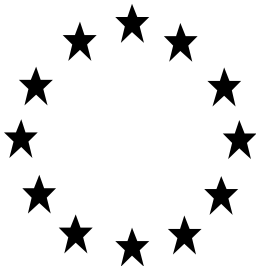
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



OWADEX

Product type(s) 18

Transfluthrin as included in the Union list of approved active substances

Case Number in R4BP:BC-RR069531-13

Evaluating Competent Authority: Belgium

Date: [25/08/2023]

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1 CONCLUSION

APCP

The biocidal product OWADEX consists of an impregnated cellulose mat, enclosed in a clean perforated plastic casing, containing 3.43% (tech.)/3.4% (pure) transfluthrin, which is equivalent to 190 mg/plaquette. It is a vapour releasing product acting through passive diffusion.

In accordance with CA-Nov16-Doc.4.3 - Final document, physical-chemical properties (excl. product stability tests) have been determined with the substance/mixture before it is applied to the carrier component (hereafter the impregnating liquid). The same goes for the physical hazards and respective characteristics.

The impregnating liquid is a colourless liquid with a distinctive odour. The pH of a 1% solution is 5.76. Its relative density is 0.965 at 20ºC. The impregnation liquid is surface-active and its kinematic viscosity is 6.2 mm^2/s and 3.5 mm^2/s at 20°C and 40°C respectively. Dynamic viscosity was similarly affected from 6.0 mPa*s to 3.3 mPa*s when measured at 20ºC and 40ºC temperatures, respectively.

Based on the available accelerated storage stability test and interim data, available for up to 1y, of the ongoing long term storage stability test at ambient temperature (running up to 5 years), a 1 year shelf life can be granted for OWADEX. The product must be stored protected from sunlight and frost. It must also be stored in a cool and dry place in its original and unopened packaging.

The impregnating liquid of the biocidal product is not explosive, self-reactive, pyrophoric, self-heating, oxidising or corrosive to metals. It has a flash-point of 77.0 ºC, which does not result in a classification as flammable liquid, and its auto-ignition temperature is 250°C.

Transfluthrin content can be determined, following extraction from the OWADEX biocidal product, based on a GC-FID method using a DB-5 column. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. The mean recovery rate is 99.8%, within a 94.6 - 105.0% range. Repeated injection of the samples resulted in a coefficient of variation which was less than 4.2%. Regarding the other analytical methods, the reader is referred to the assessment report of the active substance.

EFFICACY

In accordance with the submitted tests and the requirements of the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), Version 4.1 February 2022, the product OWADEX is efficient:

- against mosquitoes *Culex* spp. and *Aedes* spp. (adults) and fruit flies *Drosophila* spp. at application rate of 1 plaquette per 40 m^3 corresponding to 1 plaquette per 16 m^2.
  The tests performed without fan is acceptable. However, the test carried out with fan shows a better efficacy. The product should be used in combination with forced air circulation within the room (e.g. fan) during min 8h per day. The product remains efficient up to 4 months.
- against domestic flies *Musca domestica* (adults) at application rate of 1 plaquette per 40 m^3 corresponding to 1 plaquette per 16 m^2.

The tests performed without fan is acceptable. However, the test carried out with fan shows a better efficacy. The product should be used in combination with forced air circulation within the room (e.g. fan) during min 8h per day. The product remains efficient up to 4 months.

- against ants *Lasius spp.* in small, confined spaces (max 30 m³). The product remains effective up to 4 weeks.

The delay of action is 24 hours.

HUMAN HEALTH

Owadex aims at the elimination of insect in private homes. As such, the users will be non-professionals, and exposure to general public, up to and including toddlers and infants is to be expected and to be taken into account in the assessment.
Its composition insure that its classification is not problematic given the uses and applications of the product. While its classification offers the possibility of some local risks (eye irrit. 2)., the formulation and packaging when in use are made in such a way that direct exposure by contact to the product is nearly impossible. The product comes in a box with some form of grid that prevents direct dermal contact. This helps both in limiting the local risk, and in decreasing the systemic exposure, since dermal contact is therefore estimated to be unlikely.
This, combined with the fact that the application phase consist simply in placing the impregnated cellulose mat in the "in use" packaging means that dermal exposure is very unlikely and can therefore be considered as negligible for the assessment, and the assessment is thus only evaluated through the inhalation exposure that comes with the use of OWADEX.
Given the fact that OWADEX can be used in kitchen, pantries, and other places where food is stored, treated or cooked, a dietary risk assessment has been performed. In absence of a specific scenario for the dietary exposure, a worst case approach is performed that demonstrate that exposure through food is not an issue.
The risk assessment demonstrate a safe use for users and member of the general public exposed, including toddlers and infants. Since the application happens indoor in homes, risk assessment is needed also for pets and similar animals. In absence of specific guidance's and scenario to perform such an assessment, it is determined that risk assessment for toddlers and infants can be used to cover the exposure for pets.

ENVIRONMENT

The product OWADEX is to be used by general public as insecticide passive diffuser to control flying insects (flies, mosquitoes and fruit flies) indoors (bathroom, kitchen and rooms) and ants in a cabinet under a sink.
Considering the active substance and its metabolites, taking into account the intended dose (3.45% w/w of Transfluthrin), risks to the environment following the use of OWADEX are acceptable for all the compartments and all the scenarios, with respect to the use recommendations.

Therefore, the risk for the environment of the product OWADEX is acceptable when used according to the use recommendations.

ED

The biocidal product contains the active substance Transfluthrin, 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 the Directive 98/8/EC were identified for the active substance contained in the biocidal product. The biocidal product should thus be considered not to have endocrine-disrupting properties.

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. The biocidal product should thus be considered not to have endocrine disrupting properties.

2 ASSESSMENT REPORT

. Summary of the product assessment

2.1.1. Administrative information

2.1.1.1. Identifier of the product / product family

Identifier	**Country (if relevant)**
OWADEX	Belgium
Płytka na owady T	Poland

2.1.1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	Argo Chemicals sp. z o.o.
	Address	Garncarska 9, 61-817 Poznań, Poland
Authorisation number	**BE2023-0014**	
Date of the authorisation	**07/09/2023**	
Expiry date of the authorisation	**25/08/2033**	

2.1.1.3. Manufacturer(s) of the products of the family

Name of manufacturer	ARGO CHEMICALS Spółka z ograniczoną odpowiedzialnością
Address of manufacturer	Garncarska 9, 61-817 Poznań, Poland
Location of manufacturing sites	Poleska 44, 25-325 Kielce, Poland Karpia 24, 61-619 Poznań, Poland Swarzędzka 17, 62-006 Janikowo, Poland

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

Active substance	Transfluthrin
Name of manufacturer	2022 Environmental Science FR S.A.S (acting for Environmental Science U.S. LLC.)
Address of manufacturer	3, place Giovanni Da Verrazzano 69009 LYON France
Name of manufacturer	BAYER SAS
Address of manufacturer	16 rue Jean-Marie Leclair, CS 90106, F-69266 Lyon Cedex 09
Location of manufacturing sites	Bayer Vapi Private Limited (Formerly, Bilag Industries Pvt. Ltd.) II Phase, GIDC, Vapi-396195, Gujarat State, India

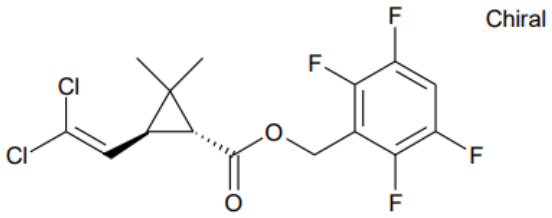
2.1.2. Product (family) composition and formulation

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	Transfluthrin
IUPAC or EC name	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	405-060-5*
CAS number	118712-89-3*
Index number in Annex VI of CLP	607-223-00-8
Minimum purity / content	≥965 g/kg
Structural formula	

* *The EU index No. and ELINCS No. refer to the 1R, trans and 1S, trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R, trans isomer. The CAS registry No. refers to the correct isomer.*

2.1.2.2. Candidate(s) for substitution

Transfluthrin is not considered to be a candidate for substitution in accordance with Article 10 of the BPR (EU) Regulation 528/2012. Therefore this product has not been subject to a comparative assessment.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	3.43% (technical) 3.4% (pure)* Purity ≥ 96.5%
MMB	3-methoxy-3-methylbutan-1-ol	Solvent	56539-66-3	260-252-4	51.6

* Equivalent to 190 mg/plaquette

For full qualitative and quantitative information on the composition of the biocidal product, refer to the confidential annex to the PAR.

2.1.2.4. Information on technical equivalence

Not applicable. The manufacturer is the same as included in the Union list of approved active substances.

2.1.2.5. Information on the substance(s) of concern

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
MMB	3-methoxy-3-methylbutan-1-ol	Solvent	56539-66-3	260-252-4	51.6

Please see the confidential annex for further details.

2.1.2.6. Type of formulation

VP Vapour releasing product

2.1.3. Hazard and precautionary statements

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

Classification	
Hazard category	Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H319: Causes serious eye irritation. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
GHS pictogram	
Hazard statements	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. P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. 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. P391 : Collect spillage. P501 Dispose of contents/container to authorised waste disposal company in accordance with local regulation.
Note	-

2.1.4. Authorised use(s)

2.1.4.1. Insecticide against mosquitoes and fruit flies for indoor use by non-professionals

2.1.4.1.1. Use description

Table 1. Use # 1 Fruit flies and mosquitoes - indoor - non-professional user

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Fruit flies: *Drosophila spp.* (adults) Mosquitoes: *Culex* spp, *Aedes* spp. (adults)
Field of use	Indoor use
Application method(s)	Passive diffuser Provide forced air circulation in the room (e.g. fan) during min 8h per day. Place it 1 m away from the walls.
Application rate(s) and frequency	Single plaquette protects an area of 16 m² (approx. 40 m^3) for up to 4 months against fruit flies and mosquitoes.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.1.2. Use-specific instructions for use

Single plaquette protects an area of 16 m² (approx. 40 m^3) for up to 4 months against fruit flies and mosquitoes.

For optimal efficacy provide forced air circulation in the room (e.g. fan) during min 8h per day. Place it 1 m away from the walls.

Unpack the plaquette and put it vertically in the area to be protected; choose a place with air circulation, yet away from open windows, draughts and sources of heat (radiator, direct sunlight).

Product begins to affect target organisms about 24 h after application.

2.1.4.1.3. Use-specific risk mitigation measures

Please see section 2.1.5.2.

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

Please see section 2.1.5.3.

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

Please see section 2.1.5.4

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

Please see section 2.1.5.5.

2.1.4.2. Insecticide against ants for indoor use by non-professionals

2.1.4.2.1. Use description

Table 2. Use # 2 Ants – indoor - non-professional user

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Ants: *Lasius spp.* (adults)
Field of use	Indoor use
Application method(s)	Passive diffuser
Application rate(s) and frequency	Single plaquette protects a cupboard or other small space (max 30 m^3) for up to 4 weeks against ants.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2.2. Use-specific instructions for use

Single plaquette protects a cupboard or other small space for up to 4 weeks against ants. Unpack the plaquette and place it in a place to be protected (max 30m^3). Product begins to affect target organisms about 24 h after application

2.1.4.2.3. Use-specific risk mitigation measures

Please see section 2.1.5.2.

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

Please see section 2.1.5.3.

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

Please see section 2.1.5.4.

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

Please see section 2.1.5.5.

2.1.4.3. Insecticide against house flies for indoor use by non-professionals

2.1.4.3.1. Use description

Table 2. Use # 3 House flies – indoor - non-professional user

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Flies: House flies *Musca domestica* (adults)
Field of use	Indoor use
Application method(s)	Passive diffuser Provide forced air circulation in the room (e.g. fan) during min 8h per day. Place it 1 m away from the walls.
Application rate(s) and frequency	Single plaquette protects an area of 16 m² (approx. 40 m^3) for up to 4 months against flies.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.3.2. Use-specific instructions for use

Single plaquette protects an area of 16 m² (approx. 40 m^3) for up to 4 months against flies. For optimal efficacy provide forced air circulation in the room (e.g. fan) during min 8h

per day. Place it 1 m away from the walls.

Unpack the plaquette and put it vertically in the area to be protected; choose a place with air circulation, yet away from open windows, draughts and sources of heat (radiator, direct sunlight).

Product begins to affect target organisms about 24 h after application

2.1.4.3.3. Use-specific risk mitigation measures

Please see section 2.1.5.2.

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

Please see section 2.1.5.3.

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

Please see section 2.1.5.4

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

Please see section 2.1.5.5.

2.1.5. General directions for use

2.1.5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.
Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
Where possible, application treatments should be recommended to be combined with non-chemical measures.
Where an extended period of control is required, treatments should be alternated with products with different modes of action.

2.1.5.2. Risk mitigation measures

Keep out of reach of children.
Wash hands thoroughly after handling.
Avoid contact with eyes.
Do not use near aquariums with fish and terrariums.
Do not use in the presence of cats.

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

Provide access to fresh air.
Protect body against hypothermia.
Wash skin with soap and water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
In every case of suspected allergic reaction, poisoning or if swallowed seek medical attention.
If medical advice is needed, have product container or label at hand.

