he stays in the room, which is set at 30 seconds.

After the contact time of 4 hours, the user can re-enter the room to ventilate (opening the window if possible).

| | Parameters | Value | Justification |
|--------|--|------------------------|---|
| Tier 1 | Concentration of cypermethrin | 4.35% w/w | Applicant's data |
| | Spray duration | 91 sec | See calculations above |
| | Exposure duration (inhalation) / release duration (dermal) | 30 sec | See explanation above |
| | Room volume | 20 m ³ | Default value from ConsExpo for unspecified room |
| | Room height | 2.5 m | Default value from ConsExpo |
| | Ventilation rate | 0.6/h | Default value from General ConsExpo Factsheet for unspecified room |
| | Inhalation rate | 1.25 m ³ /h | Ad hoc Recommendation 14 |
| | Mass generation rate | 0.44 g/s | Applicant's data (APCP section) |
| | Airborne fraction | 0.3 | Default value for air space application model from ConsExpo Pest Control Products Factsheet |
| | Density non volatile | 1.8 g/cm ³ | Default value for air space application model from ConsExpo Pest Control Products Factsheet |
| | Inhalation cut off diameter | 15 µm | Default value for air space application model from ConsExpo Pest Control Products Factsheet |
| | Median diameter | 28.2 µm | Default value for air space application model from ConsExpo Pest Control Products Factsheet |

| Description of Scenario [2] – Air space treatment (meta-SPC 3) | | | |
|---|-------------------------------------|-------|---|
| | Arithmetic coefficient of variation | 1.6 | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Maximum diameter | 50 µm | Default value for air space application model from Consexpo Pest Control Products Factsheet |
| | Inhalation absorption | 100% | Default value |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |

Calculations for Scenario [2]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenario [2] | 1/ No PPE | 2.11×10^{-4} | 6.83×10^{-2} | nr | 6.85×10^{-2} |

Scenario [3] – Treatment under building (meta-SPC 4, 5 and 7)

- Task [3.1]: Mixing and loading
- Task [3.2]: Application by spraying
- Task [3.3]: Post-application

Task [3.1] – Mixing and loading

| Description of Task [3.1] – Mixing and loading | | | |
|---|--|------------|------------------|
| <p>Before use, the product of meta-SPC 5 is to be diluted manually in water at 2% to 8% in a trigger spray. Products of meta-SPC 4 and 7 are RTU, so no dilution is needed. However, a 5L jerrycan is claimed for refill, so the loading step is considered for these products.</p> <p>According to the Consexpo Pest Control Products Factsheet (p.31), for packaging < 5L or for 5L containers with 45 or 63 mm closure, which is the case for products of meta-SPC 4, 5 and 7 (according to the packaging section and labels), the user can be dermally exposed to 0.01 ml of product per operation. With a density of 0.916, the contamination on the user's hands is equal to 9.16 mg of product.</p> | | | |
| | Parameters | Value | Justification |
| Tier 1 | Concentration of cypermethrin (meta-SPC 5) | 10.87% w/w | Applicant's data |

| Description of Task [3.1] – Mixing and loading | | | |
|---|--|-------------------|---|
| | Concentration of cypermethrin (meta-SPC 4) | 0.87% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 7) | 0.22% w/w | Applicant's data |
| | Dermal exposure value | 0.01 ml/operation | Values from Consexpo Pest Control Products Factsheet (p.31) |
| | Density (meta-SPC 5) | 0.916 | Applicant's data (APCP section) |
| | Density (meta-SPC 4 and 7) | 0.885 | Applicant's data (APCP section) |
| | Dermal absorption (meta-SPC 5) | 25% | Default value according to EFSA Guidance 2017 |
| | Dermal absorption (meta-SPC 4 and 7) | 70% | Default value according to EFSA Guidance 2017 |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |

Calculations for Task [3.1]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Task [3.1] – Meta-SPC 5 | 1/ No PPE | nr | 4.15×10^{-3} | nr | 4.15×10^{-3} |
| Task [3.1] – Meta-SPC 4 | 1/ No PPE | nr | 8.98×10^{-4} | nr | 8.98×10^{-4} |
| Task [3.1] – Meta-SPC 7 | 1/ No PPE | nr | 2.27×10^{-4} | nr | 2.27×10^{-4} |

Task [3.2] – Application by spraying

| Description of Task [3.2] – Application by spraying |
|--|
| <p>Diluted product of meta-SPC 5 and RTU products of meta-SPC 4 and 7 are sprayed with a trigger spray on surfaces under buildings (crawlspaces, etc.), outdoor. Products of meta-SPC 5 are to be diluted manually in water at 2% to 8%. As a worst-case, the 8% dilution is considered in the assessment, with a concentration of active substance equal to 0.8% w/w.</p> <p>To assess the dermal and inhalation exposure expected during the application, the Consumer product spraying and dusting Model 2 – hand-held trigger spray, from BHHM (p. 344), is used.</p> <p>The exposure values from the model are as follow:</p> <ul style="list-style-type: none"> - 36.1 mg/min (hand and forearm) - 9.7 mg/min (legs, feet & face) - 10.5 mg/m³ (inhalation) |

| Description of Task [3.2] – Application by spraying | | | |
|--|--|------------------------|--|
| In the ConsExpo Pest Control Products Fact Sheet, a spray duration of 10 minutes is proposed as a default value for general surface application. | | | |
| | Parameters | Value | Justification |
| Tier 1 | Concentration of cypermethrin (meta-SPC 5 – 8% dilution) | 0.80% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 4) | 0.87% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 7) | 0.22% w/w | Applicant's data |
| | Duration | 10 min | Value from ConsExpo Pest Control Products Fact Sheet |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |
| Dermal exposure | | | |
| Tier 1 | Dermal exposure value (hand and forearm) | 36.1 mg/min | Consumer product spraying and dusting Model 2 – BHHEM (p. 344) |
| | Dermal exposure value (legs, feet and face) | 9.7 mg/min | Consumer product spraying and dusting Model 2 – BHHEM (p. 344) |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| Inhalation exposure | | | |
| | Inhalation exposure value | 10.5 mg/m ³ | Consumer product spraying and dusting Model 2 – BHHEM (p. 344) |
| | Inhalation rate | 1.25 m ³ /h | Ad hoc Recommendation 14 |
| | Inhalation absorption | 100% | Default value |

Calculations for Task [3.2]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Task [3.2] – Meta-SPC 5 | 1/ No PPE | 2.92x10 ⁻⁴ | 4.27x10 ⁻² | nr | 4.30x10 ⁻² |
| Task [3.2] – Meta-SPC 4 | 1/ No PPE | 3.17x10 ⁻⁴ | 4.65x10 ⁻² | nr | 4.68x10 ⁻² |
| Task [3.2] – Meta-SPC 7 | 1/ No PPE | 8.02x10 ⁻⁵ | 1.18x10 ⁻² | nr | 1.18x10 ⁻² |

Task [3.3] – Post-application – Cleaning of the spray equipment**Description of Task [3.3] – Post-application – Cleaning of the spray equipment**

After the application with the trigger spray, the user can be exposed to the diluted product of meta-SPC 5 and concentrated products of meta-SPC 4 and 7 during the cleaning of the spray equipment.

Dermal exposure during this task is assessed using the **BEAT scenario Cleaning of the spray equipment**.

The exposure values from the model are as follow:

- 35.87 µl/min bp (hand)

- 19.28 µl/min bp (body)

A cleaning duration of 10 min has been considered sufficient for products of meta-SPC 4 and 7 and 5 min for products of meta-SPC 5, as they are water-based.

In Tier 2, for meta-SPC 4, the cleaning of the sprayer is not performed and the risk mitigation measure "Do not clean the trigger spray" is added.

| | Parameters | Value | Justification |
|--------|--|--------------|---|
| Tier 1 | Concentration of cypermethrin (meta-SPC 5 – 8% dilution) | 0.80% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 4) | 0.87% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 7) | 0.22% w/w | Applicant's data |
| | Dermal exposure value (hand) | 35.87 µl/min | BEAT model for Cleaning of spray equipment |
| | Dermal exposure value (body) | 19.28 µl/min | BEAT model for Cleaning of spray equipment |
| | Duration (meta-SPC 5) | 5 min | Ad hoc Recommendation 6 |
| | Duration (meta-SPC 4 and 7) | 10 min | See explanation above |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |

Calculations for Task [3.3]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------|--|--------------------------------------|------------------------------------|-------------------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Task [3.3] – meta-SPC 5 | 1/ No PPE | nr | 2.57x10 ⁻² | nr | 2.57x10 ⁻² |
| Task [3.3] – meta-SPC 4 | 1/ No PPE | nr | 5.60x10 ⁻² | nr | 5.60x10 ⁻² |

| Summary table: systemic exposure from non-professional uses | | | | | |
|---|-----------|----|-----------------------|----|-----------------------|
| Task [3.3] – meta-SPC 7 | 1/ No PPE | nr | 1.42×10^{-2} | nr | 1.42×10^{-2} |

Combined tasks for Scenario [3]

| Summary table: combined systemic exposure from non-professional uses | | | | | |
|--|-----------------|--|--------------------------------------|------------------------------------|-------------------------------------|
| Scenarios combined | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Tasks [3.1] + [3.2] + [3.3] – Meta-SPC 5 | 1/ No PPE | 2.92×10^{-4} | 7.26×10^{-2} | nr | 7.29×10^{-2} |
| Tasks [3.1] + [3.2] + [3.3] – Meta-SPC 4 | 1/ No PPE | 3.17×10^{-4} | 1.03×10^{-1} | nr | 1.04×10^{-1} |
| Tasks [3.1] + [3.2] – Meta-SPC 4 | 2/ No PPE – RMM | 3.17×10^{-4} | 4.74×10^{-2} | nr | 4.77×10^{-2} |
| Tasks [3.1] + [3.2] + [3.3] – Meta-SPC 7 | 1/ No PPE | 8.02×10^{-5} | 2.61×10^{-2} | nr | 2.62×10^{-2} |

Scenario [4] – Crack and crevices (meta-SPC 5, 6 and 7)

| Description of Scenario [4] – Crack and crevices |
|--|
| <p>Products of meta-SPC 6 are ready-to-use aerosols and products of meta-SPC 5 and 7 are used in trigger sprays (dilution at 2% for meta-SPC 5 and RTU for meta-SPC 7). They are used for applications in crack and crevices. The non-professional user can be exposed to the product via dermal and inhalation routes.</p> <p>For products of meta-SPC 5 and 7, applied in crack and crevices by trigger spray, the exposure is covered by the exposure during the application on surfaces determined in the Scenario [3]. Please refer to Scenario [3] for further details.</p> <p>For products of meta-SPC 6, applied by aerosol, the Crack and crevice model from ConsExpo Pest Control Products Fact Sheet – Exposure to spray - Spraying is used to assess the exposure during the application.</p> <p>According to the ConsExpo Factsheet, the duration of the task is 4 min with 240 min of exposure duration.</p> <p>According to the ACPC section, the spray rate for meta-SPC 6 is 2.98 g/sec.</p> <p>In a Tier 2 for Meta-SPC 6, a reverse scenario is done to determine the maximum duration the user has to stay in the room before reaching the AEL medium-term. The parameters are used to assess the exposure during the application inside, which covers the application outside.</p> |

| Description of Scenario [4] – Crack and crevices | | | |
|---|--|------------------------|--|
| | Parameters | Value | Justification |
| Tier 1 | Concentration of cypermethrin (meta-SPC 6) | 0.73% w/w | Applicant's data |
| | Spray duration | 4 min | Default value from ConsExpo (crack and crevice) |
| | Exposure duration | 240 min | Default value from ConsExpo (crack and crevice) |
| | Room volume | 20 m ³ | Default value from ConsExpo |
| | Room height | 2.5 m | Default value from Consexpo |
| | Ventilation rate | 0.6/h | Default value from General Consexpo Factsheet for unspecified room |
| | Inhalation rate | 1.25 m ³ /h | Ad hoc Recommendation 14 |
| | Mass generation rate (meta-SPC 6) | 2.98 g/s | Applicant's data (Physical, chemical and technical properties section) |
| | Airborne fraction | 0.2 | Default value for air space sprays, ethanol as main solvent from ConsExpo (p.26) |
| | Density non volatile | 1.8 g/cm ³ | Default value from ConsExpo for volatile organic solvents (p.21) |
| | Inhalation cut off diameter | 15 µm | Default value for crack and crevices model from Consexpo Pest Control Products Factsheet |
| | Median diameter | 3.6 µm | Default value for crack and crevices model from Consexpo Pest Control Products Factsheet |
| | Arithmetic coefficient of variation | 0.57 | Default value for crack and crevices model from Consexpo Pest Control Products Factsheet |
| | Maximum diameter | 50 µm | Default value for crack and crevices model from Consexpo Pest Control Products Factsheet |
| | Inhalation absorption | 100% | Default value |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |

| Description of Scenario [4] – Crack and crevices | | | |
|---|-----------------------------------|-------|-----------------------|
| Tier 2 | Exposure duration (meta-SPC 6) | 5 min | See explanation above |

Calculations for Scenario [4]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenario [4] – meta-SPC 6 | 1/ No PPE | 7.39×10^{-1} | 3.41×10^{-2} | nr | 7.73×10^{-1} |
| Scenario [4] – meta-SPC 6 | 2/ No PPE – 5 minutes | 5.11×10^{-2} | 3.41×10^{-2} | nr | 8.52×10^{-2} |

Outcome of systemic exposure and risk characterisation

For the scenario [1] – direct application on insects, the applicant claims that the products can be used “as needed”. Therefore, the non-professional user can use the products frequently. Thus, the systemic exposure is compared to the medium term AEL (0.055 mg/kg bw/d).

The systemic exposure for scenario [2] – air space application is compared to the short term AEL, as the products are only to be used during infestation and should not be used continuously.

For scenarios [3] and [4], a residual effect up to 4 months is expected. Therefore, the non-professional user is not expected to use the product frequently. Thus, the systemic exposure is compared to the short term AEL (0.088 mg/kg bw/d).

