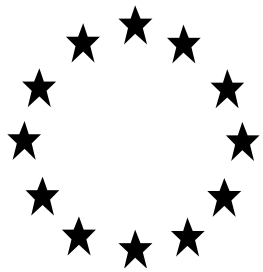
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



SAFWS002

Product type 18

Dinotefuran

Case Number in R4BP: [BC-CC062809-46]

Evaluating Competent Authority: Belgium

Date: 22 December 2022

Table of Contents

1. CONCLUSION

SAFWS002 is a printed window sticker, designed to attract and trap house flies (*Musca domestica)*, when placed on the inside of a window of a room.

EFFICACY:
The product is efficacious against house flies (*Musca domestica)*, when placed on the inside of a window of a room (30 m³). The product remains efficacious for a period up to 24 weeks (6 months).

APCP:
SAFWS002 is, based on read-across, a printed window sticker with a circular applied beige coloured paste with a weak odour of plastic foil. At 1% dilution, the pH is around 6.7 at 21°C. Its density is around 1.244 g/cm³. The viscosity is 2.241 Pa*s (20/s) to 0.915 Pa*s (100/s) at 20°C and 1.291 Pa*s (20/s) to 0.466 Pa*s (100/s) at 40°C. The product is surface active, with a surface tension of 57.9 mN/m when diluted at 1g/L.

No appreciable changes in physical-chemical properties, packaging and weight of the biocidal product were observed during (accelerated) storage. The active substance content decreased after 12 and 24 months of storage due to migration of a fraction of the active substance from the paste into the cover foil. When adding up the active substance content of stickers and foils, the active substance content was within specifications. No loss of dinotefuran of the complete test item (sticker and foil) was thus observed. Efficacy data after 12 and 24 months of storage confirm that this loss of active substance has no negative impact on the efficacy of the biocidal product.

The biocidal product is not classified for physical hazards.

HUMAN HEALTH:
Three main exposure ways are foreseen for this product: for the user during the preparation and installation of the sticker, to the general public by inhalation while being present or walking through rooms where stickers are in use, and (for toddlers and young children only) through direct contact and hand to mouth contact with the sticker.
Due to the way the product is used and already prepared when the user can apply it, expected exposure is low and not problematic. Exposure through inhalation is nearly negligible, both due to the low amount of dinotefuran present in the product, and due to the very low vapor pressure of the active substance.
As could be expected, the highest exposure by far takes place for children that comes directly into contact with the product, and start playing with it, or putting it in their mounth. It is to be noted that, even in that case, exposure remains below the AEL. However, in order to limit the risk to children and toddlers, instruction uses contain sentences such as "Place sticker on window on the inside of the windowpane out of the reach of children and pets".

ENDOCRINE DISRUPTOR:

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product SAFWS002 was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product SAFWS002.

Given the results of the calculation for the different scenario, and the addition of those instruction, it is believed that the uses proposed by the applicant are acceptable.

ENVIRONMENT:

The environmental assessment of the product SAFWS002 has been performed in accordance with the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, the technical agreement for biocides Environment (November 2011) and the ESD for Insecticides, acaricides and products to control other arthropods for household and professional uses (PT18), July 2008. The RCR values (Pec/PNEC ratio) for all relevant compartment where below the threshold level of 1 and therefore no unacceptable risk where identified for the environment. As a consequence, the used of the product SAFWS002 as proposed by the applicant is acceptable.

2. ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
SAFWS002	Belgium (Reference MS)
SAFWS002	France (concerned MS)
SAFWS002	Germany (concerned MS)
SAFWS002	Greece (concerned MS)
SAFWS002	Italy (concerned MS)
SAFWS002	Spain (concerned MS)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Sumi Agro France SAS
	Address	251 Rue du Faubourg Saint Martin 75010 PARIS France
Authorisation number	BE2022-0039	
Date of the authorisation	22/12/2022	
Expiry date of the authorisation	21/12/2027	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Sumi Agro France SAS
Address of manufacturer	251 Rue du Faubourg Saint Martin 75010 PARIS France
Location of manufacturing sites	Ledin Print und Media Center GmbH Neuhartshöfe 16 85080 Gaimersheim Germany

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

Active substance	Dinotefuran
Name of manufacturer (according art. 95)	LKC Chem-Regs Ltd (Acting for Mitsui Chemicals Agro. Inc. (Japan))
Address of manufacturer (according art. 95)	LKC Chem-Regs Ltd : 40 Mespil Road, Dublin 4, D04 C2N4, Ireland (LKC) Mitsui Chemicals Agro. Inc. : Nihonbashi Dia Building, 1-19-1 Nihonbashi, Chuo-ku Tokyo 103-0027 Japan
Location of manufacturing sites	Mitsui Chemicals Agro.Inc. : Omuta Works, 30 Asamuta-Machi, Ohmuta Shi Fukuoka 836-8610 Japan

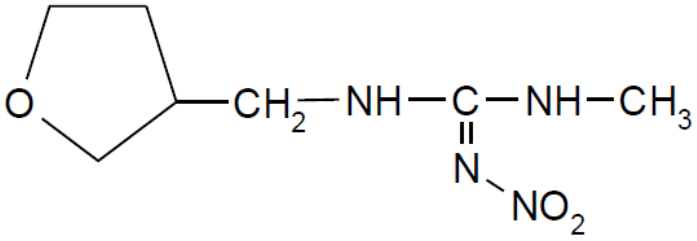
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Dinotefuran
IUPAC or EC name	(RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine
EC number	Not available
CAS number	165252-70-0
Index number in Annex VI of CLP	Not available
Minimum purity / content	991 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

Dinotefuran fulfils two (vP and T) out of the 3 criteria and must be considered as a ”candidate for substitution”.

A public consultation was started by ECHA on 29/11/2013. The deadline for providing information was 28/01/2014.

No information was received or if received, no information was published.

A draft comparative assessment is provided by the applicant in chapter 2.2.11.

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 (w/w%)**
Dinotefuran	(RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl) guanidine	Active substance	165252-70-0	Not available	0.242% (technical) 0.240% (pure) Purity ≥ 99.1%

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

The source of the active substance dinotefuran is identical to the active substance in respect of which the initial risk assessment was carried out.

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains no substances of concern. Please see confidential annex for further details on the composition and non-active substances.

2.1.2.6 Type of formulation

RB Bait (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard statement	H412 Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	Not required
Hazard statements	H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P273 Avoid release to the environment. P501 Dispose of contents to domestic waste (specified from "Dispose of contents/container in accordance with local/regional/national/international regulation")
Note	The product contains a bittering agent (denatonium benzoate).

No P statements triggered by the criteria in CLP have been excluded.

Instead, P102, P103 and P264 are proposed on a voluntary basis to comply with best practices. Only P273 (recommended) and P501 are triggered by H412.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Flysticker

Product Type	PT 18: Insecticides, acaricides and products to control other arthropods.
Where relevant, an exact description of the authorised use	Ready to use window sticker against house flies for indoor use. Window stickers acting as carriers for an insecticidal paste.
Target organism (including development stage)	*Musca domestica* – House fly : Adults
Field of use	Indoors
Application method(s)	Place sticker on window on the inside of the windowpane.
Application rate(s) and frequency	Use one sticker per room of 30 m³ Effective up to 6 months.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Folding cardboard (outer packaging) including 2 cards with 2 stickers (Ø ca. 75 mm) each, in total 4 stickers per folding cardboard.

2.1.4.2 Use-specific instructions for use

Open the outer packaging and take a paper card out of the folding cardboard. Remove white silicon paper cover. Peel off the sticker from the backing layer. Place sticker on window on the inside of the windowpane out of the reach of children and pets. Protect remaining stickers again with the white silicon paper cover and return to folding cardboard. Use one sticker per room of 30 m³; for larger room use one sticker per 30m³ without exceeding 8 stickers per house.

Replace/remove stickers after 6 months.

Application once or twice per year, with efficacy lasting for 6 months.

2.1.4.3 Use-specific risk mitigation measures

Do not touch the frontside of the activated sticker.

Do not apply the sticker on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock

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

See 2.1.5.3

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

See 2.1.5.4

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

See 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use. Avoid cleaning of the stickers. If this occurs, immediately dispose cleaning cloth to domestic waste. Inform the registration holder if the treatment is ineffective Avoid continuous use of the product If the infestation persists contact a professional.

2.1.5.2 Risk mitigation measures

-

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

Particulars of likely direct or indirect effects: No information available. Specific information on symptoms and effects caused by the product are unknown. If medical advice is needed, have product container or label at hand. If the use instructions are followed direct contact with the product is unlikely. **First aid instructions:** **IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.** **IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor** **IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.**

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
Emergency measures to protect the environment:
Environmental precautions: Discharge into the environment must be avoided.
Contaminated material should be disposed of in compliance with national and local provisions.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents to domestic waste.
Non-contaminated packages may be recycled.

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

Keep out of reach of children and non-target animals/pets.
Recommended storage temperature: 20°C.
Do not store above 40°C.
Protect from frost and sunlight.
Store in a dry place, in its original packaging.
Shelf life: 2 years.

2.1.6 Other information

Application codes:
File VIII: Type of formulation
VIII.5.1 paste
VIII.5.1.1 ready-for-use bait

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)
Folding cardboard (outer packaging)	Folding cardboard (outer packaging) including two cards of ca. 90-100 mm x ca. 160-170 mm with 2 stickers (Ø ca. 75 mm) each. Thus, in total 4 stickers per folding cardboard. Stickers (geometric shape, or alternatively a butterfly or flower motive) are printed on self-adhesive paper card (carrier), covered with a protective, removable silicon paper.	Cardboard, self-adhesive paper card (carrier), silicone paper	N/A	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 3.1.

