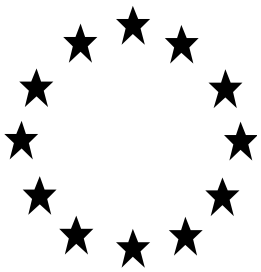
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



BitePrevent® Anti-Insect Spray

Product type 19

Ethyl butylacetylaminopropionate

Case Number in R4BP: BC-WX020761-06

Evaluating Competent Authority: Ctgb, The Netherlands

Date: 17-10-2018

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1 CONCLUSION

The biocidal product BitePrevent® Anti-Insect Spray / Nanofor® Anti-Insect Spray / BiteProtect (below: BitePrevent® Anti-Insect Spray) contains the active substance ethyl butylacetylaminopropionate. The product is an insect repellent to be applied on cotton clothing intended to protect humans from mosquitoes and ticks.
It is concluded by the eCA that sufficient data have been provided to fulfil the conditions of article 19 of regulation (EU) 528/2012. When using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

BitePrevent® Anti-insect Spray is an ethanol-based 25% IR3535® liquid formulation with a whitish appearance, pH7.5 and an alcoholic fragrance.
The relative density of BitePrevent® Anti-insect Spray is 0.840g.cm^{-3}, the surface tension is 24 mN/m and presents a viscosity of 2.5 mm^2/s.
BitePrevent® Anti-insect Spray is provisionally chemically and physically stable during 2 years in HDPE packaging based on accelerated storage stability data. A condition for authorisation is that the final shelf-life data are provided to the eCA post-registration, enabling confirmation of the claimed shelf-life of 2 years in the proposed packaging. The current (provisional) shelf life is based on the accelerated storage stability study.

The product is a category 2 flammable liquid, based on its flashpoint of 14°C.

An adequately validated analytical method is available for the determination of the active substance in the formulation.

Data gap (post-authorisation data requirement):
A two year storage stability study, including information on packaging material, the active substance content (before and after storage), spraying pattern (before and after storage), MMAD data (before and after storage), pH, appearance, physical state and odour.

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**
BitePrevent® Anti-Insect Spray	The Netherlands
Nanofor® Anti-Insect Spray	The Netherlands
BiteProtect	The Netherlands
BiteProtect	Spain
Nanofor® Spray Repelente de Insectos	Spain
BitePrevent® Anti-Insect Spray	United Kingdom
Nanofor® Anti-Insect Spray	United Kingdom
BiteProtect	Portugal
Nanofor® Spray Repelente de Insectos	Portugal

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Success Gadget, Nanotecnologia e Novos Materiais, Lda.
	Address	Rua Filipa Borges, nº 1245 4750-823, Barcelos, Portugal
Authorisation number	NL-0015633-0000	
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	Success Gadget, Nanotecnologia e Novos Materiais, Lda.
Address of manufacturer	Rua Filipa Borges, nº 1245 4750-823, Barcelos, Portugal
Location of manufacturing sites	Rua Filipa Borges, nº 1245 4750-823, Barcelos, Portugal Re-Filling operations done at: Milpossibilidades Zona industrial da Amendoeira lote 21-24 5340-021 Macedo de Cavaleiros, Portugal

2.1.1.4 Manufacturer of the active substance

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck S.L.U.
Address of manufacturer	Maria de Molina 40, 28006, Madrid, Spain
Location of manufacturing sites	Poligono Merck - 08100 Mollet de Valles, Barcelona, Spain

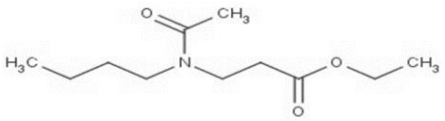
2.1.2 Product composition and formulation

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	None
IUPAC or EC name	IUPAC: ethyl 3-[*N*-acetyl-*N*-butyl] aminopropionate *Also known as IR3535®*
EC number	257-835-0
CAS number	52304-36-6
Index number in Annex VI of CLP	Non-applicable
Minimum purity / content	>99% w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

According to Regulation EU 406/2014, this active is not considered to be a candidate for substitution.

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

Common name	IUPAC name	Function *	CAS number	Content (%) *
IR3535®	ethyl 3-[*N*-acetyl-*N*-butyl] aminopropionate	Active substance	52304-36-6	25.5**
Ethanol	Ethanol	Non-active substance	64-17-5	64.885
Isopropanol	Propan-2-ol	Non-active substance	67-63-0	3.415
(3Glycidyloxypropyl)trimethoxysilane	Trimethoxy[3-(2-oxiranylmethoxy)propyl]silane	Non-active substance	2530-83-8	1.0

** Additional information in confidential section (annex 3.6)*
*** The minimum purity of the active substance is 99%. Therefore, the amount of technical concentrate and the amount of pure active are equal (25.5%w/w)*
NOTE: The formula above has a manufacturer's code of Formula A (Figueiredo I., 2016).

2.1.2.5 Information on technical equivalence

The active substance supplier Merck S.L.U is involved in the review programme.
A confirmation of the active substance manufacturing site is provided as supporting document (Van Sloun P., 2017a and 2017b).

2.1.2.6 Information on the substance(s) of concern

Please see the confidential section (annex 3.6) for information.

2.1.2.7 Type of formulation

AL (Any other liquid)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Flam. Liq. 2 Eye Irrit. 2
Hazard statement	H225 – Highly flammable liquid and vapour H319 – Causes serious eye irritation
Labelling	
Signal words	Danger
Hazard statements	H225 – Highly flammable liquid and vapour H319 – Causes serious eye irritation
Precautionary statements	P102: Keep out of reach of children P210: Keep away from sparks/open flames/hot surfaces. – No smoking. P264: Wash hand and face thoroughly after handling. P233: Keep container tightly closed. P370+P378: In case of fire: Use ABC powder extinguisher to extinguish. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P403+P235: Store in a well-ventilated place. Keep cool. P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment.
Note	-

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use 1 – Insect repellent to protect humans from mosquitoes and ticks by application on cotton clothing

Product Type	Product type 19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellent
Target organism (including development stage)	Culicidae: Mosquitoes- Adults Culicidae: Tropical mosquitoes (*Anopheles spp) -Adults* Ixodidae: Ticks –Adults and nymphs
Field of use	Indoor and outdoor The product is used on cotton clothing to repel (tropical) mosquitoes and ticks.
Application method(s)	Ready-to-use pump spray product. Shake bottle several times just before use. The spray should be applied with the bottle vertically and at 15 cm distance from the clothing. Dry clothing material with a hairdryer.
Application rate(s) and frequency	Apply 1.6 mL (about 24 pump sprays) of product per square meter of clothing (equivalent to 0.34 g of active per square meter). Dry clothing material with a hairdryer. Re-application: Re-apply to clothing if clothing gets wet (i.e. swimming with treated clothing, or walking through rain with treated clothing) to ensure efficacy. For mosquito repellance: When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required. When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required. For tropical mosquito repellance: When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required. When clothing is washed: re-apply after 1 domestic laundry cycle if repellent effect is still required. For tick repellance: When clothing is not washed: re-apply 1 month after the first application if repellent effect is still required. When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required.
Category(ies) of users	General public
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use

See general instructions for use

2.1.4.3 Use-specific risk mitigation measures

See general instructions for use

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 general instructions for use

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

See general instructions for use

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 general instructions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Ready-to-use pump spray insect repellent product to be applied on cotton clothing.

Do not spray clothings while wearing.

Use in well ventilated space only.

Can be used indoors and outdoors.

Shake bottle several times just before use.

The spray should be applied with the bottle vertically and at 15 cm distance from the clothing material.

Apply 1.6 mL (about 24 pump sprays) of product per square meter of clothing.

Dry the clothing material with a hairdryer.

Re-apply to clothing if clothing gets wet (i.e. swimming with treated clothing, or walking through rain with treated clothing) to ensure efficacy.

For mosquito repellance:

When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required.
When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required.

For tropical mosquito repellance:

When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required.
When clothing is washed: re-apply after 1 domestic laundry cycle if repellent effect is still required.
For tick repellance.

When clothing is not washed: re-apply 1 month after the first application if repellent effect is still required.
When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required.

2.1.5.2 Risk mitigation measures

Flammable: Keep away from souces of ignition – no smoking.

Keep out of reach of children.

Do not eat or drink during application. No food or drink is allowed in the room where the product is applied.

Wash hand and face thoroughly after handling.

Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Avoid sources of radiation, static electricity and contact with food.

Do not open container.

Prevent leakage and spillage, if safe to do so.

Do not decant product.

Do not let product enter drains.

Store in cool and well-ventilated place.

Do not reuse or refill this container.

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

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Get medical advice immediately and show product label.
In case of spills, soak up with inert absorbent material and dispose of in accordance with the current legislation on waste treatment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not open container.

Do not decant product.

Do not let product enter drains.

Do not reuse or refill this container.

Dispose as normal waste.

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

Keep out of reach of children.

Store in cool and well-ventilated place.

Avoid sources of radiation, static electricity and contact with food.

Flammable: Keep away from souces of ignition – no smoking.
Shelf-life under normal conditions of storage: 2 years.

Store at 10 - 40°C.

2.1.6 Other information

BitePrevent® Anti-Insect Spray is not intended to be used with other biocidal products.

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)
Plastic bottle with pump spray	50 ml	High Density Polyethylene (HDPE, opaque)	HDPE pump	Non-professional/ General public	Yes
Plastic bottle with pump spray	100 ml	High Density Polyethylene (HDPE, opaque)	HDPE pump	Non-professional/ General public	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Active Substance:
No new data.
CoA for active substances as supplied is available, indicating purity of 99.7% (Bou V., 2014).

Biocidal Product:
Please see reference list in annex 3.1

2.1.8.2 Access to documentation

The active substance supplier is Merck KgaA, submitter for the active substance Ethyl butylacetylaminopropionate under the review programme of Directive 98/8/EC and owns or has transferable acess rights to the data package.
The LoA linked to this application, gives the eCA access to the Merck KgaA active substance dossier.

2.2 Assessment of the biocidal product

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

Table 1. Intended use 1 – Insect repellent to protect humans from mosquitoes and ticks by application on cotton clothing.

Product Type(s)	EU BPR Product type 19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellent to protect humans from mosquitoes and ticks by application on cotton clothing.
Target organism (including development stage)	Common household adult mosquito Tropical adult mosquito Ticks
Field of use	Indoor and outdoor use.
Application method(s)	General public: Ready-to-use pump spray product. Shake bottle several times just before use. The spray should be applied with the bottle vertically and at 15 cm distance from the clothing. Apply 1.6 mL (about 24 pump sprays) of product per square meter of clothing (equivalent to 0.34 g of active per square meter textile). Dry the clothing material with a hairdryer.
Application rate(s) and frequency	Apply 1.6 mL (about 24 pump sprays) of product per square meter of clothing (equivalent to 0.34 g of active per square meter clothing). Re-apply to clothing if clothing gets wet (i.e. swimming with treated clothing, or walking through rain with treated clothing) to ensure efficacy. Re-application for mosquito repellance: When clothing is not washed: 3 months after first application. When clothing is washed: after 3 domestic laundry cycles. Re-application for tick repellance: When clothing is not washed: 1 month after first application. When clothing is washed: after 3 domestic laundry cycles
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	50ml and 100ml plastic bottle (HDPE) with pump spray