Summary table: estimated systemic exposure and risk characterisation for non-professional users

| Summary table: estimated systemic exposure and risk characterisation for non-professional users | | | | | | | |
|---|--|--------------------------------------|--|--|---------------------------------------|---|-----------------------------|
| Exposure scenario | Tier/PPE | Estimated oral uptake [mg/kg bw/day] | Estimated dermal uptake [mg/kg bw/day] | Estimated inhalation uptake [mg/kg bw/day] | Estimated total uptake [mg/kg bw/day] | Estimated uptake/AEL (%) AEL _{medium-term} = 0.055 mg/kg bw/d AEL _{short-term} = 0.088 mg/kg bw/d | Exposure/AEL < 100 (Yes/No) |
| Scenario [1] | 1/ no PPE – Meta-SPC 1 | nr | 1.86x10 ⁻² | 1.66x10 ⁻¹ | 1.84x10 ⁻¹ | 335% | No |
| | 2/ no PPE – Meta-SPC 1 (5 min) | nr | 1.86x10 ⁻² | 3.56x10 ⁻² | 5.43x10 ⁻² | 99% | Yes |
| | 1/ no PPE – Meta-SPC 2 | nr | 3.00x10 ⁻² | 4.54x10 ⁻² | 7.55x10 ⁻² | 137% | No |
| | 2/ no PPE – Meta-SPC 2 (20 minutes) | nr | 3.00x10 ⁻² | 2.45x10 ⁻² | 5.46x10 ⁻² | 99% | Yes |
| | 1/ no PPE – Meta-SPC 6 | nr | 7.56x10 ⁻³ | 1.14x10 ⁻² | 1.90x10 ⁻² | 35% | Yes |
| Scenario [2] | 1/ no PPE | nr | 6.83x10 ⁻² | 2.11x10 ⁻⁴ | 6.85x10 ⁻² | 78% | Yes |
| Scenario [3] | 1/ no PPE – Meta-SPC 5 | nr | 7.26x10 ⁻² | 2.92x10 ⁻⁴ | 7.29x10 ⁻² | 83% | Yes |
| | 1/ no PPE – Meta-SPC 4 | nr | 1.03x10 ⁻¹ | 3.17x10 ⁻⁴ | 1.04x10 ⁻¹ | 118% | No |
| | 2/ no PPE – RMM – Meta-SPC 4 | nr | 4.74x10 ⁻² | 3.17x10 ⁻⁴ | 4.77x10 ⁻² | 54% | Yes |
| | 1/ no PPE – Meta-SPC 7 | nr | 2.61x10 ⁻² | 8.02x10 ⁻⁵ | 2.62x10 ⁻² | 30% | Yes |
| Scenario [4] | 1/ no PPE – Meta-SPC 6 | nr | 3.41x10 ⁻² | 7.39x10 ⁻¹ | 7.73x10 ⁻¹ | 878% | No |
| | 2/ no PPE – Meta-SPC 6 (5 minutes) | nr | 3.41x10 ⁻² | 5.11x10 ⁻² | 8.52x10 ⁻² | 97% | Yes |

For the use "Direct application on insects" (scenario 1), the exposure is inferior to AEL for meta SPC 6. For meta SPC 1 and 2, the exposure is superior to AEL considering 240 minutes of exposure indoor. However, as the product is intended use outdoor, this scenario overestimates the exposure. No model is available to determine the outdoor exposure. Therefore, a reverse scenario is performed to determine the duration of exposure to this concentration necessary to achieve the AEL medium-term (tier 2). A duration of more of 5 and 20 minutes is needed for meta-SPC 1 and 2 respectively. Considering that a duration of exposure of 5 or 20 minutes at the determined concentration is unlikely outdoor, the systemic risk is considered acceptable.

For use "air space treatment" (scenario 2), the exposure is inferior to AEL.

For use "treatment under building" (scenario 3), the exposure is inferior to AEL for meta SPC 5 and 7. For meta SPC 4, the combined exposure is superior to AEL. Therefore, a RMM to not rinse the trigger spray is needed: **"Do not clean the trigger spray"**

For the use "Crack and crevices" (scenario 4), the exposure indoor is superior to AEL considering 240 minutes of exposure for meta SPC 6. Therefore, **the use indoor is unacceptable.**

As the product is intended use also outdoor, a reverse scenario is performed to determine the duration of exposure at the concentration determined previously necessary to achieve the AEL (tier 2). A duration of more of 5 minutes is needed.

Considering that a duration of exposure of 5 minutes at the determined concentration is unlikely outdoor, the systemic risk is considered acceptable. This scenario is a worst case for meta SPC 5 and 7. Therefore, the risk is also acceptable for the outdoor uses of these meta SPC.

Outcome of qualitative local risk assessment for non-professional users: Products of meta-SPC 1, 2, 3 and 6 are eye irritant.

| Hazard | | | Exposure information | | | | Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C) | Risk | |
|------------------|-------------------------|----|--|--------------------------|---|---|--|--|--|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Frequency and duration of potential exposure | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| Meta-SPC 1 | | | | | | | | | |
| LOW | Eye Irrit. Cat 2 (H319) | 18 | Spraying (direct application on insects, crack and crevices) | Eyes | Frequency: As needed for application on insects and minimum every 4 months for crack and crevices Duration: few seconds | Eye exposure through potential spraying or hand-to-eye transfer | Equal to or less than one hour per day | As the exposure of eyes is inferior to the recommendations for acceptable risk, the risk is acceptable with the following RMMs: "Wash hands after use" "Do not spray towards people and animals" | (↓) Instructions for use and RMM on the label (wash hands after use, to be sprayed downwards) (↓) Low exposure duration (less than one hour per day) (↓) Low frequency (↑) Spraying (↑) Long range and high spray rate (↓) Outdoor for several uses |
| Meta-SPC 2 and 6 | | | | | | | | | |

| | | | | | | | | | |
|----------------------------------|-------------------------|----|--|------|--|---|--|--|--|
| LOW | Eye Irrit. Cat 2 (H319) | 18 | Spraying (direct application on insects, crack and crevices) | Eyes | Frequency: As needed for application on insects and minimum every 4 months for crack and crevices Duration: few seconds | Eye exposure through potential spraying or hand-to-eye transfer | Equal to or less than one hour per day | As the exposure of eyes is inferior to the recommendations for acceptable risk, the risk is acceptable with the following RMMs: "Wash hands after use" "Indoor, to be sprayed downwards if possible" | (↓) Instructions for use and RMM on the label (wash hands after use, to be sprayed downwards) (↓) Low exposure duration (less than one hour per day) (↓) Low frequency (↑) Spraying (↓) Outdoor for several uses |
| Meta-SPC 3 (air space treatment) | | | | | | | | | |
| LOW | Eye Irrit. Cat 2 (H319) | 18 | Spraying (air space application) | Eyes | Duration: few seconds | Eye exposure through potential spraying or hand-to-eye transfer | Equal to or less than one hour per day | As the exposure of eyes is inferior to the recommendations for acceptable risk, the risk is acceptable with the following RMMs: - "Wash hands after use" - "Leave the room directly after spraying process is triggered" | (↓) Instructions for use and RMM on the label (washing on hands after use, leave the room directly after spraying process is triggered) (↓) Low exposure duration (less than one hour per day) (↓) Practically no exposure (↑) Spraying |

Conclusion

For products of the family CHIMIGET_CYPER, used by non-professional users, the risk is unacceptable for the use crack and crevices indoor of meta SPC 6. For the other uses, the risk is acceptable considering the quantitative risk assessment for systemic effects and the qualitative risk assessment for local effects.

The following risk mitigation measures (RMM) have to be applied:

- For meta-SPC 1 for direct application on insects:
 - Wash hands after use
 - Do not spray towards people and animals
- For meta-SPC 2 and 6 for direct application on insects:
 - Wash hands after use
 - Indoor, to be sprayed downwards if possible
- For meta-SPC 3:
 - Wash hands after use
 - Leave the room directly after spraying process is triggered.
- For meta-SPC 4:
 - Do not clean the trigger spray
- For meta-SPC 6 for crack & crevice application (outdoor):
 - Wash hands after use

Secondary exposure of the general public

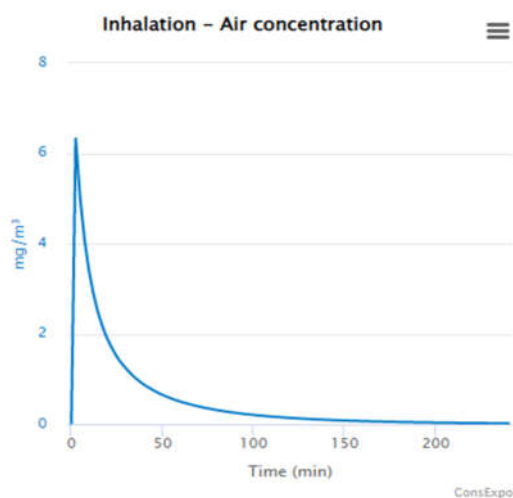
Scenario [5] – Re-entry in the treated room – inhalation (meta-SPC 3)

Description of Scenario [5] – Re-entry in the treated room – inhalation (meta-SPC 3)

After the air space application and a waiting period of 4 hours, the user can re-enter the treated room to ventilate, if a window is present, which may not be the case as this application is specific for cellars, basement, crawl space, garages, boxes, attics, barns, sheds or any other premises which are not wet-cleaned.

The ConsExpo model is used to estimate the in-air cypermethrin concentration 4h after the application started:

Description of Scenario [5] – Re-entry in the treated room – inhalation (meta-SPC 3)



| Time (min) | Air concentration (mg/m ³) | External event dose (mg/kg bw) | Internal event dose (mg/kg bw) |
|------------|--|--------------------------------|--------------------------------|
| 240 | 2.0×10^{-2} | 4.6×10^{-2} | 4.6×10^{-2} |

Then, the **Exposure to spray – instantaneous** release model is used to estimate the inhalation uptake when the adult and the infant stays in the room for 24h, with window closed as a worst-case scenario. To determine this exposure, 0.4 mg of cypermethrin (2×10^{-2} mg/m³ x 20 m³) is considered.

| | Parameters | Value | Justification |
|--------|---|--|---|
| Tier 1 | Concentration of cypermethrin | 4.35% w/w | Applicant's data |
| | Exposure duration | 240 min | Contact time claimed by the applicant |
| | In-air concentration of Cypermethrin after 4h | 2.0×10^{-2} mg/m ³ | ConsExpo – Exposure to spray – Instantaneous release model |
| | Amount of cypermethrin | 0.4 mg | See explanation above |
| | Duration of stay in the room | 24h | Default value |
| | Room volume | 20 m ³ | Default value from General Consexpo Factsheet for unspecified room |
| | Ventilation rate | 0.6 /h | Default value from General Consexpo Factsheet for unspecified room – windows closed |
| | Inhalation rate (adult / infant) | 1.25 / 0.84 m ³ /h | Ad hoc Recommendation 14 |
| | Body weight (adult / infant) | 60 / 8 kg | Ad hoc Recommendation 14 |

Calculations for Scenario [5]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenario [5] - adult | 1/ No PPE | 6.94x10 ⁻⁴ | nr | nr | 6.94x10 ⁻⁴ |
| Scenario [5] - infant | 1/ No PPE | 5.21x10 ⁻³ | nr | nr | 5.21x10 ⁻³ |

Scenario [6] – Contact with the treated surface

| Description of Scenario [6] – Contact with the treated surface | | | |
|--|--|-----------------------|---|
| <p>Products of meta-SPC 3 and 6 are the only one applied indoors. After the application of the product, either air space application for meta-SPC 3 or direct application on insects for meta-SPC 6, the general public can accidentally be in contact with wet treated surfaces.</p> <p>The exposure by dermal route is determined using the volume of product which could be in contact with the skin, using the application rate (1 ml/m³, equivalent to 0.4 ml/m² with a room height of 2.5m) and the surface area in contact with the surface, corresponding to one palm of hand.</p> <p>Calculations are made with 4.35% w/w cypermethrin.</p> <p>Exposure by inhalation for meta-SPC 3 has been assessed in Scenario [5].</p> | | | |
| | Parameters | Value | Justification |
| Tier 1 | Concentration of cypermethrin (meta-SPC 3) | 4.35% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 6) | 0.73% w/w | Applicant's data |
| | Application rate (meta-SPC 3) | 1 ml/m ³ | Applicant's data |
| | Application rate (meta-SPC 6) | 17.5 g/m ² | Applicant's data |
| | Surface area (one palm) | 205 cm ² | Ad hoc Recommendation 14 |
| | Layer of thickness | 0.01 cm | Default value |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| | Body weight | 60 kg | Ad hoc Recommendation 14 |

Calculations for Scenario [6]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------|----|-----------------------|----|-----------------------|
| Scenario [6] – meta-SPC 3 | 1/ No PPE | nr | 3.33×10^{-6} | nr | 3.33×10^{-6} |
| Scenario [6] – meta-SPC 6 | 1/ No PPE | nr | 3.06×10^{-5} | nr | 3.06×10^{-5} |

Scenario [7] – Infant crawling on treated surface and hand-to-mouth transfer

Description of Scenario [7] – Infant crawling on treated surface and hand-to-mouth transfer

Products of meta-SPC 3 and 6 are the only one applied indoors. For meta-SPC 3, after the 4h retention time of the air space treatment, infants (considered as the worst-case population) can crawl into the room and be dermally exposed to the treated surface. They also can be orally exposed to the active substances after hand-to-mouth transfer. They also can be exposed to products of meta-SPC 6 after the application on crack and crevices.

The systemic exposure by dermal and oral route is determined using the parameters established in the HEEG Opinion 7 on Choice of secondary exposure parameters for PTs 2, 3 and 4, which can also be used for PT18.

It is indicated that the external dose is calculated as follow:

$$\text{External dose} = S_{\text{area}} \times F_{\text{dislod}} \times Wf$$

S_{area} is the total area rubbed during exposure, calculated as the product of the transfer coefficient and exposure duration.

F_{dislod} is the amount of product applied on a surface area that may potentially be wiped off per unit of surface area. This factor is dependent on the application rate (1 ml/m³ pour meta-SPC 3 and 17.5 g/m² for meta-SPC 6) and the dislodgeable fraction of residues from the surface.

According to the ConsExpo Pest Control Products Fact Sheet, 10% of the dermal exposure is taken in orally due to hand-to-mouth transfer.

Products of meta-SPC 3 and meta-SPC 6 contain 4.35% w/w and 0.73% of cypermethrin respectively.