2.1.8.2 Access to documentation

A letter of access is provided to data on the active substance dinotefuran (see Section 13 of the IUCLID dossier).

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Fly sticker

Product Type(s)	PT 18: Insecticides, acaricides and products to control other arthropods.
Where relevant, an exact description of the authorised use	Window stickers acting as carriers for an insecticidal paste
Target organism (including development stage)	*Musca domestica* – House fly Adults
Field of use	Indoors
Application method(s)	Open the outer packaging and take a paper card out of the folding cardboard. Remove white silicon paper cover. Peel off the sticker from the backing layer. Place sticker on window on the inside of the windowpane out of the reach of children and pets. Protect remaining stickers again with the white silicon paper cover and return to folding cardboard.
Application rate(s) and frequency	Use one sticker per room of 30 m^3 or two stickers for a larger room (up to 8 stickers per house). Replace/remove stickers after 6 months. Application once or twice per year, with efficacy lasting for 6 months.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	Folding cardboard (outer packaging) including 2 cards with 2 stickers (Ø ca. 75 mm) each, in total 4 stickers per folding cardboard.

2.2.2 Physical, chemical and technical properties

[redacted]

Lastly, 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	EPA OPPTS 830.6303 (Physical State); Visual inspection	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	Solid sticker with a circular applied viscous liquid (paste) on it.	[redacted]
Colour at 20 °C and 101.3 kPa	equivalent or similar to EPA OPPTS 830.6302 (Color) Deviation: no colour systems/scales were used Visual inspection	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	A transparent sticker with a yellow printed flower on it. The applied paste is beige coloured.	[redacted]
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304 (Odor)	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	Weak odour of plastic foil	[redacted]
Acidity / alkalinity	CIPAC MT 75.3 [using Knick portamess	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 %	6.7 ± 0.1 [n=2, 1% dilution, at 21.2 °C]	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Typ 913 pH-meter and Knick SE102N pH-electrode]	w/w of AS in the biocidal mixture		
Relative density / bulk density	OECD 109 [using Mettler Toledo Density Determination Kit, hydrostatic balance]	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	Density: 1.244 g/cm³ ± 0.004 [n=3, at 21.5 °C]	[redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Cfr. Methods above for appearance, pH and density [using HPLC-UV, method MV193, as validated]	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	Appearance: No appreciable changes (state, colour, odour). Packaging: No appreciable changes. Weight loss: Between 3.45% and 3.69%. pH: Start: 6.7 ± 0.1 [n=2, 1% dilution, at 21.2 °C] T8w: 6.7 ± 0.1 [n=2, 1% dilution, at 20.8 °C] Density: Start: 1.244 g/cm³ ± 0.004 T8w: 1.255 g/cm³ ± 0.004 [n=3, at 21.5 °C] Content active substance: Start : 0.245%	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T8w : 0.235% (-4.08%) [Storage performed for 8 weeks at 40°C ± 2] RMM: 'Do not store above 40°C' shall appear on the label	
Storage stability test – **long term storage at ambient temperature**	Cfr. Methods above for appearance, pH and density [using HPLC-UV, method MV193, as validated]	SAFWS001; Batch No. 170728, 100 mg of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	Appearance: No appreciable changes (state, colour, odour) throughout testing. Packaging: No appreciable changes throughout testing. Weight loss: T6m: Between 0.18% and 0.22% T12m: Between 1.08% and 1.16% T24m: Between 1.01% and 1.15% pH: Start: 6.7 ± 0.1 [n=2, 1% dilution, at 21.2 °C] T6m: 6.5 ± 0.1	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[n=2, 1% dilution, at 20.0 °C] T12m: 6.4 ± 0.0 [n=2, 1% dilution, at 20.2 °C] T24m: 6.5 ± 0.1 [n=2, 1% dilution, at 20.5 °C] Density: Start: 1.244 g/cm³ ± 0.004 T6m: 1.249 g/cm³ ± 0.003 T12m: 1.244 g/cm³ ± 0.002 T24m: 1.240 g/cm³ ± 0.010 Content active substance: Start : 0.245% T6m : 0.223% (-8.98%) T12m : 0.171% (-30.2%) T24m : 0.138% (-43.7%) [Storage performed for 2 years at 20°C ± 2] Results after 6 months show a decrease in active substance content on the sticker exceeding	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			10%. However, it was demonstrated in another study (reported in the same reference) that nearly all of the 'lost' active substance had migrated to the covering foil during the storage period: Content active substance migrated into foil: T12m : 0.109% T24m : 0.119% As such, degradation of the active substance has been clearly shown to not occur. Any shelf life claim exceeding 6 months must be granted based on acceptable efficacy studies with aged product.	
Storage stability test – **low temperature stability test for liquids**	Waived	-	RMM 'Protect from frost' shall appear on the label	[redacted]
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 folding cardboard outer packaging. As these packagings	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			preclude 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 applied to the window (and thus in use) is covered in the efficacy section in the PAR since the use automatically results in exposure to light.	
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' shall appear on the label Temperature: See results under "Storage stability test". Exposure to changes in temperature and humidity once applied to the window (and thus in use) is covered in the efficacy section in the	[redacted] [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			PAR.	
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"	[redacted]
Wettability	Not applicable since the biocidal product is RTU.			
Suspensibility, spontaneity and dispersion stability	Not applicable since the biocidal product is not a wettable powder, aqueous suspension concentrate, water dispersible granule, water dispersible powder or formulation forming suspensions on dilution with water.			
Wet sieve analysis and dry sieve test	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	Not applicable since the biocidal product is not, nor is intended to form, an emulsion.			
Disintegration time	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	Not applicable since the biocidal product is not a powder or granule.			
Persistent foaming	Not applicable since the biocidal product is RTU and need not be applied in water for use.			
Flowability/Pourability/Dustability	Not applicable since the biocidal product is not a granular formulation, suspension concentrate, capsule suspension or suspoemulsion.			
Burning rate — smoke generators	Not applicable since the biocidal products is not a smoke generator.			
Burning completeness — smoke generators	Not applicable since the biocidal products is not a smoke generator.			
Composition of smoke — smoke generators	Not applicable since the biocidal products is not a smoke generator.			
Spraying pattern — aerosols	Not applicable since the biocidal products is not an aerosol.			
Physical compatibility	Not applicable since the biocidal product is not intended to be used with other products.			
Chemical compatibility	Not applicable since the biocidal product is not intended to be used with other products.			
Degree of dissolution and dilution stability	Not applicable since the biocidal product is RTU and need not be dissolved.			
Surface tension	EU Method A.5	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per	57.9 mN/m ± 0.2 Surface active.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	[using Krüss L20, ring method]	sticker, 0.24 % w/w of AS in the biocidal mixture	[1 g/l dilution, 20°C, n=5]	
Viscosity	CIPAC MT 192 [using rotational viscometer (dynamic), Anton Paar Reholab QC with software]	SAFWS001; Batch No. 170728, [redacted] of biocidal mixture per sticker, 0.24 % w/w of AS in the biocidal mixture	2.241 Pa*s (shear rate: 20/s) to 0.915 Pa*s (shear rate: 100/s) at 20°C. 1.291 Pa*s (shear rate: 20/s) to 0.466 Pa*s (shear rate: 100/s) at 40°C. Non-newtonian properties	[redacted]

Conclusion on the physical, chemical and technical properties of the product
SAFWS002 is, based on read-across, a printed window sticker with a circular applied beige coloured paste with a weak odour of plastic foil. At 1% dilution, the pH is around 6.7 at 21°C. Its density is around 1.244 g/cm³. The viscosity is 2.241 Pa*s (20/s) to 0.915 Pa*s (100/s) at 20°C and 1.291 Pa*s (20/s) to 0.466 Pa*s (100/s) at 40°C. The product is surface active, with a surface tension of 57.9 mN/m when diluted at 1g/L. No appreciable changes in physical-chemical properties, packaging and weight of the biocidal product were observed during (accelerated) storage. The active substance content decreased after 12 and 24 months of storage due to migration of a fraction of the active substance from the paste into the cover foil. When adding up the active substance content of stickers and foils, the active substance content was within specifications. No loss of dinotefuran of the complete test item (sticker and foil) was thus observed. Efficacy data after 12 and 24 months of storage confirm that this loss of active substance has no negative impact on the efficacy of the biocidal product.