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

Treat the remains of the product and its empty packaging as hazardous waste and return for disposal in accordance with local regulations to authorised company.
Avoid release to the environment.

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

Store out of children's reach, away from food, drinks and animal feed.
Store in a cool and dry place in its original and unopened packaging.
Store protected from sunlight.
Protect from frost.
Shelf life: 1 year.

2.1.6. Other information

The biocidal product consists of an impregnated cellulose mat, with approx. dimensions of 15,5cm x 10cm, enclosed in a clean perforated plastic (PP) casing.
The quantitative information on the composition of the biocidal product is equivalent to 190 mg active substance/plaquette.

2.1.7. Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bag	1 to 10 plaquettes, in intervals of 1	PET, PET/PET met/PE, PET/ALU/PE, PET/PE, PA/PE, PE, LDPE, PET/EVM, PETMET/PE,	N/A	Non-professional	Yes

		PET/PE(EVOH), PE/PE, PP/PE, PE/EVOH			
Sachet	1 to 10 plaquettes, in intervals of 1	PET, PET/PETmet/PE, PET/ALU/PE, PET/PE, PA/PE, PE, LDPE, PET/EVM, PETMET/PE, PET/PE(EVOH), PE/PE, PP/PE, PE/EVOH	N/A	Non-professional	Yes

For more information on the nature of the packaging of and the biocidal product itself, refer to the confidential annex to the PAR.

2.1.8. Documentation

2.1.8.1. Data submitted in relation to product application

Please refer to Annex 3.1 – List of studies for biocidal product.

2.1.8.2. Access to documentation

The applicant is the data holder concerning the product and has submitted the Letter of Access from Bayer S.A.S., Environmental Science to data concerning active substance Transfluthrin.

2.2 Assessment of the biocidal product (family)

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

Table 1. Intended use # 1 – Insecticide against house flies, mosquitoes and fruit flies for indoor use by non-professionals

Product Type(s)	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Flies: House flies *Musca domestica* (adults) Fruit flies: *Drosophila spp.* (adults) Mosquitoes: *Culex* spp, *Aedes* spp. (adults)
Field of use	Indoor use
Application method(s)	Passive diffuser Provide air circulation in the room (e.g. fan: place it 1 m away from the walls.)
Application rate(s) and frequency	Single plaquette protects an area of 16 m^2 (approx. 40 m^3) for up to 4 months against flies, fruit flies and mosquitoes. Full effectiveness is reached about 24 h after application.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	See section 2.1.7. for more details

Table 2. Intended use # 2 – Insecticide against ants for indoor use by non-professionals

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Ants: *Lasius spp.* (adults)
Field of use	Indoor use
Application method(s)	Passive diffuser
Application rate(s) and frequency	Single plaquette protects a cupboard or other small space for up to 4 weeks against ants. Full effectiveness is reached about 24 h after application.
Category(ies) of users	Non-professional
Pack sizes and packaging material	See section 2.1.7. for more details

2.2.2. Physical, chemical and technical properties

Notice prior to reading: The reader is referred to CA-Nov16-Doc.4.3 - Final document, which states that tests for all physical-chemical properties - with the exception of product stability tests - may be performed with the substance/mixture before it is applied to the carrier component.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Internal methods CC/001/ccq and CC/002/ccq Visual inspection	3.4% w/w Transfluthrin (impregnating liquid)	Liquid	[redacted] Report No. 21134-02C
Colour at 20 °C and 101.3 kPa	Internal method CC/001/ccq Visual inspection	3.4% w/w Transfluthrin (impregnating liquid)	Colourless/ Transparent	[redacted] Report No. 21134-02C
Odour at 20 °C and 101.3 kPa	Internal method CC/001/ccq Olfactory inspection	3.4% w/w Transfluthrin (impregnating liquid)	Distinctive	[redacted] Report No. 21134-02C
Acidity / alkalinity	CIPAC MT 75.3 [using Metrohm pH 827 lab]	3.4% w/w Transfluthrin (impregnating liquid)	5.76 ± 0.01 [n=2, 1% dilution, at 24 °C]	[redacted] Report No. 21134-02C
Relative density / bulk density	EC A.3 OECD 109 CIPAC MT 3.1 (Densimeter method)	3.4% w/w Transfluthrin (impregnating liquid)	0.965 [n=2, at 20 °C] 0.951 [n=2, at 40 °C]	[redacted] Report No. 21134-02C
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Cfr. Methods	3.4% w/w Transfluthrin (impregnating liquid) and final biocidal product 190	Appearance/Packaging : No changes (state,	[redacted] Report No. 21134-02C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	reported hereabove for appearance, pH and density [using GC-FID method, as validated]	mg A.S./plaquette.	colour, odour, packaging) for the impregnation liquid. For the final biocidal product: Start: Clean green plastic cover, containing a white cellulose inside, inside laminated bag. T8w: Wet green plastic cover, yellow liquid on the inside wall of the laminate bag. The cellulose matrix evidently drier and lighter than before storage <u>Weight loss:</u> 0.013% for the impregnation liquid as such. 0.555% for the final biocidal product <u>pH:</u> Start: 5.76 ± 0.01 [n=2, 1% dilution, at 24 °C] T8w: 5.91 ± 0.01 [n=2, 1% dilution, at 24 °C]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Rel. density: Start: 0.965 [n=2, at 20 °C] 0.951 [n=2, at 40 °C] T8w: 0.966 [n=2, at 20 °C] 0.950 [n=2, at 40 °C] Content active substance: Start : 193.1 mg/plaquette T8w : 199.2 mg/plaquette (+3.2%) [Storage performed for 2 weeks at 54 ± 2°C]	
Storage stability test – **long term storage at ambient temperature**	Visual inspection Olfactory inspection CIPAC MT 75.3 [using GC-FID method, Agilent DB-5 chromatographic column 30m x	3.4% w/w Transfluthrin (impregnating liquid) and final biocidal product 190 mg A.S./plaquette.	Appearance of the impregnation liquid: T0: Transparent, colourless liquid with distinctive odour T1y: No change. Appearance of the final biocidal product: T0: Clean green plastic cover, containing a white cellulose	[redacted] Report No. 21134-03C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	0.25mm x 0.25 µm and Perkin Elmer Autosystem XL FID detector Sample preparation: Transfluthrin extracted with n-Hexadecane 1 mg/mL in methanol]		plaquette, in a laminated bag, distinctive odour T1y: No change. <u>Packaging of the impregnation liquid:</u> T0: Bottle, not damaged or collapsed T1y: No change. <u>Packaging of the final biocidal product:</u> T0: Intact combined material bag. Mean weight of 57.46g. T1y: No change. Weight change: +0.10g <u>pH:</u> Start: 5.76 ± 0.01 [n=2, 1% dilution] T1y: 5.63 [n=2, 1% dilution] <u>Content active substance:</u> Start : 193.1 mg/plaquette (=3.3% w/w) T1y : 193.3 mg/plaquette (=3.2% w/w)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(-3.03% w/w) [Interim data available for up to 1y. Storage being performed for 5 years at ambient temperature.]	
Storage stability test – **low temperature stability test for liquids**	Waived	-	RMM 'Protect from frost' shall appear on the label	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waived	-	Not applicable since the biocidal product is stored in its laminated pouch. As this packaging precludes light, no impact on active substance content is expected due to light. The RMMs "store protected from sunlight" and "store in original packaging" are to be put on the label. Exposure to light once in use is covered in the efficacy section in the PAR. Moreover, the instructions for use clearly require the product to be placed away from direct sunlight.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived See results under "Storage stability test"	- See results under "Storage stability test"	Humidity: RMM 'store in a dry place' and 'store in unopened packaging' shall appear on the label Temperature: See results under "Storage stability test". Exposure to humidity and temperature once in use is covered in the efficacy section in the PAR. Moreover, the instructions for use clearly require the product to be placed away from open windows, draughts and sources of heat.	- [redacted] Report No. 21134-02C [redacted] Report No. 21134-03C
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	See results under "Storage stability test"	See results under "Storage stability test"	See results under "Storage stability test"	See results under "Storage stability test"
Wettability	Waived	-	Not applicable since the biocidal product is RTU.	-
Suspensibility, spontaneity and dispersion stability	Waived	-	Not applicable since the biocidal product is not a wettable powder, aqueous suspension	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			concentrate, water dispersible granule, water dispersible powder or formulation forming suspensions on dilution with water.	
Wet sieve analysis and dry sieve test	Waived	-	Not applicable since the biocidal product is not a wettable powder, suspension concentrate, water dispersible granule, aqueous capsule suspension, dispersible concentrate, suspo-emulsion, water soluble granule or powder, dust or granular formation.	-
Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	Not applicable since the biocidal product is not, nor is intended to form, an emulsion.	-
Disintegration time	Waived	-	Not applicable since the biocidal product is not a tablet and is not used in a water soluble bag.	-
Particle size distribution, content of dust/fines, attrition, friability	Waived	-	Not applicable since the biocidal product is not a powder or granule.	-
Persistent foaming	Waived	-	Not applicable since the biocidal product is RTU and need not be	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			applied in water for use.	
Flowability/Pourability/Dustability	Waived	-	Not applicable since the biocidal product is not a granular formulation, suspension concentrate, capsule suspension or suspoemulsion.	-
Burning rate — smoke generators	Waived	-	Not applicable since the biocidal products is not a smoke generator.	-
Burning completeness — smoke generators	Waived	-	Not applicable since the biocidal products is not a smoke generator.	-
Composition of smoke — smoke generators	Waived	-	Not applicable since the biocidal products is not a smoke generator.	-
Spraying pattern — aerosols	Waived	-	Not applicable since the biocidal products is not an aerosol.	-
Physical compatibility	Waived	-	Not applicable since the biocidal product is not intended to be used with other products.	-
Chemical compatibility	Waived	-	Not applicable since the biocidal product is not intended to be used with other products.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Degree of dissolution and dilution stability	Waived	-	Not applicable since the biocidal product is RTU and need not be dissolved.	-
Surface tension	EC A.5 OECD 115	3.4% w/w Transfluthrin (impregnating liquid)	30.8 mN/m Surface-active	[redacted] Report No. 22054-01C
Viscosity	OECD 114 CIPAC MT 192 (Capillary viscometer method)	3.4% w/w Transfluthrin (impregnating liquid)	Kinematic: 6.22 mm^2/s at 20°C. 3.52 mm^2/s at 40°C. [n=2] Dynamic: 6.00 mPa*s at 20°C. 3.35 mPa*s at 40°C. [n=2]	[redacted] Report No. 21134-02C

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

The impregnating liquid of the biocidal product is a colourless liquid with a distinctive odour. The pH of the 1% solution of the liquid is 5.76. Its relative density is 0.965 at 20ºC.

The accelerated storage for 2 weeks at 54ºC±2ºC showed no significant change in appearance, packaging, or relevant properties. The active ingredient content remained acceptable after accelerated storage. Interim data, available for up to 1y, of the ongoing long term storage (up to 5 years) at ambient temperature also showed no significant change in appearance, packaging, or relevant properties. The active ingredient content remained acceptable after 1y storage. As such, a 1 year shelf life can be granted. The product must be stored protected from sunlight and frost. It must also be stored in a cool and dry place in its original and unopened packaging.

The impregnation liquid is surface-active and its kinematic viscosity is 6.2 mm^2/s and 3.5 mm^2/s at 20°C and 40°C respectively. Dynamic viscosity was similarly affected from 6.0 mPa*s to 3.3 mPa*s when measured at 20ºC and 40ºC temperatures, respectively.