Exposure by inhalation for meta-SPC 3 has been assessed in Scenario [5].

| | Parameters | Value | Justification |
|--------|--|-------------------------|--|
| Tier 1 | Concentration of cypermethrin (meta-SPC 3) | 4.35% w/w | Applicant's data |
| | Concentration of cypermethrin (meta-SPC 6) | 0.73% w/w | Applicant's data |
| | Transfert coefficient | 2000 cm ² /h | Ad hoc Recommendation 12 |
| | Exposure duration | 1h | Default value. It is supposed that an infant crawls on the treated floor one hour per day. |
| | Application rate (meta-SPC 3) | 1 ml/m ³ | Applicant's data |
| | Application rate (meta-SPC 6) | 17.5 g/m ² | Applicant's data |

| Description of Scenario [7] – Infant crawling on treated surface and hand-to-mouth transfer | | | |
|--|--|------|---|
| | Dislodgeable fraction | 18% | BHHEM (p.171). For various type of surfaces. |
| | Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| | Fraction of dermal exposure taken orally | 10% | ConsExpo Pest Control Products Fact Sheet |
| | Oral absorption | 57% | CAR of Cypermethrin |
| | Body weight | 8 kg | Ad hoc Recommendation 14 |

Calculations for Scenario [7]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|---|---|---|--|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenario [7] – meta-SPC 3 | 1/ No PPE | nr | 3.94×10^{-2} | 3.57×10^{-3} | 4.30×10^{-2} |
| Scenario [7] – meta-SPC 6 | 1/ No PPE | nr | 3.62×10^{-1} | 3.28×10^{-2} | 3.95×10^{-1} |

Combined Scenarios (meta-SPC 3)

| Summary table: combined systemic exposure from non-professional uses | | | | |
|---|---|---|---|--|
| Scenarios combined | Estimated inhalation uptake (mg/kg bw/d) | Estimated dermal uptake (mg/kg bw/d) | Estimated oral uptake (mg/kg bw/d) | Estimated total uptake (mg/kg bw/d) |
| Scenarios [5] + [6] - adult | 6.94×10^{-4} | 3.33×10^{-6} | nr | 6.97×10^{-4} |
| Scenarios [5] + [7] - infant | 5.21×10^{-3} | 3.94×10^{-2} | 3.57×10^{-3} | 4.82×10^{-2} |

Outcome of systemic exposure and risk characterisation

Summary table: estimated systemic exposure and risk characterisation for general public

| Summary table: estimated systemic exposure and risk characterisation for non-professional users | | | | | | | |
|---|-----------|--------------------------------------|--|--|---------------------------------------|---|-------------------------|
| Exposure scenario | Tier/PPE | Estimated oral uptake [mg/kg bw/day] | Estimated dermal uptake [mg/kg bw/day] | Estimated inhalation uptake [mg/kg bw/day] | Estimated total uptake [mg/kg bw/day] | Estimated uptake/ AEL (%) AEL _{short-term} = 0.088 mg/kg bw/d | Exposure < AEL (Yes/No) |
| Scenario [5] – adult | 1/ no PPE | nr | nr | 6.94x10 ⁻⁴ | 6.94x10 ⁻⁴ | 1% | Yes |
| Scenario [5] – infant | 1/ no PPE | nr | nr | 5.21x10 ⁻³ | 5.21x10 ⁻³ | 6% | Yes |
| Scenario [6] – meta-SPC 3 | 1/ no PPE | nr | 3.33x10 ⁻⁶ | nr | 3.33x10 ⁻⁶ | 0.004% | Yes |
| Scenario [6] – meta-SPC 6 | 1/ no PPE | nr | 3.06x10 ⁻⁵ | nr | 3.06x10 ⁻⁵ | 0.03% | Yes |
| Scenario [7] – meta-SPC 3 | 1/ no PPE | 3.57x10 ⁻³ | 3.94x10 ⁻² | nr | 4.30x10 ⁻² | 49% | Yes |
| Scenario [7] – meta-SPC 6 | 1/ no PPE | 3.28x10 ⁻² | 3.6x10 ⁻¹ | nr | 3.95x10 ⁻¹ | 449% | No |

Combined scenarios

Outcome of combined systemic exposure and risk characterisation

Summary table: combined local exposure and risk characterisation for non-professional bystanders/general public

| Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public | | | | | | | |
|--|-----------|--------------------------------------|--|--|---------------------------------------|---|-------------------------|
| Scenarios combined | Tier/PPE | Estimated oral uptake [mg/kg bw/day] | Estimated dermal uptake [mg/kg bw/day] | Estimated inhalation uptake [mg/kg bw/day] | Estimated total uptake [mg/kg bw/day] | Estimated uptake/ AEL (%) <small>AEL_{short-term} = 0.088 mg/kg bw/d</small> | Exposure < AEL (Yes/No) |
| Scenarios [5] + [6] - adult | 1/no PPE | nr | 3.33×10^{-6} | 6.94×10^{-4} | 6.97×10^{-4} | 1% | Yes |
| Scenarios [5] + [7] - infant - meta-SPC 3 | 1/ no PPE | 3.57×10^{-3} | 3.94×10^{-2} | 5.21×10^{-3} | 4.82×10^{-2} | 55% | Yes |

Secondary exposure to the product after re-entering the room (meta-SPC 3) is considered acceptable for the general public with the application of the following RMM:

- Do not enter the room before a waiting time of 4h.

The risk is acceptable for infants crawling on the treated floor, considered the quantitative risk assessment for meta-SPC 3, with the following RMM:

- The product must be applied at the claimed application rate of 1 ml/m³.

The risk is acceptable when a treated surface is touched.

The risk is not acceptable for infants crawling on the treated floor, considered the quantitative risk assessment for meta-SPC 6. Therefore, a RMM is needed for indoor use:

- For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.

Overall conclusion

| | Conclusion and RMMs |
|---|--|
| Meta SPC 1 | |
| Direct spray on insect (outdoor) | Acceptable with the following RMM: Wash hands after use Do not spray towards people and animals |
| Meta SPC 2 | |
| Direct spray on insect (outdoor) | Acceptable with the following RMM: Wash hands after use |
| Meta SPC 3 | |
| Air space treatment (indoor) | Acceptable with the following RMMs: Wash hands after use Leave the room directly after spraying process is triggered Do not enter the room before a waiting time of 4h. The product must be applied at the claimed application rate of 1 ml/m ³ . |
| Meta SPC 4 | |
| Treatment under building (outdoor) | Acceptable with the following RMM: Do not clean the trigger spray |
| Meta SPC 5 | |
| Crack and crevice (outdoor) | Acceptable |
| Treatment under building (outdoor) | Acceptable |
| Meta SPC 6 | |
| Direct spray on insect (indoor and outdoor) | Acceptable with the following RMM: Wash hands after use Indoor, to be sprayed downwards if possible |
| Crack and crevice (indoor and outdoor) | Indoor: unacceptable Outdoor: acceptable with the following RMM → Wash hands after use |
| Meta SPC 7 | |
| Crack and crevice (outdoor) | Acceptable |
| Treatment under building (outdoor) | Acceptable |

Monitoring data

Not relevant.

Dietary exposure

The products of the CHIMIGET_CYPER family contain cypermethrin cis/trans 40/60 (CAS No. 52315-07-8). According to the Document I, Evaluation Report of this active substance (Product-Type 18, February 2017), an ARfD of 0.2 mg/kg bw and an ADI of 0.05 mg/kg/day are set, based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA February 2005. Therefore, a consumer safety evaluation is deemed necessary for this active substance.

However, the products of the Chimiget_cyper family are not intended to be used near food, feed, drinks or food-producing animals, and on surfaces and facilities in the vicinity of or likely to be in contact with food, feed and drinks. Indeed, no direct or indirect contact with food, feed and drinks is expected according to the use of the products.

For META SPC 1, the product is used outdoor and sprayed directly on the insects. Therefore, no contamination of food is expected and no specific risk mitigation measures are needed.

Nevertheless, for META SPC 2, 3, 4, 5, 6 and 7 to avoid any risk of contamination, following risk mitigation measure is proposed: *“Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock”*.

Furthermore, regarding use linked to META SPC3 (indoor space treatment by fogging), the applicant states that META SPC 3 is not intended for use in any habitable rooms within the dwelling. The product is to be used in areas which are inaccessible to children and pets (specifically cats) such as attics and crawlspaces. Since commodities can be stored in such areas, as in cellars, to prevent any risk of contamination, an additional mitigation measure is added for this meta-SPC: *“Do not use in places where food or feed is stored, prepared or eaten”*.

Taking into account authorized uses and additional RMMs residues in food are not considered relevant. Therefore, no further assessment is considered necessary.

Information of non-biocidal use of the active substance

Residue definitions

| Summary table of other (non-biocidal) uses | | | |
|--|-------------------------------|---|---|
| | Sector of use ¹ | Intended use | Reference value(s) ² |
| 1. | Plant protection products | Insecticide (authorised under Reg. 1107/2009) | Cypermethrin (Residue definition: Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) MRL from 0.05 mg/kg to 3 mg/kg (Reg. (EU) 2017/626). |
| 2 | Veterinary medicinal products | Antiparasitic agents/Agents against ectoparasites | Residue definition: Cypermethrin (sum of isomers) MRL (all ruminants)* : 20 µg/kg in muscle, liver, kidney 200 µg/kg in fat MRL (<i>Salmonidae</i>)* : 50 µg/kg in muscle and skin |

*Reg (EU) 37/2010

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

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

Not relevant

Maximum residue limits or equivalent

No specific biocide MRLs are established for this active substance. Nevertheless, MRLs are established in Regulation (EU) 1107/2009 and Regulation (EU) 37/2010 (See paragraph above "Information of non-biocidal use of the active substance").

Risk for consumers via residues in food

The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions and the RMMs (see section dietary exposure). Therefore, risk for consumers via residues in food is not considered relevant.

2.2.7 Risk assessment for animal health

In the risk assessment for human health, for meta-SPC 6, the risk is not considered acceptable for infant crawling into the treated floor and being orally exposed to the product by hand-to-mouth transfer. A RMM has been added in order to protect the general public. The same RMM is therefore required to avoid animal exposure:

- For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.

For all meta-SPC, the following RMM is required:

- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids toxicity, the product can cause severe adverse reactions in cats.

2.2.8 Risk assessment for the environment

The biocidal products of the CHIMIGET_CYPER family are insecticides containing between 0.22 and 10.87% w/w cypermethrin. They are intended to be used by non-professionals only, indoors and/or outdoors, against flying and crawling insects or wasps and hornets. The biocidal product family (BPF) contains several biocidal products (aerosol dispenser, ready to use (RTU) and concentrated liquid products) grouped into seven sub-groups (Meta-SPC).

The products used outdoor lead to the exposure of the soil as a primary receiving environmental compartment in rural area and the sewage treatment plant (STP) in urban area. While the uses of the products take place indoor, they lead to the exposure of the STP as primary receiving environmental compartment.

Substances of concern and metabolites:

No metabolites are formed and no substances of concern are identified.

The following risk assessment is therefore carried out for the active substance only according to the Competant Authority Report (CAR).

2.2.8.1 Effects assessment on the environment

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

The biocidal product family does not contain any other co-formulants that are classified for an environmental hazard. The classification of the different Meta-SPC is therefore driven by the active substance, cypermethrin. The harmonised classification of cypermethrin (ATP 17 Regulation, applicable in December 2022) is Aquatic Acute 1, H400 (with an M-factor of 100 000) and Aquatic Chronic 1, H410 (with an M-factor of 100 000).

The biocidal product family classification is summarized in the table below (see the detailed calculation based on the composition in the confidential annex).

| | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 3 | Meta-SPC 4 | Meta-SPC 5 | Meta-SPC 6 | Meta-SPC 7 |
|----------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| a.s. concentration (% w/w) | 0.54 | 0.54- 0.87 | 0.54-0.87 | 0.54-0.87 | 10.87 | 0.22 | 0.22 |
| Classification | H400 ; H410 | H400 ; H410 | H400 ; H410 | H400 ; H410 | H400 ; H410 | H400 ; H410 | H400 ; H410 |

Further Ecotoxicological studies

No new data is available.

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

No new data is available.

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

Not relevant.

| Data waiving | |
|-------------------------|---|
| Information requirement | Not relevant |
| Justification | The products are not in the form of bait or granules. |

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

Not relevant.

| Data waiving | |
|-------------------------|---|
| Information requirement | Not relevant |
| Justification | The products are 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)

Not relevant.

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

According to the intended uses, the following releases may occur:

- After **indoor spray application** and wet cleaning of treated or contaminated area, the Sewage Treatment Plant (STP) is considered as the main receiving compartment. Then, the final environmental compartments will be surface water and sediment (through STP effluent), soil and groundwater (from STP sludge application).
- After **outdoor application in rural area**, the soil is considered as the main receiving compartment due to the emissions directly on soil during loading/mixing step, application step and wash-off by rain-fall. The groundwater can be contaminated after leaching from the exposed soil.
- After **outdoor application in urban area**, the Sewage Treatment Plant (STP) is considered as the main receiving compartment. Then, the final environmental compartment will be surface water and sediment (through STP effluent), soil and groundwater (from STP sludge application).

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

No data is available.

| Data waiving | |
|-------------------------|---|
| Information requirement | No data is available. |
| Justification | The product contains a single active substance and does not contain any environmentally relevant substance of concern or co-formulant which is likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance, cypermethrin. The environmental fate and behaviour of the products may therefore be extrapolated from information available on the active substance. |

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

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.

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

Not relevant.