2.2.3 Physical hazards and respective characteristics

[redacted]

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	Desktop Assessment on Differential Scanning Calorimetry (DSC)	SAFWS001; Batch No. 170728, biocidal mixture	Exothermic event from 145.10°C which had a heat of decomposition of 622.10 J/g. No further events were observed. The sample shows evidence of having explosive properties, therefore further testing was recommended and performed.	[redacted]
	EC A.14. Differential Scanning Calorimetry (DSC) Explosive Properties - Mechanical Sensitivity – Impact Explosive Properties - Thermal Sensitivity - Koenen-Test	SAFWS002; Batch No. 20210910, biocidal mixture	DSC (n=3): A first exothermic event was observed between 120-130°C which had an average energy release of -310 J/g. A second exothermic event was observed between 310-330°C which had an average energy release of >-980 J/g. Impact test (n=6, 10 kg hammer from 40 cm height): No significant reaction observed. Koenen-Test	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(n=3/orifice plate diameter, 2.0 and 6.0 mm diameter tested): Unchanged appearance, main reaction: flame. The test item has no explosive properties according to Regulation (EC) No 440/2008, Part A, A.14.	
Flammable gases	Not applicable since the biocidal product is not a gas.			
Flammable aerosols	Not applicable since the biocidal product is not an aerosol, nor intended to be sprayed.			
Oxidising gases	Not applicable since the biocidal product is not a gas.			
Gases under pressure	Not applicable since the biocidal product is not a gas.			
Flammable liquids	EU Method A.9	SAFWS001; Batch No. 170728, biocidal mixture	No flash point before boiling (>60°C) The test substance is not considered to be flammable and not to meet the GHS/CLP criteria for classification.	[redacted]
Flammable solids	The biocidal product is a sticker (a solid) to which a biocidal paste (liquid) is applied. In accordance with CA-Nov16-Doc.4.3 – Final document, only the biocidal paste was tested in light of the flammable liquids endpoint.			
Self-reactive substances and mixtures	UN Class 4, Division 4.1	SAFWS002; Batch No. 20210910, biocidal mixture	The overall decomposition energy in the DSC measurements is above the threshold of 300 J/g and the onset of the exothermal	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			decomposition is below 200 °C. Therefore, self-reactive properties cannot be excluded.	
	UN Test H.4	SAFWS002, biocidal mixture	SADT >75°C for a 50 kg package. Therefore, self-reactive properties must not be considered for classification.	[redacted]
Pyrophoric liquids	Waived	-	[redacted]	[redacted]
Pyrophoric solids	The biocidal product is a sticker (a solid) to which a biocidal paste (liquid) is applied. In accordance with CA-Nov16-Doc.4.3 – Final document, only the pyrophoric liquids endpoint is considered.			
Self-heating substances and mixtures	The biocidal product is a sticker (a solid) to which a biocidal paste (liquid) is applied. 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 applicable to liquids.			
Substances and mixtures which in contact with water emit flammable gases	Waived	-	[redacted]	-
Oxidising liquids	EC A.21.	SAFWS002; Batch No. 20210910, biocidal mixture	Mean pressure rise time test item (n=6): 27.79s Mean pressure rise time reference item (n=5): 2.29s The test item showed no	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			oxidizing properties according to Regulation (EC) No. 440/2008 Method A.21.	
Oxidising solids	The biocidal product is a sticker (a solid) to which a biocidal paste (liquid) is applied. In accordance with CA-Nov16-Doc.4.3 – Final document, only the oxidising liquids endpoint is considered.			
Organic peroxides	Not applicable since the biocidal product does not contain organic peroxide structures (R-O-O-R').			
Corrosive to metals	UN Test Methods C.1	SAFWS002; biocidal mixture	Weight loss: - Alu: 0.03% - Steel: 0.21% Localized corrosion: - Alu: None - Steel: max. 39 µm Overall thus not corrosive as per the guideline.	[redacted]
Auto-ignition temperatures of products (liquids and gases)	Waived	-	Not applicable since no flash point could be determined for the biocidal paste prior to boiling (>60°C).	[redacted]
Relative self-ignition temperature for solids	The biocidal product is a sticker (a solid) to which a biocidal paste (liquid) is applied. 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	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 biocidal product is not classified for physical hazards.

2.2.4 Methods for detection and identification

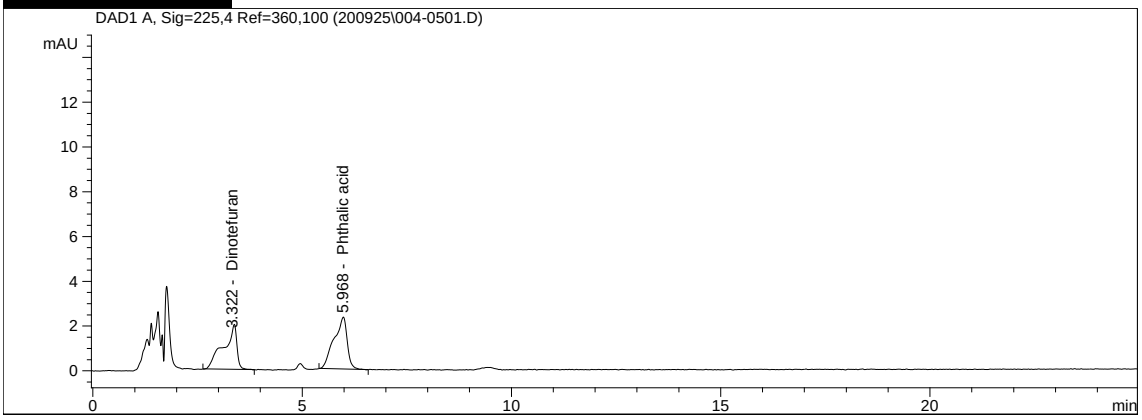
[redacted]

For a comparison regarding full qualitative and quantitative information on the composition of these composition, refer to the confidential annex to the PAR.

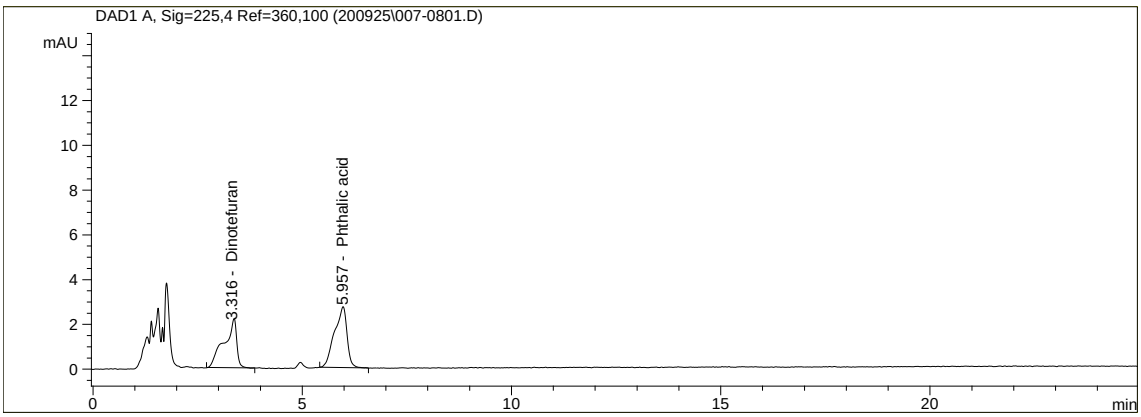
Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
[redacted]									

[redacted]

[redacted]



[redacted]



[redacted]

[redacted]

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 tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
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		
Not required as proposed use will not lead to contact with food/feeding stuff									

Conclusion on the methods for detection and identification of the product*
The active substance content in the test item can be determined using HPLC-UV, in accordance with internal method MV193 "SMA: HPLC-Determination of dinotefuran in Fly sticker", which has been validated in accordance with SANCO/3030/99 rev.4. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. [redacted] For other analytical methods refer to the CAR of the active substance. (*)Note: A formulation change has been shown not to impact the specificity.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group 3: Pest control - Product type 18: Insecticides, acaricides and products to control other arthropods.
The biocidal product is intended for use indoor by the general public, to control adult house flies (*Musca domestica*) in private houses.

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

Organisms to be controlled are adult house flies (*Musca domestica*).

Organisms or objects to be protected are private houses against house fly infestation.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product achieves over 80% knock-down or mortality in house flies within 8-10 hours after exposure, and over 90% mortality after 24 hours.
Unacceptable suffering is not considered relevant for use of insecticide against flies.

2.2.5.4 Mode of action, including time delay

Dinotefuran is a neonicotinoid in the nitroguanidine class, acting as an agonist of insect nicotinic acetylcholine receptors, and disrupting the insect's nervous system by inhibiting the nicotinic acetylcholine receptors.
Rapid knockdown and death occur within several hours after contact or ingestion of dinotefuran.

2.2.5.5 Efficacy data

[redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide (PT18) against flies	indoor use in private houses by non-professionals	[redacted]	house fly (*Musca domestica*) 3-4 days old adults mixed sex 100 per replicate	simulated-use test (large room test)	Test system: free flying adult house flies in 30 m³ practical test rooms with two external windows. 2 foor sources are present. One window with sticker per room (0.24mg a.s. per sticker/room) Exposure time: Knock-down is evaluated after 8 - 10 hours and mortality after 24 hours Residuality: new flies were exposed to the product 2, 4, 8, 12, 16, 20 and 24 weeks after activation. 4 replicates temperature: 22 – 27°C RH : 27 – 51%	Results: % Knock-down after 8 – 10h and Mortality % after 24h % K.D. / % M fresh 87 / 98 week 2 93 / 100 week 4 85 / 93 week 8 80 / 96 week 12 90 / 94 week 16 82 / 95 week 20 83 / 91 week 24 75 / 87 Negative control mortality after 24 hours ranged from 4 – 10%. Conclusion: From week 1 – week 20, >80% knock-down and >90% mortality is achieved.	[redacted]
Insecticide	indoor use in	[redacted]	house fly	simulated-	Test system: free flying	Results:	[redacted]