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results		Reference
Physical state at 20 °C and 101.3 kPa	NA	25.01% a.s CoA 20160609	Liquid 20ºC, 101.3 kPa		Pivato M 2016
Colour at 20 °C and 101.3 kPa	N/A	25.01% a.s CoA 20160609	Whitish		Pivato M 2016
Odour at 20 °C and 101.3 kPa	N/A	25.01% a.s CoA 20160609	Alcoholic		Pivato M 2016
Acidity / alkalinity	CIPAC MT 75.3	25.01% a.s CoA 20160609	7.5 At 20°C (no dilution)		Pivato M 2016
Relative density / bulk density	OECD Test Guideline 109:2012 - Pycnometer (liquids and solids)	25.01% a.s CoA 20160609	0.840±0.002 g.cm^{-3}		Pinho E., 2014
Storage stability test – **accelerated storage**	CIPAC MT 46.3	25.01% a.s CoA 20160609	T0: 26.84% a.s pH 7.16 White Liquid with no sediment. The container showed no sign of seepage, clogging or residues after use. Amount of spray delivered with each operation is 0.10 g. Packaging material: HDPE	T14 (54^{0}C): 26.76% a.s pH 7.36 Appearance: WhiteLiquid with no sediment. The container showed no sign of seepage. The spray showed no clogging or residues after use and storage. Spraying pattern is homogeneous and comparable to T0. Conclusion: No change from T0, stable	Semenzin M. 2016

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results		Reference
			container with trigger spray	for 14days at 54°C. Packaging material unchanged.	
eCA remark: The active substance content at T0 (26.84%) is slightly outside the upper tolerance level (26.78%w/w) as described in the FAO WHO manual for active substance content in the range of 250 to 500 g/L. Eventhough the active substance is outside the tolerance boundaries the study is still considered representative for the product.					
Storage stability test – **long term storage at ambient temperature**	SANCO 3030/99 rev4 guidelines Testing points: T0 T12 T18 (data not yet available) T24 (data not yet available)	25.01% a.s CoA 20160609 T12 = Stored in the stability chamber SRA 212 at 25°C / 60% RH for 12 months.	T0: pH 7.16 White Liquid tiny sediment, no, seepage, no clogging and no residues	T12: pH 7.23 White, Liquid, Tiny sediment, no seepage, no clogging and no residues. Conclusion: No significant change from T0, stable for 12 months at room temperature.	Molin L. 2017 & Perin F, 2017
eCA remark: The accelerated storage stability study was performed in HDPE. Based on the accelerated storage stability data a provisional shelf-life of 2 years is assigned. The provided interim data of the long term storage stability study is considered insufficient as it contains no information on the packaging material, active substance content, spraying pattern and MMAD data. A new long term storage stability study is a post-authorisation data requirement. This 2 year long term storage stability study should include information on the active substance content (before and after storage), spraying pattern (before and after storage), MMAD data (before and after storage), pH, appearance physical state and odour.					
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	25.01% a.s CoA 20160609	No change in the aspect, colour and odour was observed after the storage of the test item at 0ºC for 7 days.		Pivato M 2016
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	NA	NA	The product is packed in an opaque HDPE packaging with a label wrapped around the bottle. Exposure to light is considered to be negligible		Casimiro E., 2016a
Effects on content of the active substance and	NA	NA	Results from accelerated storage stability test and low temperature stability		Pivato M. 2016 ^ Semenzi

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results	Reference
technical characteristics of the biocidal product / temperature and humidity			test indicate no change on active substance and product characteristics	n M. 2016
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual inspection	> 99 25.01% a.s CoA 20160609	Results from the storage accelerated test show: No seepages No clogging after use. No residues after use.	Semenzi n M. 2016
Wettability	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Suspensibility, spontaneity and dispersion stability	CIPAC MT 184	25.01% a.s CoA 20160609	99.7%	Pivato M 2016
Wet sieve analysis and dry sieve test	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Emulsifiability, re-emulsifiability and emulsion stability	NA	NA	The product is not an emulsion, therefore this test can be waived.	Casimiro E., 2016a
Disintegration time	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 (Lazer diffraction)	20.5% a.s CoA 20160623	10% of particles ≤ 27µm 50% of particles ≤ 60µm 90% of particles ≤ 139µm	Rodrigue z N., 2016
Persistent foaming	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Flowability/Pourability/Dustability	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Burning rate — smoke generators	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Burning completeness — smoke generators	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a
Composition of smoke — smoke generators	NA	NA	The product is a ready-to-use liquid, therefore this test can be waived.	Casimiro E., 2016a

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results	Reference
Spraying pattern — aerosols	NA	NA	The product is not an aerosol, therefore this test can be waived.	Casimiro E., 2016a
Physical compatibility	NA	NA	Ready-to-use product not co-applied with other substances/mixtures. Test not applicable	Casimiro E., 2016a
Chemical compatibility	NA	NA	Ready-to-use product not co-applied with other substances/mixtures. Test not applicable	Casimiro E., 2016a
Degree of dissolution and dilution stability	NA	NA	the product is a ready-to-use liquid. Test not applicable.	Casimiro E., 2016a
Surface tension	UNI EN 14370:2004	21.5% a.s CoA 20151013	24 mN/m at 25°C (assumed undiluted)	Moulard & Perin 2016
Viscosity	CIPAC MT 22.1 (HB F)	21.5% a.s CoA 20151013	2.5 mm^2/s at 20°C	Moulard & Perin 2016

* Please note that the active substance is at a purity of > 99%. The active is present in the product at ±25.5%. All physical – chemical tests are conducted in the product.

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

BitePrevent® Anti-insect Spray is an ethanol-based 25% IR3535® liquid formulation with a whitish appearance, pH7.5 and an alcoholic fragrance.
The relative density of BitePrevent® Anti-insect Spray is 0.840$g.cm^{-3}$, the surface tension is 24 mN/m and presents a viscosity of 2.5 mm^2/s.
BitePrevent® Anti-insect Spray is provisionally chemically and physically stable during 2 years in HDPE packaging based on accelerated storage stability data. A two year storage stability study is set as a post-authorisation data requirement, and should include information on the packaging material, active substance content (before and after storage), spraying pattern (before and after storage), MMAD data (before and after storage), pH, appearance, physical state and odour.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results	Reference
Explosives	NA	NA	None of the ingredients have explosive properties. This study is not applicable	Casimiro E., 2016b
Flammable gases	NA	NA	The product is	Casimiro E.,

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results	Reference
			a liquid therefore the study is not applicable	2016b
Flammable aerosols	NA	NA	The product is not an aerosol therefore the study is not applicable	Casimiro E., 2016b
Oxidising gases	NA	NA	The product is not a gastherefore the study is not applicable	Casimiro E., 2016b
Gases under pressure	NA	NA	The product is not a gas under pressure therefore the study is not applicable	Casimiro E., 2016b
Flammable liquids	EC A9 (closed cup)	25.01% a.s CoA 20160623	14ºC	Younis S. 2016
Flammable solids	NA	NA	The product is not a solid therefore the test is not applicable	Casimiro E., 2016b
Self-reactive substances and mixtures	NA	NA	None of the ingredients have self-reactive properties. This test is not applicable	Casimiro E., 2016b
Pyrophoric liquids	NA	NA	the product does not ignite when exposed to air at room temperature. Furthermore, product auto-ignition temperature is above room temperature.	Casimiro E., 2016b
Pyrophoric solids	NA	NA	The product is not a solidtherefore the test is not applicable	Casimiro E., 2016b
Self-heating substances and	NA	NA	None of the ingredients are	Casimiro E., 2016b

Property	Guideline and Method	Purity of the test substance (% (w/w) *	Results	Reference
mixtures			self-heating subtances or mixtures	
Substances and mixtures which in contact with water emit flammable gases	NA	NA	None of the ingredients emit flammable gases when in contact with water. Furthermore, the product forms a stable mixture when diluted with water.	Casimiro E., 2016b
Oxidising liquids	NA	NA	None of the ingredients have oxidizing properties	Casimiro E., 2016b
Oxidising solids	NA	NA	The product is not a solid therefore the test is not applicable	Casimiro E., 2016b
Organic peroxides	NA	NA	None of the ingredients are organic peroxides	Casimiro E., 2016b
Corrosive to metals	NA	NA	None of the ingredients are corrosive to metals. Furthermore, the product pH is close to neutral.	Casimiro E., 2016b
Auto-ignition temperatures of products (liquids and gases)	ASTM E 659-78 (2014)	21.5% a.s CoA 20151013	424ºC	Moulard & Perin 2016
Relative self-ignition temperature for solids	NA	NA	The product is not a solid therefore the test is not applicable	Casimiro E., 2016b
Dust explosion hazard	NA	NA	The product is a liquid therefore the test is not applicable	Casimiro E., 2016b

* Please note that the active substance is at a purity of > 99%. The active is present in the product at ≠25.5%. All physical hazard tests are conducted in the product.

Conclusion on the physical hazards and respective characteristics of the product

BitePrevent® Anti-insect Spray is a liquid ethanol-based 25% IR3535® formulation with flash point temperature of 14°C and an auto-ignition temperature of 424 °C.
No additional testing was conducted on the product as these were not applicable taking into consideration the physical state of the product, the formulation type (AL) and the properties of each ingredient.
Based on the test data the product is classified as flammable liquid (Category 2).

2.2.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Bite Prevent anti-insect spray 20.05% a.s CoA 20160104	SANCO 3030/99 Rev 4. HPLC-UV	Linearity: 5 concentration levels with range 16g/100g to 30g/100g Repeatability: 5 independent replicates Accuracy: 3 Fortified samples: with range 16g/100g to 30g/100g.	r^2=0.998 n=5(799-1498 ml/l)) Y = 5108x +0 (concentration units = mg/l)	No significant interferenace detected. SST verified	Fortification level 1- (16 g/100g): Recovery of 100% Fortification level 2- (20 g/100g): Recovery of 100% Fortification level 3- (30 g/100g): 101%	100%	0.47 % (n=5). Horwitz of ≤ 1.71 % for 20g/100g.	-	Bazza G., 2016
Formula A* (spray product) 25.01% a.s (CoA 20160609)	SANCO 3030/99 Rev 4. HPLC-DAD	Linearity: 5 concentration levels with range 499mg/l to 1497 mg/l corresponding to 50%-150% the target concentration of the a.s. Repeatabilit	r^2=1 n=5 (499–1497 mg/l) Y = 5435x +0 (concentration units = mg/l)	No significant interferenace detected. SST verified	Fortification level 1- (12.49 g/100g): Recovery of 101% Fortification level 2- (25.13 g/100g)	100.7 %	1.15 % (n=5). Horwitz of ≤ 1.65 % for 25g/100g	-	Pivato M. 2016

		y: 5 independent replicates Accuracy: 3 Fortified samples: with range 12g/100g to 40g/100g.			: Recovery of 102% Fortification level 3- (40.34 g/100g) : 99%				

* Formula A is identical to the product BitePrevent® Anti-Insect Spray.

Analytical methods to detect the active and residues in the various environmental media are described in the CAR.

Conclusion on the methods for detection and identification of the product

Two High-Pressure Liquid Chromatography (HPLC) methodologies for determination of the active in the product matrix are available:

1- – A full validated method where concentration of IR3535® in BitePrevent® Anti-Insect Spray can be determined for a linear concentration range of 16g/100g – 30g/100g, with a mean recovery rate of 100%.
2 - A full validated method where concentration of IR3535® in Formula A (Spray product) can be determined for a linear concentration range of 499 mg/l – 1497 mg/l, with a mean recovery rate of 100.7%.

Analytical methods to detect the active and residues in the various environmental media are described in the CAR.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

BitePrevent® Anti-Insect Spray is an insect repellent that protects humans from mosquitoes and ticks by application on cotton clothing.

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

The product is intended to repel adult mosquitoes and adult tropical mosquitoes to protect humans from mosquito bites. The product is also intended to repel ticks from humans and thus protect humans from tick bites.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product has a repellent effect (no killing).