2.2.3. Physical hazards and respective characteristics

Notice prior to reading: The reader is referred to CA-Nov16-Doc.4.3 - Final document, which states that tests for all physical-chemical properties - with the exception of product stability tests - may be performed with the substance/mixture before it is applied to the carrier component.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	OECD 113 EC A.14. UN Class 1 Differential Scanning Calorimetry (DSC)	3.4% w/w Transfluthrin (impregnating liquid)	DSC was performed on 3 different samples, each with 2 or 3 measurements, up to 500°C: A first exothermic event was observed between 90-120°C which had an average energy release of -27 J/g. An endothermic event was observed between 200-290°C which had an average energy uptake of 180 J/g. A second exothermic event was observed between 290-350°C which had an average energy release of -93 J/g. A third exothermic event was observed at 390°C which had an average energy release of -150 J/g.	[redacted] Report No. CSL-23-0276.01 [redacted] Report No. CSL-23-0277.01 [redacted] Report No. CSL-23-0278.01

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Considering that the sum of the mean exothermic events is below 500 J/g and the onset of exothermic decomposition is below 500 ºC. , the product is not considered explosive.	
Flammable gases	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, the flammable liquids endpoint is considered.	-
Flammable aerosols	Waived	-	Not applicable since the biocidal product is not an aerosol, nor intended to be sprayed.	-
Oxidising gases	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, the oxidising liquids endpoint is considered.	-
Gases under pressure	Waived	-	Not applicable since the biocidal product is not a gas.	-
Flammable liquids	EC A.9	3.4% w/w Transfluthrin (impregnating liquid)	Flash point: 77°C The impregnation liquid is not	[redacted] Report No. 21134-04C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			considered to be flammable and not to meet the GHS/CLP criteria for classification.	
Flammable solids	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, the flammable liquids endpoint is considered.	-
Self-reactive substances and mixtures	OECD 113 EC A.14. UN Class 1 Differential Scanning Calorimetry (DSC)	3.4% w/w Transfluthrin (impregnating liquid)	DSC was performed on 3 different samples, each with 2 or 3 measurements, up to 500°C: A first exothermic event was observed between 90-120°C which had an average energy release of -27 J/g. An endothermic event was observed between 200-290°C which had an average energy uptake of 180 J/g. A second exothermic event was observed between 290-350°C which had an average energy release of -93 J/g. A	[redacted] Report No. CSL-23-0276.01 [redacted] Report No. CSL-23-0277.01 [redacted] Report No. CSL-23-0278.01

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			third exothermic event was observed at 390°C which had an average energy release of -150 J/g. Considering that the sum of the mean exothermic events is below 300 J/g, the product is not considered self-reactive.	
Pyrophoric liquids	Waived	-	Based on experience in handling and use, it is known that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures	-
Pyrophoric solids	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, only the pyrophoric liquids endpoint is considered.	-
Self-heating substances and mixtures	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, only the liquid is considered. It should be noted that the test method is not	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			applicable to liquids.	
Substances and mixtures which in contact with water emit flammable gases	Waived	-	Based on experience in handling and use, it is known that the substance or mixture does not react with water.	-
Oxidising liquids	Waived	-	As per the CLP guidance, the classification procedure for this hazard class need not to be applied if the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.	Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures - Version 5.0, July 2017 – section 2.13.4.1.1.
Oxidising solids	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, only the oxidising liquids endpoint is considered.	-
Organic peroxides	Waived	-	Not applicable since the biocidal product does not contain organic peroxide structures (R-O-O-R').	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Corrosive to metals	UN Test C1	3.4% w/w Transfluthrin (impregnating liquid)	No visible corrosion to low carbon grade steel and aluminium ; nor are these materials corroded by weight or dept beyond the defined acceptable levels.	[redacted] Report No. DNA6728
Auto-ignition temperatures of products (liquids and gases)	EC A.15	3.4% w/w Transfluthrin (impregnating liquid)	250°C	[redacted] Report No. 22054-01C
Relative self-ignition temperature for solids	Waived	-	In accordance with CA-Nov16-Doc.4.3 – Final document, only the Auto-ignition temperatures of products (liquids and gases) endpoint is considered.	-
Dust explosion hazard	Waived	-	Not applicable since the biocidal product is not a dust, nor can it generate dust.	-

Conclusion on the physical hazards and respective characteristics of the product
The impregnating liquid of the biocidal product is not explosive, self-reactive, pyrophoric, self-heating, oxidising or corrosive to metals. It has a flash-point of 77.0 ºC, which does not result in a classification as flammable liquid, and its auto-ignition temperature is 250°C.

2.2.4. Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance [in accordance with SANCO/3030/99 rev 5]	GC-FID [using Agilent DB-5 chromatographic column 15m x 0.53mm x 1.5 µm and Perkin Elmer Autosystem XL FID detector Sample preparation : Transfluthrin extracted with n-Hexadecane 1 mg/mL in methanol.	Fortification range 80-120% n=5	0.8024 – 1.9056 mg/mL 0.80 - 1.91 % w/w (*) 2.15 – 5.12 % w/w (**) R^2 = 0.9969	Retention time match	94.6 - 105.0	99.8	4.2(***) 3.8 (****)	Not specified	[redacted] Report No. 21134-01C

(*)Corresponding to 0.80 - 1.91 %w/w based on nominal test item solution concentration of 100.0 mg/mL and considering an amount of 5.59g of impregnated liquid on a total weight of 15g of plaquettes.

(**)Corresponding to 2.15 – 5.12 %w/w based on the quantity of impregnated liquid on plaquettes.
(***)Corresponding to 1.2 ± 0.1 %w/w based on nominal test item solution concentration of 100.0 mg/mL and considering an amount of 5.59g of impregnated liquid on a total weight of 15g of plaquettes.
(****)Corresponding to 3.3 ± 0.1 %w/w based on the quantity of impregnated liquid on plaquettes.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Reader is referred to the AR on the active substance									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Reader is referred to the AR on the active substance									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Reader is referred to the AR on the active substance									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Reader is referred to the AR on the active substance

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Reader is referred to the AR on the active substance									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Reader is referred to the AR on the active substance									

Conclusion on the methods for detection and identificationof the product

Transfluthrin content can be determined, following extraction from the OWADEX biocidal product, based on a GC-FID method using a DB-5 (15m x 0.53mm x 1.5 µm) column. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. The mean recovery rate is 99.8%, within a 94.6 - 105.0% range. Repeated injection of the samples resulted in a coefficient of variation which was less than 4.2%. The limit of quantification (LOQ) has not been specified.

For other analytical methods, the reader is referred to the assessment report of the active substance.

2.2.5. Efficacy against target organisms

2.2.5.1. Function and field of use

MG 03: Pest Control

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

Owadex is an insecticidal plaquette consisting of a mat impregnated with the active substance solution in a perforated plastic casing. The product contains 3.4% of transfluthrin (CAS 118712-89-3) as active substance that evaporates at a suitable rate to provide an adequate level of protection.

The continuous action passive diffuser has been developed to eliminate flies (*Musca domestica*), mosquitoes (*Aedes* spp, *Culex* spp.) and fruit flies (*Drosophila* spp.) effectively for up to 4 months and ants (*Lasius spp.*) in small, confined spaces up to 4 weeks.

The product is intended to be used indoor by the general public (non-professional).

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

According to the claimed uses, the product OWADEX is intended to be used to control house flies *Musca domestica* (adults), mosquitoes *Aedes* spp. and *Culex* spp. (adults), fruit flies *Drosophila spp.* (adults) and ants *Lasius spp*. (workers, no nest kill).

The products, organisms or objects to be protected are human health.

2.2.5.3. Effects on target organisms, including unacceptable suffering

As described in the CAR, transfluthrin is a synthetic pyrethroid which acts on harmful organisms by contact, ingestion and inhalation. It expresses a strong knock-down effect, followed by mortality of insects.
Target organisms are insects so suffering is not considered relevant.

2.2.5.4. Mode of action, including time delay

The active substance, Transfluthrin, is a member of the pyrethroid family which is according to the IRAC Mode of Action Classification Scheme (IRAC 2016) group 3a. It is a broad spectrum insecticide which acts as sodium channel modulator. The mode of action comprises of deregulation of nerve and muscle cell membrane permeability to sodium and potassium ions resulting in insect's rapid knockdown. The active substance disrupts the transmission of nerve impulses at the nicotinic acetylcholine receptor. Affected insects rapidly develop hyperexcitation and tremors, which are followed by paralysis and finally death.

2.2.5.5. Efficacy data

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td>
<td>OWADEX – insecticidal plaquette (transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>House flies (Musca domestica) 60 (4 cages x 15 insects) per replicate mixed sex adults, laboratory cultured</td>
<td>Simulated-use including residual effect
<u>Test conditions:</u>
temperature: 24 ± 2°C
relative humidity: 37-50 %
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.
Room size: 40 m³ or 16 m² (4x4x2.5m)
During the test a 20 cm diameter fan was placed inside the room in one corner to provide air circulation with the room.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of house flies.
New batches of caged house flies were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.
Four replicates with test product were conducted with knockdown counts taken at 30, 60, 120, 240, 360 and 480 minutes after house flies introduction.
Mortality counts are taken at 24 hours.
24 hours after exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check the mortality after next 24 h.

House flies were also tested after 2 and 4 months after product application. Between the various test periods the tested plaquettes were stored in a similar, conditioned room at 25 °C for ageing. The distance/set up "product to fan" were identical to the test rooms. The fan was run for 8 hours per 24 h. The evaluation of aged product was done with identical procedure as for the fresh ones.</td>
<td>Results for Musca domestica:
KD ≥ 80% reached (mean of 4 replicates):
<table><tr><th>Introduction after</th><th>24h</th><th>24h + 4h</th><th>24h + 8h</th></tr><tr><td>Fresh product</td><td>480 min (84.5%)</td><td>480 min (86.7%)</td><td>480 min (96.2%)</td></tr><tr><td>2 month product</td><td>480 min (81.6%)</td><td>480 min (85.6%)</td><td>480 min (88.8%)</td></tr><tr><td>4 month product</td><td>480 min (83.3%)</td><td>480 min (83.8%)</td><td>480 min (87.9%)</td></tr></table>for all negative control replicates, knock down levels remained 0% after 480 minutes of testing.
% Mortality after 24h (mean of 4 replicates):
<table><tr><th>Introduction after</th><th>24h</th><th>24h + 4h</th><th>24h + 8h</th></tr><tr><td>Fresh product</td><td>97.9</td><td>97.1</td><td>100</td></tr><tr><td>2 month product</td><td>91.7</td><td>95.4</td><td>94.2</td></tr><tr><td>4 month product</td><td>92.1</td><td>92.5</td><td>93.8</td></tr></table>for all negative control replicates, mortality levels remained <1% for the entire testing period.
Conclusion :
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 3.0 April 2018, the results of the simulated use trial including residual effect meet the criteria for house flies Musca domestica (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 4 months against house flies (Musca domestica) at the rate of 1 plaquette per 40 m³ of volume or 16 m² of surface.</td>
<td>[redacted] (April 06, 2021) – Report no. LZ/MD95-Md/14122020-06042021 – "Efficacy evaluation of Owadex" against Musca Domestica (SIM-USE TEST)"</td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor</td>
<td>OWADEX – insecticidal plaquette</td>
<td>Mosquitoes: Culex pipiens 60 (4 cages x</td>
<td>Simulated-use including residual effect</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.</td>
<td>Results for Culex pipiens,
KD ≥ 80% reached (mean of 4 replicates):
<table><tr><th>Introduction</th><th>24h</th><th>24h + 4h</th><th>24h + 8h</th></tr></table></td>
<td>[redacted] (April 06,</td>
</tr>
</table>

<table>
<tr>
<td>use by general public (non-professional)</td>
<td>(transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>15 insects) per replicate female adults, laboratory cultured</td>
<td><u>Test conditions:</u>
temperature: 27 ± 2°C
relative humidity: 60 ± 5%
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td>Room size: 40 m³ or 16 m² (4x4x2.5m)
During the test a 20 cm diameter fan was placed inside the room in one corner to provide air circulation with the room.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of mosquitoes.
New batches of caged mosquitoes were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.
Four replicates with test product were conducted with knockdown counts taken at 15, 30, 60, 90, 120 and 180 minutes after mosquitoes introduction. Mortality counts were taken at 24 hours.
24 hours after exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check the mortality after next 24 h.

Mosquitoes were also tested after 2 and 4 months after product application. Between the various test periods the tested plaquettes were stored in a similar, conditioned room at 25 °C for ageing. The distance/set up "product to fan" were identical to the test rooms. The fan was run for 8 hours per 24 h. The evaluation of aged product was done with identical procedure as for the fresh ones.</td>
<td>
<table>
<tr><td>after</td><td></td><td></td><td></td></tr>
<tr><td>Fresh product</td><td>120 min (84.5%)</td><td>120 min (90.0%)</td><td>120 min (85.0%)</td></tr>
<tr><td>2 month product</td><td>180 min (81.6%)</td><td>180 min (85.8%)</td><td>180 min (83.8%)</td></tr>
<tr><td>4 month product</td><td>180 min (80.8%)</td><td>180 min (82.0%)</td><td>180 min (83.8%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 180 minutes of testing.
<table>
<tr><th colspan="4">% Mortality after 24h (mean of 4 replicates):</th></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>2 month product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>4 month product</td><td>100</td><td>100</td><td>100</td></tr>
</table>
for all negative control replicates, mortality levels remained <1% for the entire testing period.
Conclusion :
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 3.0 April 2018, the results of the simulated use trial including residual effect meet the criteria for mosquitoes, Culex pipiens (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 4 months against Culex pipiens mosquitoes at the rate of 1 plaquette per 40 m^3 of volume or 16 m² of surface.
</td>
<td>2021) – Report no. LZ/MD95-Cp/14122020-06042021 – "Efficacy evaluation of Owadex" against Culex Pipiens (SIM-USE TEST)"</td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td>
<td>OWADEX – insecticidal plaquette (transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>Mosquitoes: Aedes albopictus 60 (4 cages x 15 insects) per replicate female adults, laboratory cultured</td>
<td>Simulated-use including residual effect

<u>Test conditions:</u>
temperature: 27 ± 2°C
relative humidity: 60 ± 5%
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.
Room size: 40 m³ or 16 m² (4x4x2.5m)
During the test a 20 cm diameter fan was placed inside the room in one corner to provide air circulation with the room.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of mosquitoes.
New batches of caged mosquitoes were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all</td>
<td>Results for Aedes albopictus
<table>
<tr><th colspan="4">KD ≥ 80% reached (mean of 4 replicates):</th></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>90 min (86.7%)</td><td>90 min (90.4%)</td><td>90 min (88.8%)</td></tr>
<tr><td>2 month product</td><td>90 min (85.4%)</td><td>90 min (84.1%)</td><td>90 min (83.8%)</td></tr>
<tr><td>4 month product</td><td>120 min (84.2%)</td><td>120 min (84.6%)</td><td>120 min (83.8%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 180 minutes of testing.
<table>
<tr><th colspan="4">% Mortality after 24h (mean of 4 replicates):</th></tr>
<tr><td>Introduction</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
</table>
</td>
<td>[redacted] (April 06, 2021) – Report no. LZ/MD95-Aalb/14122020-06042021 – "Efficacy evaluation of Owadex" against Aedes albopictus</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>time.
Four replicates with test product were conducted with knockdown counts taken at 15, 30, 60, 90 and 120 minutes after mosquitoes introduction.
Mortality counts were taken at 24 hours.
After 24 hours of insect exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check the mortality after next 24 h.