(PT18) against flies	private houses by non-professionals	[redacted]	(*Musca domestica*) 3-4 days old adults mixed sex 100 per replicate	use test (large room test)	adult house flies in 30 m³ practical test rooms with two external windows. 2 foor sources are present. One window with sticker per room (0.24mg a.s. per sticker/room) <u>Exposure time:</u> Knock-down is evaluated after 8 hours and mortality after 24 hours <u>Residuality:</u> new flies were exposed to the product 12, 16, 20 and 24 weeks after activation. 4 replicates temperature: 22 – 26°C RH : 22 – 51%	% Knock-down after 8h and Mortality % after 24h | | % K.D. | % M | | fresh | 96 | 97 | | week 12 | 92 | 95 | | week 16 | 95 | 97 | | week 20 | 91 | 94 | | week 24 | 83 | 96 | Negative control mortality after 24 hours ranged from 2 – 10%. <u>Conclusion:</u> After a storage period at ambient temperature for 12 months, the product shows >80% knock-down and >90% mortality. This effect remains 24 weeks after activation.	[redacted]
Insecticide (PT18) against flies	indoor use in private houses by non-professionals	[redacted]	house fly (*Musca domestica*) 3-4 days old adults mixed sex 100 per replicate	simulated-use test (large room test)	<u>Test system:</u> free flying adult house flies in 30 m³ practical test rooms with two external windows. 2 foor sources are present. One window with sticker per room (0.24mg a.s. per sticker/room) <u>Exposure time:</u> Knock-down is evaluated after 8 hours and mortality after 24 hours <u>Residuality:</u> new flies were exposed to the product 12	<u>Results:</u> % Knock-down after 8h and Mortality % after 24h | | % K.D. | % M | | fresh | 89 | 97 | | week 12 | 93 | 99 | | week 24 | 81 | 91 | Negative control mortality after 24 hours ranged from 1 – 3%. <u>Conclusion:</u> After a storage period at ambient temperature for 24 months, the product	[redacted]

					and 24 weeks after activating 4 replicates temperature: 21 – 28°C RH : 20 – 50%	shows >80% knock-down and >90% mortality. This effect remains 24 weeks after activation.	
Insecticide (PT18) against flies	indoor use in private houses by non-professionals	[redacted]	house fly (*Musca domestica*) 3-4 days old adults mixed sex 100 per replicate	simulated-use test (large room test) Comparative efficacy test of two formulations (bridging study)	Test system: free flying adult house flies in 30 m³ practical test rooms with two external windows. 2 foor sources are present. One window with sticker per room (0.24mg a.s. per sticker/room) Exposure time: Knock-down is evaluated after 8 hours and mortality after 24 hours 4 replicates temperature: 22 – 23°C RH : 35 – 43%	Results: % Knock-down after 8h and Mortality % after 24h % K.D. / % M SAFWS001: 81 / 90 SAFWS002: 84 / 89 N.C.: 0 / 0 Conclusion: both product formulations show similar knock-down and mortality rates, indicating the change in the composition does not have an impact on the efficacy of the product.	[redacted]

Conclusion on the efficacy of the product

The biocidal product shows good efficacy against house flies (*Musca domestica*) during a period of 6 months (24 weeks), with >80% knock-down and mortality rates of 90% for the fresh product as well as after a storage period at ambient temperatures for 12 months and 24 months.

[redacted]

2.2.5.6 Occurrence of resistance and resistance management

It is postulated that dinotefuran affects the nicotinic acetylcholine; binding in a mode that differs from other neonicotinoid insecticides (the Insect Resistance Action Committee (IRAC) group 4A).
In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted. Therefore, the same strategies to reduce the risk of resistance developing such as recommendations to treat to levels that ensure complete kill of target pest infestations and to use dinotefuran alternately with substances with a different mode of action are recommended.

2.2.5.7 Known limitations

No limitations are known. The product is pasted on the inside of a window, where it is submitted to effect of sunshine. The efficacy tests were performed in all type of weather conditions, for a period of 24 weeks. No significant effects of sunlight is observed.

2.2.5.8 Evaluation of the label claims

The product is efficacious against house flies (Musca domestica), when placed on the inside of a window, in a room up to 30 m^3. The product remains efficacious for a period up to 24 weeks (6 months).

The shelf life of 2 years is also supported by the efficacy data.

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

Not relevant. The biocidal product is not intended to be authorised for use with other biocidal product(s).

2.2.6 Risk assessment for human health

No toxicological studies have been conducted with SAFWS002. The biocidal product consists of a paper-based sticker onto which the mixture as described in the confidential annex has been applied ([redacted] of biocidal mixture, containing 0.24 mg of the active substance per sticker). All concentrations discussed in the following sections refer to the biocidal mixture without the sticker matrix, i.e. the paste formulation that is printed onto the sticker backing.

The biocidal mixture contains 0.24% dinotefuran as active substance, which is not classified for human health effects. The biocidal mixture contains a component that is classified as eye damaging and as skin sensitizer but at a level below the generic concentration limit triggering classification of a mixture.

In addition, it contains water and feed components based on food ingredients which are of no toxicological relevance.

The toxicological hazard assessment for the biocidal mixture relies on the information available on the components.

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	The biocidal mixture does not contain components that are classified for skin corrosion and irritation at levels that trigger classification of the mixture.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.1.1 of the IUCLID file and to the confidential annex of this PAR.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes
Justification for the value/conclusion	The biocidal mixture does not contain components that are classified for eye irritation at levels that trigger classification of the mixture.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.1.2 of the IUCLID file and to the confidential annex of this PAR.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	The biocidal mixture does not contain components that are classified as irritating to the respiratory tract.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study technically not feasible.
Justification	There are no designated tests for respiratory tract irritation. The available information on the ingredients allows the conclusion that the biocidal product is not a respiratory tract irritant. In addition, the biocidal product is a window sticker with only non-volatile components and thus not in an inhalable form.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin
Justification for the value/conclusion	The biocidal mixture does not contain components that are classified for skin sensitisation at levels that trigger classification of the mixture.
Classification of the product according to CLP and DSD	No classification.

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.3.1 of the IUCLID file and to the confidential annex of this PAR.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitizer
Justification for the value/conclusion	The biocidal mixture does not contain components that are known to be respiratory sensitizers.
Classification of the product according to CLP and DSD	No classification.

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.3.2 of the IUCLID file and to the confidential annex of this PAR. In addition, the biocidal product is a window sticker with only non-volatile components and is thus not in an inhalable form.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Non-toxic via the oral route
Justification for the selected value	The biocidal mixture does not contain components that are classified for acute oral toxicity at a concentration exceeding the generic cut-off value of ≥ 0.1% (w/w).
Classification of the product according to CLP and DSD	No classification.

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.5.1 of the IUCLID file and to the confidential annex of this PAR.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Non-toxic via the inhalation route
Justification for the selected value	The biocidal mixture does not contain components that are classified for acute inhalation toxicity at a concentration exceeding the generic cut-off value of ≥ 0.1% (w/w).
Classification of the product according to CLP and DSD	No classification.

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.5.2 of the IUCLID file and to the confidential annex of this PAR.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Non-toxic via the dermal route
Justification for the selected value	The biocidal mixture does not contain components that are classified for acute dermal toxicity at a concentration exceeding the generic cut-off value of ≥ 0.1% (w/w).
Classification of the product according to CLP and DSD	No classification.

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	Testing on the product/mixture does not need to be conducted. 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) and synergistic effects between any of the components are not expected. Please refer to Section 8.5.3 of the IUCLID file and to the confidential annex of this PAR.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Dinotefuran
Value(s)*	70%
Justification for the selected value(s)	[redacted]

Data waiving	
Information requirement	Study scientifically not necessary / other information available
Justification	The human risk assessment for SAFWS002 shows acceptable risks using the EFSA default value. Experimental data for the biocidal product are therefore not necessary.

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

According to the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, the biocidal product contains no substances of concern:

1. Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).
2. Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation). This criterion identifies other active substances in the biocidal product that act as co-formulants (e.g. in-can preservatives). It is noted that active substances (acting as co-formulants in a product) should be regarded as SoCs because, due to their intrinsic biological activity, they are likely to possess toxicological activity. It is also noted that as many active substances do not hold harmonised classifications under the CLP Regulation, they may fail to be identified as SoCs by the first two indents of Art 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.
3. Substances that enhance the effect of the active substance in the product, e.g. synergists. For such substances, critical information/data shall relate to the interaction between the active substance and the synergist, not only to the synergist itself. In such situations, an appropriate evaluation of the risks posed by the active substance in the presence of the synergist rather than an evaluation of the risks posed by the synergist itself should be undertaken. A generic concentration cut-off value (for their presence in a product) applicable to all synergists cannot be specified. On a case-by-case basis, a synergist should be considered a SoC, if it is present at a concentration that enhances the toxicity of the active substance, as indicated by the available data.

4. Substances that have been included in the list (the candidate list) established in accordance with the REACH Regulation, Article 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%. It is noted this criterion will ultimately capture, over and above the clearly-defined SoCs specified in Art 3(f) of the BPR, endocrine disruptors (EDs) and substances with hazards of equivalent concern to CMR 1A or 1B (under the CLP Regulation).
5. Substances for which there are Community workplace exposure limits. A generic concentration cut-off value (for their presence in a product) applicable to all such substances cannot be specified. This should be determined on a case-by-case basis depending on the hazard profile, potency and exposure potential of the substance.

Available toxicological data relating to a mixture

No toxicological data is available on the biocidal mixture.

Other

There are no other relevant information and considerations not covered above e.g. food and feeding stuffs studies, effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product and other test(s) related to the exposure to humans.

The biocidal product is not considered to have endocrine disruption (ED) properties.

It does not contain:

a) active substance(s) and/or non-active substance(s) having ED properties on the basis of the scientific criteria in Regulation (EU) 2017/2100 and/or,
b) active substance(s) and/or non-active substance(s) having ED properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, and/or,
c) active substance(s) with an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s).

With regard to the endocrine disrupting properties of the active substance it is referred to the Assessment Report.