2.2.5.4 Mode of action, including time delay

Similar to other insect repellents, the mode of action is poorly understood.
Information provided in the CAR indicates that the mode of action is not a passive masking of an attracting odour of a victim, but rather an active repellent effect as insects avoid entering the region with IR3535® vapours. The exact biochemical mode of action of the active substance is not well known yet, but it is assumed that the active substance has an olfactory-based effect. There is no time delay.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism (s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Mosquito Repellent	*PT19*	*Biocidal product (Sil2u spray solution) with (25.5% IR3535)* ® = BitePrevent® Anti-Insect Spray	*Anopheles Gambiae*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 4 volunteers (humans): 2 of each sex. Measured number of bites.	White cotton textile, with application of 1.6 ml product (24 spray pumps) per m^2 (equivalent to 0.34g IR3535®/m^2) Textile not washed, tested at T0.	96.62% repellency (compared to arm in untreated fabric)	*Hussain A. 2014*
					White cotton textile with application of 1.6 ml product (24 spray pumps) per m^2 (equivalent to 0.34g IR3535®/m^2) Textile with 3 washes before testing. (T0 with 3 washes)	88.83% repellency (compared to arm in untreated fabric)	
Mosquito Repellent	*PT19*	*Formula A* = BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Aedes aegypti (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove.	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control - T0: untreated textile. Cotton + Formula A - T0: Cotton textiles with Formula A application and efficacy evaluation immediately after application of Formula A.	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings was 98.3% -	*Hussain A., 2016a*

				Each test is conducted with 8 volunteers (humans): 4 of each sex. *Mosquito density: 100 females/20,000 cm^3*	Assessment Frequency: 8 exposures of 3 minute period for each volunteer with interval of 60 minutes. Measured number of bites and landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile.*	100% during 8 hours. % protection, assessed based on number of bites was 97.95% - 100% during 8hours.	
Mosquito Repellent	*PT19*	*Formula A =* BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Aedes aegypti (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4 of each sex. *Mosquito density: 100 females/20 000cm^3*	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control – T3 Months: untreated textile. Cotton + Formula A – T3 Months: Cotton textiles with Formula A application (aged for 3 months). Assessment Frequency: 8 exposures of 3 minute period for each volunteer with interval of 60 minutes. Measured number of bites and landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric:*	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings was 99.13% - 100% during 8 hours. % protection, assessed based on number of bites was 98.94% - 100% during 8 hours.	*Hussain A., 2016b*

					Formula A applied to cotton textile at 0.34 g of active per square meter textile. Cotton allowed to age for 3 months before being tested.		
Mosquito Repellent	*PT19*	*Formula A =* BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Aedes aegypti (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4 of each sex. Mosquito density: *100 females/20,000cm^3*	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control – 3 Washes: untreated textile. Cotton + Formula A – 3 Washes: Cotton textiles with Formula A application Assessment Frequency: 8 exposures of 3 minute period for each volunteer with interval of 60 minutes. Measured number of bites and landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile. Cotton fabric washed 3 times before being tested.*	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings was 99.41% - 100% during 8 hours. % protection, assessed based on number of bites was 99.50% - 100% during 8 hours.	*Hussain A., 2016c*
Mosquito Repellent	*PT19*	*Formula A =* BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Culex quinquefasciatus (adults) showing trophic*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines)	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30	*Hussain A., 2017a*

			activity.	The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4 of each sex. Mosquito density: *100 females/20 000cm^3*	the following pre-treatment: Cotton Control - T0: untreated textile. Cotton + Formula A - T0: Cotton textiles with Formula A application and efficacy evaluation immediately after application of Formula A. Assessment Frequency: 8 exposures of 5 minute period for each volunteer with interval of 60 minutes. Measured number of landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile.*	sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings was 100% during 8 hours.	
Mosquito Repellent	*PT19*	*Formula A =* BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Culex quinquefasciatus (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control – T1: untreated textile. Cotton + Formula A – T1: Cotton textiles with Formula A application (aged for one month). Assessment Frequency: 8 exposures of 5 minute period for each volunteer with interval of 60 minutes.	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings was 100% during 8 hours.	*Hussain A., 2017b*

				of each sex. Mosquito density: *100 females/20 000cm^3*	Measured number of landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile. Cotton allowed to age for one month before being tested.*		
Mosquito Repellent	*PT19*	*Formula A =* BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Culex quinquefasciatus (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4 of each sex. Mosquito density: *100 females/20 000cm^3*	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control – T3: untreated textile. Cotton + Formula A – T3: Cotton textiles with Formula A application (aged for 3 months). Assessment Frequency: 8 exposures of 5 minute period for each volunteer with interval of 60 minutes. Measured number of landings. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile.*	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings ranged from 99.57% - 100% during 8 hours.	*Hussain A., 2017c*

					Cotton allowed to age for 3 months before being tested.		
Mosquito Repellent	*PT19*	Formula A = BitePrevent® Anti-Insect Spray	*Target organism: 5 day old Culex quinquefasciatus (adults) showing trophic activity.*	Arm in Cage Study Protocol for Mosquito Repellent products (EPA OPPTS 810.3700 guidelines) The test subject's forearm, wrist to elbow, is used as the test area. The test subject's hand is protected by a latex glove. Each test is conducted with 8 volunteers (humans): 4 of each sex. Mosquito density: *100 females/20 000cm^3*	<u>Mosquito Propensity:</u> Bare forearm inserted into cage for up to 30 seconds to test biting pressure. <u>Repellence Test</u>: Test fabric wrapped on forearm. Fabric with the following pre-treatment: Cotton Control – 3 Washes: untreated textile. Cotton + Formula A – 3 Washes: Cotton textiles with Formula A application (3 washes). Assessment Frequency: 8 exposures of 3 minute period for each volunteer with interval of 60 minutes. Measured number of landings and bites. *System control: Bare forearm* *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric: Formula A applied to cotton textile at 0.34 g of active per square meter textile. Cotton fabric washed 3 times before being tested.*	<u>Mosquito Propensity:</u> All volunters had ≥ 10 mosquito bites in 30 sec. <u>Repellence Test</u>: % efficacy, assessed based on number of landings from 99.41% - 100% during 8 hours. % protection, assessed based on number of bites was 99.50% - 100% during 8 hours.	*Hussain A., 2016d*
Tick Repellent	*PT19*	Formula A = BitePrevent® Anti-Insect Spray	*Target organism: Ixodes ricinus* 10 adult ticks per test subject (mouse)	Mouse feed method for tick repellent products (EPA OPPTS 810-3700: Insect repellents for human skin and outdoor premises) Test subject: Swiss albino Mouse (*Mus*	Hand warmers wrapped in fabric that were untreated/treated with ticks repellent spray were placed on each mouse (T0). Mice exposed to ticks for 30 minutes. Recorded number of ticks per heat pack (mouse).	% efficacy, assessed based on number of ticks in heat pack was 100%. All control treatments had at least 1 tick	*Hussain A., 2017d*

				musculus) is the heat source for the tick as attractant. 20 mice in total.	*Untreated control: Cotton fabric* *Test sample: Treated cotton fabric. Formula A applied to cotton textile at 0.34 g of active per square meter textile.*	attached after 5 minutes, the number of attached ticks in the control treatments ranged from 4 to 7 after 30 minutes.	
Tick Repellent	*PT19*	Formula A = BitePrevent® Anti-Insect Spray	*Target organism: Ixodes ricinus* 10 adult ticks per test subject (mouse)	Mouse feed method for tick repellent products (EPA OPPTS 810-3700: Insect repellents for human skin and outdoor premises) Test subject: Swiss albino Mouse (*Mus musculus*) is the heat source for the tick as attractant. 20 mice in total.	Hand warmers wrapped in fabric that were untreated/treated with ticks repellent spray (T=1 Month) were placed on each mouse. Mice exposed to ticks for 30 minutes. Recorded number of ticks per heat pack (mouse). *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric. Formula A applied to cotton textile at 0.34 g of active per square meter textile. Cotton allowed to age for one month before being tested.*	% efficacy, assessed based on number of ticks in heat pack was 100%. All control treatments had at least 1 tick attached after 5 minutes, the number of attached ticks in the control treatments ranged from 5 to 7 after 30 minutes.	*Hussain A., 2016e*
Tick Repellent	*PT19*	Formula A = BitePrevent® Anti-Insect Spray	*Target organism: Ixodes ricinus* 10 adult ticks per test subject (mouse)	Mouse feed method for tick repellent products (EPA OPPTS 810-3700: Insect repellents for human skin and outdoor premises) Test subject: Swiss albino Mouse (*Mus musculus*) is the heat source for the tick as attractant. 20 mice in total.	Hand warmers wrapped in fabric that were untreated/treated with ticks repellent spray (washed 3 times before sed in test) were placed on each mouse. Mice exposed to ticks for 30 minutes. Recorded number of ticks per heat pack (mouse). *Untreated control: Cotton fabric* *Test sample: Treated cotton fabric. Formula A applied to cotton*	% efficacy, assessed based on number of ticks in heat pack was 100%. All control treatments had at least 1 tick attached after 5 minutes, the number of attached ticks in the control treatments	*Hussain A., 2016f*

					textile at 0.34 g of active per square meter textile. Cotton fabric washed 3 times before being tested.	ranged from 5 to 7 after 30 minutes.	
Mosquito repellent	*PT19*	Insect Repellents SiL2U – Spray = BitePrevent® Anti-Insect Spray	*Anopheles atroparvus*	Cage test adapted from Pennetier et al. (2007), applied according to the recommendations of the WHO (2006).	Test set-up: Acrylic rectangular box (25cm high, 21 cm wide and 60 cm long) divided into two identical compartments by a frame containing a fabric which was perforated before being inserted into the frame. Test: Box with treated fabric Control: Box with untreated fabric 100 females (3-4 days old) per cage In each test, A of each box (test and control). In the other compartment, designated as compartment B, a female of the species *Rattus norvegicus* Wistar strain was placed as bait, being anesthetized and immobilized during the course of the experiment. The tests took place for one hour and a count was made of the number of mosquitoes that had moved from compartment A to compartment B at different times, namely at 5, 10, 20, 40 and 60 minutes. After completion of the experiment, the mosquitoes present in all compartments (compartments A and B of test and control boxes) were collected and the number of females in each compartment that had blood-fed was calculated. Based on	Blood Feeding Inhibition Index (BFI): 100, 100, 100 and 83.33 after 35, 56, 104 and 127 days respectively. Repellence Index (RI): 92.45, 73.37, 92.86 and 84.85 % after 35, 56, 104 and 127 days respectively.	*Sousa & Ribeiro, 2015*

					these data, the blood feeding inhibition index (BFI) and the repellence index (RI) were calculated. Application rate: *Treated cotton fabric. Insect Repellent Sil2U-spray applied to cotton textile at 0.35 g of active per square meter textile.*		

Conclusion on the efficacy of the product
When used according to the use instructions in the SPC, the product is effective at repelling *Aedes*, *Culex* and *Anopheles* mosquitoes as well as ticks. Repellance efficacy for mosquitoes is maintained when treated clothes undergo 3 wash cycles as well as for 3 months (without clothes washing). Repellance efficacy for ticks is maintained when treated clothes undergo 3 wash cycles as well as for one month (without clothes washing).

2.2.5.6 Occurrence of resistance and resistance management

Information provided in the CAR indicates that as the active substance is a repellent (no killing action) no resistance can be developed.

For IR3535®, development of resistance is not known. Due to the repellent action of IR3535®, insects are repelled, but not killed. Therefore there is no selection pressure and no resistance can be developed, as explained in detail as follows:
IR3535® is an insect repellent and not an insecticide. Resistance is typically developed if there is a selection pressure on a population of species, in such a way that individuals that are more tolerant against the substance in question do not die and can therefore reproduce.
Unlike insecticides, IR3535® is not used to kill insects, but only to hinder them from entering areas where IR3535® has been applied. Generally, a repellent applied on human or animal skin hinders, e.g. blood sucking insects, from biting. One could argue that this effect constitutes a positive selection pressure, in such a way that the repelled insects may die of starvation and would therefore be removed from the population, so that insects, which are more tolerant, i.e. which are less repelled, would have a feeding advantage and would therefore be in favour for reproduction. Such a scenario would only be of relevance if the majority of potential hosts in an habitat of a population of insects was treated with an insect repellent, so that the insects would have severe problems to find hosts which are not treated with the repellent. Such a scenario is extremely unlikely, as the occurrence of insect repellent treated hosts in a habitat of a population of insects is only sporadic. In other words, the amount of blood not available for the insects, due to the protection by a repellent, is negligible compared to the overall amount of blood available from other sources.