PNEC values summary table

Based on the cypermethrin assessment report, the relevant PNECs for the environmental risk characterisation are reported below.

| PNEC | | Justification |
|------------------------------|-----------------|---|
| PNEC _{STP} | 1.63 mg/L | An EC ₅₀ of 163 mg/L from a microbial activity inhibition test is reported in the CAR (2019). An assessment factor (AF) of 100 was applied to the EC ₅₀ to derive the PNEC. |
| PNEC _{water} | 4.00E-06 mg/L | The PNEC _{water} presented in the CAR (2019) was derived from the NOEC of 0.04 µg/L for daphnia and an AF of 10. |
| PNEC _{sediment,EPM} | 0.005 mg/kg wwt | Equilibrium partitioning method. This value already considers the additional factor of 10 needed in case of high Koc value |
| PNEC _{soil} | 0.07 mg/kg wwt | The PNEC _{soil} presented in the CAR (2019) was derived from the chronic earthworm NOEC reproduction (4 mg/kg dwt) with an AF of 50. |
| PNEC _{oral bird} | 33.3 mg/kg feed | The PNEC _{oral} for secondary poisoning of birds is derived by applying an assessment factor of 30 to the chronic NOEC of 1000 mg/Kg feed. |

| | | |
|------------------------------|----------------|---|
| PNEC _{Coral mammal} | 3.3 mg/kg food | The PNEC _{Coral} for secondary poisoning of mamal is derived by applying an assessment factor of 30 to the chronic rat study NOEC of 5 mg/Kg bw/d. |
|------------------------------|----------------|---|

2.2.8.2 Exposure assessment

General information

| | |
|---------------------------------|---|
| Assessed PT | PT 18 |
| Assessed scenarios | <p>Scenario 1: Indoor spot application by spray in cracks and crevices (along windows and doors)</p> <p>Scenario 2: Indoor spot application by spray on surface</p> <p>Scenario 3: Indoor fogging application for an air space treatment (one-shot aerosol)</p> <p>Scenario 4: Spray application in crawling space</p> <p>Scenario 5: Outdoor spot application by spray in cracks and crevices (along windows and doors)</p> <p>Scenario 6: Direct spray on insects outdoor – application on bare soil</p> <p>Scenario 7: Direct spray on insects outdoor – application on impermeable ground</p> |
| ESD(s) used | Emission Scenario Document for Product Type 18: Insecticides, Acaricides and products to control other arthropods for household and professional uses |
| Approach | For all scenarios: Average consumption |
| Distribution in the environment | <p>Estimated according to:</p> <ul style="list-style-type: none"> - Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) - Technical Agreements for Biocides Environment, Version DB, 09 November 2021. |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | <p>All scenarios:</p> <p>Production: No</p> <p>Formulation: No</p> <p>Use: Yes</p> <p>Service life: No</p> |
| Remarks | - |

Emission estimation

Scenario 1: Indoor spot application by spray in cracks and crevices (along windows and doors)

The scenario for the indoor spot application by spray in cracks and crevices covers the use #2 of Meta-SPC 6 with the following use description: Spray the product as target spots, into cracks and crevices where the insects pass (spots near the windows, around the doors, on the skirting boards...). As the product is applied by non-professionals, only domestic houses have been considered.

Local emission due to targeted spraying (spot application) in cracks and crevices was calculated using ESD for PT18 Emission models for indoor treatments – application by spraying (incl. cleaning) – spot application. In fact, the use of a 2 m² application can also be justified by the TAB entry ENV 35 that defines the length of doorstep and window treatment to be 10 m. As the treatment is in the cracks and crevices, it is reasonable to consider a width of the barrier lower than 20 cm corresponding to a worst-case surface of 2 m².

The product of Meta-SPC 6 is ready-to-use RTU aerosol. No dilution and no loading are needed. Therefore, no emission occurs during the mixing/loading step.

According to the assay GENVPF5561 (see the confidential annex) provided by the applicant, the aerosol can be considered similar to a spray. In fact, the applicant demonstrated that the diameter of the treated area was around 10 cm and the spray is described as regular, homogeneous, powerful and flowing. Therefore, according to the ESD PT18, the cleaning efficiency used must be 0.25 as for a spray application, as this type of aerosol does not allow a targeted application that would justify a cleaning efficiency of only 0.03.

| Input parameters for calculating the local emission | | | |
|--|--------|--------------------|--------------------------------|
| Input | Value | Unit | Remarks |
| Fraction of active substance in the commercial product (F_{AI}) | 0.0022 | [-] | Set value |
| Number of private houses connected to the same STP (N_{house}) | 4000 | [-] | Default value |
| Total area applied with insecticide in a standard house ($AREA_{treated}$) | 2 | m ² | TAB ENV 144 (spot application) |
| Quantity of commercial product applied per m ² (Q_{prod}) | 0.0175 | kg.m ⁻² | Set value |
| Number of applications per day (N_{appl}) | 1 | d ⁻¹ | Default value |
| Fraction emitted to air during application step ($F_{application,air}$) | 0.02 | [-] | Default value |
| Fraction emitted to applicator during application step ($F_{application,applicator}$) | 0.02 | [-] | Default value |
| Fraction emitted to floor during application step ($F_{application,floor}$) | 0.11 | [-] | Default value |
| Fraction emitted to treated surfaces during application step ($F_{application,treated}$) | 0.85 | [-] | Default value |

| | | | |
|---|----------|-----|---|
| Simultaneity factor for indoor uses of insecticide in standard houses (F_{sim}) | 0.008151 | [-] | Default value for 3-11 times a year considering a residual effect of 4 months |
| Cleaning efficiency (F_{CE}) | 0.25 | [-] | Default value for a spray in cracks and crevices |

Calculations for Scenario 1:

$$E_{appli,applicator} = N_{appl} * Q_{prod} * F_{AI} * AREA_{treated} * F_{application,applicator} * 0.001$$

$$E_{appli,floor} = N_{appl} * Q_{prod} * F_{AI} * AREA_{treated} * F_{application,floor} * 0.001$$

$$E_{appli,treated} = N_{appl} * Q_{prod} * F_{AI} * AREA_{treated} * F_{application,treated} * 0.001$$

$$E_{local,water} = (E_{appli,applicator} + E_{appli,floor} * F_{CE} + E_{appli,treated} * F_{CE}) * N_{house} * F_{sim}$$

| Resulting local emission to relevant environmental compartments | | |
|---|---|---------|
| Compartment | Local emission ($E_{local,water}$) [kg/d] | Remarks |
| STP | 6.53E-04 | - |

Scenario 2: Indoor spot application by spray on surface

The scenario for the indoor application by spraying on surface covers the following uses of Meta-SPC 6:

- Direct spraying on insects indoor (use#1)
- Target surface spraying as spots application indoor (use#2)

Local emission due to surface application was calculated using ESD for PT18 Emission models for indoor treatments – application by spraying (incl. cleaning) – spot application.

The product of Meta-SPC 6 is ready-to-use RTU aerosol. No dilution and no loading are needed. Therefore, no emission occurs during the mixing/loading step.

For the use#1 (direct spraying on insect) from the Meta SPC 6, only an application of 2.5 g of product is claimed (no application rate in g/m² is available). This application rate corresponds to 1 second of spray. In a best case, two sprays of one second is considered to calculate the local emission.

The product of Meta-SPC 6 is an aerosol, therefore the respective cleaning efficiency is 0.2. It is considering as a best case as, according to the assay GENVPF5561 provided by the applicant (see the confidential annex), the aerosol can be considered similar to a spray. In fact, the applicant demonstrated that the diameter of the treated area was around 10 cm and the spray is described as regular, homogeneous, powerful and flowing. Therefore, according to the ESD PT18, the cleaning efficiency used should be 0.5 as for a spray application, as this type of aerosol does not allow a targeted application that would justify a

cleaning efficiency of only 0.2. As risks are already foreseen with a cleaning efficiency of 0.2, the assessment was kept with this best case value.

| Input parameters for calculating the local emission | | | | |
|--|-------------------------|-------------------------|--------------------|---|
| Input | Value | | Unit | Remarks |
| | Meta SPC 6 Use#1 | Meta SPC 6 Use#2 | | |
| Fraction of active substance in the commercial product (F_{AI}) | 0.0022 | 0.0022 | [-] | Set value |
| Number of private houses connected to the same STP (N_{house}) | 4000 | | [-] | Default value |
| Total area applied with insecticide in a standard house ($AREA_{treated}$) | - | 2 | m ² | TAB ENV 144 (spot application) |
| Number of spray (equal to 1 second) per day | 2 | - | [-] | As an unrealistic best case |
| Quantity of commercial product applied per m ² (Q_{prod}) | - | 0.0175 | kg.m ⁻² | Set value |
| Quantity of commercial product applied by spray of 1 second | 0.0025 | - | kg | Set value |
| Number of applications per day (N_{appl}) | 1 | | d ⁻¹ | Set value |
| Fraction emitted to air during application step ($F_{application,air}$) | 0.02 | | [-] | Default value |
| Fraction emitted to applicator during application step ($F_{application,applicator}$) | 0.02 | | [-] | Default value |
| Fraction emitted to floor during application step ($F_{application,floor}$) | 0.11 | | [-] | Default value |
| Fraction emitted to treated surfaces during application step ($F_{application,treated}$) | 0.85 | | [-] | Default value |
| Simultaneity factor for indoor uses of insecticide in standard houses (F_{sim}) | 0.055162 | 0.008151 | [-] | Use#1: Default value for daily use as no restriction is proposed in the SPC Use#2: Default value for 3-11 times a year considering a residual effect of 4 months |

| | | | |
|----------------------------------|-----|-----|--|
| Cleaning efficiency (F_{CE}) | 0.2 | [-] | Default value for a RTU aerosol – surface (unrealistic best case*) |
|----------------------------------|-----|-----|--|

* According to the assay GENVPF5561 (see the confidential annex) provided by the applicant, the aerosol can be considered similar to a spray.

Calculations for Scenario 2:

See details of the local wastewater emission equations in the 'Calculation for Scenario 1' section above.

| Resulting local emission to relevant environmental compartments | | | |
|---|---|----------|---------|
| Compartment | Local emission ($E_{local,water}$) [kg/d] | | Remarks |
| | Use#1 | Use#2 | |
| STP | 5.15E-04 | 5.32E-04 | - |

The local emission calculated for the use#1 is covered by the one calculated for the use#2 (5.32E-04 kg.d-1). The $E_{local,water}$ for use#2 will be used for the risk assessment as both emission values are considered equivalent.

Scenario 3: Indoor fogging application for an air space treatment (one-shot aerosol)

The scenario for the application by fogging with a one-shot aerosol for an air space treatment covers the following use #1 of Meta-SPC 3 with the following use description: One-shot aerosol insecticide against flying and crawling insects used in cellars, basements, crawl spaces, garages, boxes, attics, barns, sheds or any other premises which are not wet-cleaned ...). As the product is applied by non-professionals, only domestic houses have been considered.

Local emission due to this application in premises was calculated using the ESD for PT18 Emission models for indoor treatments – application by spraying (incl. cleaning) for air space application, considering the wet cleaning of premises as a worst case.

The product of Meta-SPC 3 is a one-shot aerosol. No dilution and no loading are needed. Therefore, no emission occurs during the mixing/loading step. The applicator is not in the room for the application; there is no emission to the applicator during application.

| Input parameters for calculating the local emission | | | |
|---|--------|------|---------------|
| Input | Value | Unit | Remarks |
| Fraction of active substance in the commercial product (F_{AI}) | 0.0087 | [-] | Set value |
| Number of private houses connected to the same STP (N_{house}) | 4000 | [-] | Default value |

| | | | |
|---|----------|--------------------|---|
| Total volume applied with insecticide in a standard house (total volume treated) (VOLUME _{treated}) | 325 | m ³ | Default value |
| Wet cleaning zone leading to releases to the STP (standard house) (AREA _{cleaned}) | 38.5 | m ² | Default value |
| Quantity of commercial product applied per m ³ (Q _{prod}) | 7.99E-04 | kg.m ⁻³ | According to the claimed application rate (corresponding to 1 mL/m ³ with a product density of 0.799 kg/L) |
| Number of applications per day (N _{appl}) | 1 | d ⁻¹ | Set value |
| Fraction emitted to air during application step (F _{application,air}) | 0.02 | [-] | Default value |
| Fraction emitted to applicator during application step (F _{application,applicator}) | 0 | [-] | Default value (one-shot aerosol) |
| Fraction emitted to floor during application step (F _{application,floor}) | 0.98 | [-] | Default value considering an F _{application,applicator} = 0 |
| Fraction emitted to treated surfaces during application step (F _{application,treated}) | 0 | [-] | Default value |
| Simultaneity factor for indoor uses of insecticide in standard houses (F _{sim}) | 0.008151 | [-] | Default value for 3-11 times a year considering a residual effect of 4 months |
| Cleaning efficiency (F _{CE}) | 1 | [-] | Default value for a RTU aerosols - space spray/diffuser |

Calculations for Scenario 3:

$$E_{\text{local water}} = N_{\text{appl}} * Q_{\text{prod}} * F_{\text{AI}} * \text{VOLUME}_{\text{treated}} * F_{\text{application,floor}} * F_{\text{CE}} * N_{\text{house}} * F_{\text{sim}} * (\text{AREA}_{\text{cleaned}}/130)$$

| Resulting local emission to relevant environmental compartments | | |
|---|---|---------|
| Compartment | Local emission (E _{local water}) [kg/d] | Remarks |
| STP | 2.14E-02 | - |

Scenario 4: Spray application in crawling space

The scenario for the spray application in crawling space covers the use#1 of Meta-SPC 4, and the use#2 of Meta-SPC 5 and Meta-SPC 7, flying and crawling insects - surface spray

under buildings, with the following use instructions: Spray the product under buildings (crawlspaces...)

Local emission due to spray application under building was calculated using ESD for PT18 Emission models for outdoor treatments – treatment of crawling insects by spray. According to the ESD for PT18, this scenario is relevant only in rural areas.

The products of Meta-SPC 4 and 7 are ready-to-use. No dilution and no loading are needed. Therefore, no emission occurs during the mixing/loading step for these Meta-SPCs. However, a dilution of 2% to 8% is to be taken into account for the preparation step of Meta-SPC 5. Therefore, an emission is calculated for the mixing/loading step for this Meta-SPC 5.