For the assessment of co-formulants, the steps described in the guidance "CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants" were followed and documented for each co-formulant (Anonymous 2020d).

According to this assessment, the co-formulants in the biocidal product SAFWS002 do not have endocrine disruption (ED) properties.

2.2.6.2 Exposure assessment

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

Each sticker contains [redacted] of the mixture equivalent to 0.24 mg (0.24% w/w) dinotefuran. The sticker has a diameter of ca. 7.5 cm equivalent to a radius of 3.75 cm, giving rise to a surface area

$$A = \pi \times (3.75\ cm)^2 = 44.2\ cm^2.$$

The calculations are based on an efficacy of each sticker of six months. Accordingly, for the human health risk assessment, applications are envisaged to occur in 6-month intervals. It is assumed that eight stickers are used per house (one sticker per 30 m³ room or two stickers for larger rooms). Thus, eight is the maximum number of stickers applied by a single user within the service life of the stickers.

Skin contact with the dinotefuran-containing strip can occur when sticking the product onto a surface. Inhalation exposure is expected to be low because of the low vapour pressure (5.0×10^{-5} Pa at 25°C) of dinotefuran. Oral exposure is going to be negligible if the stickers are placed outside the reach of toddlers, which is part of the label instructions, especially as the mixture contains an effective bittering agent.

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	no
Dermal	n.a.	n.a.	yes	n.a.	n.a.	yes	no
Oral	n.a.	n.a.	no	n.a.	n.a.	yes	no

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	Application	Primary exposure: application of sticker	Non-professional
2	Post-application	Secondary exposure: dermal contact with sticker, oral exposure via hand-to-mouth transfer and chewing a sticker (toddlers)	General public
3	Post-application	Secondary exposure: inhalation of volatilised residues (toddlers + adults)	General public
4	Post-application	Secondary exposure: ingestion of a dead house fly (toddlers)	General public
5	Post-application	Secondary exposure: dermal contact with removed protective film, oral exposure via hand-to-mouth transfer and chewing (toddlers)	General public

Industrial exposure

Not relevant.

Professional exposure

Not relevant.

Non-professional exposure

Scenario 1 – Application of sticker

Description of Scenario 1		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		

a. Effects of Using Multiple Hands and Fingers on Haptic Performance, V Morash, Perception, 2013, volume 42, pages 759–777

Calculations for Scenario 1 (from Consexpo pest control fact sheet).

[redacted]

Summary table: exposure (mg/kg bw/day) from non-professional uses				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1	–	0.0051	–	**0.0051**

Exposure of the general public

Secondary exposure can result from touching the stickers.
Secondary scenario 2 involves toddlers touching the sticker with their hands followed by hand-to-mouth transfer. Hand-to-mouth transfer is minimised by the inclusion of an effective bittering agent into the biocidal mixture.
Secondary exposure is assessed using the US EPA SOP for Residential Exposure Assessment[1], Section 7 "Indoor Environments".

Scenario 2 – Touching of sticker and hand-to-mouth transfer

Dermal exposure is calculated as follows:

$$D = SR \times (SA / BW) \times TE \times DA$$

where: D = Systemic dose via skin (mg/kg bw/day);
SR = Surface residue concentration (mg/cm²);
SA = Surface area in contact with AS (cm^2)
BW = Body weight (kg)
TE = Daily material-to-skin transfer efficiency (fraction/day); and
DA = Dermal absorption (fraction)

In addition, exposure from hand-to-mouth activity is calculated as follows:

$$OE_{HtM} = [HR \times (F_M \times SA_H) \times (ET \times N\_Replen) \times (1-(1-SE)^{(Freq\_HtM/N\_Replen)})] \times OA / BW$$

where:
OE_{HtM} = oral dose from hand-to-mouth activity (mg/kg bw/day);
HR = hand residue loading (mg/cm²);
F_M = fraction hand surface area mouthed / event (fraction/event);
ET = exposure time (h/day);
SA_H = surface area of one hand (cm²);
N_Replen = number of replenishment intervals per hour (intervals/hour);
SE = saliva extraction factor (i.e., mouthing removal efficiency); and
Freq_HtM = number of hand-to-mouth contacts events per hour (events/hour).
OA = oral absorption (fraction)
BW = body weight (kg)
and

$$HR = SR \times TE$$

[1] US EPA: Standard Operating Procedures for Residential Pesticide Exposure Assessment. October 2012, available at https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf

Description of Scenario 2
A toddler touches a sticker with the palm of one hand. As a worst-case assumption, the entire insecticidal paste is transferred to the hand. Subsequently, the toddler licks his or her hands and thereby ingests the entire material adhering to the hand. [redacted]

Parameter	**Value**	**Justification**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Calculations for Scenario 2

Summary table: systemic exposure [mg/kg bw/day] from non-professional uses				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2 - Toddler	–*	0.022	0.130	**0.152**

* covered in Scenario 3

Scenario 3 – Inhalation of AS vapours released from stickers (adults + toddlers)

Description of Scenario 3		
A person (adult or toddler) spends the entire day in a non-ventilated room saturated with dinotefuran vapour. The SVC cannot be exceeded, independent of the actual amount of dinotefuran applied in the room. The exposure estimate is therefore independent of the actual number of stickers per room and the room volume. [redacted]		
Parameters	**Value**	**Justification**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

Calculations for Scenario 3

Summary table: systemic exposure [mg/kg bw/day] from secondary exposure				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3 - Adult	0.0011	–	–	**0.0011**
Scenario 3 - Toddler	0.0033	–	–	**0.0033**

Those value being way below the AEL long term, it is therefore propose to consider them negligible for the rest of the assessment.

Combined scenarios (non-professional exposure and general public)

Summary table: combined systemic exposure from non-professional uses (mg/kg bw/d)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1 + 3 (adults)	negligible	0.0051	–	**0.0051**
Scenarios 2 + 3 (toddlers)	negligible	0.022	0.130	**0.152**

Scenario 4 – Ingestion of dead house flies (toddlers)

Description of Scenario 4
A toddler picks up a dead house fly (killed by dinotefuran) and swallows the fly. A reverse risk assessment scenario is developed for this unlikely scenario. A house fly may weigh up to [redacted] mg and is assumed to have ingested the LD50. There are no reliable data available on the lethal dinotefuran dose for a house fly. If the LD50 for flies were as high as the oral LD50 for rats (2450 mg/kg bw), the fly would contain 245 µg dinotefuran. This is a very conservative estimate, given that neonicotinoids are much more toxic to insects than to mammals. The ARfD for dinotefuran is 1.75 mg/kg bw, equivalent to 17.5 mg dinotefuran for a 10-kg toddler. This amount is equivalent to 71 flies. This number is much higher than what could be considered an accidental ingestion.

Scenario 5 – Touching of plastic film and hand-to-mouth transfer

As it has been showed that part of the product remains on the protective plastic film once it has been removed and that the stickers comes into use, exposure of toddlers to some remaining product on the plastic film that would be picked up by toddlers cannot be excluded.

The following consideration are taken into account:

- Up to maximum 50% of the product can remain on the plastic film;
- Scenario 2 covers the chewing and dermal contact of a toddler with a sticker that supposedly has still 100% of the product on it.

Based on this, it is considered that scenario 2 covers scenario 5 as well, and no additional calculation and/or contribution are needed.

Monitoring data

Not available.

Dietary exposure

Contact with food is not foreseen for the biocidal product The biocidal product is also not intended for application onto animals, especially not onto livestock. With these precautions, dietary exposure of humans or animals can be prevented.

Residue definitions: Not applicable.

Information of non-biocidal use of the active substance

Not applicable.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not relevant.

Aggregated exposure

Not relevant.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1.	non-professional	1 / no PPE	0.0051
2.	general public, toddler	1 / no PPE	0.152
3.	general public, adult	1 / no PPE	0.00negligible
	general public, toddler	1 / no PPE	0.00negligible
1 + 3	general public, adult	1 / no PPE	0.0051
2 + 3	general public, toddler	1 / no PPE	0.152

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation – <u>Dinotefuran</u>

Reference	Study	NOAEL (LOAEL)	AF	Correction for absorption	Value
$AEL_{short\text{-}term}$	Dev.tox, rabbit	175 mg/kg/d	100	No	1.75 mg/kg/d
$AEL_{medium\text{-}term}$	1-year dog	22 mg/kg/d	100	No	0.22 mg/kg/d
$AEL_{long\text{-}term}$	1-year dog	22 mg/kg/d	100	No	0.22 mg/kg/d
ADI	1-year dog	22 mg/kg/d	100	No	0.22 mg/kg/d
ARfD	Dev.tox, rabbit	175 mg/kg/d	100	No	1.75 mg/kg/d

The exposure scenarios described above have an acute (dermal, once every 6 months) and a medium-term (inhalation, continuous) component. The conservative choice is to use the medium-term AEL for risk characterisation.

Maximum residue limits or equivalent

Dinotefuran is not approved as plant protection product unter Reg. (EC) No 1107/2009. However, a default MRL of 0.01 mg/kg has been set for food commodities according to Art 18(1)(b) Reg 396 / 2005.

Specific reference value for groundwater

Not applicable.

Risk for industrial users

Not applicable.

Risk for professional users

Not applicable.

Risk for non-professional users

Systemic effects

Scenario	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1	22	0.22	0.0051	2.3%	Yes

Combined scenarios
Not relevant

Local effects
Not relevant

Conclusion
The reasonable worst-case scenario for **primary exposure** of adults is acceptable.