2.2.5.7 Known limitations

Re-apply to clothing if it gets wet (i.e. swimming with treated clothing, or walking through rain with treated clothing) to ensure efficacy.

Efficacy testing was only conducted on cotton fabric, hence product use is limited to cotton clothing.

2.2.5.8 Evaluation of the label claims

Mosquito Repellence

Efficacy against *Aedes egypti* was demonstrated in arm-in-cage tests at an application rate of 0.34 g active substance per square meter of fabric. Repellency was 98.3% - 100% (based on landings) and 97.95% - 100% (based on bites) during 8 hours on freshly treated fabric. Repellency was 99.13% - 100% (based on landings) and 98.94% - 100% (based on bites) during 8 hours on treated fabric that had been aged for 3 months. Repellency was 99.41% - 100% (based on landings) and 99.50% - 100% (based om bites) during 8 hours on treated fabric that had been washed 3 times.

Efficacy against *Culex quinquefasciatus* was demonstrated in arm-in-cage tests at an application rate of 0.34 g active substance per square meter of fabric. Repellency was 100% (based on landings) during 8 hours on freshly treated fabric. Repellency was 100% (based on landings) during 8 hours on treated fabric that had been aged for 1 month. Repellency was 99.57 - 100% (based on landings) during 8 hours on treated fabric that had been aged for 3 months. Repellency was 99.41% - 100% (based on landings) and 99.5% - 100% (based om bites) during 8 hours on treated fabric that had been washed 3 times.

For mosquito repellents on clothes ~100% efficacy should be demonstrated according to the efficacy guidance. This criterion is met for both species from the *Culex* and *Aedes* genera for freshly treated fabric, treated fabric that has been aged for 3 months and treated fabric that has been washed 3 times. A claim against mosquitoes can therefore be granted for these use conditions.

Tropical mosquito repellence

To demonstrate efficacy against mosquito species of the genus *Anopheles* two studies were provided. One arm-in-cage test (Hussain, 2014) with *Anopheles gambiae* was performed with a too low number of volunteers and was therefore disregarded.

Efficacy against *Anopheles atroparvus* was demonstrated in a cage test with rats at an application rate of 0.35 g active substance per square meter of fabric. Based on Blood Feeding Inhibition Index (BFI) repellency was demonstrated to be 100, 100, 100 and 83.33% after 1 hour of exposure after 35, 56, 104 and 127 days respectively. Based on Repellence Index (RI) repellency was demonstrated to be 92.45, 75.37, 92.86 and 84.84% after 1 hour of exposure after 35, 56, 104 and 127 days respectively. Efficacy of the product on treated fabric that has been washed 3 times was not tested with *Anopheles*.

Although the study with *Anopheles* was performed according to a protocol that differs from the tests used for *Culex* and *Aedes,* it is considered that efficacy against *Anopheles* is sufficiently demonstrated based on the BFI (biting/feeding) results for freshly treated and aged treated fabric. Efficacy after washing the fabric 3 times was not demonstrated for *Anopheles*.

Tick repellence

Efficacy against *Iodes ricinus* was demonstrated in a mouse bioassay at an application rate of 0.34 g per square meter of fabric. Repellency was 100% (based on mite attachment rates to mice) during 30 minutes on freshly treated fabric, treated fabric stored for 1 month and treated fabric that had been washed 3 times.

For tick repellents on clothes >90% efficacy should be demonstrated according to the efficacy guidance. This criterion is met for *Ixodes riconus* on freshly treated fabric, treated

fabric that has been aged for 1 month and treated fabric that has been washed 3 times. A claim against ticks can therefore be granted for these use conditions.

In addition to the efficacy studies, a study (Pinho, 2016) on the release rate of IR3535 from treated fabric both over time and as a consequence of washing was provided. In this study, a placebo, reference product and test product with Formula Awere tested.Formula A product was applied in line with the dose rate in the use instructions. Washing of the cotton fabric was done according to ISO 105-C06:2010, AS2. IR3535 was extracted from the fabric samples according to ISO 3071:2005 with some alterations. IR3535 was quantified by HPLC. After 3 washing cycles, 71.4% of the applied IR3535 remained in the fabric. After 3 months without washing 94.6% of the applied IR3535 remained in the fabric. Combining the results of this analytical study and the efficacy tests, it can be concluded that after either 3 months (for mosquitoes) or 1 month (for ticks) after application or after 3 washing cycles, sufficient product is present in the treated fabric to remain efficacious.

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

BitePrevent® Anti-Insect Spray is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

BitePrevent® Anti-Insect Spray was not a reference product included in the CAR. No studies with the product are submitted, the classification and labelling was prepared based on the calculation rules as included in the CLP guidance.

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	The biocidal product is not a skin irritant
Justification for the value/conclusion	CLP classification based on information of raw material indicates that the biocidal product is not a skin irritant (see confidential annex).
Classification of the product according to CLP and DSD	Not skin irritant

Data waiving	
Information requirement	Skin corrosion and irritation test
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritant
Justification for the value/conclusion	CLP classification based on information of raw material indicates that the biocidal product is an eye irritant.
Classification of the product according to CLP and DSD	H319: Eye Irrit. 2

Data waiving	
Information requirement	Eye Irritation/Corrosion test (EU Test Guideline B.5)
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Data from raw materials do not indicate concerns for this endpoint.
Classification of the product according to CLP and DSD	Not a respiratory tract irritant.

Data waiving	
Information requirement	Respiratory tract irritant test
Justification	Scientifically unjustified. Data from raw materials do not indicate concerns for this endpoint (see confidential annex).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitiser
Justification for the value/conclusion	CLP classification based on information of raw material indicates that the biocidal product is not a skin sensitiser.
Classification of the product according to CLP and DSD	Not skin sensitiser

Data waiving	
Information requirement	LLNA test for skin sensitisation
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitiser
Justification for the value/conclusion	Data from raw materials do not indicate concerns for this endpoint.
Classification of the product according to	Not respiratory sensitiser

CLP and DSD	

Data waiving	
Information requirement	Test not required.
Justification	Test not required (ADS).

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	No acute oral toxicity
Justification for the selected value	CLP classification based on information of raw material indicates that the biocidal product is not acute tox (oral).
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity test
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No acute inhalation toxicity
Justification for the selected value	CLP classification based on information of raw material indicates that the biocidal product is not acute tox (inhalation).
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity test
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No acute dermal toxicity
Justification for the selected value	CLP classification based on information of raw material indicates that the biocidal product is not acute tox (dermal).
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute dermal toxicity test
Justification	Scientifically unjustified. Biocidal product CLP classification for this endpoint was calculated based on the CLP classifications of the raw materials (see confidential annex).

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Active substance: IR3535®		
Value(s)*	14%		
Justification for the selected value(s)	Worst case value reported in CAR.		

Data waiving	
Information requirement	Dermal penetration study
Justification	Scientifically unjustified. This biocidal product is an ethanol/water based formula similar to the one assessed in the CAR for IR3535® for dermal penetration, allowing for read across to be done to the CAR value of 14% which was the worst case dermal penetration observation. Note eCA; The dermal absorption value included in the CAR is based on a human volunteer study in which the volunteers were exposed for 12 hours, exposed area: legs, arms, face, neck, hands, feet (ca. 50% of the body surface).

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

In this biocidal product three substances of concerns have been identified in accordance with the EU guidance (CA-Nov14-Doc.5.11). Among the three SoCs propan-2-ol and

ethanol are identified as SoCs for which full risk assessment should be performed due to the presence of community workplace exposure limits. Furthermore propan-2-ol is a biocide active substance for which a draft final CAR is available. A co-formulant ((3Glycidyloxypropyl)tri methoxysilane) is also identified as a SoC because it leads the classification of the product as eye irritant cat 2 (H319). As H319 is in the Band A described in the EU guidance (page 7), application of P-statements is considered sufficient and no risk assessment for this compound is required. Further information on the identified SoCs and the risk assessment are found in the annex.

Available toxicological data relating to a mixture

No information

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property.

Subsequently, it was examined if there are any concerns for adverse effect to meet the critaria a) as described above using ECHA REACH database. This examination resulted that ethanol and another co-formulant X (see confidential Annex) may have reproductive toxicity.

Regarding ethanol, there is an on-going consideration as an active substance under BPR. Therefore the possible ED property of ethanol was not further considered in this application as it is a subject to be discussed by the relevant bodies in EU.
Regarding the co-formulant X, the applicant has stated that the substance does not meet the critaria b): endocrine mode of action. The statement is found in the Confidential Annex. Based on the statement this co-formulant X is also considered not to possess ED concern.

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

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	No	No	Yes	No	No	Yes	No
Dermal	No	No	Yes	No	No	Yes	No
Oral	No	No	No	No	No	Yes	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Spray Application onto clothing	Primary exposure: Inhalation & Dermal	Non-professional: Adult
2	Spray Application onto clothing (bystander)	Secondary exposure : Inhalation & dermal	Bystander: child
3.A	Direct skin contact with treated clothing by wearing	Secondary exposure: Dermal	Adult
3.B			Child
3.C			Infant
4.A	Mouthing treated clothing	Secondary exposure: Oral	Infant
4.B			Child
5	Hand to mouth from treated clothing	Secondary exposure: Dermal & Oral	Infant

Industrial exposure

Not applicable – no industrial use.

Professional exposure

Not applicable – no professional use.

Non-professional exposure

Scenario [1] Spray Application onto clothing (Adult)

Description of Scenario [1] - Spray Application onto clothing (Adult)		
The product is a ready to use liquid in a spray pump bottle (aerosol). The active substance concentration is 25.5%. The product is applied(sprayed) by an adult onto clothing at a dose of 1.6ml (about 24x pump sprays) per m^2 fabric. 1.6ml product equates to 1.34g product which is equivalent to 0.34g active substance. In this scenario, as the worst case we estimate that the non-professional user uses the entire can of the product (100 mL=84 g), assuming the application takes 5 minute. The exposure duration was set to be 60 min, assuming the non-professional stays in the same room to dry all the treated clothings. As a worst case application in a room of 20 m^3 and ventilation rate 0.6 /hr was assumed. Inhalation exposure was assessed using the exposure to spray in ConsExpo Web. ConsExpo Web result is provided in annex 3.2.		
	Parameters	Value
Tier 1	Body weight[1]	60Kg
	Active substance	25.5%
	Application duration	5 min (worst case)
	Inhalation exposure (exposure to spray[3])	
	Inhalation rate[1]	1.25 m^3/hr
	Inhalation uptake	100%
	Room volume	20 m^3
	Ventilation rate	0.6 /hr
	Exposure duration	60 min
	Mass generation rate[3]	0.8 g/s
	Airborne fraction[5]	15%
	Density non volatile[5]	0.7 g/cm^3
	Inhalation cut off diameter[5]	15 µg
	Aerosol diameter	Distribution type normal; Mean diameter: 50 µm[5] Standard deviation: 0.6[5] Maximum diameter: 139 µm (product information, based on the 90th percentile)
	Dermal exposure (constant rate)	

	Exposed area[1]	10890 cm^2 (total body surface 16600 cm^2– trunk 5710 cm^2)
	Contact rate[2]	100 mg/min
	Release duration	5 min
	Amount product used	84 g (=100 mL)
	Dermal absorption	14%

[1]HEEG opinion 17, [2]ConsExpo Guidance Report for Cleaning and Washing Products RIVM report 320104003, [3]HEAdhoc recommendation no. 11, [4] General Fact Sheet (RIVM report 090013003/2014)- natural ventilation, [5] Pest Control Products Fact Sheet (RIVM report 613340003/2002).