The Meta-SPC 5 with a dilution of 2% was used as the worst case for the environmental risk assessment of the Meta-SPC 7. In fact, considering the product density of 0.916 kg/L, the concentration in the pure solution of 108.7 g cypermethrin/L and the dilution of 2%, the application rate corresponds to 39.8 mg cypermethrin/m² (i.e. 20 mL/m²) for Meta-SPC 5, when the application rate for the Meta-SPC 7 is slightly lower (i.e. 38.9 mg/m²). Therefore, the concentration of cypermethrin in Meta-SPC 5 with a dilution of 2% covers the concentration of cypermethrin in Meta-SPC 7. The same reasoning was made to cover the upper concentration limit of Meta SPC 4 by Meta SPC 5 (dil 2%) as explained by the table below.

| | Meta-SPC 4 (upper concentration limit) | Meta-SPC 4 (lower concentration limit) | Meta-SPC 5 (Dilution 8%) | Meta-SPC 5 (Dilution 2%) | Meta-SPC 7 | Unit |
|---|---|---|---------------------------------|---------------------------------|--------------------------------|------------------------|
| Fraction of active substance in the commercial product (F _{AI}) | 0.0087 | 0.0054 | 0.1087 | 0.1087 | 0.1087 | [-] |
| Product density (D) | 0.885 | 0.885 | 0.916 | 0.916 | 0.916 | kg.L ⁻¹ |
| Dilution (Dil) | n.r. | n.r. | 8 | 2 | n.r. | % |
| Application rate (final product) | 20 | 20 | 20 | 20 | 20 | mL/m ² |
| Application rate (AI) | 154 | 95.6 | 159.3 | 39.8 | 38.9 | mg ai / m ² |
| Conclusion | Converved by Meta SPC 5 (dil 8%) | To calculate | To calculate | To calculate | Covered by Meta SPC 5 (dil 2%) | |

| Input parameters for calculating the local emission | | | | | |
|--|---|---------------------------------|---------------------------------|-------------|----------------|
| Input | Value | | | Unit | Remarks |
| | Meta-SPC 4 (lower concentration limit) | Meta-SPC 5 (Dilution 8%) | Meta-SPC 5 (Dilution 2%) | | |
| | | | | | |

| | | | | | |
|--|----------|----------|----------|---------------------------------|---|
| Fraction of active substance in the commercial product (F_{AI}) | 0.0054 | 0.1087 | 0.1087 | [-] | Set values |
| Product density (D) | 0.885 | 0.916 | 0.916 | kg.L ⁻¹ | Set values |
| Dilution (Dil) | n.r. | 8 | 2 | % | Set values |
| Quantity of product used for one preparation event ($Q_{prod,prep}$) | n.r. | 4.21E+02 | 1.05E+02 | g | Output – Considering an application rate of 20 mL diluted product/m ² |
| Number of preparations per day (N_{prep}) | | 1 | | d ⁻¹ | According to the intended use |
| Fraction emitted to soil during preparation step ($F_{prep,soil}$) | | 4.00E-03 | | [-] | Default value |
| Soil volum for the mixing loading step ($V_{prep,soil}$) | | 0.4 | | m ³ | Default value |
| Quantity of pure product applied (Q_{prod}) | 1.77E-02 | 1.47E-03 | 3.66E-04 | kg.m ⁻² | According to the intended use (application rate of 20 mL diluted product/m ²) |
| Area of walls and ceiling (crawling space) treated per day ($AREA_{crawling}$) | 156 | | | m ² .d ⁻¹ | Default value |
| Area of soil (crawling space) treated per day ($AREA_{soil}$) | 131 | | | m ² .d ⁻¹ | Default value |
| Fraction emitted to soil during crawling space spray application on walls and ceiling ($F_{spray,wall-ceiling}$) | 0.3 | | | [-] | Default value |
| Fraction emitted to soil during crawling space spray application on soil ($F_{spray,soil}$) | 1 | | | [-] | Default value |
| Soil volume for deposition and application ($V_{spray,treated_soil}$) | 66 | | | m ³ .d ⁻¹ | Default value |

Calculations for Scenario 4:

$$E_{prep} = F_{AI} * Q_{prod,prep} * N_{prep} * F_{prep,soil} * 0.001$$

$$E_{local,soil} = Q_{prod} * F_{AI} * (AREA_{crawling} * F_{spray,wall-ceiling} + AREA_{soil} * F_{spray,soil})$$

| Resulting local emission to relevant environmental compartments | | | | |
|---|--|--------------------------|--------------------------|---------|
| Local emission [kg/d] | Meta SPC 4 (lower concentration limit) | Meta-SPC 5 (Dilution 8%) | Meta-SPC 5 (Dilution 2%) | Remarks |
| Local emission to soil during preparation step (E_{prep}) | n.r. | 1.83E-04 | 4.57E-05 | - |

| Resulting local emission to relevant environmental compartments | | | | |
|--|---|-----------------------------|-----------------------------|---------|
| Local emission [kg/d] | Meta SPC 4 (lower concentration limit) | Meta-SPC 5 (Dilution 8%) | Meta-SPC 5 (Dilution 2%) | Remarks |
| Local emission to soil due to application on crawling space ($E_{local,soil}$) | 1.70E-02 | 2.83E-02 | 7.08E-03 | - |

$$C_{prep,soil} = E_{prep} * 10E6 / (RHO_{soil} * V_{soil})$$

$$C_{soil} = E_{crawling,soil} * 10E6 / (RHO_{soil} * V_{soil})$$

| Resulting local concentration to relevant environmental compartments | | | | |
|---|---|-----------------------------|-----------------------------|---------|
| Local emission [mg.kg _{ww} ⁻¹] | Meta SPC 4 (lower concentration limit) | Meta-SPC 5 (Dilution 8%) | Meta-SPC 5 (Dilution 2%) | Remarks |
| Local concentration of active substance in soil during mixing/loading ($C_{prep,soil}$) | n.r. | 2.69E-01 | 6.72E-02 | - |
| Concentration of active ingredient in soil (C_{soil}) | 1.51E-01 | 2.52E-01 | 6.31E-02 | - |

Scenario 5: Outdoor spot application by spray in cracks and crevices (along windows and doors)

The scenario for the spray application in cracks and crevices (outdoor) covers the use#1 of Meta-SPC 5 and 7 and use#2 of Meta-SPC 6 with the following description: Spray the product as target spots, into cracks and crevices where the insects pass (spots near the windows, around the doors, on the skirting boards...)

Local emission due to spray application in crack and crevices was calculated using ESD for PT18 Emission models for outdoor treatments – treatment around the building.

The uses of Meta SPC 5, 6 and 7 claims an application as spot in cracks and crevices only on very localised areas (like the frames of windows and doors). According to the ESD for PT18: "where specific data on the application pattern are available, the surface treated should be recalculated according to label or material technical data sheet (e.g. walls/soil treatment or soil only, different width of treated area, etc...)". Therefore, the treated area has been re-calculated to correspond to the actual claimed uses. Parameters from the "Outdoor-Window/ Door step scenario" for ants from TAB 2019 ENV A21 are used to calculate the area of windows and door's frames of houses. Thus, the surface treated for such application is 2 m² (considering a worst case spray width of 20 cm).

To cover all claimed doses, the concentration of cypermethrin in Meta SPC 5 was used as the worst case for the environmental risk assessment of the scenario 5. In fact, considering the product density of 0.916 kg/L, the concentration in the pure solution of 10.87 g

cypermethrin/L and the dilution of 2%, the application rate corresponds to 39.8 mg cypermethrin/m² (i.e. 20 mL/m²) for Meta-SPC 5, when the applications rates for the other Meta-SPC are slightly lower (i.e. 38.5 and 38.9 mg/m² for Meta-SPC 6 and 7 respectively). See the table below for more details.

| | Meta-SPC 5 (Dilution 2%) | Meta-SPC 6 | Meta-SPC 7 | Unit |
|---|-------------------------------------|--------------------------------|--------------------------------|------------------------|
| Fraction of active substance in the commercial product (F_{AI}) | 0.1087 | 0.0022 | 0.0022 | [-] |
| Product density (D) | 0.916 | n.r. | 0.885 | kg.L ⁻¹ |
| Dilution (Dil) | 2 | n.r. | n.r. | % |
| Application rate (final product) | 20 mL/m ² | 17.5 g/m ² | 20 mL/m ² | - |
| Application rate (AI) | 39.8 | 38.5 | 38.9 | mg ai / m ² |
| Conclusion | To calculate | Covered by Meta SPC 5 (dil 2%) | Covered by Meta SPC 5 (dil 2%) | |

A dilution of 2% max is to be taken into account for the preparation step for the Meta-SPC 5 only. No emission occurs during the mixing/loading step for products from Meta SPC 6 and 7 as they are RTU.

| Input parameters for calculating the local emission | | | |
|--|-----------------------------|-----------------------------------|--|
| Input | Value Meta SPC 5 | Unit | Remarks |
| Fraction of active substance in the commercial product (F_{AI}) | 0.1087 | [-] | Set value |
| Dilution | 2 | % | Set value |
| Product density | 0.916 | kg.L ⁻¹ | Set value |
| Application rate (in-use product) | 20 | mL. m ⁻² | Set value |
| Application rate (active substance) | 3.98E-05 | kg | Output |
| Number of private houses connected to the same STP (N_{house}) | 2500 | [-] | Default value |
| Bulk density of wet soil (RHO_{soil}) | 1700 | kg _{ww} .m ⁻³ | Default value |
| Quantity of product used for one preparation event ($Q_{prod,prep}$) | 7.33E-01 | g | Output (application rate of 20 mL diluted product/m ²) |
| Number of preparations per day (N_{prep}) | 1 | d ⁻¹ | According to the intended use |
| Fraction emitted to soil during preparation step ($F_{prep,soil}$) | 4.00E-03 | [-] | Default value (wort case) |
| Soil volum for the mixing loading step ($V_{prep,soil}$) | 0.4 | m ³ | Default value |
| Quantity of product applied (Q_{prod}) | 3.66E-04 | kg.m ⁻² | Set value |

| | | | |
|---|----------|--------------|---|
| Area treated per day ($AREA_{wall,house}$) | 2 | $m^2.d^{-1}$ | See details above - TAB 2019 ENV A21 |
| Soil volume around building ($V_{spray,soil}$) | 13 | $m^2.d^{-1}$ | Default value |
| Fraction emitted to soil during outdoor spray application on crack&crevices (F_{spray}) | 0.2 | [-] | Default value initially defined for bait station and used as the product is placed in cracks and crevices (i.e. partly protected from weathering) |
| Simultaneity factor for outdoor uses of insecticide (F_{sim}) | 0.008151 | [-] | Default value for 3-11 times a year considering a residual effect of 4 months |

Calculations for Scenario 5:

$$E_{prep\ soil} = F_{AI} * Q_{prod,prep} * N_{prep} * F_{prep,soil} * 0.001$$

$$E_{prep, wastewater} = E_{prep\ soil} * N_{house} * F_{sim}$$

$$E_{local\ soil} = Q_{prod} * F_{AI} * AREA_{wall,house} * F_{spray}$$

$$E_{local\ wastewater} = Q_{prod} * F_{AI} * AREA_{wall,house} * F_{spray} * N_{house} * F_{sim}$$

| Resulting local emission to relevant environmental compartments | | |
|--|------------|---------|
| Local emission [kg/d] | Meta SPC 5 | Remarks |
| Emission to soil during preparation step ($E_{prep\ soil}$) | 3.19E-07 | - |
| Local emission to soil due to application ($E_{local\ soil}$) | 1.59E-05 | - |
| Local emission to wastewater during preparation step ($E_{local\ wastewater}$) | 3.19E-07 | - |
| Local emission to wastewater during application step ($E_{local\ wastewater}$) | 3.31E-04 | - |

$$C_{prep,soil} = E_{prep} * 10E6 / (RHO_{soil} * V_{soil})$$

$$C_{soil} = E_{local\ soil} * 10E6 / (RHO_{soil} * V_{soil})$$

| Resulting local concentration to relevant environmental compartments | | |
|---|------------|---------|
| Local concentration [mg.kg _{ww} ⁻¹] | Meta SPC 5 | Remarks |
| Local concentration of active substance in soil during mixing/loading ($C_{prep,soil}$) | 4.69E-04 | - |
| Local concentration of active substance in soil (C_{soil}) | 7.21E-04 | - |

Scenario 6: Direct spray on insects outdoor – application on bare soil

The local emission of spray application on bare soil was calculated in case of treatment for crawling/flying insects (direct spray on insects) when the spray application is close to the

soil. The scenario spot application on bare soil (outdoor) covers the use#1 of Meta-SPC 1, 2 and 6.

Only the local emission for Meta SPC 2 and 6 was calculated. In fact, as risks are already foreseen for the Meta-SPC 2 with an application rate of 21.8 mg of cypermethrin, risks are also expected with a higher application rate (i.e. 94.5 mg of cypermethrin in Meta-SPC 1).

| | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 6 | Unit |
|---|------------------------------------|--------------|--------------|-------|
| Fraction of active substance in the commercial product (F_{AI}) | 0.0054 | 0.0087 | 0.0022 | [-] |
| Dilution (Dil) | n.r. | n.r. | n.r. | % |
| Application rate (final product) | 17.5 | 2.5 | 2.5 | g |
| Application rate (AI) | 94.5 | 21.75 | 5.5 | mg ai |
| Conclusion | Cover by Meta-SPC 2 as a best case | To calculate | To calculate | |

| Input parameters for calculating the local emission | | | | |
|--|------------------|------------------|-----------------------------------|--------------------------|
| Input | Value Meta SPC 2 | Value Meta SPC 6 | Unit | Remarks |
| Fraction of active substance in the commercial product (F_{AI}) | 0.0087 | 0.0022 | [-] | Set values |
| Quantity of commercial product per application (Q_{prod}) | 2.50E-03 | 2.50E-03 | kg | Set values |
| Number of application | 1 | | [-] | Set values |
| Fraction emitted to soil during outdoor spray application ($F_{spray,soil}$) | 1 | | [-] | Default value - ESD PT18 |
| Volume of soil exposed (V_{soil}) | 0.125 | | m ³ | Default value |
| Bulk density of wet soil (RHO_{soil}) | 1700 | | kg _{ww} .m ⁻³ | Default value |

Calculations for Scenario 6:

$$E_{local,soil} = Q_{prod} * N_{appl} * F_{AI} * F_{spray,soil}$$

| Resulting local emission to relevant environmental compartments | | | |
|--|------------|------------|---------|
| Local emission [kg] | Meta SPC 2 | Meta SPC 6 | Remarks |
| Local emission to soil due to application I ($E_{local,soil}$) | 2.18E-05 | 5.50E-06 | - |

$$C_{soil} = E_{local,water} * 10E6 / (RHO_{soil} * V_{soil})$$

| Resulting local concentration to relevant environmental compartments | | | |
|--|------------|------------|---------|
| Local concentration [mg.kg _{ww} ⁻¹] | Meta SPC 2 | Meta SPC 6 | Remarks |
| Local concentration of active substance in soil (C _{soil}) | 1.02E-01 | 2.59E-02 | - |

Scenario 7: Direct spraying on insects outdoor – application on impermeable ground

The local emission of spray application (direct on insects) on impermeable ground was calculated in case of treatment for crawling insects on terrace and an application close to the terrace floor for the treatment of flying insects. This scenario covers the use#1 of Meta-SPC 1, 2 and 6.

The terrace scenario for spot application was adapted for a spray application directly on insects. Therefore, four applications on the floor of the terrace are considered as the four default bait stations used on a terrace (EDS PT18 section 4.3.4).