Risk for the general public

Systemic effects

Scenario	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 - Adults	22	0.22	0.0051	2.3%	Yes
2 – Toddlers	22	0.22	0.152	69.1%	Yes
3 - Adults	22	0.22	negligible	n.a.	Yes
3 - Toddlers	22	0.22	negligible	n.a.	Yes
1+ 3 Adults	22	0.22	0.0051	2.3%	Yes
2 + 3 Toddlers	22	0.22	0.152	69.1%	Yes

Combined scenarios
See table above.

Local effects
Not relevant.

Conclusion from calculations performed using exposure and risk assessment models
Based on the assumption that 8 stickers are used per house, the AEL for dinotefuran is neither reached nor exceeded by the estimated systemic exposure. Hence, the proposed use of the dinotefuran-containing stickers does not entail any foreseeable health risk to the consumer.
Exposure of children is unlikely, if the label instructions to keep the stickers out of children's reach are followed, especially as the insecticidal paste contains an effective bittering agent.

It is also reasonable to assume that there will be some ventilation in the treated rooms (otherwise there would not be any flies to control). Hence, the present exposure and risk assessment is inherently conservative.
A toddler accidentally ingesting dead flies containing extreme levels of dinotefuran (Scenario 4) is not a relevant scenario since more than 71 flies need to be ingested in order for a toddler to reach the ARfD. This is unrealistic and thus not considered a relevant contribution to the overall risk associated with the product.

Risk for consumers via residues in food

Not relevant. Based on the human risk scenario for toddlers (Scenario 2, oral exposure via hand-to-mouth transfer) no risk for people drinking or eating in rooms where the biocidal product is in use and food come accidential in contact with the.biocidal product is likely.

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

The biocidal product contains two classified substances. They have no impact on the classification of the product and are not considered substances of concern for human health. The active substance dinotefuran is not classified for health effects.

2.2.7 Risk assessment for animal health

Relevant animal exposure is not foreseen in the proposed use pattern. Therefore, a risk assessment for animal health is not deemed necessary.

2.2.8 Risk assessment for the environment

The biocidal product contains the active substance dinotefuran and the active substance triggers classification for the environment as H412.

No other component of the biocidal mixture contributes to the classification of the biocidal product.

According to the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017, the biocidal product contains no further substances of concern:

1. CLP A substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or A substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation;
2. POP, PBT, vPvB A substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;
3. Active Substances Active substances (AS) from other product types (PTs) contained in the product (e.g. in-can preservatives) for which a draft final Competent Authority Report (CAR, with an agreed risk assessment) is available. This criterion identifies other active substances in the biocidal product that act as co-formulants. Those substances should be regarded as SoCs because they potentially affect environmental organisms due to their intrinsic biological activity. They should be considered as SoCs if they are present in the biocidal product at a concentration ≥ 0.1%. This concentration limit is not applicable to PBT- or vPvB-substances and endocrine disrupting chemicals (EDs), as safe concentration limits cannot be derived for those substances. No concentration limit applies to substances that are classified as such. It needs to be checked whether this concentration limit is valid for the respective substance as highly toxic substances may contribute to the overall toxicity of the product even when contained to very small amounts in the product, i.e a co-formulant should be regarded as SoC if the PNEC of the respective substance is lower than the PNEC of the a.s. even though its concentration in the product is below the 0.1% criterion. Any active substance contained in the product other than the active substance declared by the applicant. However, exemptions are possible under the following condition: the substance is contained in Annex I of the BPR.

4. Synergists Substances that enhance the effect of the active substance in the product, e.g. synergists. For synergists, information/data shall be provided related to the interaction between the active substance and the synergist, not only for the synergist itself. For such substances, an appropriate evaluation of the risks posed by the active substance in the presence of the synergist rather than an evaluation of the risks posed by the synergist itself should be undertaken. A generic concentration cut-off value for the presence of a synergist in a product, applicable to all synergists cannot be specified. On a case-by-case basis, a synergist should be considered a SoC, if it is present at a concentration that enhances the toxicity of the active substance, as indicated by the available data. Furthermore, the hazard profile, potency and exposure potential of the substance enhancing the effects of the active substance should be taken into account. Further details on the identification of synergists can be found in section 10.2.3. Also diluents, (lipophilic) organic solvents and surfactants like e.g. naptha may influence the toxicity of a mixture by enhancing the bioavailability of the active substance(s) and should therefore be regarded carefully. In principle, all co-formulants need to be checked for a potential influence on the toxicity of the other product components.
5. Candidate List Substances that have been included in the candidate list established in accordance with the REACH Regulation (1907/2006/EC, as amended), Article 57 (f) and 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR (see above). This criterion will capture, the clearly-defined SoCs specified in Article 3(f) of the BPR as well as endocrine disruptors (EDs) and PBT-substances which are not covered by Article 57 (d-e) of the REACH Regulation.
6. PBT, EQS Substances which meet two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006, as amended. Substances for which an Environmental Quality Standard (EQS) has been derived under Directive 2000/60/EC (Water Framework Directive; according to paragraph 67, Annex VI, BPR).

Details on non active substances are listed in the confidential annex.

Safety Data Sheets are attached to the respective data sets in the IUCLID dossier.

The biocidal product applied for authorisation is not identical to the representative product in the CAR and a new environmental risk assessment had to be performed.

2.2.8.1 Effects assessment on the environment

PNECs for dinotefuran (as described in assessement report)

Compartment	Value	AF	Based on
$PNEC_{STP}$	100 mg/L	10	NOEC, activated sewage sludge respiration inhibition test
$PNEC_{water}$	0.254 µg/L	10	NOEC, chronic test, water spiked study
$PNEC_{sediment}$	0.372 µg/kg_{wwt}	-	Equilibrium partioning method (EPM) **
$PNEC_{soil}$	0.00017 mg/kg_{wwt} 0.00176 mg/kg_{wwt} 0.0016 mg/Kg_{wwt}	- 100 10	Equilibrium partioning method (EPM) NOEC, 56-day earthworm reproduction study Organism: *Enchitraeus crypticus* Endpoint: 0.052 mg/kg dwt soil, normalised for organic matter content and converted to soil wet weight = 0.016 mg/kg wwt soil.
*$PNEC_{secondary\ poisoning}$	2.93 mg/kg_{food}	300	NOAEL,dog oral, dietary, repeated dose (22mg/kg_{bw}/d * 40kg_{bw}*d/kg_{food} = 880mg/kg_{food})

*not given in assessment report of dinotefuran, calculated as described in ECHA (2017): Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C). Version 2.0.
** PNECsed = (Ksusp_water/RHOsusp)*PNECwater*1000

Metabolites of dinotefuran

Aquatic systems (fresh water, sediment)
According to the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, as a first step a qualitative or semi-quantitative assessment of these metabolites using the available data and expert judgement to fill data gaps may be sufficient. If the assessment does not indicate a potential risk, a quantitative assessment is not required.

According to the assessment report for dinotefuran only one major metabolite (DN) was detected at significant concentrations (i.e. >10 %) in a water-sediment degradation study. The major metabolite is significantly less toxic to aquatic organisms than its parent. Therefore, it is clear that environmental risks are likely to be driven by the presence of the active substance in aquatic systems rather than its degradation products and so calculation of DN concentrations in surface waters has not been considered relevant. The risk assement of the metabolite is expected to be covered by the risk assessment for dinotefuran.

Terrestrial compartement (soil)
According to the assessment report for dinotefuran only one major metabolite (MNG) was detected at significant concentrations (i.e. >10 %) under aerobic conditions in a soil

degradation study using silt loam as test substrate. Maximum formation of MNG did not exceed 20 % AR and, due to controlled indoor use of the biocidal product, indirect emissions of dinotefuran to the terrestrial compartment are negligible (<1% sorption to sewage sludge). However, there is concern that the major soil metabolite MNG may be persistent in soil, so as a first tier "worst case" no degradation for soil was assumed in the risk assessment for dinotefuran. Hence, the risk assement of the metabolite is covered by the risk assessment for dinotefuran.
Furthermore, in the absence of effects data on terrestrial or aquatic organisms, it is commonly accepted under other EU legislation (such as EC Regulation No. 1107/2009 concerning plant protection products) to assume that metabolites could potentially be 10 times more toxic than their parent compound such that a PNEC value of 1.64 x 10-4 mg kg-1 wwt could crudely be set for MNG. Whilst this extremely conservative approach is not standard for assessment of biocidal active substances, it would offer an additional safeguard in a simplistic risk assessment, especially as MNG contains the nitroguanidine structure of the parent compound and therefore could be considered as possessing similar soil toxicity.

PBT assessment

According to the assessment report even though dinotefuran may appear to fulfil two (vP and T) out of the 3 criteria that need to be considered, it can be accepted that it is neither a PBT nor a vPvB substance. However, it must be considered as a ”candidate for substitution”.

For detailed information see assessment report of Dinotefuran.

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

The biocidal product is classified and labelled as Hazardous to the aquatic environment: Aquatic Chronic 3, H412 due to the active substance dinotefuran that is present at levels above 0.1% and that is classified as Aquatic acute 1, H400; M=10 and Aquatic chronic 1, H410, M=10.

The biocidal product is not considered to have endocrine disruption (ED) properties.

It does not contain:
a) active substance(s) and/or non-active substance(s) having ED properties on the basis of the scientific criteria in Regulation (EU) 2017/2100 and/or,
b) active substance(s) and/or non-active substance(s) having ED properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, and/or,
c) active substance(s) with an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s).

With regard to the endocrine disrupting properties of the active substance it is referred to the Assessment Report.

For the assessment of co-formulants, the steps described in the guidance “CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants” were followed and documented for each co-formulant (Anonymous 2020d).