Mosquitoes were also tested after 2 and 4 months after product application. Between the various test periods the tested plaquettes were stored in a similar, conditioned room at 25 °C for ageing. The distance/set up "product to fan" were identical to the test rooms. The fan was run for 8 hours per 24 h. The evaluation of aged product was done with identical procedure as for the fresh ones.</td>
<td>
<table>
<tr><td>after</td><td></td><td></td><td></td></tr>
<tr><td>Fresh product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>2 month product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>4 month product</td><td>100</td><td>100</td><td>100</td></tr>
</table>
for all negative control replicates, mortality levels remained <1% for the entire testing period.
Conclusion
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 3.0 April 2018, the results of the simulated use trial including residual effect meet the criteria for mosquitoes, Aedes albopictus, (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 4 months against mosquitoes (Aedes albopictus) at the rate of 1 plaquette per 40 m^3 of volume or 16 m² of surface.
</td>
<td>(SIM-USE TEST)"</td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td>
<td>OWADEX – insecticidal plaquette

(transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>Fruit flies (Drosophila melanogaster),

60 (4 cages x 15 insects) per replicate

mixed sex adults, laboratory cultured</td>
<td>Simulated-use including residual effect

<u>Test conditions:</u>
temperature: 27 ± 2°C
relative humidity: 60 ± 5%

<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.
Room size: 40 m³ or 16 m² (4x4x2.5m)
During the test a 20 cm diameter fan was placed inside the room in one corner to provide air circulation with the room.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of fruit flies. New batches of caged fruit flies were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.

Four replicates with test product were conducted with knockdown counts taken at 15, 30, 60, 90, 120 and 180 minutes after fruit flies introduction.
Mortality counts were taken at 24 hours.
After 24 hours of insect exposure, the cages were removed from the room and placed in a control room (pesticide free), provided with water and sugar, to check the mortality after next 24 h.

Fruit flies were also tested after 2 and 4 months after product application.
Between the various test periods the tested</td>
<td>Results for Drosophila melanogaster

<table>
<tr><td colspan="4">KD ≥ 80% reached (mean of 4 replicates):</td></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>180 min (100%)</td><td>180 min (100%)</td><td>180 min (100%)</td></tr>
<tr><td>2 month product</td><td>180 min (87.5%)</td><td>180 min (92%)</td><td>180 min (90.3%)</td></tr>
<tr><td>4 month product</td><td>180 min (90.8%)</td><td>180 min (89.2%)</td><td>180 min (89.2%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 180 minutes of testing.

<table>
<tr><td colspan="4">% Mortality after 24h (mean of 4 replicates):</td></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>2 month product</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>4 month product</td><td>100</td><td>100</td><td>100</td></tr>
</table>
for all negative control replicates, mortality levels remained 0% for the entire testing period.
Conclusion:
No specification on pass criteria for products against fruit flies are specified in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 3.0 April 2018. However, norms and criteria against flies can be applied. Therefore, the results</td>
<td>[redacted] (April 06, 2021) – Report no. LZ/MD95-Dm/14122020-06042021 – "Efficacy evaluation of Owadex" against Drosophila melanogaster (SIM-USE TEST)"</td>
</tr>
</table>

<table>
<tr>
<td></td><td></td><td></td><td></td><td>plaquettes were stored in a similar, conditioned room at 25 °C for ageing. The distance/set up "product to fan" were identical to the test rooms. The fan was run for 8 hours per 24 h.The evaluation of aged product was done with identical procedure as for the fresh ones.</td><td>of the simulated use trial including residual effect meet the criteria for fruit flies Drosophila melanogaster (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 4 months against fruit flies (Drosophila melanogaster) at the rate of 1 plaquette per 40 m^3 of volume or 16 m^2 of surface.</td><td></td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td><td>OWADEX – insecticidal plaquette (transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td><td>Black garden ants Lasius niger 20 per replicate adults workers, laboratory cultured</td><td>Simulated-use including residual effect

<u>Test conditions:</u>
temperature: 25 ± 1°C
relative humidity: 60 ± 5%
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td><td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per cabinet.
Room size: 30 m^3 or 9.92 m^2 (3.15 x 3.15 x 3.03m)
<u>Test description:</u>
The test product was placed in the center of the cabinet, on the bottom, inside a non-ventilated room.
After 24 hours, a plastic cup containing 20 ant workers is introduced into the cabinet. Knockdown counts taken at different time intervals up to 8 hours. Insects are kept for 24 hours inside the cabinet. Mortality was evaluated outside the cabinet, at 24 hours after the end of the exposure. Additionally, four replicates of untreated controls were conducted with knockdown and mortality counts taken at the same times.
Ants were also tested after 1, 2 and 4 weeks after product application.</td><td>Results for Lasius niger
<table>
<tr><th rowspan="2">Time (min)</th><th colspan="4">No of knocked down / dead insects Mean of 4 replicates (%)</th></tr>
<tr><th>Fresh product</th><th>1 week product</th><th>2 week product</th><th>4 week product</th></tr>
<tr><td>60</td><td>7.50</td><td>15.00</td><td>2.50</td><td>0.00</td></tr>
<tr><td>120</td><td>57.50</td><td>32.50</td><td>3.75</td><td>3.75</td></tr>
<tr><td>180</td><td>77.50</td><td>51.25</td><td>27.50</td><td>7.50</td></tr>
<tr><td>240</td><td>90.00</td><td>80.00</td><td>62.50</td><td>28.75</td></tr>
<tr><td>300</td><td>98.75</td><td>93.75</td><td>73.75</td><td>32.50</td></tr>
<tr><td>360</td><td>98.75</td><td>98.75</td><td>85.00</td><td>42.50</td></tr>
<tr><td>420</td><td>100.00</td><td>100.00</td><td>88.75</td><td>50.00</td></tr>
<tr><td>480</td><td>100.00</td><td>100.00</td><td>100.00</td><td>53.75</td></tr>
<tr><td>Dead after 24h</td><td>100.00</td><td>100.00</td><td>100.00</td><td>100.00</td></tr>
</table>

negative control mortality remained <5% after 24h.

Conclusion:
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 3.0 April 2018, the results of the simulated use trial including residual effect meet the criteria for ants Lasius niger (mortality after 24 hours > 90%).
The product is effective for 4 weeks against ants (Lasius niger) at the rate of 1 plaquette per 30 m^3 of volume.
No nest kill is claimed or validated.</td><td>[redacted] (April 30, 2021) – Report no. Q037A-21-01 – "Insecticidal efficacy evaluation of "Owadex" against Lasius Niger – Simulated use test.</td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor</td><td>OWADEX – insecticidal plaquette</td><td>Mosquitoes: Culex pipiens 60 (4 cages x</td><td>Simulated-use including residual</td><td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.</td><td>Results for Culex pipiens,
KD ≥ 80% reached (mean of 4 replicates):</td><td>[redacted] (May 26,</td>
</tr>
</table>

<table>
<tr>
<td>use by general public (non-professional)</td>
<td>(transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>15 insects) per replicate female adults, laboratory cultured</td>
<td>effect

<u>Test conditions:</u>
temperature: 26 ± 2°C
relative humidity: 62 ± 5%
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td>Room size: 40 m³ or 16 m² (4x4x2.5m)
Test was conducted with fresh product and 3-months aged product.
During the test no fan was used.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of mosquitoes. New batches of caged mosquitoes were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.
Four replicates with test product were conducted with knockdown counts taken at 15, 30, 60, 90, 120 and 180 minutes after mosquitoes introduction. Mortality counts were taken at 24 hours.
24 hours after exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check additionally the mortality after next 24 h.

Mosquitoes were also tested after 3 months after product application. The product was taken out of the package and placed in a 40 m³ room (without mechanical air movement) for 3 months during which the temperature was between 20 – 25°C and humidity between 50 – 65% RH.</td>
<td>
<table>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>180 min (83.8%)</td><td>180 min (85.0%)</td><td>180 min (80.8%)</td></tr>
<tr><td>3 month product</td><td>180 min (80.4%)</td><td>180 min (80.8%)</td><td>180 min (82.5%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 180 minutes of testing.
<table>
<tr><td colspan="4">% Mortality after 24h (mean of 4 replicates):</td></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>95.8</td><td>94.5</td><td>96.7</td></tr>
<tr><td>3 month product</td><td>90.8</td><td>93.3</td><td>95.0</td></tr>
</table>
for all negative control replicates, mortality levels remained <1% for the entire testing period.
Conclusion :
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 4.1 February 2022, the results of the simulated use trial conducted without fan including residual effect meet the criteria for mosquitoes, Culex pipiens (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 3 months against Culex pipiens mosquitoes at the rate of 1 plaquette per 40 m³ of volume or 16 m² of surface when used in room without fan.
</td>
<td>2022) – Report no. LZ/MD95-Cp/ 23-26052022 – "Efficacy evaluation of Owadex" against Culex Pipiens (SIM-USE TEST)"</td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td>
<td>OWADEX – insecticidal plaquette (transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>Mosquitoes: Culex pipiens 60 (4 cages x 15 insects) per replicate female adults, laboratory cultured</td>
<td>Simulated-use including residual effect

<u>Test conditions:</u>
temperature: 26 ± 2°C
relative humidity: 62 ± 5%
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.
Room size: 40 m³ or 16 m² (4x4x2.5m)
Test was conducted with fresh product and 3-months aged product.
During the test no fan was used.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of mosquitoes. New batches of caged mosquitoes were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.
Four replicates with test product were conducted with knockdown counts taken at 30, 60, 90, 120, 180 and 240 minutes after mosquitoes</td>
<td>Results for Culex pipiens,
<table>
<tr><td colspan="4">KD ≥ 80% reached (mean of 4 replicates):</td></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>180 min (83.8%)</td><td>180 min (85.0%)</td><td>180 min (80.8%)</td></tr>
<tr><td>4 month product</td><td>240 min (80.8%)</td><td>240 min (85.8%)</td><td>180 min (81.7%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 180 and 240 minutes of testing.
<table>
<tr><td colspan="4">% Mortality after 24h (mean of 4 replicates):</td></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>95.8</td><td>94.5</td><td>96.7</td></tr>
<tr><td>4 month product</td><td>92.1</td><td>92.5</td><td>94.6</td></tr>
</table>
for all negative control replicates, mortality levels remained <1% for the entire testing period.
</td>
<td>[redacted] (May 26, 2022) – Report no. LZ/MD95-Cp/ 20-23062022 – "Efficacy evaluation of Owadex" against Culex Pipiens (SIM-USE TEST – part 2)"</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>introduction. Mortality counts were taken at 24 hours.
24 hours after exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check additionally the mortality after next 24 h.

Mosquitoes were also tested after 4 months after product application. The product was taken out of the package and placed in a 40 m³ room (without mechanical air movement) for 3 months during which the temperature was between 20 – 25°C and humidity between 50 – 65% RH.</td>
<td>Conclusion :
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 4.1 February 2022, the results of the simulated use trial conducted without fan including residual effect meet the criteria for mosquitoes, Culex pipiens (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).