According to the Technical Agreement of Biocide (TAB) entry 159, for spot applications, 'no release to sewer/STP is assumed, only releases to soil compartment around a terrace'.

To cover all claimed doses, the application rate of cypermethrin in Meta SPC 1 (17.5 g/spray at 0.54 %w/w) was used as the worst case for the environmental risk assessment of the scenario 7. Please refer to the table below.

| | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 6 | Unit |
|---|--------------|-----------------------|-----------------------|--------------|
| Fraction of active substance in the commercial product (F _{AI}) | 0.0054 | 0.0087 | 0.0022 | [-] |
| Dilution (Dil) | n.r. | n.r. | n.r. | % |
| Application rate (final product) | 17.5 | 2.5 | 2.5 | g |
| Application rate (AI) | 94.5 | 21.75 | 5.5 | mg ai / spot |
| Conclusion | To calculate | Covered by Meta SPC 1 | Covered by Meta SPC 1 | |

| Input parameters for calculating the local emission | | | |
|---|------------------|------|-----------|
| Input | Value Meta SPC 1 | Unit | Remarks |
| Fraction of active substance in the commercial product (F _{AI}) | 0.0054 | [-] | Set value |
| Quantity of commercial product applied per spot (Q _{prod}) | 1.75E-02 | kg | Set value |

| | | | |
|--|------|-----------------------------------|---------------|
| Number of application/spot (N_{appl}) | 4 | [-] | Default value |
| Fraction emitted to soil during outdoor spray application ($F_{\text{spot,soil}}$) | 0.9 | [-] | Default value |
| Soil volume around terrace (V_{soil}) | 4.25 | m ³ | TAB ENV153 |
| Bulk density of wet soil (RHO_{soil}) | 1700 | kg _{ww} .m ⁻³ | Default value |

Calculations for Scenario 7:

$$E_{\text{localsoil}} = Q_{\text{prod}} * F_{\text{AI}} * F_{\text{spray,soil}} * N_{\text{appl}}$$

| Resulting local emission to relevant environmental compartments | | |
|--|------------|---------|
| Local emission [kg] | Meta SPC 1 | Remarks |
| Local emission due to application on soil ($E_{\text{localsoil}}$) | 3.40E-04 | - |

$$C_{\text{soil}} = E_{\text{localsoil}} * 10E6 / (\text{RHO}_{\text{soil}} * V_{\text{soil}})$$

| Resulting local concentration to relevant environmental compartments | | |
|---|------------|---------|
| Local concentration [mg.kg _{ww} ⁻¹] | Meta SPC 1 | Remarks |
| Local concentration of active substance in soil (C_{soil}) | 4.71E-02 | - |

Fate and distribution in exposed environmental compartments

| Identification of relevant receiving compartments based on the exposure pathway | | | | | | | | | |
|---|-------------|---------------------|-----------|-------------------|-----|-----|------|--------------|-------|
| | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes | n.r. |
| Scenario 2 | Yes | Yes | No | No | Yes | No | Yes | Yes | n.r. |
| Scenario 3 | Yes | Yes | No | No | Yes | No | Yes | Yes | n.r. |
| Scenario 4 | No | No | No | No | No | No | Yes | No* | n.r. |
| Scenario 5 | Yes | Yes | No | No | Yes | No | Yes | Yes | n.r. |
| Scenario 6 | No | No | No | No | No | No | Yes | No | n.r. |
| Scenario 7 | No | No | No | No | No | No | Yes | No | n.r. |

* TAB ENV157

| Input parameters (only set values) for calculating the fate and distribution in the environment | | | |
|--|---------------------------|----------------------------------|---------|
| Input | Value | Unit | Remarks |
| Molecular weight | 416.3 | g/mol | |
| Vapour pressure (at 25°C) | 6.00E-07 | Pa | |
| Water solubility (at 20°C) | 4.00E-03 | mg/l | |
| Log Octanol/water partition coefficient | 5.45 | Log 10 | |
| Organic carbon/water partition coefficient (Koc) | 575000 | l/kg | |
| Henry's Law Constant (at 20°C) | 0.024 | Pa/m ³ /mol | |
| Biodegradability | Not readily biodegradable | - | |
| DT ₅₀ for degradation in soil | 17.2 | d (at 12°C) | |
| k volat (arable land) | 3.10E-07 | d ⁻¹ | |
| k leach (arable land) | 1.39E-07 | d ⁻¹ | |
| k total (arable land) | 4.03E-02 | d ⁻¹ | |
| BCF fish | 417 | L/kg _{wwt} , measured | |
| BCF earthworm | 3383 | L/kg _{wwt} , calculated | |
| BMF fish | 1 | [-] | |

| Calculated fate and distribution in the STP (SimpleTreat 4.0) | | |
|--|----------------|---------|
| Compartment | Percentage [%] | Remarks |
| Air | 6.74E-04 | - |
| Water | 8.356 | - |
| Sludge | 91.65 | - |
| Degraded in STP | 0 | - |

Calculated PEC values

Indirect releases to the STP

| Summary table on calculated PEC values | | | | | | |
|--|-------------------------------|--------------------------|----------------------------|--------------------------|---------------------------|-------------------------|
| | Elocal_{water} | PEC_{STP} | PEC_{water} | PEC_{sed} | PEC_{soil} | PEC_{GW} |
| | [kg/d] | [mg/l] | [mg/l] | [mg/kg _{wwt}] | [mg/kg] | [µg/l] |
| Scenario 1 – indoor spot cracks and crevices (windows and doors) | 6.53E-04 | 2.73E-05 | 1.46E-06 | 1.83E-02 | 6.46E-04 | 1.51E-05 |

| | | | | | | |
|--|----------|----------|----------|----------|----------|----------|
| Scenario 2 – indoor spot surface | 5.32E-04 | 2.22E-05 | 1.19E-06 | 1.49E-02 | 5.27E-04 | 1.23E-05 |
| Scenario 3 – indoor air space treatment | 2.14E-02 | 8.93E-04 | 4.80E-05 | 5.99E-01 | 2.12E-02 | 4.95E-04 |
| Scenario 4 – crawling space | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Preparation | 3.19E-07 | 1.33E-08 | 7.15E-10 | 8.93E-06 | 3.15E-07 | 7.38E-09 |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) | 3.31E-04 | 1.38E-05 | 7.43E-07 | 9.29E-03 | 3.28E-04 | 7.67E-06 |
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |

n.r. : not relevant

Direct releases to soil

| Summary table on calculated local concentration in soil and groundwater | | | | |
|--|--|--------------------------------------|--------------------------------------|-------------------------|
| | | C_{prep,soil} | C_{appli,soil} | PEC_{GW} |
| | | [mg.kg _{ww} ⁻¹] | [mg.kg _{ww} ⁻¹] | [µg/l] |
| Scenario 1 – indoor spot cracks and crevices (windows and doors) | | n.r. | n.r. | n.r. |
| Scenario 2 – indoor spot direct on insects | | n.r. | n.r. | n.r. |
| Scenario 3 – indoor air space treatment | | n.r. | n.r. | n.r. |
| Scenario 4 – under building | Meta SPC 4 (lower concentration limit) | n.r. | 1.51E-01 | n.r. |
| | Meta SPC 5 with 8% dilution | 2.69E-01 | 2.52E-01 | 2.65E-02* |
| | Meta SPC 5 with 2% dilution | 6.72E-02 | 6.31E-02 | 6.63E-03* |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) | Meta SPC 5 | 4.69E-04 | 7.21E-04 | 7.11E-05** |
| | Meta SPC 2 | n.r. | 1.02E-01 | 1.01E-02 |

| | | | | |
|--|------------|------|----------|----------|
| Scenario 6 – outdoor spot direct on insect (bare soil) | Meta SPC 6 | n.r. | 2.59E-02 | 2.55E-03 |
| Scenario 7 - outdoor spot direct on insect (terrace) | Meta SPC 1 | n.r. | 4.71E-02 | 4.64E-03 |

n.r. : not relevant

* for the preparation step only as the contamination of groundwater is not relevant for crawling spaces

** for the application step as a worst case

Primary and secondary poisoning

Primary poisoning

Primary poisoning, *i.e.* the direct consumption of insecticide by birds or mammals is relevant only for outdoor uses. However, the biocidal product family CHIMIGET_CYPER is used as spray outdoor. The products are not in the form of bait or granules. Therefore, primary poisoning is not considered as relevant for this family of products.

Secondary poisoning

As cypermethrin has a $\log K_{ow} > 3$ ($\log K_{ow} = 5.45$ at 25°C) and a $BCF > 100$ (BCF in fish = 417 L/kg and BCF in earthworm = 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

The concentrations were calculated according to the biocidal guidance Vol IV Part B+C.

Indirect releases via the STP

| Summary table on estimated theoretical exposition | | |
|--|------------------------------|-----------------------------------|
| | Concentration in fish | Concentration in earthworm |
| | [mg/kg] | [mg/kg] |
| Scenario 1 – indoor spot cracks and crevices (windows and door) | 3.05E-04 | 3.08E-05 |
| Scenario 2 – indoor spot direct on insects | 2.49E-04 | 2.51E-05 |
| Scenario 3 – indoor air space treatment | 1.00E-02 | 1.01E-03 |
| Scenario 4 – under building | n.r. | n.r. |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Preparation | 1.49E-07 | 1.50E-08 |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Application | 1.55E-04 | 1.56E-05 |

| | | |
|--|------|------|
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. | n.r. |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. | n.r. |

n.r.: not relevant

Direct releases

For the direct releases to soil, only the worst case concentration is presented for calculation.

| Summary table on estimated theoretical exposition | | |
|--|------------------------------|-----------------------------------|
| | Concentration in soil | Concentration in earthworm |
| | [mg/kg wwt] | [mg/kg] |
| Scenario 4 – Crawling space – Preparation step for Meta SPC 5 with 8% dilution | 2.69E-01 | 5.40E-02 |

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Due to the low volatility of cypermethrin (vapour pressure equal to 2.3E-07 Pa at 20°C), the risk of contamination of the atmosphere can be considered as negligible and this foreseeable route of entry in the environment is not of concern.

Sewage treatment plant (STP)

| Summary table on calculated PEC/PNEC values | |
|--|-------------------------------|
| | PEC/PNEC_{STP} |
| Scenario 1 – indoor spot cracks and crevices (windows and door) | 1.67E-05 |
| Scenario 2 – indoor spot direct on insects | 1.36E-05 |
| Scenario 3 – indoor air space treatment | 5.48E-04 |
| Scenario 4 – under building | n.r. |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Preparation | 8.17E-09 |

| | |
|--|----------|
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Application | 8.49E-06 |
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. |

n.r.: not relevant

Conclusion: The PEC/PNEC ratios are below the trigger value of 1 for all the relevant scenarios. Then, risk for STP microorganisms is acceptable for the intended uses of the products CHIMIGET_CYPER.

Aquatic compartment

| Summary table on calculated PEC/PNEC values | | |
|--|---------------------------------|-------------------------------|
| | PEC/PNEC_{water} | PEC/PNEC_{sed} |
| Scenario 1 – indoor spot cracks and crevices (windows and door) | 3.66E-01 | 3.66E+00 |
| Scenario 2 – indoor spot direct on insects | 2.89E-01 | 2.89E+00 |
| Scenario 3 – indoor air space treatment | 1.20E+01 | 1.20E+02 |
| Scenario 4 – under building | n.r. | n.r. |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Preparation | 1.79E-04 | 1.79E-03 |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) - Application | 1.86E-01 | 1.86E+00 |
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. | n.r. |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. | n.r. |

n.r.: not relevant

Conclusion: The PEC/PNEC ratios are above the trigger value of 1 for the aquatic compartment (sediment and/or surface water) for the all the relevant scenarios (except for the preparation step of scenario 5). Therefore, these proposed uses of the products CHIMIGET_CYPER do pose a risk to aquatic compartment when the releases are directed to the STP.

Risk mitigation measures to totally prevent any release to the STP can be proposed for some uses:

For the indoor use "air space treatment with a one-shot aerosol" of Meta-SPC 3 covered by scenario 3 , as the product is intended to be applied in non wet cleaned areas:

- **The product is only for indoor use and to be strictly applied in non wet-cleaned premises (cellars, basements, crawl spaces, garages, attics, barns, sheds)**
- **Do not use where the biocidal product is likely to be discharged to a wastewater treatment plant and/or surface water.**
- **Dry clean (broom or vacuum cleaner) treated area and dispose of residues to hazardous solid waste in order to prevent releases to water.**

For the outdoor uses "application as spot in cracks and crevices only on very localised areas (windows and doors)" (Meta SPC 5, Meta-SPC 6 and 7) covered by scenario 5:

- **Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.**

Note that the applicant also recommends a surface application which is not covered by the proposed scenario 5 (conducted for cracks and crevices applications). Nevertheless, as the application in cracks and crevices already leads to unacceptable risks, the assessment was deemed sufficient.

However, the expected dilution of 2% for this use of Meta-SPC 5 is not feasible for a non-professionnel and therefore this use cannot be authorised for Meta-SPC 5. In fact, a dilution of 2% would require to measure 0.8 ml to dilute the product (considering the targeted application restricted to small surfaces of around 2m²) and no device is provided to measure such a quantity.

For the indoor uses "application as spot in crack and crevices" and "direct application on insects" of Meta SPC 6 covered by scenario 1 and 2, no risk mitigation measure is feasible to lead to acceptable risks when releases are directed to the STP and these uses cannot be authorised indoor.

Terrestrial compartment

| Calculated PEC/PNEC values | | | |
|----------------------------|--|--------------------------|--|
| | | PEC/PNEC _{soil} | PEC/PNEC _{soil} (Direct emission) |
| | | | |

| | Meta-SPC specific | (Indirect emission via the STP) | Preparation step | Application step |
|--|--------------------|---------------------------------|------------------|------------------|
| Scenario 1 – indoor spot cracks and crevices (windows and door) | - | 9.23E-03 | n.r. | n.r. |
| Scenario 2 – indoor spot direct on insects | - | 7.53E-03 | n.r. | n.r. |
| Scenario 3 – indoor air space treatment | - | 3.02E-01 | n.r. | n.r. |
| Scenario 4 – under building | Meta SPC 4 | n.r. | n.r. | 2.16E+00 |
| | Meta SPC 5 Dil. 8% | n.r. | 3.84E+00 | 3.61E+00 |
| | Meta SPC 5 Dil. 2% | n.r. | 9.61E-01 | 9.02E-01 |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) | - | 4.60E-03 | 6.69E-03 | 1.03E-02 |
| Scenario 6 – outdoor spot direct on insect (bare soil) | Meta SPC 2 | n.r. | n.r. | 1.46E+00 |
| | Meta SPC 6 | n.r. | n.r. | 3.70E-01 |
| Scenario 7 - outdoor spot direct on insect (terrace) | - | n.r. | n.r. | 6.73E-01 |

Conclusion:

Releases via the STP:

The PEC/PNEC ratios are below the trigger value of 1 when releases are directed to the STP.