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses: IR3535®					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] Adult	Tier 1	0.27 mg/kg/day	0.30 mg/kg/day	-	0.57 mg/kg/day

Local effects
The ready to use product is classified as H319 Causes serious eye irritation (Eye Irritant 2). The local effects are covered in the risk assessment/management by means of assignment of H-codes and P-statements in accordance with the CLP regulation ((EC) No 1272/2008).

Exposure of the general public

Once applied to the clothing (Scenario 1), the treated clothing is used by the general public. Secondary exposure is thus possible by:

- being present in the same room as clothings are treated
- direct skin contact with the treated clothing
- through migration of the substance from mouthing the treated clothing
- through hand to mouth from hand contact with the treated clothing

Scenario [2] Bystander present during application (child)

Description of Scenario [2] – Bystander present during application (child)		
The general public can be exposed to the product if they are present in the room during the application. The product is a ready to use liquid in a spray pump bottle (aerosol). The active substance concentration is 25.5%. The product is applied (sprayed) by an adult onto clothing at a dose of 1.6 ml (about 24x pump sprays) per m^2 fabric. 1.6 ml product equates to 1.34 g product which is equivalent to 0.34 g active substance. In this scenario, we assess the exposure of a child present in the room where as the worst case a non-professional user uses the entire can of the product (100 mL=84 g), assuming the application takes 5 minute. The exposure duration was set to be 60 min, assuming the non-professional stays in the same room to dry all the treated clothings. As a worst case application in a room of 20 m^3 and ventilation rate 0.6 /hr was assumed. Inhalation exposure was assessed using the exposure to spray in ConsExpo Web. The model result is provided in annex 3.2.		
	Parameters	Value
Tier 1	Body weight[1]	23.9 Kg
	Active substance	25.5%
	Application duration	5 min (worst case)
	Inhalation exposure (exposure to spray[3])	
	Inhalation rate[1]	1.32 m^3/hr
	Inhalation uptake	100%
	Room volume	20 m^3
	Ventilation rate	0.6 /hr
	Exposure duration	60 min
	Mass generation rate[5]	0.8 g/s
	Airborne fraction[5]	15%
	Density non volatile[5]	0.7 g/cm^3
	Inhalation cut off diameter[5]	15 µg

	Aerosol diameter	Distribution type normal; Mean diameter: 50 µm[5] Standard deviation: 0.6[5] Maximum diameter: 139 µm (product information, based on the 90th percentile)
	Dermal exposure (constant rate)	
	Exposed area[1]	5824 cm^2 (total body surface 9200 cm^2– trunk 3376.4 cm^2)
	Contact rate[2]	100 mg/min
	Release duration	5 min
	Dermal absorption	14%

[1]HEEG opinion 17, [2]ConsExpo Guidance Report for Cleaning and Washing Products RIVM report 320104003, [3]HEAdhoc recommendation no. 11, [4] General Fact Sheet (RIVM report 090013003/2014)- natural ventilation, [5] Pest Control Products Fact Sheet (RIVM report 613340003/2002).

Scenario [3.A-C] Direct contact of treated clothing with skin

Description of Scenario [3.A-C] Direct contact with skin		
The general public including adults (3A), children (3B) and infants (3C) is exposed to the active substance by wearing treated clothing. The exposure route is dermal. The product is applied onto clothing at a dose of 1.6 ml (about 24x pump sprays) per m^2 fabric, equivalent to 0.34 g active substance per m^2.		
	Parameters[1]	Value
Tier 1	Residual concentration	0.34 g /m^2 clothing (applied dose)
	Transfer coefficient[1]	20% Dislodgeable, dried fluid residue on cotton and knitwear to dry hand
	Exposed body area (arms, trunk, legs, feet)[2]	14440 cm^2 (adult) 7992 cm^2 (child) 3406 cm^2 (infant)
	Dermal absorption	14%
	Body Weight[2]	60 kg (adult) 23.9 kg(child) 8 kg (infant)

[1] *Technical Notes for Guidance, 2007,* [2] HEEG recommendation 17

Uptake dermal exposure (adult) = Residual concentration x Transfer coefficient x Exposed body area x Dermal absorption / BW
= 0.34 x 0.2 x 1.444 x 0.14/60
= 0.229 mg/kg bw/day

Uptake dermal exposure (child) = Residual concentration x Transfer coefficient x Exposed body area x Dermal absorption / BW
= 0.34 x 0.2 x 0.799 x 0.14/23.9

= 0.318 mg/kg bw/day

Uptake dermal exposure (infant) = Residual concentration x Transfer coefficient x Exposed body area x Dermal absorption / BW
= 0.34 x 0.2 x 0.341 x 0.14/8
= 0.405 mg/kg bw/day

Scenario [4.A-B] Mouthing treated clothing

Description of Scenario [4.A-B] Mouthing treated clothing		
The general public, especially children and infants may be exposed to the product by chewing part of the treated clothing (e.g. sleeves). The exposure route is oral. The product is applied onto clothing at a dose of 1.6 ml (about 24x pump sprays) per m^2 fabric, equivalent to 0.34 g active substance per m^2. As there is no generic/default values agreed for the size of cloths to be ingested, reverse reference scenario is used to calculate the maximum size of treated cloths that can be ingested before reaching long-term AEL (5 mg/kg bw/day) of IR3535 for a child and infant.		
	Parameters[1]	Value
Tier 1	Residual concentration	0.34g /m^2 clothing (applied dose)
	Transfer coefficient[1]	30% Dislodgeable, dried fluid residue on cotton and knitwear to wet hand
	Fraction dislodged by mouthing ingested	1 (worst case)
	Oral absorption	100%
	Body Weight[2]	23.9 kg(child) 8 kg (infant)

[1] Technical Notes for Guidance, 2007

Cloths size (child) = (long term AEL x BW)/(Residual concentration x Transfer coefficient x oral absorption)
= (5 x 23.9)/(340 x 0.3 x 1)
= 1.17 m^2

Cloths size (infant) = (long term AEL x BW)/(Residual concentration x Transfer coefficient x oral absorption)
= (5 x 8)/(340 x 0.3 x 1)
= 0.39 m^2

Scenario [5] Hand to mouth from treated clothing

Description of Scenario [5] Hand to mouth from treated clothing
The general public especially children may be exposed to the product by touching treated clothing and putting the contaminated hands into the mouth. However, the exposure levels from this scenario is considered to be lower than scenario 4, in which a child or infant was assumed to put a piece of treated clothing into mouth and chew.

Calculations for Scenario [2-5]

Summary table: systemic secondary exposure of the general public: IR3535®					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2] child	Tier 1	0.73 mg/kgbw/day	0.75 mg/kgbw/day	-	1.5 mg/kgbw/day
Scenario [3.A] adult	Tier 1	-	0.229 mg/kgbw/day	-	0.229 mg/kgbw/day
Scenario [3.B] child	Tier 1	-	0.318 mg/kgbw/day	-	0.318 mg/kgbw/day
Scenario [3.C] infant	Tier 1	-	0.405 mg/kgbw/day	-	0.405 mg/kgbw/day
Scenario [4.A] child	Tier 1	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 1.17 m^2			
Scenario [4.B] infant	Tier 1	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.39 m^2			
Scenario [5] infant	Tier 1	Not calculated as the exposure level is expected to be lower than Scenario 4.			

Further information and considerations on scenario [2-5]
No additional information

Combined scenarios

The following combined scenarios are possible for chronic exposure to the active substance. For infant Scenario 5 is not relevant to combine as the hand-to-mouth exposure is considered acute.

Summary table: combined systemic secondary exposure of the general public: IR3535®				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**

Adult: Scenarios [1+3.A]	0.27 mg/kgbw/day	0.30 + 0.229 = 0.529 mg/kgbw/day	-	0.799mg/kgbw/day
Child: Scenarios [2+3.B+4.A]* Tier 1	0.73 mg/kgbw/day	0.75+0.318= 1.067 mg/kgbw/day	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.75 m^2	5 mg/kgbw/day
Infant Scenarios [3.C+ 4.B]* Tier 1	-	0.405 mg/kgbw/day	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.36 m^2	5 mg/kgbw/day

* As there is no generic/default values agreed for the size of cloths to be ingested, reverse reference scenario is used to calculate the maximum size of treated cloths that can be ingested before reaching long-term AEL (5 mg/kg bw/day) of IR3535 for a child and infant. However, as the child and infant is also exposure in scenario 2 and 3, the amount that can be ingested before reaching the long-term AEL is recalculated.

Cloths size (child) = ((long term AEL - total exposure scenario 2 – total exposure scenario 3.B.) x BW) /(Residual concentration x Transfer coefficient x oral absorption)
= ((5 – 1.5 – 0.318) x 23.9) /(340 x 0.3 x 1)
= 0.75 m^2

Cloths size (infant) = ((long term AEL – total exposure scenario 3.C.) x BW) /(Residual concentration x Transfer coefficient x oral absorption)
= ((5-0.405) x 8) /(340 x 0.3 x 1)
= 0.36 m^2

Monitoring data
No information available.

Dietary exposure
Not relevant, because the product is used for clothings. In addition, no food or drinks may be present when the product is applied (see SPC).

Aggregated exposure
No information available.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**

1	Non-professionals (adult, chronic)	Tier 1 (no PPE)	0.57 mg/kg/day
2	General public (child)	Tier 1 (no PPE)	1.5 mg/kg/day
3.A	General public (adult)	Tier 1 (no PPE)	0.229 mg/kgbw/day
3.B	General public (child)	Tier 1 (no PPE)	0.318 mg/kgbw/day
3.C	General public (infant)	Tier 1 (no PPE)	0.405 mg/kgbw/day
4.A	General public (child)	Tier 1 (no PPE)	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 1.17 m^2
4.B	General public (infant)	Tier 1 (no PPE)	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.39 m^2
5	General public (infant)	Tier 1 (no PPE)	Not calculated as the exposure level is expected to be lower than Scenario 4.
1 + 3.A	Non-professionals (adult, chronic)	Tier 1 (no PPE)	0.799 mg/kgbw/day
2+3.B+4.A	General public (child)	Tier 1 (no PPE)	5 mg/kgbw/day Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.75 m^2
3.C+4.B	General public (infant)	Tier 1 (no PPE)	5 mg/kgbw/day Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.36 m^2

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	1) Rabit oral developmental toxicity study 2) Rabit oral 28-day toxicity study	500 mg/kg bw/day	100	1 (none)	5 mg/kg bw/day
AELmedium-term		500 mg/kg bw/day	100	1 (none)	5 mg/kg bw/day
AELlong-term		500 mg/kg bw/day	100	1 (none)	5 mg/kg bw/day
ARfD	NA				
ADI	NA				

[1] Toxicity studies, safety factor and NOAEL as described in the CAR.

Maximum residue limits or equivalent

Not applicable.

Specific reference value for groundwater

Not applicable.

Risk for industrial users

Not applicable. The product if for non-professional use only.

Risk for professional users

Not applicable. The product if for non-professional use only.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1– adultchronic	1	500	5	0.57 mg/kg/day	11%	Yes

Local effects

The ready to use product is classified as H319 Causes serious eye irritation (Eye Irritant 2). The local effects are covered in the risk assessment/management by means of assignment of H-codes and P-statements in accordance with the CLP regulation ((EC) No 1272/2008).

Furthermore a qualitative local risk assessment is conducted for the task "spraying onto clothes" in the current application as per the Guidance on BPR: Vol III Part B, April 2015.