The product is effective for 4 months against Culex pipiens mosquitoes at the rate of 1 plaquette per 40 m^3 of volume or 16 m² of surface when used in room without fan.</td>
<td></td>
</tr>
<tr>
<td>PT 18 Insecticide for indoor use by general public (non-professional)</td>
<td>OWADEX – insecticidal plaquette (transfluthrin 3.4% (w/w); 190 mg per one plaquette)</td>
<td>House flies (Musca domestica) 60 (4 cages x 15 insects) per replicate mixed sex adults, laboratory cultured</td>
<td>Simulated-use including residual effect

<u>Test conditions:</u>
temperature: 27 ± 2°C
relative humidity: 37-50 %
<u>Replicates:</u>
Test : 4 replicates
Negative control : 4 replicates</td>
<td><u>Dosage:</u>
The applied dose of product was 1 plaquette (190 mg of transfluthrin) per 1 room.
Room size: 40 m³ or 16 m² (4x4x2.5m)
Test was conducted with fresh product and 3-months aged product.
During the test no fan was used.
<u>Test description:</u>
The test product was hung 1 m above the floor 24 hours prior to the introduction of the first batch of house flies. New batches of caged house flies were introduced 24 h after product application and then after 4 and 8 hours. Insects were provided with a piece of cotton soaked with water and sugar at all time.
Four replicates with test product were conducted with knockdown counts taken at 30, 60, 120, 240, 360, 480 and 720 minutes after house flies introduction. Mortality counts are taken at 24 hours.
24 hours after exposure, the cages were removed from the room and placed in a control room, provided with water and sugar, to check the mortality after next 24 h

Fresh product and 3-moth aged product (exposed) were tested. The product was taken out of the package and placed in a 40 m³ room (without mechanical air movement) for 3 months during which the temperature was between 20 – 25°C and humidity between 50 – 65% RH.</td>
<td>Results for Musca domestica:

<table>
<tr><th colspan="4">KD ≥ 80% reached (mean of 4 replicates):</th></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>720 min (83.3%)</td><td>720min (82.9%)</td><td>720 min (84.6%)</td></tr>
<tr><td>3 month product</td><td>720 min (80.4%)</td><td>720min (81.7%)</td><td>720 min (87.5%)</td></tr>
</table>
for all negative control replicates, knock down levels remained 0% after 720 minutes of testing.
<table>
<tr><th colspan="4">% Mortality after 24h (mean of 4 replicates):</th></tr>
<tr><td>Introduction after</td><td>24h</td><td>24h + 4h</td><td>24h + 8h</td></tr>
<tr><td>Fresh product</td><td>92.1</td><td>95.8</td><td>98.3</td></tr>
<tr><td>3 month product</td><td>91.7</td><td>94.6</td><td>95.4</td></tr>
</table>
for all negative control replicates, mortality levels remained <1% for the entire testing period.
Conclusion :
As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 4.1 February 2022, the results of the simulated use trial including residual effect meet the criteria for house flies Musca domestica (knock down efficacy ≥ 80%, mortality after 24 hours > 90%).
The product is effective for 3 months against house flies (Musca domestica) at the rate of 1 plaquette per 40 m^3 of volume or 16 m² of surface when used in room without fan.</td>
<td>[redacted] (July 29, 2022) – Report no. LZ/ MD95-Md/ 25-29072022– "Efficacy evaluation of Owadex" against Musca Domestica (Sim-useTEST without fan)</td>
</tr>
</table>

Conclusion on the efficacy of the product

In accordance with the submitted tests and the requirements of the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), Version 4.1 February 2022, the product OWADEX is efficient:

- against domestic flies *Musca domestica* (adults), mosquitoes *Culex* spp. and *Aedes* spp. (adults) and fruit flies *Drosophila* spp. at application rate of 1 plaquette per 40 m^3 corresponding to 1 plaquette per 16 m^2.
  The tests performed without fan is acceptable. However, the test carried out with fan shows a better efficacy. The product should be used in combination with forced air circulation within the room (e.g. fan) during min 8h per day. The product remains efficient up to 4 months.

- against ants *Lasius spp.* in small, confined spaces (max 30 m^3). The product remains effective up to 4 weeks.

The delay of action is 24 hours.

2.2.5.6. Occurrence of resistance and resistance management

Resistance against pyrethroids in some insect pests has been observed. A recent study of Khan et al.[1] showed a significant level of resistance to transfluthrin tested against house flies collected from urban areas in Punjab Pakistan. Therefore a possible development of resistance is not to be discarded. In the publication of Tan, J (Tan, J., McCaffery, A.R. (2007))[2] resistance to pyrethroids and other types of insecticides in *Helicoverpa armigera* has been documented. In this study an isogenic metabolic resistance CMR strain was successfully isolated from a field pyrethroid-resistant population of *H. armigera*.
With this strain, cross-resistance among 19 pyrethroid insecticides with varying chemical structures was analysed. The resistant strain isolated in the publication showed varying degree of susceptibility to different members of the pyrethroid family.
For this dossier relevant was the observation that Transfluthrin still was able to overcome most of the resistance mechanism of the strain.
Product OWADEX has been found to work effectively against flies, mosquitoes, fruit flies and ants, and therefore likelihood of resistance is considered low when used in accordance with instruction for use.

Management strategies to avoid resistance:

- Always read the label or leaflet before use and follow all the instructions provided.
- Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Where an extended period of control is required, treatments should be alternated with products with different modes of action.

2.2.5.7. Known limitations

The tests of the product against flies, fruit flies, and mosquitoes were performed without fan. As stated in the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B&C) Version 4.1 February 2022, the results of the simulated use trial including residual effect meet the criteria for flies, fruit flies, and mosquitoes *(*knock down efficacy ≥ 80%, mortality after 24 hours > 90%*)*. However, the tests carried out with fan are more efficient. For optimal efficacy , the product should be used in combination with forced air circulation within the room (e.g. fan) during min 8h per day.

1 Hafiz Azhar Ali Khan, Waseem Akram and Ammara Fatima, Resistance to pyrethroid insecticides in house flies, *Musca domestica* L., (Diptera: Muscidae) collected from urban areas in Punjab, Pakistan

2 Jianguo Tan, Alan R McCaffery, Efficacy of various pyrethroid structures against a highly metabolically resistant isogenic strain of Helicoverpa armigera (Lepidoptera : Noctuidae) from China, 2007

2.2.5.8. Evaluation of the label claims

The product OWADEX has shown a sufficient efficacy, for the following use claimed:

- 1 plaquette per 40 m^3 corresponding to 1 plaquette per 16 m^2 against house flies *(Musca domestica)*, mosquitoes (*Aedes* spp. and *Culex* spp) and fruit flies (*Drosophila spp.),* when used indoors by consumers (non-professionals). For optimal efficacy , the product should be used in combination with forced air circulation within the room (e.g. fan) during min 8h per day. The product remains efficacious up to 4 months.
- 1 plaquette per small, confined spaces (max 30m^3) against ants *Lasius* spp. for consumers (non-professionals). The product remains efficacious up to 4 weeks.

The delay of action is 24 hours.

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

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

2.2.6. Risk assessment for human health

No new data submitted. Classification of the product is addressed using available data on the individual ingredients of the formulation. The inert carrier of the biocidal product was not included as part of the product composition when considering the classification and labelling.

2.2.6.1. Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin.
Justification for the value/conclusion	A skin irritation study has not been conducted. None of the ingredients classified for skin irritation/corrosion are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008 the product does not need to be classified for skin corrosion/irritation.
Classification of the product according to CLP and DSD	According to CLP, no classification for skin irritation/corrosion is necessary.

Data waiving	
Information requirement	Skin irritation/corrosion (IUCLID 8.1.1)
Justification	Study scientifically not necessary / other information available. The toxicity of active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Moreover, the casing excludes direct contact with the product.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product has to be classified as an eye irritant according to (EU) No 1272/2008 (Eye Irrit. 2, H319)
Justification for the value/conclusion	No studies on eye irritation is available for biocidal product. The concentration of the solvent leads to the classification as Eye Irrit. 2 (H319). There are no co-formulants classified as Eye Dam. 1 (H318). Moreover, the casing excludes direct contact with the product.
Classification of the product according to CLP and DSD	Eye irritation cat. 2, H319

Data waiving

Information requirement	Eye irritation (IUCLID 8.1.2)
Justification	Study scientifically unjustified. Since the eye irritation can be assessed on the basis of the properties of the ingredients, the performance of eye irritation study with the biocidal product is scientifically not justified. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Based on a consideration of the composition of the formulation the biocidal product meets the criteria for classification for eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No experimental data on respiratory irritation of the product is available. None of the ingredients are classified for Specific target organ toxicity – Single exposure Cat 3 for respiratory tract irritation (H335). Therefore the product does not need to be classified as STOT SE3 (H335)
Classification of the product according to CLP and DSD	According to CLP, no classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Study scientifically not necessary / other information available. The toxicity of active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	A skin sensitisation study with the product has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Moreover, the casing excludes direct contact with the product.
Classification of the product according to CLP and DSD	According to CLP, no classification for skin sensitization is necessary.

Data waiving	
Information requirement	Skin sensitisation (IUCLID 8.3.1)
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No data on respiratory sensitisation of the product is available. None of the components in the product is classified for respiratory sensitisation Category 1 (H334).
Classification of the product according to CLP and DSD	According to CLP, no classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Respiratory sensitisation (IUCLID 8.3.2)
Justification	Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

Acute toxicity

No new data submitted. Classification of the product is addressed using available data on the individual ingredients of the formulation. The carrier of the biocidal product has not been included as part of the product composition when considering the classification and labelling.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route
Justification for the selected value	Acute toxicity studies with the product have not been conducted. None of the ingredients classified for acute oral toxicity (H302) are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008 the product does not need to be classified for acute oral toxicity.
Classification of	According to CLP, no classification for acute oral toxicity is necessary.

the product according to CLP and DSD	

Data waiving	
Information requirement	Acute toxicity: oral (IUCLID 8.5.1)
Justification	Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Moreover, the casing excludes direct contact with the product.

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	Acute toxicity studies with the product have not been conducted. None of the ingredients classified for acute inhalation toxicity (H332) are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008 the product does not need to be classified for acute inhalation toxicity.
Classification of the product according to CLP and DSD	According to CLP, no classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	Acute inhalation toxicity (IUCLID 8.5.2)
Justification	Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

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	Acute toxicity studies with the product have not been conducted. None of the ingredients of the product are classified for dermal toxicity. According to Regulation EC 1272/2008 the product does not need to be classified for acute dermal toxicity.
Classification of the product according to CLP	According to CLP, no classification for acute dermal toxicity is necessary.

and DSD	

Data waiving	
Information requirement	Acute toxicity: dermal (IUCLID 8.5.2)
Justification	Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Moreover, the casing excludes direct contact with the product.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Transfluthrin
Value(s)*	70%
Justification for the selected value(s)	A default dermal absorption value for a dilution of organic solvent-formulation. Guidance on dermal absorption, EFSA Journal 2017;15(6):4873

** please include the concentration range(s) the values are applicable for, if relevant*

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

There are valid data available on each of the components in the product, sufficient to allow its classification according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
The biocidal product contains a solvent which is considered a substance of concern since it is present in a concentration leading to classification of the biocidal product according to the CLP Regulation. The solvent (3-methoxy-3-methyl-1-butanol) contributes to classification of the product as an Eye Irritant cat. 2 which is associated with the hazard statement H319.

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of.

Not applicable – no mixtures present in the composition.

Available toxicological data relating to endocrine disruption

The biocidal product does not contain any active substances having endocrine-disrupting properties. Based on the available information, no indications of endocrine-disrupting

properties according to Regulation (EU) No 2017/2100, Regulation (EU) 2018/605 or Article 57(f) and 59(l) of Regulation (EC) No 1907/2006 were identified for the non-active substances contained in the biocidal product.

2.2.6.2. Exposure assessment

The risk assessment is performed taking into account the conclusions agreed in the evaluation of the active substance transfluthrin as reported in the CAR document for transfluthrin (2014). Therefore, the data relating to the active substance (active substance properties and agreed absorption rates and AEL values) is extracted from the CAR, while the data relating to the product (application patterns and frequency of use) is assumed based on intended use. Additionally, the dermal absorption rate is the default value from the EFSA guidance on dermal absorption 2017.
Risk related to presence of SoCs was assessed in a qualitative manner as stated above, given their nature and their classification.
The exposure values have been calculated based on "Human Exposure to Biocidal Products Technical Notes For Guidance" (June 2007), Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017) and the relevant "Guidance on the Biocidal Products Regulations, Vol. III Human Health – Parts B+C Assessment & Evaluation" (Version 4.0 December 2017) as published on ECHA website.
The ConsExpo Web Tool and "Pest Control Products Fact Sheet" (RIVM report 320005002/2006) were used to perform the assessment. However, the model suggested in the document dated on 2006 was consulted with RIVM in order to confirm the validity of approach. As outcome of the consultation with ConsExpo experts it was decided that a novel approach should be implemented to better address actual exposure. Correction of release area and duration of exposure are currently considered an improper way of handling exposure assessment. Evaluation of inhalation of vapour in a constant rate model was suggested to the applicant. During the service life the active substance will evaporate gradually and the user will replace the plaquette when needed (see instructions) due to product depletion.

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

The biocidal product is an insecticidal product for non-professional use against flies, fruit flies, mosquitoes present in living areas and ants in sealed areas, such as cabinets.
One impregnated mat in a plastic casing protects an area of 16 m^2 (approx. 40 m^3) for up to 4 months against flies, fruit flies and mosquitoes, and when used in a sink cabinet or other similar small space, it protects against ants for up to 4 weeks. Full effectiveness is reached about 24 h after application. The product can be replaced after 4 months. Product will be supplied always and only in a casing, therefore strongly limiting the possibilities of exposure though dermal contact, as well as the possibility that young children gain access to the impregnated mat and put it in their mouth.

Exposure during product service life:

Dermal route: exposure of children or adults through the dermal route is unlikely, due to the plastic casing with a dense grid preventing the possibility of contact with the inner mat

impregnated with the formulation. If the fingers are pressed under the grid deliberately, only their tips can contact the mat, hence the dermal exposure is considered negligible.