Direct releases to soil:

For the use "Spray application under building" covered by scenario 4,

- **unacceptable risks** are foreseen for:
 - o Meta-SPC 5 with a dilution of 8% regarding preparation of the product and its use. The assessment for this dilution of Meta-SPC 5 covers the use of the upper range limit of Meta-SPC 4 (0.87% w/w cypermethrin).
 - o To consider the lower range limit (0.54 % w/w) of Meta-SPC 4, for which the risk ratios have been calculated, does not change the conclusions of non-acceptable risks for this Meta-SPC.

- **acceptable risks** are reached only for Meta-SPC 5 (dilution of 2%, application and use) and Meta-SPC 7, covered by calculations with Meta-SPC 5 (dil. 2%).

In conclusion, the outdoor application by spray under buildings cannot be proposed for authorisation for Meta-SPC 4 and Meta-SPC 5 (dilution of 8%).

For the outdoor use as spot application in cracks and crevices (windows and door) covered by scenario 5, acceptable risks are foreseen for all the proposed Meta-SPC (5, 6 and 7). Note that the applicant also recommends a surface application which is not covered by the proposed scenario 5 (in cracks and crevices). Nevertheless, as the application in cracks and crevices already leads to unacceptable risks for the STP and a RMM is proposed to prevent any releases to the environment, the assessment was deemed sufficient. It is also worth noting that in considering a emission fraction of 0.9 instead of 0.2 would lead to the same conclusions for the terrestrial compartment.

For the outdoor use as a direct spray on insects (bare soil application) covered by scenario 6,

- **unacceptable risks** are foreseen for Meta-SPC 2 covering Meta-SPC-1.
- risks are considered acceptable for Meta-SPC 6.

A risk mitigation measure is proposed to prevent emission to the terrestrial compartment for the Meta SPC 1 and 2:

- **Do not use on bare soil.**

For the outdoor use as a direct spray on insects (on impermeable surface) covered by scenario 7, acceptable risks are foreseen for all the proposed Meta-SPC (1, 2 and 6).

Groundwater

| | PEClocalgroundwater (µg/l) | |
|--|-------------------------------|-------------------------|
| | Indirect releases via the STP | Direct releases to soil |
| Scenario 1 – indoor spot cracks and crevices (windows and door) | 1.51E-05 | n.r. |
| Scenario 2 – indoor spot direct on insects | 1.23E-05 | n.r. |
| Scenario 3 – indoor air space treatment | 4.95E-04 | n.r. |
| Scenario 4 – under building | n.r. | 2.65E-02* |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) | 7.67E-06 | 7.11E-05** |

| | | |
|--|------|--|
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. | 1.01E-02 (Meta-SPC 2) 2.55E-03 (Meta-SPC 6) |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. | 4.64E-03 (Meta-SPC 1) |

* for the preparation step only (dilution 8% as a worst case) as the contamination of groundwater is not relevant for crawling spaces

** for the application step as a worst case

Conclusion: The calculated value for groundwater contamination doesn't exceed the limit value of 0.1 µg.L⁻¹ for biocides (Directives 2006/118/EC and 98/83/EC). Therefore, risks are acceptable for groundwater for all the proposed uses.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not considered as relevant for the biocidal product family CHIMIGET_CYPER.

Secondary poisoning

As cypermethrin has a log K_{ow} > 3 (log K_{ow} = 5.45 at 25°C) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm = 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

The PNEC_{oral mammal} is lower to the PNEC_{oral bird}, therefore the ratios PEC/PNEC_{mammals} cover the ratios PEC/PNEC_{birds}.

Indirect releases via the STP

| Summary table on secondary poisoning | | |
|--|-----------------------------------|-----------------------------------|
| | Aquatic food chain | Terrestrial food chain |
| | PEC/PNEC_{mammals} | PEC/PNEC_{mammals} |
| Scenario 1 – indoor spot cracks and crevices (windows and door) | 9.25E-05 | 9.33E-06 |
| Scenario 2 – indoor spot direct on insects | 7.54E-05 | 7.60E-06 |
| Scenario 3 – indoor air space treatment | 3.03E-03 | 3.05E-04 |
| Scenario 4 – under building | n.r. | 1.64E-02 |
| Scenario 5 – outdoor spot cracks and crevices (windows and door) | 4.69E-05 | 4.73E-06 |

| | | |
|--|------|------|
| Scenario 6 – outdoor spot direct on insect (bare soil) | n.r. | n.r. |
| Scenario 7 - outdoor spot direct on insect (terrace) | n.r. | n.r. |

Direct releases to soil

| Summary table on secondary poisoning | | |
|---|-----------------------------------|-----------------------------------|
| | Aquatic food chain | Terrestrial food chain |
| | PEC/PNEC_{mammals} | PEC/PNEC_{mammals} |
| Scenario 4 – under building | n.r. | 1.64E-02 |

Conclusion: The PEC/PNEC ratios are below the trigger value of 1. Then, risks for birds and mammals following secondary poisoning are acceptable when using the products CHIMIGET_CYPER according to label recommendations.

Mixture toxicity

The product contains only one active substance and no environmentally relevant substances of concern. Therefore, a mixture assessment is not necessary.

Aggregated exposure (combined for relevant emission sources)

According to the decision scheme developed by UBA (see Figure 1), an assessment of aggregated exposure is relevant for releases via the STP. Nevertheless, as no use with releases to the STP are proposed for authorisation, the aggregated exposure is not presented.

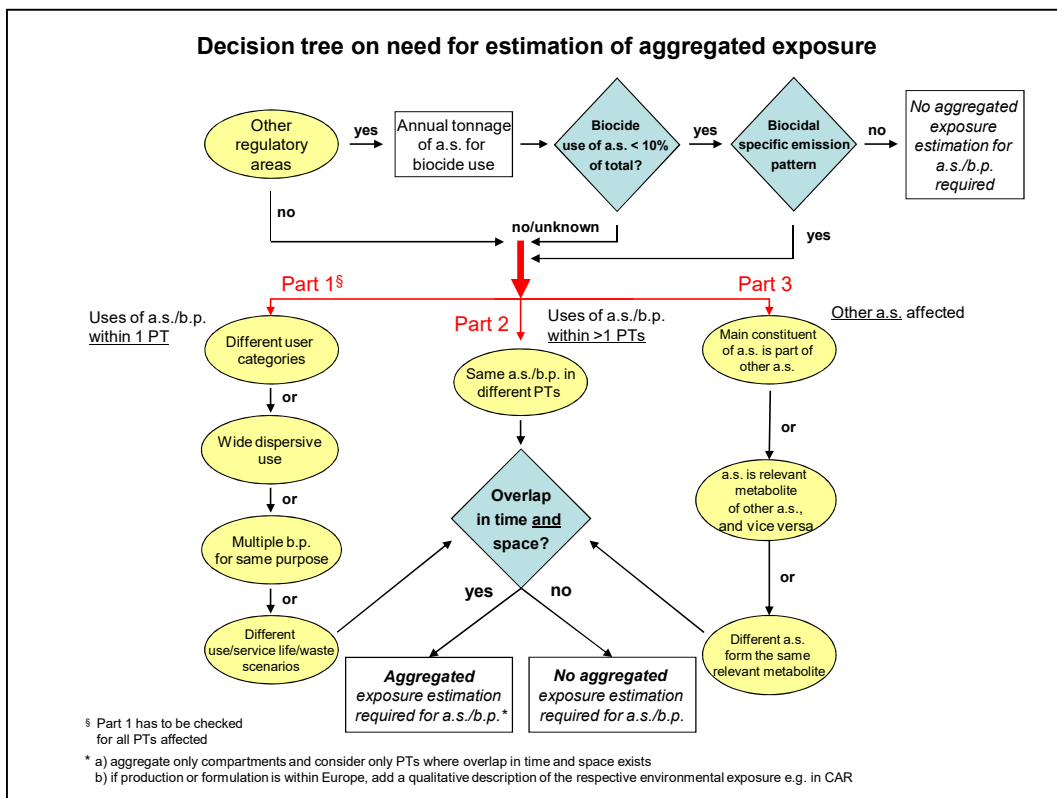


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product

The risk assessment has been conducted for the active substance only. No substance of concern has been identified for the environment.

The conclusions of the risk assessment is presented in the table below :

| Meta-SPC | Use | Indoor/Outdoor | Conclusion | RMM/remarks |
|------------|--|----------------|---------------------------------|---------------------------------------|
| Meta SPC 1 | Use#1 - AE WH - wasps and hornets aerosol - Direct spraying on insects | Outdoor | Acceptable with RMM | Proposed RMM: Do not use on bare soil |
| Meta SPC 2 | Use#1 - AE FC - flying and crawling insects - Direct spraying on insects | Outdoor | Acceptable with RMM | Proposed RMM: Do not use on bare soil |
| Meta SPC 3 | Use # 1 - OS - flying and crawling insects - | Indoor | Acceptable with RMM (leading to | Proposed RMMs: |

| | | | | |
|------------|--|---------|--|---|
| | space treatment with a one-shot aerosol | | no release to the environment) | <ul style="list-style-type: none"> - The product is only for indoor use and to be strictly applied in non wet-cleaned premises (cellars, basements, crawl spaces, garages, attics, barns, sheds) - Do not use where the biocidal product is likely to be discharged to a wastewater treatment plant and/or surface water. - Dry clean (broom or vacuum cleaner) treated area and dispose of residues to hazardous solid waste in order to prevent releases to water. |
| Meta SPC 4 | Use # 1 – RTU – flying and crawling insects - under buildings | Outdoor | Not acceptable | Unacceptable risks for the terrestrial compartment |
| Meta SPC 5 | Use # 1 – EC – flying and crawling insects - Target surface spraying as spots application or in cracks and crevices (Dil 2%) | Outdoor | Not acceptable | A dilution of 2% would require to measure 0.8 ml to dilute the product (considering the targeted application restricted to small surfaces of around 2m ²) and no device is provided to measure such a quantity. Therefore, it is not feasible for a non-professionnel. |
| | Use # 2 – EC – flying and crawling insects surface spray - under buildings | Outdoor | Not acceptable with dilution of 8% Acceptable <u>with dilution of 2%</u> | Unacceptable risks for the terrestrial compartment with a dilution of 8% |
| Meta SPC 6 | Use # 1 – AE FC1 – flying and crawling insects - direct spraying on insects | Indoor | Not acceptable | Unacceptable risks for the aquatic compartment |
| | | Outdoor | Acceptable | - |

| | | | | |
|------------|---|---------|-----------------------|---|
| | Use # 2 – AE FC1 – flying and crawling insects - Target surface spraying as spots application or in cracks and crevices | Indoor | Not acceptable | Unacceptable risks for the aquatic compartment |
| | | Outdoor | Acceptable with RMM | Proposed RMM: Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. |
| Meta SPC 7 | Use # 1 – RTU1 – flying and crawling insects - Target surface spraying as spots application or in cracks and crevices | Outdoor | Acceptable with RMM | Proposed RMM: Apply outdoor only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. |
| | Use # 2 – RTU1 – flying and crawling insects - under buildings | Outdoor | Acceptable | - |

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product family

| Author(s) | Year | Title Reference type Report and/or Study No. Source or Testing facility, if different from Sponsor | Study sponsor | IUCLID section (endpoint) | IUCLID document name | GLP | Data protection claimed |
|-----------------|------|--|------------------|---|---|------------------------------------|-------------------------------|
| Halbwachs P. | 2020 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the product AÉROSOL VOLANTS/RAMPANTS In compliance with CIPAC Handbook J - MT 46.3 method (2000) Study report Report No.: 20-903071-003 [REDACTED] (Brindas, France) | CHIMIGET | 3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour) | 3.1.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPA NTS): Appearance (at 20°C and 101.3 kPa) before and after accelerated storage_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPA NTS): Accelerated storage test (8 weeks at 40 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical characteristics of the biocidal product (particle size distribution, content of dust/fines, | 3.5.6.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPA NTS): Spray droplet size distribution_updat | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|---|----------|---|---|--------------------------|-----|
| | | | | attrition, friability) | ed July 2021 | | |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Satisfactory operation of the sprayer and the spray volume, the spray diameter and pattern before and after accelerated storage_updated July 2021 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the product ONE-SHOT AUTO PERCUTANT In compliance with CIPAC Handbook J - MT 46.3 method (2000) Study report Report No.: 20-903071-008 [REDACTED] (Brindas, France) | CHIMIGET | 3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour) | 3.1.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Appearance (at 20°C and 101.3 kPa) before and after accelerated storage_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.1.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Accelerated storage test (8 weeks at 40 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical | 3.5.6.2. Product | yes (incl. | yes |