- Local effect of concern:
  - Eye Irritation Cat 2
- Hazard category of local effect:
  - Low
- Exposure scenario(s):
  - Recommended use: Adult non-professinal user
- Potential exposure routes:
  - Skin
  - Respiratory tract
  - Eye & Mouth (accidental)
- Frequency & duration of exposure:
  - << 1 min per day / 2-3 times a week / 90 day period
- Potential dgrees of exposure:
  - 2.85 ml of product/day

Relevant RMM	Conclusion on risk	Uncertainties
Labelling as eye irritant Instructions for use Packaging reducing risk of eye exposure by splashes Wash hand and face thoroughly after handling Do not open container	Acceptable since: - Reversible effect - Used for short duration - Low exposure per day - Low likelihood for exposure of critical initial site of contact (eyes)	(±) Frequency of use may be lower or higher than recommended (±) Instructions for use may not be followed

Conclusion

Based on the risk characterisation no adverse health effects are expected for unprotected non-professional users, when used in accordance with the instructions described in the SPC.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2- child, chronic	Tier 1	500	5	1.5	30%	Yes
3.A –adult, chronic	Tier 1	500	5	0.229	5%	Yes
3.B –child, chronic	Tier 1	500	5	0.318	6%	Yes
3.C –infant, chronic	Tier 1	500	5	0.405	8%	Yes
4.A – child, chronic	Tier 1	500	5	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 1.17 m^2		Yes, is it is not realistic that a child would ingest 1.17 m^2 of clothing.
4.B – infant, chronic	Tier 1	500	5	Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.39 m^2		Yes, is it is not realistic that an infant would ingest 0.39 m^2 of clothing.
5 – infant, acute	Tier 1	500	5	Not calculated as the exposure level is expected to be lower than Scenario 4.		Yes, as the scenario 4 is acceptable

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [1+ 3.A]-adult, chronic	Tier 1	500	5	0.799	16%	Yes
Scenarios [2+3.B+4.A]-child, chronic	Tier 1	500	5	5 mg/kgbw/day Reverse reference scenario: Max. size of treated clothing	100%*	Yes, it is not realistic that a child would ingest 0.75 m^2 of clothing.

				that can be mouthed : 0.75 m^2		
Scenarios [3.C+4.B]-infant, chronic	Tier 1	500	5	5 mg/kgbw/day Reverse reference scenario: Max. size of treated clothing that can be mouthed : 0.36 m^2	100%*	Yes, it is not realistic that an infant would ingest 0.36 m^2 of clothing.

** As there is no generic/default values agreed for the size of cloths to be ingested, reverse reference scenario is used to calculate the maximum size of treated cloths that can be ingested before reaching long-term AEL (5 mg/kg bw/day) of IR3535 for a child and infant. However, as the child and infant is also exposure in scenario 2 and 3, the amount that can be ingested before reaching the long-term AEL is recalculated.

Local effects
The product is classified as eye irritant 2 based on the CLP regulations. The exposure of eyes of the general public to a relevant concentration of IR3535 to cause eye irritation is an unlikely event to occur. It is considered unlikely because 1) treated clothings are usually worn dry, and 2) even when the clothings are wet, the IR3535 is not considered to be released easily considering the biocidal effects of the product remain after two times of laundry. Therefore no adverse local effects are expected due to exposure to IR3535 from the use of the product.

Conclusion
Based on the risk characterisation no adverse health effects are expected for the general public, when used in accordance with the instructions described in the SPC.

Risk for consumers via residues in food

Not relevant, because the product is used for clothings. In addition, no food or drinks may be present when the product is applied (see SPC).

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product
The product only has one active substance, hence combined exposure to several active substances is not applicable.

The combinational risk assessment for the active substance and Substance of concerns (SoCs) does not need to be performed according to the BPR guidance.

2.2.7 Risk assessment for animal health

Not relevant as exposure of animals is not expected.

2.2.8 Risk assessment for the environment

The environmental risk assessement is based on the concept of releases of active substance to the environment taking into account all relevant life cycle stages. The estimation of predicted environmental concentrations (PECs) for the product as well as the derivation of predicted no effect concentrations (PNECs) for different environmental compartments was performed according to the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Risk Assessment (Active Substances; 2017) and the Environmental Emission Scenario Document for Product Type 19 (2015).

2.2.8.1 Effects assessment on the environment

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

The ecotoxicity data for the a.s. as indicated in the CAR, was used to perform the product effect assessment.
Trimethoxy[3-(2-oxiranylmethoxy)propyl]silane is not a substance of concern for the environment as it does not meet the criteria laid down in article 3(f) of the BPR regarding substance of concern identification, further specified in the Guidance vol IV part B+C (2017), chapter 8.
Ethanol and propan-2-ol are substances of concern in the product as they are active substances in PT2,3 and 4 and present in the products with a concentration > 0.1 % (i.e. a maximum of 68.46% w/w and 6.83 % w/w pure ingredient respectively). These substances are solvents which will quickly evaporate from treated clothing. The main emission route for the environment will be to air, no emission to the sewer is expected. Considering that the substances are diluted in the air and moreover degraded quickly once deposited on surface water and soil, concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable.
Furthermore, the substances are resistant to hydrolysis, but readily biodegradable. The degradation products of these substances are water and carbon dioxide. These are not considered relevant for the environmental risk assessment as these are natural occurring compounds.

Further Ecotoxicological studies

No data is available

Data waiving	
Information requirement	-
Justification	No further studies used, other than the ones included in the CAR for the active substance

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

Not relevant

Data waiving	
Information requirement	-

Justification	Not required for PT 19

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

Not relevant

Data waiving	
Information requirement	-
Justification	Not required because the biocidal product is not in the form of bait or granules.

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

Not relevant

Data waiving	
Information requirement	-
Justification	Not required because the biocidal product is not in the form of bait or granules.

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

Not relevant for the product use.

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

The product is to be used by general public, indoors and outdoors as a insect repellent to protect humans from insects by application on clothing only.

According to the ESD for PT19 the emissions to the environment resulting from indoor and outdoor product application are considered to be negligible. Therefore, this life-cycle was not considered relevant for this risk assessment, and consequently not assessed.

The main emissions to the environment resulting from the application of the product on clothes occur during the removal phase of the insect repellent:

- Through washing of the clothes treated with the repellent formulation: Sewage Treatment Plants (STP) are the primary compartment for emissions, whereas surface water (including sediment) and soil (including groundwater) are secondary exposed compartments for remnants via STP effluents and sewage slude applications, respectively.
- Through direct release to surface water if people with treated clothing or swimsuits go swimming in outdoor surface waters.

The concentrations in each relevant compartment were calculated based on the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Risk Assessment (Active Substances; 2017) and the Environmental Emission Scenario Document for Product Type 19 (2015).

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

No data is available

Data waiving	
Information requirement	-
Justification	No further studies used, other than the ones included in the CAR for the active substance

Leaching behaviour (ADS)

For the leaching rate determination a laboratory release rate test was performed and the release rate was assessed after the textile was subjected to 3 wash cycles. The amount of IR3535® lost after 3 wash cycles was 71.4 % (Pinho E. 2016).

Testing for distribution and dissipation in soil (ADS)

No additional data is available for distribution and dissipation in soil

Data waiving	
Information requirement	-
Justification	No further studies on soil, other than the ones included in the CAR for the active substance, used for the environmental risk assessment

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

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

Testing for distribution and dissipation in air (ADS)

No additional data is available for distribution and dissipation in air

Data waiving	
Information requirement	-
Justification	No further studies on water, sediment and air, other than the ones included in the CAR for the active substance, used for the environmental risk assessment.

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)

Acute aquatic toxicity

Data waiving	
Information requirement	-
Justification	The product is not to be sprayed near surface waters

Chronic aquatic toxicity

Data waiving	
Information requirement	-
Justification	The product is not to be sprayed near surface waters

Measured aquatic bioconcentration

No data is available.

Estimated aquatic bioconcentration

Data waiving	
Information requirement	-
Justification	The product is not to be sprayed near surface waters. No further studies on aquatic bioconcentration, other than the ones included in the CAR for the active substance, used for the environmental risk assessment

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

Not relevant

Derivation of PNECs

Compartment	PNEC	Remarks/Justification
Freshwater	**$PNEC_{water}$:** **0.1 mg/L**	Organisms: fish, daphnia and algae Endpoint: EC_{50} > 100 mg/L Assessment factor: 1000 Extrapolation method: assessment factor Justification: Since the three taxonomic groups (fish, invertebrates, algae) are covered but only acute toxicity data are available, an assessment factor is applied. In all studies, the highest required test concentration was tested according to the respective guidelines. With all tested species the required endpoint lies above this concentration, which means a more sensitive species cannot be defined. The applicant of the AR justifies the use of an assessment factor of 100 for the risk assessment based on these studies and results. Nevertheless, the RMS prefers to use an assessment factor of 1000 as a worst-case. Therefore a PNECwater of 0.1 mg/l is used.
Sediment	**$PNEC_{sediment}$:** **1.11 mg/kg wwt**	Organism: none Endpoint: $PNEC_{water}$ 0.1 mg/L Assessment factor: n/a Extrapolation method: equilibrium partitioning method Justification: No data on sediment dwelling organisms has been submitted. A $PNEC_{sediment}$ has been calculated based on the assumptions of the equilibrium partitioning method and using $PNEC_{water}$.
Micro-organisms (Sewage Treatment Plant)	**$PNEC_{microorganisms\ (STP)}$:** **100 mg/L**	Organism: activated sewage sludge Endpoint: EC_{50} and NOEC > 1000 mg / L Assessment factor: 10 Extrapolation method: assessment factor Justification: Since no adverse effects were observed in the available test data up to a concentration of 1000 mg/l, both the EC50 as the NOEC are considered to be larger than 1000 mg/l. To derive the PNEC for microorganisms an assessment factor of 10 is used.
Soil	**$PNEC_{soil}$:** **0.85 mg/kg wwt**	Organism: none Endpoint: $PNEC_{water}$ 0.1 mg/L Assessment factor: n/a Extrapolation method: equilibrium partitioning method Justification: No data on terrestrial organisms has been submitted. A $PNEC_{soil}$ has been calculated based on the assumptions of the equilibrium partitioning

Compartment	PNEC	Remarks/Justification
		method and using $PNEC_{water}$.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 19
Assessed scenarios	Scenario 1:Washing of clothes treated with the repellent formulation. Scenario 2: Swimming with treated clothing or swimming suits
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015
Approach	Consumption-based approach
Distribution in the environment	Calculations based on the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Risk Assessment (Active Substances; 2017)
Groundwater simulation	Scenarios 1 and 2: No simulation for leaching to groundwater was performed
Confidential Annexes	None
Life cycle steps assessed	Production: No Formulation No Use: No Service life: Yes
Remarks	None

Emission estimation

Indoor use of Insect repellent on clothing: "Washing of clothes treated with the repellent formulation".

Emissions to the environment can take place during the application of the product on garments. During the life-cycle step the main emissions to the environment occur during the removal phase of the insect repellent which can take place through washing of clothes treated with the repellent formulation. In this scenario, Sewage Treatment Plants (STP) are the primary compartment for emissions, whereas surface water (including sediment) and soil, (including groundwater) are secondary exposed compartments for remnants via STP effluents and sewage slude applications, respectively.