Inhalation route: Due to the characteristics of the active substance and the mode of action of the product, the inhalation route is the main exposure route during product placement and during its whole use period (4 months). Adults can be exposed to the active substance during opening and removal of the packaging and placing the plate in the room/kitchen/bathroom. This exposure is considered negligible in comparison to everyday inhalation exposure during normal use of the product.

Oral route: the plastic casing is considered a reasonable barrier, preventing children from chewing or hand-to-mouth transfer. This route is considered negligible.

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	application phase	During the product service life exposure to vapours in living areas occurs.	non-professionals, general public: adults, children
2.	application phase	During the product service life exposure to vapours in sealed areas (such as cabinets) occurs.	non-professionals, general public: adults, children

Link between scenarios and uses		
Use number:	**Covered by Scenario number:**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
Use #1 Insecticide against mosquitoes and fruit flies for indoor use by non-professionals	1.	non-professionals, general public: adults, children
Use #2 Insecticide against ants for indoor use by non-professionals		
Use #3 Insecticide against house flies for indoor use by non-professionals		
Use # 4 – Insecticide against ants for indoor use by non-professionals	2.	non-professionals, general public: adults, children

Industrial exposure

not applicable

Professional exposure

not applicable

Non-professional exposure

Scenario 1

Description of Scenario 1		
Adults and children occupying a room were the product is placed are exposed to transfluthrin by inhalation. The impregnated mat in the plastic casing contains 190 mg a.s. and protects up to 40 m^3 of space. The product is effective up to 4 months. A realistic worst case is defined in the ConsExpo scenario "Use of strips and cassettes in living area".		
	Parameters[1]	Value
Tier 1	Amount of active substance per mat	190 mg (applicant's data)
	Body weight	8 kg - infant, 10 kg - toddler, 23.9 kg - child 6-11 y.o., 60 kg – adult (BPC default)
	Inhalation absorption	100% (CAR for transfluthrin)
	Exposure duration	24 hours
	Frequency	180 days (period of year when the target organisms occur)
	Emission duration	4 months (applicant's data)
	Room volume	15 m^3 (as a worst case scenario – a kitchen or a small bedroom; default RIVM report)
	Ventilation rate	0.6/hour (default RIVM report)
	Inhalation rate	5.4, 8, 12, 16 m^3/day respectively (BPC default)

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

Output tables from exposure assessment tools are included in Annex 3.2 to complement the table.

Scenario 2

Description of Scenario 2		
Adults and children (1-12 y.o) are exposed to transfluthrin in the product placed in a cabinet (sealed area) by occasional inhalation, when reaching into the cabinet (e.g. under the kitchen sink). Exposure of infants is not foreseen in this scenario. The impregnated mat in the plastic casing contains 190 mg a.s. The modeling used for exposure estimation is ConsExpo Exposure to vapour - Constant rate in sealed areas.		
	Parameters	Value
Tier 1	Amount of active substance per mat	190 mg (applicant's data)
	Body weight	10 kg - toddler, 23.9 kg - child 6-11 y.o., 60 kg – adult (BPC default)*
	Inhalation absorption	100% (CAR for transfluthrin)
	Exposure duration	5 min (default RIVM report)
	Frequency	180 days (period of year when the target organisms occur)
	Emission duration	4 months (applicant's data)
	Room volume	1.5 m^3 (default RIVM report)
	Ventilation rate	0.3/hour (default RIVM report)
	Inhalation rate	1.26, 1.32, 1.25 m^3/h respectively (BPC default)

**infants are not expected to be exposed in this scenario*

Output tables from exposure assessment tools are included in Annex 3.2 to complement the table.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 adult	Tier 1/no PPE	1.8×10^{-3} mg/kg bw/day	n/a	n/a	1.8×10^{-3} mg/kg bw/day
Scenario 1 child 6-11 y.o.	Tier 1/no PPE	3.4×10^{-3} mg/kg bw/day	n/a	n/a	3.4×10^{-3} mg/kg bw/day
Scenario 1 toddler	Tier 1/no PPE	5.4×10^{-3} mg/kg bw/day	n/a	n/a	5.4×10^{-3} mg/kg bw/day
Scenario 1 infant	Tier 1/no PPE	4.5×10^{-3} mg/kg bw/day	n/a	n/a	4.5×10^{-3} mg/kg bw/day
Scenario 2 adult	Tier 1/no PPE	0.000003 mg/kg bw/d	n/a	n/a	3.1×10^{-6} mg/kg bw/day
Scenario 2 child 6-11 y.o.	Tier 1/no PPE	0.000619 mg/kg bw/d	n/a	n/a	6.2×10^{-4} mg/kg bw/day
Scenario 2 toddler	Tier 1/no PPE	0.00002 mg/kg bw/d	n/a	n/a	1.9×10^{-5} mg/kg bw/d

Combined scenarios

Summary table: combined systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 +2 adult	Tier 1/no PPE	1.803×10^{-3} mg/kg bw/day	n/a	n/a	1.803×10^{-3} mg/kg bw/day
Scenario 1+ 2 child 6-11 y.o.	Tier 1/no PPE	4.02×10^{-3} mg/kg bw/day	n/a	n/a	4.02×10^{-3} mg/kg bw/day
Scenario 1+2 toddler	Tier 1/no PPE	5.42×10^{-3} mg/kg bw/day	n/a	n/a	5.42×10^{-3} mg/kg bw/day

Exposure of the general public

Covered by the primary exposure

Monitoring data

Not applicable

Dietary exposure

The product can be applied in spaces were the target organisms occur. That means that it can be placed in kitchens or dining rooms. The food items may come in contact with biocide residues deposited on surfaces. Hence, a Dietary Risk Assessment should be performed. The DRA calculations were based on ConsExpo modelling, assuming placing the product in a kitchen of a default volume of 15 m^3 (RIVM Report 090013003/2014). Scenario used in the calculations is the same as in the exposure of general public to reflect the actual conditions of product application (Exposure to vapour – Constant rate).
The air concentration of the evaporated product in peak moment has been calculated with use of ConsExpo model Exposure to vapour, constant rate. Emission duration has been set to 4 months (product service life) and user exposure to 24 hours, as the product is constantly present in the protected area. The target organisms are usually present in the household about 6 months a year, what is represented by 180 days of product use frequency. Kitchen ventilation has been set to 2,5 per hour in accordance with the default value in the RIVM report 090013003/2014. This value is representative for various house types, parts of the day and year. Based on the above described assumptions the peak concentration (TWA 15 min) of the active substance is 1.7×10^{-3} mg/m^3.

Exposure model	Exposure to vapour - Constant rate	
Exposure duration	24	hour
Product amount	190	mg
Weight fraction substance		1
Room volume	15	m^3
Ventilation rate	2.5	per hour
Emission duration	4	month
Results for scenario OWADEX TSF 190 mg / 15 m^3 mean air concentration		
Mean concentration on day of exposure	1.7×10^{-3} mg/m^3	

The dietary risk has been assessed with use of the BfR Calculator with modelling assuming a worst-case distribution of the biocidal product, that is on kitchen surfaces, dishes and exposed food.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of the product is not required under BPR. Therefore no exposure from production of the biocidal product is further considered.

Aggregated exposure

not applicable

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1	non-professionals, adults	Tier 1, no PPE	1.8×10^{-3} mg/kg bw/day
1	non-professionals, children 6-11 y.o.	Tier 1, no PPE	3.4×10^{-3} mg/kg bw/day
1	non-professionals, toddler	Tier 1, no PPE	5.4×10^{-3} mg/kg bw/day
1	non-professionals, infant	Tier 1, no PPE	4.5×10^{-3} mg/kg bw/day
2	non-professionals, adult	Tier 1, no PPE	3.1×10^{-6} mg/kg bw/day
2	non-professionals, children 6-11 y.o.	Tier 1, no PPE	6.2×10^{-4} mg/kg bw/day
2	non-professionals, toddler	Tier 1, no PPE	1.9×10^{-5} mg/kg bw/day
1	non-professionals, adults	Tier 1, no PPE	1.803×10^{-3} mg/kg bw/day
1	non-professionals, children 6-11 y.o.	Tier 1, no PPE	4.02×10^{-3} mg/kg bw/day
1	non-professionals, toddler	Tier 1, no PPE	5.42×10^{-3} mg/kg bw/day

2.2.6.3. Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
AELacute oral	developmental toxicity study, rabbit	15 mg/kg bw/day	100	No correction for oral absorption	0.15 mg/kg bw
AEL acute dermal	3 week dermal toxicity study, rabbit	1000 mg/kg bw/day	100	No correction for oral absorption	1 mg/kg bw
AEL acute inhalation	13-week inhalation study, rat	46.7 mg/m^3 equivalent to 17 mg/kg	100	No correction for oral absorption	0.17 mg/kg bw/d

		bw/day			
AEL medium-term/long-term	2-year dietary study in rat	20 ppm equal to 1 mg/kg	100	No correction for oral absorption	0.01 mg/kg bw
ARfD	Developpment study, rabbit	15 mg/kg	100	No correction for oral absorption	0.15 mg/kg bw
ADI	2-year dietary study in rat	1 mg/kg	100	No correction for oral absorption	0.01 mg/kg bw

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 adult	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	1.8×10^{-3} mg/kg bw/day	18%	yes
1 child 6-11 y.o.	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	3.4×10^{-3} mg/kg bw/day	34%	yes
1 toddler	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	5.4×10^{-3} mg/kg bw/day	54%	yes
1 infant	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	4.5×10^{-3} mg/kg bw/day	45%	yes
2 adult	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	3.1×10^{-6} mg/kg bw/day	0.03%	yes
2 child 6-11 y.o.	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	6.2×10^{-4} mg/kg bw/day	6.2%	yes
2 toddler	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	1.9×10^{-5} mg/kg bw/day	0.19%	yes
1 +2 adult	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	1.803×10^{-3} mg/kg bw/day	18%	yes
1+ 2 child 6-11 y.o.	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	4.02×10^{-3} mg/kg bw/day	40.2%	yes
1+2 toddler	Tier 1, no PPE	20 ppm equal to 1 mg/kg	0.01 mg/kg bw	5.42×10^{-3} mg/kg bw/day	54,2%	yes

The product used according to instructions on the label does not pose a health risk to any exposed group and can be safely applied.

Dietary Risk Assessment

The DRA assumes an unrealistic approach in which food is continuously exposed to the product for the total 4 months of product use. Calculation of concentration of the active substance in air is based on ConsExpo simulation with a default kitchen ventilation proposed in the RIVM report. No refinement factors were implemented for the seasonal use of the product (in fact the target insects are present in the household for

approximately 4 months of the year). In the outcome of the evaluation, none of the results for each age group exceeds the limit of 10% of ADI (0.01 mg/kg bw/day) and/or ARfD (0.15 mg/kg bw/day). The product is safe for use in rooms were food can be exposed to the product.

Calculation of consumer exposure*	adult (60 kg bw)	toddler (10 kg bw)	child (23,9 kg bw)
Estimation of chronic consumer exposure via food (mg/kg bw/d)	0,000	0,000	0,000
Estimation of chronic consumer exposure via food (% ADI)	0,2	1,1	0,5
Estimation of acute consumer exposure via food (mg/kg bw/d)	0,000	0,000	0,000
Estimation of acute consumer exposure via food (% ARfD)	0,0	0,2	0,1

Combined scenarios

not applicable

Local effects

The biocidal product is classified as an eye irritant cat. 2, H319.

Hazard		**Exposure**						**Risk**
Hazard Cat.	Local effects in terms of C&L	Exposed groups	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Rough degree of exposure	Relevant RMM & PPE	Conclusion on risk
Low	Eye irritant - H319 cat. 2	Non-professional - adults	- Loading (removal of the plate from the packaging and placing in a proper area) - Product disposal after service life	Accidental transfer from skin after dermal exposure during handling the product (the impregnated mat is enclosed in a plastic case with a dense grid – dermal contact is limited in normal handling)	After potential dermal contact - 3 times a year for each task; few minutes for a task	Practically no exposure (only tips of fingers can contact the mat if pressed under the grid deliberately)	- no PPE - application of P-statement: 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. - packaging minimising risk for exposure – plastic frame enclosing the impregnated mat	During normal handling of the product the risk of eye irritation is practically eliminated.
Low	Eye irritant - H319 cat. 2	General public – adults and children	- accidental contact with the impregnated mat inside	accidental transfer from skin after dermal	Accidental manner - limited time and frequency	Practically no exposure (only tips of fingers can contact the	- no PPE - application of P-statement: P102: Keep out of reach of children.	During normal handling of the product and parental supervision the risk of eye irritation is practically eliminated.

			the plastic casing with a dense grid	exposure during handling the product (the impregnated mat is enclosed in a plastic case with a dense grid – dermal contact is limited in normal handling)		mat if pressed under the grid deliberately)	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. - packaging minimising risk for exposure – plastic frame enclosing the impregnated mat	

Risk related to local effects which may be caused by the product is considered low based on above mentioned aspects of exposure.