According to this assessment, the co-formulants in the biocidal product SAFWS002 do not have endocrine disruption (ED) properties.

Further Ecotoxicological studies

Not available.

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

The biocidal product is used indoors in private houses to control house flies. The insecticide is directly applied onto the indoor surface of windows by a carrier material. As a result, the insecticide will generally not reach directly the environmental compartments usually considered in emission scenario documents: surface water (including sediments), groundwater, soil and air. However, surfaces (either target or not) will be cleaned. The cleaning step will therefore lead to releases either to wastes (e.g. through dry cleaning methods like vacuuming) or to waste water (e.g. through wet cleaning methods). Therefore the sewage treatment plant (STP) is considered as one of the main "receiving compartment" where insecticides will be released through wet cleaning events. In Europe, estimates of potential exposures resulting from STPs are carried out according to the standard calculation frameworks presented in the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017. Then, the "final" environmental compartment will logically be the surface water/sediment, the groundwater (through STP), the soil (from sludge application) and the outdoor air.

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

Not available.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

Not available.

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

Not available.

Testing for distribution and dissipation in air (ADS)

Not available.

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

Not applicable.

Acute aquatic toxicity

It is referred to the PNECs for dinotefuran further above (as described in assessement report).

Chronic aquatic toxicity

It is referred to the PNECs for dinotefuran further above (as described in assessement report).

Measured aquatic bioconcentration

No data available. According to the assessment report of dinotefuran no data were submitted to address bioconcentration potential of dinotefuran in the aquatic compartment on the basis that this would be unnecessary due to a reported log Kow of -0.644 at pH 7 and 25 °C.

Estimated aquatic bioconcentration

The estimated aquatic bioconcentration in fish is 0.068 L/kg_{wwt} according to the assessment report of dinotefuran. This value strongly suggests a low potential to bioconcentrate and hence bioaccumulate in fish (QSAR modelling also suggests a similar lack of bioconcentration in earthworms with an estimated BCF <1).

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF fish = 0.068 L/kg_{wwt}. This value strongly suggests a low potential to bioconcentrate and hence bioaccumulate in fish
Justification for the value/conclusion	Valid QSAR modelling. For details refer to the assessment report of dinotefuran

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

Not applicable.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Control of house flies in private rooms/houses.
ESD(s) used	ESD for Insecticides, acaricides and products to control other arthropods for household and professional uses (PT18), July 2008
Approach	Scenario 1: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C). Version 2.0. October 2017. Technical Agreements for Biocides Environment (ENV), November 2021.
Groundwater simulation	No. As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken.
Confidential Annexes	No.
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes Service life: Yes
Remarks	As a tier 1 worst case scenario it was assumed that the complete amount of active substance within the biocidal product reaches the sewage treatment plant (STP).

Emission estimation

Scenario 1

As a tier 1 worst case scenario it was assumed that the total amount of the active substance from 8 stickers/house was emitted to wastewater during a cleaning event.

This scenario covers any releases resulting from evaporation, washing of the windows, washing of hands of operators (as well as clothes) etc.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Controll of house flies in private rooms/houses.			
Application rate of biocidal product	1	b.p./30 m³	
Concentration of active substance in the product*	0.24	mg/b.p.	
Rooms per house	8	room/house	

[redacted]

Calculations for Scenario 1

EUSES output is included in Annex 3.2.

Amount of active substance emitted to wastewater from one house			
Input	**Value**	**Unit**	**Remarks**
Application rate of biocidal product	1	b.p./room	
Concentration of active substance in the product	0.24	mg/b.p.	
Rooms per house	8	room/house	
Calculations			
Application rate of biocidal product x Concentration of active substance in the product x Rooms per house 1 b.p/room*0.24mg a.s/b.p.*8 room/house = 1.92 mg a.s./house			
Output			
Active substance emitted to wastewater	1.92	mg/house	

Amount of active substance emitted to STP (per day)			
Input	**Value**	**Unit**	**Remarks**
Active substance emitted to wastewater	1.92	mg/house	

Number of houses per STP	4000	house	
Simultaneity factor	5.52	%/d	Default ESD p39
Calculations			
Active substance emitted to wastewater during application from one house x Number of houses per STP x Simultaneity factor/100% 1.92 mg/house x (4000 house x 0.0552/d)= 422.4 mg/d = 4.224E-04 kg/d			
Output			
Active substance emitted to STP (per day)	4.239E-04	kg/d	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	4.239E-04	This value was inserted directly into EUSES 2.2.0 under • Release estimation • Intermediate results • Release fractions and emission results • Private use • Select formulation/use

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
Scenario 1	Yes, via STP	Yes, via STP	No	No	Yes	Not relevant	Yes, via STP	Yes, via STP

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	202.2	g/mol	Set value
Melting point	107.5	°C	Set value
Boiling point	-	°C	Decomposition occurred before boiling
Vapour pressure (at 25°C)	5.0E-05	Pa	Set value

Input parameters (only set values) for calculating the fate and distribution in the environment			
Water solubility (at 20°C)	5.45E+04	mg/l	Set value
Water solubility (at 25°C)	-	mg/l	Calculated by EUSES
Log Octanol/water partition coefficient	-0.644	Log 10	Set value
Organic carbon/water partition coefficient (Koc)	31.4	l/kg	Set value
Henry's Law Constant (at 25°C)*[if measured data available]*	-	Pa/m3/mol	Calculated by EUSES
Biodegradability	No		Default
Rate constant for STP *[if measured data available]*	0	h^{-1}	Default
DT_{50} for biodegradation in surface water	0	d or hr (at 12ºC)	Default
DT_{50} for hydrolysis in surface water	1E+06	d (at 12ºC /pH)	Default
DT_{50} for photolysis in surface water	1E+06	d	Default
DT_{50} for degradation in soil	1E+06	d (at 12ºC)	Default
DT_{50} for degradation in air	0	d or hr	Default
bioconcentration factor for fish (BCF)	0.068	L/kg_{wwt}	Set value
bioconcentration factor for earthworm (BCF)	0.843	L/kg_{wwt}	Calculated

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Simple Treat 4.0 (Fraction)	EUSES 2.2.0 (Fraction)
Fraction of emission directed to air by STP	3.946E-09	2.600E-09
Fraction of emission directed to water by STP	0.99595	0.99590
Fraction of emission via primary settler	0.00283	0.00283
Fraction of emission via surplus sludge	0.00122	0.00122
Fraction sludge , total	0.00405	0.00405
Fraction of the emission degraded in STP	0	0
Total of fractions	1	1

Calculated PEC values

Summary table on calculated PEC values

	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}[1]	PEC_{air}
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	2.11E-04	2.11E-05	3.09E-05	5.61E-06	7.18E-06	3.06E-16

[1] PEC_{GW} values are $PEC_{pore\ water}$ values; calculations by using a simulation tool (e.g. one of the FOCUS models) were not required.

Primary and secondary poisoning

Primary poisoning

Not applicable. Use of the product will not result in primary poisoning of mammals and birds.

Secondary poisoning

Chemicals showing bioaccumulation and biomagnification may pose an additional threat due to exposure of organisms higher in the food chain (secondary poisoning), e.g. top predators. This has to be addressed if a chemical fulfils several criteria, e.g. indication of a bioaccumulation potential.

According to BPR (2017) a substance has bioaccumulation potential if it has a log Kow ≥ 3 or BCF/BAF ≥ 100 L/kg_{wwt} or BMF ≥ 1 or is highly adsorptive or belongs to a class of substances known to have a potential to accumulate in living organisms or there are indications from structural features and there is no mitigating property such as hydrolysis (half-life less than 12 hours). Thus a risk assessment for secondary poisoning does not need to be performed for dinotefuran, according to Guidance. Nevertheless for completeness a risk assessment for secondary poisoning was also performed by the applicant. Please note that the RMS did not further control the accuracy of the secondary poisoning evaluation performed by the applicant!

PECs for evaluating secondary poisoning				
Scenario	**Concentration in fish (from freshwater) [mg/kg_{wwt}]**	**$PEC_{oral\ fish\text{-}eating\ predator}$* [mg/$kg_{wwt}$]**	**Concentration in earthworm (from soil) [mg/kg_{wwt}]**	**$PEC_{oral\ terrestrial\ predator}$* [mg/$kg_{wwt}$]**
1	1.82E-06	9.08E-07	5.92E-06	2.96E-06

**50 % of the concentration in fish/earthworm is used as PECoral, predator (BPR 2017 / EUSES 2.2.0) due to use of the local concentration may lead to an overestimation of the risk as predators do also forage from other sites than the area around the point of discharge. Also biodegradation is not taken into account.*

2.2.8.3 Risk characterisation

Atmosphere

No ecotoxicity data are available based on atmospheric exposures and a PEC air /PNEC air ratio cannot be calculated. According to the ESD, the concentration in air will be not relevant because of instant dilution. Furthermore the predicted environmental concentration for air is very low for the active substance (PECair = 3.05E-16 mg/m3). In addition the product is used only by non-professionals in private houses and not on a large industrial scale. Thus no risk for the atmosphere is expected.