The calculation of the emissions to the STP were based on the Exposure scenario for insect repellents applied to human skin and garments (ESD § 3.1, p.20): *"Removal through showering and bathing of humans as well as washing of garments (ESD § 3.1.4.1, p.22)".*

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: *Washing of clothes treated with the repellent formulation.*			
Consumption per application	0.034	mg a.s./cm^2	1.6 ml of product to be applied in 1 m^2 textile
Concentration of active substance in the product	25.5	%	density of the product is 0.840±0.002 $g.cm^{-3}$
Number of applications per day	1	d^{-1}	ESD PT 19 Table 3.2
Treated area of garments	17838	cm^2	ESD PT 19 Table 3.4 and 3.4: Realistic worst case for outdoor garment set
Fraction of inhabitants using a repellent product	0.01	-	ESD PT 19 Table 3.5

Calculations

The relevant calculations for the environmental exposure estimation are calculated according to Table 3.6 from the ESD. The local emission from the STP to surface water is indicated below.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	7.79 $x10^{-03}$	Primary exposed compartment

Indoor or outdoor use of insect repellent on clothing: ''Swimming with treated clothing or swimming suits''

The intended use indicates that the product also can be used on clothing used for swimming. Therefore direct release of repellents from treated clothing or swimming suits to ponds, lakes or reservoirs during swimming is also evaluated. As this specific scenario is not included in the ESD, the default treated area of garments of 17838 cm^2 was used as

input for the emission calculations instead of the default treated area of human skin of 16600 cm^2.
The calculation of the emissions to surface water bodies were based on the Exposure scenario for insect repellents applied to human skin and garments (ESD § 3.1, p.20): "*Release to surface water bodies through swimming (ESD § 3.1.4.2, p.28)".*

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor use of insect repellent on human skin (direct exposure due to swimming)			
Daily number of swimmers ($N_{swimmer}$)	1500	[-]	ESD PT19 Table 3.7
Fraction of swimmers using the repellent product (F_{swim})	0.1	[-]	ESD PT19 Table 3.7
Number of applications per day (N_{appl})	1	[d^{-1}]	ESD PT19 Table 3.7
Fraction released to surface water body ($F_{waterbody}$)	1	[-]	ESD PT19 Table 3.7
Consumption per application	0.034	mg a.s./cm^2	1.6 ml of product to be applied in 1 m^2 textile density of the product is 0.840±0.002 g.cm^{-3}
Concentration of active substance in the product	25.5	%	-
Treated area of garments	17838	cm^2	ESD PT 19 Table 3.4 and 3.4: Realistic worst case for outdoor garment set

Calculations

The relevant calculations for the environmental exposure estimation are calculated according to Table 3.7 from the ESD. The local emission from the STP to surface water is indicated below.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Surface water	4.64 x10^{-03}	Primary exposed compartment

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other

Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	No	No	No	No	No

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks*
Molecular weight	215.9	g/mol	
Melting point	<-90	°C	Test substance is liquid at room temperature
Boiling point	300	°C	Metastable boiling point
Vapour pressure (at 20ºC)	0.15±0.01	Pa	
Water solubility (at 20°C)	$7x10^4$	mg/l	
Log Octanol/water partition coefficient	1.7	Log Pow	HPLC method
Organic carbon/water partition coefficient (Koc)	475.25	l/kg	value obtained from adsorption/desorption test
Henry's Law Constant (at 20 °C)	$4.613x10^{-4}$	Pa/m3/mol	
Biodegradability	Not Ready biodegradable		IR3535® Failed on the ready biodegradability tests. However an STP simulation test showed elimination > 99% after 28 days, indicating that the substance is biodegradable in STP
Removal in STP	99%	-	IR3535 is not ready biodegradable according to two screening tests, but in a STP simulation test, 99% elimination was measured during 28 days indicating that IR3535 is biodegradable.
DT_{50} for biodegradation in surface water	12.88-15.59	d (at 12ºC)	
DT_{50} for hydrolysis in surface water	866.13	h (at 12ºC /pH 9)	
DT_{50} for photolysis in surface water	-	d or hr	
DT_{50} for degradation in soil	-	d or hr (at 12ºC)	Not determined, not relevant
DT_{50} for degradation in air	0.5482	d	$0.5x10^6$ OH radicals/cm^3 and 24 hr day

** All information listed regarding the Input parameters for calculating the fate and distribution in the environment are from the CAR*

99 % elimination based on the STP simulation test (Doc. No.: 713-002, Doc. IIIA, Section A7.1.2.1.1/01) included in the CAR for IR3535 was used for the assessment of the STP pathway. indicating that IR3535 is biodegradable. In an aerobic water/sediment degradation study, IR3535 was shown to remain mainly in the water phase. There it was first rapidly degraded to its free acid, after which this metabolite ultimately degraded after a lag phase.The default value for inherently biodegradable substances is therefore considered relevant and used in the calculations.

	fate and distribution in the STP	
Compartment	Percentage [%]	
	Scenario 1	Scenario 2
Air	Not relevant	-
Water	1	-
Sludge	Not relevant	-
Degraded in STP	99	-

Calculated PEC values

The Predicted Environmental Concentrations were calculated based on the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Risk Assessment (Active Substances; 2017) and the Environmental Emission Scenario Document for Product Type 19 (2015).
Information on the active substance, available in the CAR was used as input for the exposure determination. In the absence of available data from CAR, default values from the above guidance were used.

Summary table on calculated PEC values							
	PEC_{STP}	**PEC_{water*}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m^3]	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
Scenario 1	3.90×10^{-5}	3.89×10^{-6}	-	-	**	**	-
Scenario 2	-	9.70×10^{-4}	-	-	-	-	-

* Because predicted no-effect concentrations (PNECs) are not available for sediments (see section 2.2.8.1), the ecotoxicological endpoint have to be derived from the PNECfreshwater using equilibrium partitioning. However, PECsediment is also derived by using equilibrium partitioning from PECfreshwater and therefore the ratio PEC:PNEC for freshwater covers that of sediment as well. Calculation of PECsediment is therefore not included in the current risk assessment.

** No PECs for soil and groundwater were calculated as the possible emissions to soil and groundwater are negligible due to the large elimination in the STP.

The worst case PEC value for the risk assessment for the aquatic compartment for scenario 2 corresponds to the Clocalwater, 91d value.

Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Not relevant.

Waiving justification: The low BCF values suggest that the substance has a low bioaccumulation potential according to the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Risk Assessment (Active Substances; 2017, BCF_{Fish} =5.6 L/kg; $BCF_{earthworms}$= 1.44 kg/kg). It has a low log Kow (1.7), it is not highly adsorptive (Koc= 475.25 L/kg) and its structural features does not indicate accumulation. Due to the failing of the ready biodegradability screening tests, the substance could initially be classified as potentially persistent. However, an STP-simulation test showed elimination up to 99% after 28 days, indicating that IR3535® is biodegradable. The degradation half-life of 12.88 – 15.85 days (12°C) in the water/sediment test is well below the P-criterion of 40 days. Given these evidences, no further assessment of secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: According to the ESD for PT19 the Evaporation from treated garments is considered negligible. Therefore, this compartment is not at risk by the use of BitePrevent® Anti-Insect Spray.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	< 0.001

Conclusion: No risks to sewage treatment plants from the use of BitePrevent® Anti-Insect Spray have been identified. PEC/PNEC ratio was below 1.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1	< 0.001	< 0.001	-	-
Scenario 2	< 0.001	< 0.001	-	-

Conclusion: No risks to surface water and sediments from the use of BitePrevent® Anti-Insect Spray have been identified. PEC/PNEC ratio was below 1 for both compartments.

Terrestrial compartment

Emissions towards the terrestrial compartment do not occur directly from the indoor applications of BitePrevent® Anti-Insect Spray.

The only possible emissions towards the terrestrial compartment can occur when sludge form the STP is spread on land. However no emissions to the soil or groundwater, due to sludge application are expected, because 99 % elimination in the STP is taken into account.

Conclusion: No risks to soil organisms from the use of BitePrevent® Anti-Insect Spray have been identified. PEC/PNEC ratio was below 1.

Groundwater

Emission to groundwater is considered negligible as the active substance is almost completely degraded in the STP and therefore not brought on soils along with sewage sludge. Significant emission to groundwater is consequently not expected.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

Not relevant

Mixture toxicity

Not relevant

Conclusion: According to the guidance on mixture toxicity, this assessment is not applicable for this product because none of the raw material substances/compounds are classified as hazardous to the environment.

Aggregated exposure (combined for relevant emission sources)

According to Articles 9 and 19 of the BPR substances shall be included in Annex I, IA and IB also taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances. This refers to environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs.

Acording to the ECHA list of authorised biocidal products, currently there no approved product containing the active substance IR3535®. Also, the active substance was only approved for PT 19, and there is only one user category on this application (non-professional).

Given these evidences, the aggregated exposure estimation for the biocidal product is not relevant for the main application.

Overall conclusion on the risk assessment for the environment of the product
No risks to the environment from the use of BitePrevent® Anti-Insect Spray have been identified. PEC/PNEC ratios were below 1 for all the relevant compartments.

2.2.9 Measures to protect man, animals and the environment

The overall conclusion on the risk assessment of this product is that it is safe when used as recommended.

Given the inhert hazardous properties of the product, the following directions of use are recommended:

Use instructions:

Ready-to-use pump spray insect repellent product to be applied on cotton clothing.

Do not spray clothings while wearing.

Use in well ventilated space only.

Can be used indoors and outdoors.

Shake bottle several times just before use.

The spray should be applied with the bottle vertically and at 15 cm distance from the clothing material.

Apply 1.6 mL (about 24 pump sprays) of product per square meter of clothing.

Dry the clothing material with a hairdryer.

Re-apply to clothing if clothing gets wet (i.e. swimming with treated clothing, or walking through rain with treated clothing) to ensure efficacy.

For mosquito repellance:
When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required.
When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required.

For tropical mosquito repellance:
When clothing is not washed: re-apply 3 months after the first application if repellent effect is still required.
When clothing is washed: re-apply after 1 domestic laundry cycle if repellent effect is still required.

For tick repellance.
When clothing is not washed: re-apply 1 month after the first application if repellent effect is still required.
When clothing is washed: re-apply after 3 domestic laundry cycles if repellent effect is still required.

Risk mitigation measures:

-Flammable: Keep away from souces of ignition – no smoking.
-Keep out of reach of children.
-Do not eat or drink during application. No food or drink is allowed in the room where the product is applied.
-Wash hand and face thoroughly after handling.
-Avoid breathing vapours, mist or gas. Ensure adequate ventilation.
-Avoid sources of radiation, static electricity and contact with food.
-Do not open container.
-Prevent leakage and spillage, if safe to do so.
-Do not decant product.
-Do not let product enter drains.

-Store in cool and well-ventilated place.
-Do not reuse or refill this container.

Emergency measures:
In case of fire: Use ABC powder extinguisher to extinguish.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Get medical advice immediately and show product label.

In case of spills, soak up with inert absorbent material and dispose of in accordance with the current legislation on waste treatment.

Disposal
Do not open container.
Do not decant product.
Do not let product enter drains.
Do not reuse or refill this container.
Dispose as normal waste.

2.2.10 Assessment of a combination of biocidal products

Not relevant as the biocide product is not used in combination with other biocidal product(s).

2.2.11 Comparative assessment

Not applicable.