Conclusion
Proper use, i.e. correct use of the product in compliance with instructions on the label, is considered safe for adults and children. There is no concern for adults or children related to the direct and indirect use of a product.

Risk for the general public

Covered by the risk assessment for non-professional users.

2.2.7. Risk assessment for animal health

A risk assessment for pets is not considered necessary as the assessment performed for humans will cover companion animals as well. Since the product is classified as very toxic to aquatic life the use nearby aquariums with fish is contraindicated. The product will be labelled accordingly.

2.2.8. Risk assessment for the environment

2.2.8.1. Effects assessment on the environment

Environmental risk assessment for biocidal product OWADEX is based on data for the active substance transfluthrin. The commercial product is sold as a plaquette consisting of plastic casing and inner mat impregnated with transfluthrin solution. However, the mat as a carrier material may not be regarded in the risk assessment, as the biocidal product itself does not include the carrier material.
In addition to the active substance the biocidal product contains two other co-formulants which have no environmental classification according to the SDS and no other grounds of concern for the environment are known. Therefore, these co-formulants are not considered further in the environmental risk assessment.
The applicant provided a letter of access to the data from the active substance dossier (Assessment Report Transfluthrin, eCA NL, March 2014). After active substance approval, new data were provided for transfluthrin that are also covered by the LoA. These data were discussed and new PNECs for water, sediment and soil for transfluthrin were agreed on WG meeting IV-2017 as presented below. New endpoints are included in Transfluthrin Assessment Report amended in October 2019.
The PNECs applied in the environmental risk assessment are summarised in the table below.

Summary table for PNECs used in Risk Assessment			
Parameters	Value	Unit	Notes
Transfluthrin			
$PNEC_{STP}$	0.057	mg/L	Transfluthrin Assessment Report – Amended (October 2019)
$PNEC_{water}$	1.75	ng/L	Transfluthrin Assessment Report - Amended (October 2019)
$PNEC_{sed}$	1.64E-03	mg/kg dw	Transfluthrin Assessment Report - Amended (October 2019)
	3.57E-04	mg/kg wwt	
$PNEC_{soil}$	0.1	mg/kg dw	Transfluthrin Assessment Report - Amended (October 2019)
	8.8E-02	mg/kg wwt	
$PNEC_{oral,mammals}$	6.67	mg/kg feed	Transfluthrin Assessment Report - Amended (October 2019)
$PNEC_{oral,birds}$	Not available		Transfluthrin Assessment Report - Amended (October 2019)
TFB-OH (2,3,5,6-Tetrafluorobenzyl alcohol)			
$PNEC_{water}$	>0.1	mg/L	Transfluthrin Assessment Report - Amended (October 2019)
TFB-COOH (2,3,5,6-Tetrafluorobenzoic acid)			
$PNEC_{water}$	>0.1	mg/L	Transfluthrin Assessment Report - Amended (October 2019)
$PNEC_{soil}$	0.012	mg/kg wwt soil	Calculated using EPM (TFL-PAI-Version 9, 2015)
Permethric Acid (DCVA)			

Summary table for PNECs used in Risk Assessment			
Parameters	Value	Unit	Notes
$PNEC_{water}$	0.0064	mg/L	Transfluthrin Assessment Report – Amended (October 2019)
$PNEC_{soil}$	0.0128	mg/kg wwt soil	Transfluthrin Assessment Report – Amended (October 2019)

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

Regarding ecotoxicological properties, the formulation is very toxic to aquatic organisms with long-lasting adverse effects in the aquatic environment. The proposed classification of the biocidal product according to the regulation (EC) 1272/2008 is Aquatic Acute 1, and the hazard statement H400 and Aquatic Chronic 1, and the hazard statement H410.

Further Ecotoxicological studies

No data are available.

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

No further study is needed.

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

Not required because the biocidal product is 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 required because the biocidal product is not in the form of bait or granules.

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

Secondary ecological effect studies may be required when a habitat such as a water body, wetland, forest or field is treated. No testing on secondary ecological effect is needed, as product will not be applied to large proportions of a specific habitat.

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

The product is to be used by general public as insecticide passive diffuser to control flying insects (flies, mosquitoes and fruit flies) indoors (bathroom, kitchen and rooms) and ants

in a cabinet under a sink. For both scenarios and uses, the emission paths will be the same.

According to the Emission Scenario Document, the relevant emissions when using diffusers are only envisaged during the application stage (diffuser is ready-to-use and, thus, no mixing/loading stage is necessary, and no emission is calculated for the preparation step of diffusers). During application, two relevant emission pathways are defined:

- Emission to air: the product releases the active substance to the surrounding air by evaporation,
- Emission to floor: a fraction of the product deposits on the floor, which may be wet cleaned, subsequently releasing the product to the Sewage Treatment Plants (STP). The Transfluthrin will not directly reach the environmental compartments surface water (including sediment), groundwater and soil, but indirectly via STP as a result from cleaning of the floor where the active substance has been deposited. The cleaning step will therefore lead to releases to waste water (e.g. through wet cleaning methods). Therefore, in compliance with the ESD, the compartment primarily exposed is the STP.

Air and STP are the primary compartment for emissions, whereas surface water (including sediment) and soil (including groundwater) are secondary exposed compartments for remnants via STP effluents and sewage sludge applications, respectively.

The environmental exposure assessment has been performed only for the Transfluthrin and its three major metabolites:

- TFB-OH,
- TFB-COOH,
- DCVA.

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

No further studies are considered necessary to assess the fate and behaviour in the environment for the product. The exposure and risk assessment has demonstrated a safe use without further refinements necessary.

Leaching behaviour (ADS)

No further data are available.

Testing for distribution and dissipation in soil (ADS)

No additional data is available for distribution and dissipation in soil.

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

No additional data is available for distribution and dissipation in water and sediment.

Testing for distribution and dissipation in air (ADS)

No additional data is available for distribution and dissipation in air.

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

No new data was submitted or is required.

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

No new data was submitted or is required.

2.2.8.2. Exposure assessment

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Consumer use of insecticide diffuser product to control flying insects indoors Scenario 2: Consumer use of insecticide diffuser product to control ants in small spaces such as cabinet under sink
ESD(s) used	OECD Series on Emission Scenario Documents No. 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users. OECD, Paris. 17th July 2008.
Approach	Scenario 1: Consumption-based approach, taking account of product-specific dose rate Scenario 2: Consumption-based approach, taking account of product-specific dose rate
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017) Technical Agreements for Biocides (TAB) Environment November 2021
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenario 1 (Production: No, Formulation No, Use: Yes, Service life: No) Scenario 2 (Production: No, Formulation No, Use: Yes, Service life: No)
Remarks	None

Emission estimation

Scenario 1: Consumer use of insecticide diffuser product to control flying insects indoor

According to ESD PT18 and the use of the product, the main releases towards wastewater are from the cleaning of the floor exposed to the biocidal product after application.

Emission to STP is only a result of emission from wet cleaning of the floor. For the indoor use of passive diffusers in general, the ESD considers that the major part of the active substance (90%) will be emitted to air and that the remaining 10% will be emitted to the floor. The product is ready-to-use. It is then assumed that cleaning of the floor will result in emissions to waste water.
The parameters used for the emission calculation are presented below:

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Consumer use of insecticide passive diffuser product indoor				
Fraction of technical active substance in the commercial product	F_{AI}	0.0345	-	3.45% (w/w)
Quantity of commercial product contained in the device/diffuser	Q_{prod}	5.6	g	Total amount of biocidal product included in OWADEX
Maximal duration of use of the device/diffuser	T_{Max}	2880	h	The product is intended for continual use and provides protection for up to 4 months (120 days)
Duration of use per day	T_{Day}	24	h.d-1	Default for passive diffuser
Number of diffusers in a standard house	$N_{diffusers}$	2	-	TAB ENV 148
Fraction emitted to air during use	$F_{application,air}$	0.9	-	Default ESD PT18
Fraction emitted to floor during use	$F_{application,floor}$	0.1	-	Default ESD PT18
Fraction of the total surface area which is cleaned	$Fraction\_Area_{cleaned}$	0.3	-	TAB ENV 148
Simultaneity factor for indoor uses of insecticide	$F_{simultaneity}$	0.055	-	Default ESD PT18
Cleaning efficiency	F_{CE}	1	-	Default ESD PT18

Calculations for Scenario 1

Please see Annex 3.2. for calculations of local emission.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.13E-05	Local emission to wastewater (STP) from use of insecticide passive diffuser

Scenario 2: Consumer use of insecticide diffuser product to control ants in small spaces such as cabinet under sink

To determine the potential emissions from small spaces such as cabinet under sink, the wardrobe scenario described in TAB ENV 150 was used. This scenario is the most relevant for this use.
This model indicates that the default value for the number of wardrobes per household used in emissions assessment should be 2.5 that is why the number of diffusers in a standard house used for calculations is 2.5.

ENV 148 of TAB also introduces the concept that only 30% of all flooring within a house may be subject to wet cleaning and that would be equivalent to reducing the FCE from 1 to only 0.3 – only 30% of available a.s. on floors would actually be removed and discharged to drains.

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Consumer use of insecticide passive diffuser product in small spaces				
Fraction of technical active substance in the commercial product	F_{AI}	0.0345	-	3.45% (w/w)
Quantity of commercial product contained in the device/diffuser	Q_{prod}	5.6	g	Total amount of biocidal product included in OWADEX
Maximal duration of use of the device/diffuser	T_{Max}	672	h	The product is intended for continual use and provides protection for up to 4 weeks (28 days)
Duration of use per day	T_{Day}	24	h.d-1	Default for passive diffuser
Number of diffusers in a standard house	$N_{diffusers}$	2.5	-	TAB ENV 150
Fraction emitted to air during use	$F_{application,air}$	0.9	-	Default ESD PT18

Fraction emitted to floor during use	$F_{application,floor}$	0.1	-	TAB ENV 150
Fraction of the total surface area which is cleaned	$Fraction\_Area_{cleaned}$	0.3	-	TAB ENV 148
Simultaneity factor for indoor uses of insecticide	$F_{simultaneity}$	0.055	-	TAB ENV 150
Cleaning efficiency	F_{CE}	1	-	TAB ENV 150

Calculations for Scenario 2

Please see Annex 3.2. for calculations of local emission.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.14E-04	Local emission to wastewater (STP) from use of insecticide passive diffuser in small spaces such as cabinet under sink

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^{++}	NR$^{(+)}$	Yes^{+}	Yes^{+}	No
Scenario 2	Yes^{+}	Yes^{+}	No	No	Yes^{++}	NR$^{(+)}$	Yes^{+}	Yes^{+}	No

$^{+}$ Compartment secondarily exposed (surface water from STP discharge, agricultural soil from sludge application, groundwater further to soil exposure)

$^{++}$ Compartment primarily exposed (soil, STP)

$^{(+)}$Compartment potentially exposed

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Transfluthrin			
Molecular weight	371.2	g/mol	Transfluthrin Assessment Report (2014)
Melting point	32	°C	Transfluthrin Assessment Report (2014)
Boiling point	242	°C	Transfluthrin Assessment Report (2014)
Vapour pressure (at 20°C)	9E-04	Pa	Transfluthrin Assessment

			Report (2014)
Water solubility (at 20°C)	0.057	mg/L	Transfluthrin Assessment Report (2014)
Log Octanol/water partition coefficient	5.94	Log 10	Transfluthrin Assessment Report (2014)
Organic carbon/water partition coefficient (Koc)	50119	L/kg	Transfluthrin Assessment Report (2014)
Henry's Law Constant	5.86	$Pa/m^3/mol$	Transfluthrin Assessment Report (2014)
Biodegradability	Not ready biodegradable	-	Transfluthrin Assessment Report (2014)
DT50 for degradation in sediment	-	-	No value reported
DT50 for degradation in soil	5.17	d (at 12ºC)	According to the conclusion of the technical meeting WGIV2017_ENV.
DT50 for degradation in the STP	0.284	d (at 21.7ºC)	According to the updated Assessment Report, 2019.
Bioconcentration factor (fish)	1783	L/kg fish	Average of measured values (1704 and 1861 L/kg ww)

The fate and distribution of transfluthrin within the STP was estimated using SimpleTreat 4.0.

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1 and 2	
Air	0.22	-
Water	1.31	-
Sludge	59.94	-
Degraded in STP	38.52	-

General Note:
In all scenarios, the OECD 314B study was used in Simple Treat 4 to assess the fate and distribution of transfluthrin in the STP (as data for the degradation constant and DT50 in the activated sludge are already included in the updated version of Transfluthrin's CAR).

Calculated PEC values

The compartmental PEC values were determined using the equations and default values taken from the Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017) and Emission Scenario Document for Product Type 18 (2008).