Conclusion: Emission to air is considered to be negligible from an environmental point of view. No risk for the atmosphere is expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	2.11E-04 mg/L / 100 mg/L = 2.11E-06

Conclusion: The PEC/PNEC ratio is clearly below 1. Thus no effects on the micro-organisms in the STP are expected.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
Scenario 1	2.11E-02 µg/L / 0.254 µg/L = 0.0831	3.08E-02 µg/kgwwt / 0.372 µg/kgwwt = 0.0831

Conclusion: PEC/PNEC ratios are clearly below 1. Thus no effects on the aquatic compartment are expected.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	5.59E-06 mg/kgwwt / 0.00016* mg/kgwwt = 3.49E-02

*0.0016 mg/KG_{wwt}/10 to takke into account MNG potential toxicity

Conclusion: The PEC/PNEC ratio is clearly below 1. Thus no effects on the terrestrial compartment are expected.

Groundwater

The predicted environmental concentration for groundwater ($PEC_{groundwater}$ = 7.18E-06 µg/l) did not exceed the maximum permissible concentration laid down by Directive 98/83/EC of 0.10 µg/l (=1E-01 µg/l). Considering that MNG may form in soil at max 16% of parent compound initial concentration, and further considering that this amount may 100% be directed to ground water, the $PEC_{groundwater\_MNG}$ = 1.14E-06µg/l below the 0.10 µg/l limit.

Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Summary table on secondary poisoning		
Scenario	**PEC/PNEC$_{fish\text{-}eating\ birds\ and\ mammals}$**	**PEC/PNEC$_{worm\text{-}eating\ birds\ and\ mammals}$**
1	9.08E-07 mg/kgwwt / 2.93 mg/kg = 3.10E-07	2.96E-06 mg/kgwwt / 2.93 mg/kg = 1.01E-06

Conclusion: PEC/PNEC ratios are clearly below 1. Thus, as expected because of the low bioaccumulation potential of the active substance, a risk for secondary poisoning is very unlikely.

Mixture toxicity

The biocidal product is classified as H412 due to the active substance (dinotefuran: H400).

Two coformulants are classified for the environment but have no impact o the classification of the biocidal product. Nevertheless, a qualitative mixture toxicity assessment was performed.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

All compartments exposed by the STP including the STP itself are likely to be exposed. These are the STP (micro-organisms), the aquatic (fresh water, fresh water sediment), the terrestrial (soil) compartment and birds and mammals via secondary poisoning.

Screening Step 2: Identification of relevant substances

The biocidal product contains two substances that are classified and potentially relevant for the surface water and sediment. However, bothare present at low levels and synergistic effects are not expected.

Screening Step 3: Screen on synergistic interactions

Screening step	
	Significant exposure of environmental compartments? (Y)
	Number of relevant ssubstances >1? (Y)
	Indication for synergistic effects for the product or its constituents in the literature? (N)

The PEC values of the coformulants are estimated to be lower than the PEC values for the active substance. Likewise, PNEC values are higher than for the active substance.

A quantitative environmental risk assessment is not considered to be required.

Aggregated exposure (combined for relevant emmission sources)

Not relevant.

Overall conclusion on the risk assessment for the environment of the product
All PEC/PNEC ratios for the active substance are below 1. In addition $PEC_{groundwater}$ is below 0.1 µg/l (groundwater) for dinotefuran and for the main soil metabolite MNG. The highest calculated PEC/PNEC ratio is 0.0831 for surface water (respectively sediment), based on the assumption that 8 stickers are used per house. No unacceptable risk has been identified for the environment and therefore the use of the product is acceptable.

2.2.9 Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in SAFWS002:

1. Assessment of the ED properties of the active substances in SAFWS002:
   - According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Dinotefuran is not part of the list[2] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
   - Therefore, BE eCA considers that there are no concerns regarding ED properties of Dinotefuran.

2. Assessment of the ED properties of non-active substances (co-formulants) in SAFWS002:
   - After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product SAFWS002.
If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

[2] Please refer to CA-September18.Doc.7.5.a-final .

2.2.10 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage
Relevant parts of SDS Section 7 (possibly applicable to persons handling the paste, but not applicable to persons handling the biocidal product):
Advice on protection against fire and explosion: Usual measures for fire prevention.
Requirements for storage rooms and vessels: Keep container tightly closed in a cool, well-ventilated place.
Advice on storage compatibility: Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.
Further information on storage conditions: Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Recommended storage temperature: 20°C. Protect against: Light. UV-radiation/sunlight. Heat. Moisture.

Recommended methods and precautions concerning handling and transport
Relevant parts of SDS Section 8 (possibly applicable to persons handling the paste, but not applicable to persons handling the biocidal product):
Additional advice on limit values: To date, no national critical limit values exist.
Appropriate engineering controls: Provide adequate ventilation.
Protective and hygiene measures: Always close containers tightly after the removal of product. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.
Relevant parts of SDS Section 5 (possibly applicable to persons handling the paste, but not applicable to persons handling the biocidal product):
Suitable extinguishing media: Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Atomized water.
Unsuitable extinguishing media: High power water jet.
Special hazards arising from the substance or mixture: Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).Nitrogen oxides (NOx).
Advice for firefighters: In case of fire: Wear self-contained breathing apparatus.
Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

Particulars of likely direct or indirect adverse effects
Relevant parts of SDS Section 4:
No information available.

First aid instructions, antidotes
Relevant parts of SDS Section 4:
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
After inhalation: In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.
After contact with skin: Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes: Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.
After ingestion: Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect).
Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.
Treat symptomatically.

Emergency measures to protect the environment in case of accident

Relevant parts of SDS Section 6 (possibly applicable to persons handling the paste, but not applicable to persons handling the biocidal product):
Environmental precautions: Discharge into the environment must be avoided.
Methods and material for containment and cleaning up: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal. Clean contaminated objects and areas thoroughly observing environmental regulations.

2.2.11 Assessment of a combination of biocidal products

The biocidal product is not intended to be authorised for the use with other biocidal products.

2.2.12 Comparative assessment

The applicant provides a separate draft Comparative Assessment Report (Anonymous 2020e), which is attached to Section 13 of the IUCLID file.

Screening phase

According to the search, three eligible alternative active substances were identified for the relevant market area:

- Imidacloprid
- Spinosad
- Transfluthrin

Two of these are themselves Candidates for Substitution:

- Imidacloprid
- Spinosad

Eligible biocidal products with transfluthrin are approved only in France and Germany.

Dinotefuran and Imidacloprid are both competitive modulators of nicotinic acetylcholine receptor (nAChR) in nervous membranes. The substances bind to the acetylcholine site on nAChRs, causing a range of symptoms from hyper-excitation to lethargy and paralysis. Acetylcholine is the major excitatory neurotransmitter in the insect central nervous system.

Spinsoad is an allosteric modulator which activate Nicotinic acetylcholine receptor (nAChRs), causing hyperexcitation of the nervous system. Acetylcholine is the major excitatory neurotransmitter in the insect central nervous system.
Transfluthrin is a synthetic pyrethroid which act on the nervous system by preventing the closure of the voltage-gated sodium channels in the axonal membranes.

Concerning the eligible alternative biocidal products, the chemical diversity is adequate if at least 3 different active substances/ mode of actions in authorised products remain.

The criteria for the chemical diversity for the use "houseflies – indoor – non-professional" is not fulfilled. There are only 2 modes of action (i.e. action on nAChR and the nervous system) among the eligible BPs. Eligible alternative BPs for the use of the relevant BP with other modes of action are not found.

Tier IA
Not relevant.

Tier IB
Not relevant.

Tier II
Not relevant.

Overall conclusion

The assessment steps Tier IA/ Tier IB and Tier 2 are not applicable since there are not enough eligible alternative BPs available with different modes of action. Therefore, the assessment could be stopped after the screening step according to the decision scheme of the document of the European Commission "CA-May15-Doc.4.3.a – Final – TNG on comparative assessment.doc".

Dinotefuran is a candidate for substitution according to Art 10(1), but from the comparative assessment it can be concluded that, as of 11 March 2020, the relevant BP SAFWS002 can be authorized in the relevant market area.

3. ANNEXES[3]

3.1 List of studies for the biocidal product

Note: The study reports are attached to the IUCLID file.

[redacted]

[redacted]

[redacted]

3.2 Output tables from exposure assessment tools

3.2.1 Human Health Risk Assessment

Scenario 2 – Touching of sticker and hand-to-mouth transfer

Parameter	Value	Unit	Explanation
SR	5.43E-03	mg/cm²	5.43 µg AS/cm²
BW	10	kg	Child, 1-2 years(US EPA)
TE	1.00	fraction	Worst case
SA	57.6	cm²	one palm, toddler
DA	0.50	fraction	EFSA default for diluted, water-based products (2017)
D toddler	0.01565	mg/kg bw/day	Systemic dose via skin
F_H	1	fraction	Worst case
F_M	0.13	fraction	US EPA
HR	5.43E-03	mg/cm²	SMP
SA_H	115.2	cm²	US EPA
N_Replen	4	intervals/h	US EPA
SE	1		Worst case
ET	4	h/day	Indoor environments (Toddlers, US EPA)
Freq_HtM	20	events/h	Toddlers, US EPA

[3] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

OA	100%	fraction	BPR AR, 17 June 2014
OEHtM	0.1302	mg/kg bw/day	Systemic dose via oral route
Total exposure toddler	**0.14581**	**mg/kg bw/day**	**Total systemic dose**

3.2.2 Environmental Risk Assessment


Dinotefuran_SAFWS002.docx


Dinotefuran_SAFWS002.EXF

3.3 New information on the active substance

Not available.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

Not relevant.

3.6 Confidential annex

See confidential annex

3.7 Other

Not relevant.

Information on the substance(s) of concern

The active substance leads to the classification of the biocidal product. There are no other substances of concern in the biocidal product. The two non active components that are classified are not present in the biocidal mixture at a concentration leading to classification of the biocidal product and therefore do not meet the criteria for substances of concern.

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