| | | | | | | | |
|--------------|------|---|----------|--|--|---------------------------|-----|
| | | | | characteristics of the biocidal product (particle size distribution, content of dust/fines, attrition, friability) | OS 1 (ONE-SHOT AUTO PERCUTANT): Spray droplet size distribution_updated October 2020 | QA statement) | |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.3. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Satisfactory operation of the sprayer and the spray volume, the spray diameter and pattern before and after accelerated storage_updated October 2020 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2021 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the product LIQUIDE PAE In compliance with CIPAC Handbook J - MT 46.3 method (2000) Study report Report No.: 20-903071-026 [REDACTED] (Brindas, France) | CHIMIGET | 3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour) | 3.1.3. Product RTU 1 (LIQUIDE PAE): Appearance (at 20°C and 101.3 kPa) before and after accelerated storage_updated July 2021 | yes (incl. QA statement) | yes |
| | | | | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.1.3. Product RTU 1 (LIQUIDE PAE): Accelerated storage test (8 weeks at 40 ± 2°C)_updated | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|--|----------|--|--|--------------------------|-----|
| | | | | | July 2021 | | |
| | | | | 3.5 Technical characteristics of the biocidal product (particle size distribution, content of dust/fines, attrition, friability) | 3.5.6.3. Product RTU 1 (LIQUIDE PAE): Spray droplet size distribution_updated July 2021 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.5. Product RTU 1 (LIQUIDE PAE): Satisfactory operation of the sprayer and the spray volume before and after accelerated storage_updated July 2021 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the product LIQUIDE CONCENTRÉ In compliance with CIPAC Handbook J - MT 46.3 method (2000) Study report Report No.: 20-903071-018 [REDACTED] Brindas, France) | CHIMIGET | 3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour) | 3.1.4. Product EC (LIQUIDE CONCENTRÉ): Appearance (at 20°C and 101.3 kPa) before and after accelerated storage_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.2 Acidity, alkalinity (pH) | 3.2.1. Product EC (LIQUIDE CONCENTRÉ): pH value (at 20°C and 101.3 kPa) before and after accelerated | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|---|----------|---|---|---------------------------|-----|
| | | | | | storage_updated October 2020 | | |
| | | | | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.1.4. Product EC (LIQUIDE CONCENTRÉ): Accelerated storage test (8 weeks at 40 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical characteristics of the biocidal product (persistent of foaming) | 3.5.7.1. Product EC (LIQUIDE CONCENTRÉ): Persistent foaming before and after accelerated storage_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.7 Degree of dissolution and dilution stability (dilution stability) | 3.7.1. Product EC (LIQUIDE CONCENTRÉ): Dilution stability before and after the accelerated storage | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests on the product AÉROSOL VOLANTS/RAMPANTS Study report Report No.: 20-903071-001 [REDACTED] (Brindas, France) | CHIMIGET | 3.3 Relative density (liquids) and bulk, tap density (solids) (relative density) | 3.3.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Relative density (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|--|----------|--|---|---------------------------|-----|
| | | | | 3.8 Surface tension (surface tension) | 3.8.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Surface tension (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.9 Viscosity (viscosity) | 3.9.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Viscosity (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests on the product ONE-SHOT AUTO PERCUTANT Study report Report No.: 20-903071-006 [REDACTED] (Brindas, France) | CHIMIGET | 3.3 Relative density (liquids) and bulk, tap density (solids) (relative density) | 3.3.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Relative density (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.8 Surface tension (surface tension) | 3.8.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Surface tension (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|--|----------|---|--|---------------------------|-----|
| | | | | 3.9 Viscosity (viscosity) | 3.9.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Viscosity (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests on the product LIQUIDE CONCENTRÉ Study report Report No.: 20-903071-017 [REDACTED] (Brindas, France) | CHIMIGET | 3.3 Relative density (liquids) and bulk, tap density (solids) (relative density) | 3.3.3. Product EC (LIQUIDE CONCENTRÉ): Relative density_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.3.3. Product EC (LIQUIDE CONCENTRÉ): Low temperature stability test (liquids) (7 days at 0 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.8 Surface tension (surface tension) | 3.8.3. Product EC (LIQUIDE CONCENTRÉ): Surface tension_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.9 Viscosity (viscosity) | 3.9.3. Product EC (LIQUIDE CONCENTRÉ): Viscosity_updated October 2020 | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|---|----------|---|--|---------------------------|-----|
| Halbwachs P. | 2020 | Physico-chemical tests on the product AÉROSOL GUÊPE/FRELON Study report Report No.: 20-903071-010 [REDACTED] (Brindas, France) | CHIMIGET | 3.3 Relative density (liquids) and bulk, tap density (solids) (relative density) | 3.3.4. AÉROSOL GUÊPE/FRELON: Relative density (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.8 Surface tension (surface tension) | 3.8.4. Product AÉROSOL GUÊPE/FRELON: Surface tension (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.9 Viscosity (viscosity) | 3.9.4. Product AÉROSOL GUÊPE/FRELON: Viscosity (liquid formulation without propellant gas)_updated October 2020 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2022 | Physico-chemical tests and analyses before, during and after a storage procedure for 24 months at 20 ± 2°C on the product AEROSOL VOLANTS/RAMPANTS In compliance with Technical Monograph No. 17, 2nd edition CropLife International Study report Report No.: 20-903071-004 [REDACTED] (Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.2.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Long-term storage test at ambient temperature (24 months at 20 ± 2°C)_updated August 2022 | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|---|----------|---|--|---------------------------|-----|
| Halbwachs P. | 2022 | Physico-chemical tests and analyses before, during and after a storage procedure for 24 months at 20 ± 2°C on the product ONE-SHOT AUTO PERCUTANT In compliance with Technical Monograph No. 17, 2nd edition CropLife International Study report Report No.: 20-903071-009 [REDACTED] Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.2.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Long-term storage test at ambient temperature (24 months at 20 ± 2°C)_updated August 2022 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2023 | Physico-chemical tests and analyses before, during and after a storage procedure for 24 months at 20 ± 2°C on the product LIQUIDE PAE In compliance with Technical Monograph No. 17, 2nd edition CropLife International Study report Report No.: 20-903071-027 [REDACTED] (Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.2.3. Product RTU 1 (LIQUIDE PAE): Long-term storage test at ambient temperature (24 months at 20 ± 2°C)_updated July 2023 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2022 | Physico-chemical tests and chemical stability during and after a storage procedure for 24 months at 20 ± 2°C on the product LIQUIDE CONCENTRÉ In compliance with Technical Monograph No. 17, 2nd edition CropLife International | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.2.4. Product EC (LIQUIDE CONCENTRÉ): Long-term storage test at ambient temperature (24 months at 20 ± | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|---|----------|---|--|---------------------------|-----|
| | | Study report Report No.: 20-903071-019 [REDACTED] (Brindas, France) | | | 2°C)_updated August 2022 | | |
| Halbwachs P. | 2020 | Physico-chemical tests before and after a low temperature storage procedure for 7 days at 0 ± 2°C on the product AÉROSOL GUÊPE/FRELON In compliance with CIPAC MT 39.3 CIPAC Handbook J (2000) Study report Report No.: 20-903071-011 [REDACTED] (Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.3.4. Product AÉROSOL GUÊPE/FRELON: Low temperature stability test (liquids) (7 days at 0 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| Halbwachs P. | 2020 | Physico-chemical tests before and after a low temperature storage procedure for 7 days at 0 ± 2°C on the product AÉROSOL VOLANTS/RAMPANTS In compliance with CIPAC MT 39.3 CIPAC Handbook J (2000) Study report Report No.: 20-903071-002 [REDACTED] (Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.3.1. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Low temperature stability test (liquids) (7 days at 0 ± 2°C)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.2. Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Satisfactory operation of the | yes (incl. QA statement) | yes |

| | | | | | | | |
|--------------|------|--|----------|---|--|---------------------------|-----|
| | | | | | sprayer and the spray volume, the spray diameter and pattern before and after low temperature storage_updated July 2021 | | |
| Halbwachs P. | 2020 | Physico-chemical tests before and after a low temperature storage procedure for 7 days at $0 \pm 2^\circ\text{C}$ on the product ONE-SHOT AUTO PERCUTANT In compliance with CIPAC MT 39.3 CIPAC Handbook J (2000) Study report Report No.: 20-903071-007 [REDACTED] (Brindas, France) | CHIMIGET | 3.4.1 Storage stability tests (storage stability and reactivity towards container material) | 3.4.1.3.2. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Low temperature stability test (liquids) (7 days at $0 \pm 2^\circ\text{C}$)_updated October 2020 | yes (incl. QA statement) | yes |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.4. Product OS 1 (ONE-SHOT AUTO PERCUTANT): Satisfactory operation of the sprayer and the spray volume, the spray diameter and pattern before and after low temperature storage_updated October 2020 | yes (incl. QA statement) | yes |
| Demangel B. | 2021 | Physico-chemical tests and chemical analysis of cypermethrin in the product AE WH | CHIMIGET | 3.5 Technical characteristics of the biocidal product (particle | 3.5.6.4. Product AE WH: Spray droplet size distribution_updat | yes (incl. QA statement) | yes |

| | | | | | | | |
|---------------|------|---|----------|---|--|---------------------------|-----|
| | | Study report Report No.: 21-903071-001 [REDACTED] (Brindas, France) | | size distribution, content of dust/fines, attrition, friability) | ed July 2021 | | |
| | | | | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.6. Product AE WH: Satisfactory operation of the sprayer and the spray volume, the spray diameter and pattern before and after accelerated storage_updated July 2021 | yes (incl. QA statement) | yes |
| Guignon J.P. | 2022 | Rapport d'essais GENVPF5561 - Evaluation du diamètre de spray Study report Report No.: 5561-156-22 [REDACTED] (Saint-Michel-sur-Orge, France) | Chimiget | 3.5 Technical characteristics of the biocidal product (spraying pattern - aerosols) | 3.5.12.7. Product AE FC1_spraying pattern_July 2023 | no | yes |
| Yaverian J-M. | 2021 | Détermination du point d'éclair – méthode rapide à l'équilibre en vase clos - NORME NF EN ISO 3679 Study report <i>Report and Study No. not provided</i> [REDACTED] (France) | Chimiget | 4.6 Flammable liquids (flash point of flammable liquids) | 4.6.1 Product EC: flash point_updated July 2021 | no | yes |
| | | | | | 4.6.2 Product RTU 1: flash point_updated July 2021 | no | yes |
| Padilla P. | 2022 | Flash point test on the product RTU3 In | Chimiget | 4.6 Flammable | 4.6.3 Product RTU | yes (incl. | yes |

| | | | | | | | |
|------------|------|---|----------|--|---|---------------------------|-----|
| | | compliance with Regulation (EC) No.1907/2006, Council Regulation (EC) No.440/2008 - EC A.9. method (2008) and ISO Standard 3679 (2015) Study report Report No.: 22-903071-001 ██████████ (Brindas, France) | | liquids (flash point of flammable liquids) | 3: flash point_updated April 2023 | QA statement) | |
| Padilla P. | 2022 | Test methods for corrosion to metals on the product OS2 Study report Report No.: 22-903071-002 ██████████ (Brindas, France) | Chimiget | 4.16 Corrosive to metals (corrosive to metals) | 4.16.1 Corrosion to metals_OS2_updated April 2023 | yes (incl. QA statement) | yes |
| Padilla P. | 2022 | Physico-chemical tests on the product EC Study report Report No.: 22-903071-003 ██████████ (Brindas, France) | Chimiget | 4.16 Corrosive to metals (corrosive to metals) | 4.16.2 Corrosion to metals_EC_updated April 2023 | yes (incl. QA statement) | yes |
| | | | | 4.17.1 Auto-ignition temperature (liquids and gases) (auto-ignition temperature (liquids)) | 4.17.1 Auto-ignition temperature (liquids)_EC_updated April 2023 | yes (incl. QA statement) | yes |
| Ricau H. | 2020 | Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product AÉROSOL GUÊPE/FRELON In compliance with SANCO/3030/99 rev.5 from 22/03/2019 | Chimiget | 5 Methods of detection and identification (analytical methods) | 5.1.1 Product AÉROSOL GUÊPE/FRELON: Determination of cypermethrin | yes (incl. QA statement) | yes |

| | | | | | | | |
|-------------|------|---|----------|--|--|---------------------------|-----|
| | | Study report Report No.: 20-903071-014 ██████████ (Brindas, France) | | | cis/trans 40/60 content in the product_updated October 2020 | | |
| Ricau H. | 2020 | Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product AÉROSOL VOLANTS/RAMPANTS In compliance with SANCO/3030/99 rev.5 from 22/03/2019 Study report Report No.: 20-903071-005 ██████████ (Brindas, France) | Chimiget | 5 Methods of detection and identification (analytical methods) | 5.1.2 Product AE FC 1 (AÉROSOL VOLANTS/RAMPANTS): Determination of cypermethrin cis/trans 40/60 content in the product_updated October 2020 | yes (incl. QA statement) | yes |
| Ricau H. | 2020 | Validation of the analytical method for the determination of cypermethrin cis/trans 40/60 in the product LIQUIDE CONCENTRÉ In compliance with SANCO/3030/99 rev.5 from 22/03/2019 Study report Report No.: 20-903071-020 ██████████ (Brindas, France) | Chimiget | 5 Methods of detection and identification (analytical methods) | 5.1.3 Product EC (LIQUIDE CONCENTRÉ): Determination of cypermethrin cis/trans 40/60 content in the product_updated October 2020 | yes (incl. QA statement) | yes |
| Guicherd A. | 2020 | Study of the efficacy of a cypermethrin aerosol (AE WH) applied in direct spray under laboratory conditions on Hymenoptera <i>Reference type not provided</i> | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_01_Direct spray_AE WH_update202107 | not specified | yes |

| | | | | | | | |
|-------------|------|--|----------|---|--|---------------|-----|
| | | Report No.: 20STALab006 [REDACTED] | | | | | |
| Guicherd A. | 2020 | Study of the efficacy of a cypermethrin aerosol (AE FC1) applied in direct spray under laboratory conditions on crawling and flying insects Study report Report No.: 20STALab001 [REDACTED] | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_02_Direct spray_AE FC1 | not specified | yes |
| Guicherd A. | 2020 | Study of the efficacy and residual effect of a cypermethrin aerosol (AE FC1) applied in simulated-use conditions on crawling and flying insects Study report Report No.: 20STALab004 [REDACTED] | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_03_Simulated-use_AE FC1_update202107 | not specified | yes |
| Guicherd A. | 2020 | Study of the efficacy of a cypermethrin one-shot fogger aerosol (OS1) applied in simulated-use conditions on crawling and flying insects. Study report Report No.: 20STALab005 [REDACTED] | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_04_Simulated-use_OS1_update202107 | not specified | yes |

| | | | | | | | |
|-------------|------|--|----------|---|---|---------------|-----|
| Guicherd A. | 2020 | Study of the efficacy of a cypermethrin trigger spray (RTU1) applied in forced contact under laboratory conditions on crawling and flying insects Study report Report No.: 20STALab002 [REDACTED] | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_05_Laboratory surface_RTU1 | not specified | yes |
| Guicherd A. | 2020 | Study of the efficacy and residual effect of a cypermethrin trigger spray (RT1) applied in simulated-use conditions on crawling and flying insects. Study report Report No.: 20STALab003 [REDACTED] | Chimiget | 6.7 Efficacy data to support these claims (efficacy data) | 6.7_06_Simulated - use_RTU1_update 202107 | not specified | yes |

3.2 Output tables from exposure assessment tools

Exposure assessment calculation files are not presented in this version of the PAR.
For access to the files, please contact directly the eCA (helpdesk-biocides@anses.fr).

3.3 Confidential annex

See the confidential PAR.