The following Summary Tables report the PEC values calculated for the above mentioned scenarios for transfluthrin and relevant metabolites.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/l]	[mg/kg_{dwt}]	[mg/kg_{dwt}]	[µg/l]
Scenario 1	1.40E-07	1.31E-08	6.51E-05	2.69E-05	1.11E-06
Scenario 2	7.47E-07	6.94E-08	3.48E-04	1.44E-04	5.95E-06

METABOLITES

Local PEC values for the major metabolites of each a.i have been calculated and presented below for the relative compartments. Metabolite exposures in water, sediment, soil and groundwater compartments were calculated based on the estimated emissions for the parent, taking into account the molecular weight difference between parent and metabolites along with the maximum observed levels of the metabolites, according to the equation:

$$\mathbf{PEC_{metabol} = (PEC_{transflu}/MW_{transflu}) * Formation\ fraction_{comp} * MW_{metab}}$$

Substance	Molecular weight (g/mol)	Formation fraction in water (%)	Formation fraction in sediment (%)	Formation fraction in soil (%)
Transfluthrin	371.2	-	-	-
TFB-OH	180.1	38	2.9	-
TFB-COOH	194.08	59	26	61.9
DCVA	209.07	59	26	61.9

Calculated PEC values for TFB-OH

Summary table on calculated PEC values	
	PEC_{water}
	[mg/l]
Scenario 1	2.42E-09
Scenario 2	1.28E-08

Calculated PEC values for TFB-COOH

Summary table on calculated PEC values		
	PEC_{water}	**PEC_{soil}**
	[mg/l]	[mg/kg]wwt
Scenario 1	4.04E-09	6.51E-06
Scenario 2	2.14E-08	3.63E-06

Calculated PEC values for DCVA

Summary table on calculated PEC values		
	PEC_{water}	**PEC_{soil}**
	[mg/l]	[mg/kg]wwt
Scenario 1	4.35E-09	7.01E-06
Scenario 2	2.31E-08	3.91E-05

Primary and secondary poisoning

Primary poisoning

This product is designed for use indoors. The use of the product will not result in primary poisoning of birds and mammals.

Secondary poisoning

The risks of secondary poisoning of birds and mammals is estimated for the food chains:
water => fish => fish eating bird or mammal and
soil => earthworm => worm-eating bird or mammal.

As transfluthrin has a high log Kow (>5), a bioaccumulation potential of the substance is indicated and thus assessment of secondary poisoning is required.

According to Guidance on BPR (2017), the scenario for secondary poisoning foresees that 50% of the diet comes from a local area and 50% of the diet comes from a regional area. Therefore, PEClocal water, PEClocal soil and PEC groundwater values are reduced to 50% for the assessment of PECbiota.

Default values for biomagnification in fish (BMF) have been picked from table 23, Guidance on BPR (2017). The experimental BCF fish for transfluthrin is estimated to be < 2000 L/kg, leading to a BMF of 1. Based on a PEC_{water} of 1.31E-08mg/l for scenario 1 and 6.94E-08mg/l for scenario 2and an average BCF for fish of 1783 L/kg, a $PEC_{oral,fish}$ of 1.16E-05 mg/kg_{wwt} transfluthrin and 6.19E-05 mg/kg_{wwt} can be derived, respectively.

The concentration of transfluthrin in earthworms is calculated according to equation 100 to 104d of the Guidance on the BPR (2017). Using the estimated log K_{ow}- value of 5.94, the

$BCF_{earthworm}$ is estimated to be 10452 L/kg. In case of scenario 1 the concentration of transfluthrin in groundwater and soil (concentration averaged over a period of 180 days) due to the application of OWADEX is predicted to be 1.11E-06 µg/l and 2.01E-05 mg/kg_{wwt}, leading to a $PEC_{oral,worm}$ 5.34E-06 mg/kg wet worm. In case of scenario 2 the concentration of transfluthrin in groundwater and soil (concentration averaged over a period of 180 days) due to the application of OWADEX is predicted to be 5.95E-06 µg/l and 1.12E-04 mg/kg_{wwt}, leading to a $PEC_{oral,worm}$ 2.86E-05 mg/kg wet worm

Summary table on calculated PEC values for secondary poisoning		
	$PEC_{oral,fish}$	**$PEC_{oral,worm}$**
	[mg/kg_{wwt}]	[mg/kg_{wwt}]
Scenario 1	1.16E-05	5.34E-06
Scenario 2	6.19E-05	2.86E-05

2.2.8.3. Risk characterisation

Atmosphere

Under the proposed conditions of use, transfluthrin may be emitted to outdoor air, as a result of ventilation in treated rooms. However, according to the ESD, effects on non-target species are expected to be low, even for outdoor uses of insecticides, because of instant dilution and turbulence in air. Exposure of the air compartment is thus limited in time and restricted to local scale. Accordingly, quantitive risk characterisation for biota is not performed for this compartment.

Furthermore, the transfluthrin Assessment Report (2014) concludes that, considering the relative small total amounts used and the volume of the atmospheric compartment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible.

Moreover, as explained in ESD, in the cleaning step: the fraction emitted to air during cleaning events is considered to be negligible. Releases to air are not considered to be significant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	2.45E-06
Scenario 2	1.31E-05

Conclusion: The calculated PEC/PNEC values for the sewage treatment plant (STP) are significantly < 1. Therefore, the proposed use of the product OWADEX does not pose a risk to microorganisms in the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1	7.41E-03	3.97E-02
Scenario 2	3.97E-02	2.12E-01

Conclusion: The PEC/PNEC values for surface water and sediment are <1 in all scenario, indicating that there is no unacceptable risk to both compartments.

Insecticides applied indoor will generally not reach directly the environmental compartments. Therefore, indoor receiving materials will be considered as "intermediate compartments". But as a matter of fact most surfaces will be cleaned. The cleaning step will therefore lead to releases either to wastes or to waste water. Therefore the sewage treatment plants (STP) is considered as one of the main "receiving compartment" where insecticides will be released through wet cleaning events. Then, the "final" environmental compartment will logically be the surface water, the soil (from sludge application) and then the groundwater.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	2.69E-04
Scenario 2	1.44E-03

Conclusion: In all cases, PEC/PNEC values are < 1 for the active substance. As a result, it can be concluded that use of the product will not result in unacceptable risk to the terrestrial compartment.

Groundwater

Calculated PEC/PNEC values	
	PEC/PNEC$_{gw}$
Scenario 1	1.11E-05
Scenario 2	5.95E-05

Conclusion: The predicted environmental concentration for groundwater for transfluthrin did not exceed the maximum permissible concentration laid down by the EU Drinking Water Directive 98/83/EC of 0.10 µg/l .

Metabolites

Calculated PEC/PNEC values					
	TFB-OH	TFB-COOH		DCVA	
	$PEC/PNEC_{water}$	$PEC/PNEC_{water}$	$PEC/PNEC_{soil}$	$PEC/PNEC_{water}$	$PEC/PNEC_{soil}$
Scenario 1	2.41E-08	4.04E-08	5.42E-05	6.80E-07	5.48E-04
Scenario 2	1.28E-07	2.14E-07	3.02E-04	3.60E-06	3.05E-04

Conclusion: No unacceptable risk to surface water and soil has been identified, as PEC/PNEC ratio is less than 1 for all metabolites.

Primary and secondary poisoning

Primary poisoning

Not relevant for this product.

Secondary poisoning

Summary table on secondary poisoning		
Scenario	PEC/PNEC mammals via fish	PEC/PNEC mammals via earthworms
Scenario 1	1.73E-06	8.00E-10
Scenario 2	9.28E-06	4.28E-09

Conclusion: All calculated PEC/PNEC values for secondary poisoning of mammals are <1. Therefore, no unacceptable risk is expected from the use of Owadex.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

The formula will not be released directly to the environment.

Screening Step 2: Identification of relevant substances

Other than the active substance, there are no environmentally classified ingredients or substances of concern in the product.

Screening Step 3: Screen on synergistic interactions

There are no known synergists or components declared as synergists present in the product.

Screening step	
	Significant exposure of environmental compartments? (Y/N) No
	Number of relevant substances >1? (Y/N) None
	Indication for synergistic effects for the product or its constituents in the literature? (Y/N) No

Aggregated exposure (combined for relevant emmission sources)

Summary table of calculated ΣPEC/PNEC values					
Active substance	**$\Sigma PEC/PNEC_{STP}$**	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{sed}$**	**$\Sigma PEC/PNEC_{soil}$**	**ΣPEC_{GW}**
Transfluthrin	1.55E-05	4.71E-02	2.51E-01	1.71E-03	7.06E-05

Conclusion: No unacceptable risk has been identified for aggregated exposure, as ΣPEC/PNEC ratio is less than 1. The aggregated exposure is acceptable.

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

The product OWADEX is to be used by general public as insecticide passive diffuser to control flying insects (flies, mosquitoes and fruit flies) indoors (bathroom, kitchen and rooms) and ants in a cabinet under a sink.
Considering the active substance and its metabolites, taking into account the intended dose (3.45% w/w of Transfluthrin), risks to the environment following the use of OWADEX are acceptable for all the compartments and all the scenarios, with respect to the use recommendations.

➔ **Therefore, the risk for the environment of the product OWADEX is acceptable when used according to the use recommendations.**

2.2.9. Measures to protect man, animals and the environment

Please see §2.1.4 and §2.1.5 above and the SPC.

2.2.10. Assessment of a combination of biocidal products

Not relevant. A use with other biocidal products is not intended.

2.2.11. Comparative assessment

Transfluthrin is not a candidate for substitution. As a result, a comparative assessment is not required.

3 ANNEXES

3.1 List of studies for the biocidal product (family)

List of studies for OWADEX					
Author(s)	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published**	**Data protection Claimed (Yes / No)**	**Owner (PUB / ORG)**	**Date of first submission**
Efficacy					
[redacted]	2021	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST MUSCA DOMESTICA (SIM-USE TEST) Product: OWADEX Report no.: LZ/ MD95-Md/ 14122020-06042021 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2021	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST CULEX PIPIENS (Sim-useTEST) Product: OWADEX Report no.: LZ/ MD95-Cp/ 14122020-06042021 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2021	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST AEDES ALBOPICTUS (Sim-useTEST) Product: OWADEX Report no.: LZ/ MD95-Aalb/ 14122020-06042021 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2021	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST DROSOPHILA MELANOGASTER (Sim-use TEST) Product: OWADEX Report no.: LZ/ MD95-Dm/ 14122020-06042021 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	

List of studies for OWADEX					
[redacted]	2021	Final Report: INSECTICIDAL EFFICACY EVALUATION OF "OWADEX" AGAINST LASIUS NIGER – SIMULATED USE TEST Product: OWADEX Report no.: Q037A-21-01 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2022	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST CULEX PIPIENS (Sim-useTEST) Product: OWADEX Report no.: LZ/ MD95-Cp/ 23-26052022 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2022	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST CULEX PIPIENS (Sim-useTEST -part 2) Product: OWADEX Report no.: LZ/ MD95-Cp/ 20-23062022 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2022	Final Report: EFFICACY EVALUATION OF "OWADEX" AGAINST *MUSCA DOMESTICA* (Sim-useTEST without fan) Product: OWADEX Report no.: LZ/ MD95-Md/ 25-29072022 GLP: No	YES	ARGO CHEMICALS Marcin Pawlak	
APCP					
[redacted]	2021	Determination of the Physical-Chemical properties of the OWADEX product Before and After Accelerated Storage for 14 days at 54±2 °C Product: OWADEX Report No: 211034-02C GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2021	Determination of the Active Ingredient Content of the Product OWADEX, Including Validation of the Analytical Method and Emission of Certificate of Analysis Product: OWADEX Report No: 211034-01C GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	

List of studies for OWADEX					
[redacted]	2021	Determination of the Flash point of impregnating liquid of Owadex product Product: OWADEX Report No: 211034-04C GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2022	Determination of the Physical-Chemical properties of the Owadex product Product: OWADEX Study No: 22054-01C GLP: Yes	Yes	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2023	Determination of the Five Year Storage Stability and Shelf –Life Data of Owadex product: Interim Report 1 year Product: OWADEX Report No: 21134-03C GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2022	Analysis of the Corrosivity of Owadex formulation containing 3,4% Transfluthrin, in compliance with Good Laboratory Practice. Product: OWADEX Report No: DNA6728 GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2023	Determination of physico-chemical properties Thermal Stability (OECD 113) Screening Explosive Properties (EC A.14. and UN Class 1) Product: OWADEX Report No: CSL-23-0276.01 GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	
[redacted]	2023	Determination of physico-chemical properties Thermal Stability (OECD 113) Screening Explosive Properties (EC A.14. and UN Class 1) Product: OWADEX Report No: CSL-23-0277.01 GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	

List of studies for OWADEX					
[redacted]	2023	Determination of physico-chemical properties Thermal Stability (OECD 113) Screening Explosive Properties (EC A.14. and UN Class 1) Product: OWADEX Report No: CSL-23-0278.01 GLP: Yes	YES	ARGO CHEMICALS Marcin Pawlak	

3.2 Output tables from exposure assessment tools

Błąd! Nieprawidłowe łącze.

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Product is intended for non-professional use in houses. For dietary risk assessment please see p. 2.2.6.2.
The product is not intended to be used in livestock facilities or food production areas, hence no contamination of food/feedstuff is expected.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

Not relevant, IUCLID file available.

3.6 Confidential annex

See the confidential annex in a separate document.

3.7 Other

Not applicable.

3 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.