3 ANNEXES

3.1 List of studies for the biocidal product

List of studies reviewed

List of new data submitted in support of the evaluation of the biocidal products

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
1.3 Active Substance Manufacturer	NA	Van Sloun P.	2017a	No Title (Statement) Topic: Production Site Confirmation	Merck KGaA	X	
1.3 Active Substance Manufacturer	NA	Van Sloun P.	2017b	No Title (Statement) Topic: Article 95	Merck KGaA	X	
NA	NA	Bou V.	2014	Certificate of Analysis IR3535	Merck KGaA	X	
NA	NA	LoA	2016	Supply Agreement Merck – IR3535, Appendix 5, Letter of Access pursuant of the BPR to a Regulatory Authority	Merck KGaA	X	
2.1 Trade name	NA	Figueiredo I.	2016	Declaration: Trade names	Success Gadget	X	
2.3 Complete quantitative composition	NA	Figueiredo I.	2016	Declaration: QQ	Success Gadget	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
3.1.1 - Physical state at 20 °C and 101.3 kPa 3.1.2 - Colour at 20 °C and 101.3 kPa 3.1.3 - Odour at 20 °C and 101.3 kPa 3.2 - Acidity / alkalinity	16.560538.0001	Pivato M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	
3.3 Relative density	PCR 20140513	Pinho E	-	Product Characterization Report	Success Gadget	X	
3.4.1.1 - Storage stability test – accelerated storage	08a/2016	Semenzi M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	
3.4.1.2 - Storage stability test – long term storage at ambient temperature	16.560538.0005	Molin L.	2017	Stability Evaluation of Insecticide Product named Formula A (batch 20160609) in terms of Aspect and pH, after 12, 18 and 24 months at 25°C	Success Gadget	X	
	17/000322336	Perin F.	2017	Stability study: ANALYTICAL RESULTS			
3.4.1.4 - Storage stability test – low temperature stability test for liquids	16.560538.0001	Pivato M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
3.4.2.3- Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	08a/2016	Semenzi M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	
3.5.2 Suspensibility	16.560538.0001	Pivato M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	
3.5.6 Droplet size	Mo5535	Rodriguez N.	2016	Determination of the Particle Size Distribution of formula A	Success Gadget	X	
3.8 Surfance tension	16/000232759	Moulard & Perin	2016	Analytical Results	Success Gadget	X	
3.9 Viscosity							
4.6 Flammable liquids	GLP3016000030R1V1/2016	Younis S.	2016	Flash Point Testing on a Sample of Formula A	Success Gadget		
4.17.1 Auto ignition temperature	16/000232759	Moulard & Perin	2016	Analytical Results	Success Gadget	X	
5.1 Analytical method for active in product	16.560538.0001	Pivato M.	2016	Validation of a method for the Determination of IR3535 assay in Insecticide Product named Formula A & Stability Evaluation	Success Gadget	X	
	15.538485.0004	Bazza G.	2016	Validation of a method and determination of assay of IR3535 in BitePrevent® Anti-Insect Spray			
6.7 Efficacy data	SiRi/SG/E/006/029	Hussain A.	2014	Arm in Cage Method – Fabric Samples: Anopheles gambiae, T0 and 3 Washes	Success Gadget	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
	C0003/1617/08/ET/0001	Hussain A.	2016a	Study Report: Efficacy Testing of Mosquito Repellent: Aedes aegypti, T0			
	C0003/1617/08/ET/0002	Hussain A.	2016b	Study Report: Efficacy Testing of Mosquito Repellent: Aedes aegypti, T3 Months			
	C0003/1617/08/ET/0003	Hussain A.	2016c	Study Report: Efficacy Testing of Mosquito Repellent: Aedes aegypti, 3 Washes			
	C0003/1718/07/ET/0002	Hussain A.	2017a	Study Report: Efficacy Testing of Mosquito Repellent: Culex quinquefasciatus, T0			
	C0003/1718/07/ET/0002	Hussain A.	2017b	Study Report: Efficacy Testing of Mosquito Repellent: Culex quinquefasciatus, T1 Month			
	C0003/1718/09/ET/0001	Hussain A.	2017c	Study Report: Efficacy Testing of Mosquito Repellent: Culex quinquefasciatus, T3 Months			
	C0003/1617/08/ET/0003	Hussain A.	2016d	Study Report: Efficacy Testing of Mosquito Repellent: Culex quinquefasciatus, 3 Washes			
	C0003/1718/07/ET/0001	Hussain A.	2017d	Study Report: Assessment Of Repellency Of Ticks: T0			
	C0003/1718/07/ET/0001	Hussain A.	2016e	Study Report: Assessment Of Repellency Of Ticks: one month			
	C0003/1718/07/ET/0001	Hussain A.	2016f	Study Report: Assessment Of Repellency Of Ticks: 3 Washes			
NA	NA	Pinho E.	NA	CoA for products (all CoA)	Success Gadget	X	
NA	NA	Pinho E.	2016	Determination Of Ethyl 3-[Acetyl(Butyl)Amino]Propanoat Release Rate From Textiles Treated With Formula A	Success Gadget	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
NA	NA	Casimiro E.	2016a	Data Waiving Justification for Physical, Chemical & Technical Properties.	Success Gadget	X	
NA	NA	Casimiro E.	2016b	Data Waiving Justification Physical Hazards & Respective Characteristics	Success Gadget	X	

3.2 Output tables from exposure assessment tools

3.2.1 Human Health

Non-Professional – Direct Exposure

Scenario 1 Adult Spraying Clothing

Substance	Model report
IR3535®	**Exposure to spray onto clothing/adult**

Substance		
Name	IR3535	
CAS number		
Molecular weight	216	g/mol
Kow	1.7	10Log
Product		
Name		
Weight fraction substance	25.5	%
Population		
Name		
Body weight	60	kg

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	5	minute
Exposure duration	60	minute
Weight fraction substance	25.5	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	0.8	g/s
Airborne fraction	15	%
Density non volatile	0.7	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	Normal	
Mean diameter	50	µm
Standard Deviation	30	µm
Maximum diameter	139	µm
Include oral non-respirable material exposure	no	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	10900	cm^2
Weight fraction substance	25.5	%
Contact rate	100	mg/min
Release duration	5	minute
Absorption model	Fixed fraction	
Absorption fraction	14	%

Results for scenario *spray onto clothing*

☐ Show dose description

Inhalation

Mean event concentration	1.3×10^{1}	mg/m³
Peak concentration (TWA 15 min)	2.3×10^{1}	mg/m³
Mean concentration on day of exposure	–	
Year average concentration	–	
External event dose	2.7×10^{-1}	mg/kg bw
External dose on day of exposure	–	
Internal event dose	2.7×10^{-1}	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Dermal

Dermal load	1.2×10^{-2}	mg/cm²
External event dose	2.1	mg/kg bw
External dose on day of exposure	–	
Internal event dose	3.0×10^{-1}	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Integrated

Internal event dose	5.7×10^{-1}	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Propan-2-ol

ConsExpo 4.1 report

Report date: 12/06/2016

Compound

Compound name :	propan-2-ol		
CAS number :	67-63-0		
molecular weight		60	g/mol
vapour pressure		5.78E3	Pascal
KOW	0.05	10Log	

Populations

Adult

body weight	60	kilogram

Products

BitePrevent® Anti-Insect Spray

	weight fraction compound 3.4 % **Aggregate Exposures** **Aggregate exposure for Adult :** Total chronic systemic dose (mg/kg/day): 0.07 Inhalation chronic systemic dose (mg/kg/day): 0.00006 Dermal chronic systemic dose (mg/kg/day): 0.07 Total acute systemic dose (mg/kg/day): 0.28 Inhalation acute systemic dose (mg/kg/day): 0.00024 Dermal acute systemic dose (mg/kg/day): 0.283 Mean even concentration (mg/m^3) 139 **Details for scenario: Adult, BitePrevent® Anti-Insect Spray : spraying clothing** **Inhalation model: Exposure to vapour : instantaneous release** weight fraction compound 3.4 % exposure duration 5 minute room volume 20 m3 ventilation rate 0.6 1/hr applied amount 84 gram **Uptake model: Fraction** uptake fraction 1 fraction inhalation rate 1.25 m3/hr **Dermal model: Direct dermal contact with product : instant application** weight fraction compound 3.4 % exposed area 1.09E4 cm2 applied amount 84 gram **Uptake model: fraction** uptake fraction 1 fraction **Uptake model: Fraction** uptake fraction 1 fraction
Ethanol	**ConsExpo report (Tier 3, constant release)** Report date: 30-04-2018 **Compound** Compound name : ethanol CAS number : 67-17-5 molecular weight 60 g/mol vapour pressure 5.73E3 Pascal KOW -0.31 10Log **Populations** **Adult**

	body weight 60 kilogram **Products** **BitePrevent® Anti-Insect Spray** weight fraction compound 64.9 % **Aggregate Exposures** Mean event concentration (mg/m^3) 360 **Details for scenario: Adult, BitePrevent® Anti-Insect Spray : spraying clothing** **Inhalation model: Exposure to vapour : constant release** weight fraction compound 64.9 % exposure duration 5 minute room volume 20 m3 ventilation rate 0.6 1/hr applied amount 22.3 gram applied duration 5 min

Scenario 2 Bystander (child present in the room)

Substance	Model report
IR3535®	**Bystander present during application (child)**

Substance		
Name	IR3535	
CAS number		
Molecular weight	216	g/mol
Kow	1.7	10Log
Product		
Name		
Weight fraction substance	25.5	%
Population		
Name		
Body weight	23.9	kg

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	5	minute
Exposure duration	60	minute
Weight fraction substance	25.5	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.32	m^3/hr
Spraying towards person	No	
Mass generation rate	0.8	g/s
Airborne fraction	15	%
Density non volatile	0.7	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	Normal	
Mean diameter	50	µm
Standard Deviation	30	µm
Maximum diameter	139	µm
Include oral non-respirable material exposure	no	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	5824	cm^2
Weight fraction substance	25.5	%
Contact rate	100	mg/min
Release duration	5	minute
Absorption model	Fixed fraction	
Absorption fraction	14	%

Results for scenario *pump spray onto clothing /bystander child*

☐ Show dose descript

Inhalation

Mean event concentration	1.3×10^{1}	mg/m³
Peak concentration (TWA 15 min)	2.3×10^{1}	mg/m³
Mean concentration on day of exposure	–	
Year average concentration	–	
External event dose	7.3×10^{-1}	mg/kg bw
External dose on day of exposure	–	
Internal event dose	7.3×10^{-1}	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Dermal

Dermal load	2.2×10^{-2}	mg/cm²
External event dose	5.3	mg/kg bw
External dose on day of exposure	–	
Internal event dose	7.5×10^{-1}	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Integrated

Internal event dose	1.5	mg/kg bw
Internal dose on day of exposure	–	
Internal year average dose	–	

Propan-2-ol

ConsExpo 5.0 report

Report date: 04/10/2017

Compound

Compound name : propanol
CAS number :

molecular weight	60	g/mol
vapour pressure	5.8E3	Pascal
KOW	0.05	10Log

Populations

Child

body weight	24	kilogram

Products

BitePrevent

weight fraction compound	3.4	%

Aggregate Exposures

Aggregate exposure for Child :

Total chronic systemic dose (mg/kg/day):
1.6

Inhalation chronic systemic dose (mg/kg/day):
1.4

Dermal chronic systemic dose (mg/kg/day):
0.17

Total acute systemic dose (mg/kg/day):
6.5

Inhalation acute systemic dose (mg/kg/day):
5.8

Dermal acute systemic dose (mg/kg/day):
0.71

Details for scenario: Child, BitePrevent : Bystander

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	3.4	%	
exposure duration	60	minute	
room volume	20	m3	
ventilation rate	0.6	1/hr	
applied amount	84	gram	

Uptake model: Fraction

uptake fraction	1E2	%
inhalation rate	1.3	m3/hour

Dermal model: Direct dermal contact with product : constant rate

weight fraction compound	3.4	%	
exposed area	5.8E3		cm2
contact rate	1E2	mg/min	
release duration	5	minute	

Uptake model: fraction

uptake fraction	1E2	%

Non-Professional – Secondary Exposure

No additional information.

3.3 New information on the active substance

No additional information

3.4 Residue behaviour

No additional information

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[1]

Efficacy studies are included in IUCLID and in section 2.2.5.5 of this PAR.

3.6 Confidential annex

See separate document.

3.7 Other

3.7.1 Information on product trade names and CoA

The product formula listed in section 3.6.1 (Confidental annex) has a manufacture's code of "Formula A". Products with this formula are/have been commercialized with the following trade names (Figueiredo I., 2016):

BitePrevent® Anti-Insect Spray
BitePrevent®
Nanofor® Spray Repelente de Insectos
Sil4US
BiteProtect
SilEvolution
Sil4safe
Sil2U® Anti-Insect Spray Solution
Nanofor® Anti-Insect Spray

The table below lists the active substance concentrations as per the CoA of different production runs (lotes) of Formual A. Copies of the individual CoA is available in IUCLID (CoA).

CoA code	% IR3535 w/w
20140506	29.90
20150127	24.81
20150416	25.05
20150703	20.05

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

20151013	21.50
20160104	20.05
20160106	24.70%
20160117	24.81
20160501	24.81
20160105	24.81
20160502	25.11
20160519	24.72
20151013	21.50
20160623	20.50
20160609	25.01
20170608	22.00

3.7.2 Information on the substance(s) of concern

Taking into consideration the guidance provided in "Note for discussion with Competent Authorities for Biocidal Products" document CA-Nov14-Doc.5.11, this formual contains three SoC:

- Ethanol
- Propan-2-ol
- (3Glycidyloxypropyl)tri methoxysilane

Risk assessments on all three substances are presented in the confidential annex.