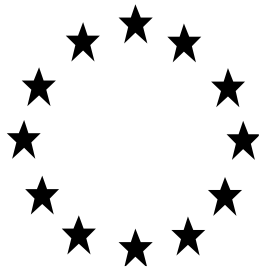
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Montplet insect repellent IR3535 10%

Product type 19

Ethyl butylacetylaminopropionate

Case Number in R4BP: BC-KK020575-39

Evaluating Competent Authority: SPAIN

Date: March 2022

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1 CONCLUSION

MONTPLET INSECT REPELLENT IR3535 10% is a limpid and light yellow liquid with a pleasant odour. The density is 1.0361 g/cm3.

The product is stable after 30ºC during 18 weeks. The study of storage stability at long-term storage shows the product is stable during 30 months.

MONTPLET INSECT REPELLENT IR3535 10% is not considered potentially explosive and nor oxidising properties.

Regarding analytical methods, all acceptance criteria were satisfied: the applied method fit the requirements of the validation for the quantitative analysis the active substance.

In relation to the efficacy of the product MONTPLET INSECT REPELLENT IR3535 10%, it is efficient as a mosquito repellent (Aedes spp., Culex spp., Anopheles spp.) for 6 hours in temperate conditions when applied on skin at the application rate of 1,15 mg product / cm^2. The efficacy of the product MONTPLET INSECT REPELLENT IR3535 10% against ticks has not been proven.

Regarding the effect of human health, eye irritation was identified (Eye Irrir. 2). No other effects were identified and ED properties were not detected.

The applicant submits a human health risk assessment (HHRA) for MONTPLET INSECT REPELLENT IR3535 10% in line with the latest agreements reached at UE level. This HHRA, as performed by the applicant, concludes that the biocidal product would not pose risk for human health with regard to the intended uses. At the time of submission, the Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure for harmonizing the assessment of human exposure to repellents (18 January 2018) were available. The assessment has been updated in order to include the latest agreements on this matter.

It should be noted that the HHRA has been calculated using a efficacy tests dose (1,15 mg/cm^2) obtained from the data from active substance's supplier, which, which has proved to be efficacious during the protection time for each climate zone. This conclusion is in line with the Commission implementing Decision (EU) 2018/1477 on the terms and conditions of the authorisations of biocidal products containing ethyl butylacetylaminopropionate.

The product under evaluation is safe when it is used under the instructions of the SPC.

Environment

Based on this risk assessment and on available data, «Montplet Insect repellent IR3535 10%» should not cause any unacceptable risks to the environement.

In conclusion the product Montplet Insect repellent IR3535 10% can be authorized taking into account the specifications included in the SPC.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
MONTPLET REPELENTE DE INSECTOS INFANTIL Adittional names: APOSAN REPELENTE DE INSECTOS INFANTIL ACOFAR REPELENTE DE INSECTOS INFANTIL RELEC INFANTIL REPELENTE DE INSECTOS SPRAY RELEC PEDIÁTRICO REPELENTE DE INSECTOS SPRAY CUIDAPLUS REPELENTE DE INSECTOS INFANTIL NOSA-KIT REPELENTE DE INSECTOS INFANTIL CHICCO REPELENTE DE INSECTOS INFANTIL BIOVECTROL REPELENTE DE INSECTOS INFANTIL Bloom Derm Loción Baby Bloom Derm Loción Baby&Kids DNINS Repelente Insectos Infantil NEWELL ANTIMOSQUITOS Repelente Insectos Infantil AntiMosquitos ISDIN Pediatrics Spray TECSANIA Repelente Insectos Infantil PARASITAL REPELENTE DE INSECTOS INFANTIL ACOFARMA NESIRA® REPELENTE DE INSECTOS INFANTIL	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratorios Montplet, S.L.U.
	Address	Via Trajana 53-55 08020 Barcelona Spain
Authorisation number	ES-APP(NA)-2021-19-00802	
R4BP asset reference number	ES-0024221-0000	
Date of the authorisation	14/03/2022	
Expiry date of the authorisation	14/03/2032	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Laboratorios Montplet, S.L.U.
Address of manufacturer	Via Trajana 53-55 08020 Barcelona Spain
Location of manufacturing	Via Trajana 53-55

1 Please fill in here the identifying product name from R4BP.

sites	08020 Barcelona Spain

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

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck KGaA Frankfurter Strase 250 64293 Darmstadt Germany
Address of manufacturer	Frankfurter Strase 250 64293 Darmstadt Germany
Location of manufacturing sites	Merck S.L.U. Polígono Merck 08100 - Mollet del Vallés (Barcelona)

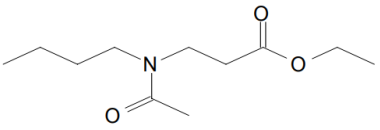
2.1.2 Product composition and formulation

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	Ethyl butylacetylaminopropionate, IR3535®
IUPAC or EC name	3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester
EC number	257-835-0
CAS number	52304-36-6
Index number in Annex VI of CLP	None
Minimum purity / content	≥ 990 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance contained in the biocidal formulation of biocidal single product „ Montplet insect repellent IR3535 10%" is not a candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate, IR3535®	3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester	Active substance	52304-36-6	257-835-0	10.00 (pure) 10.00 (technical)
		Non-active substance[3]			

For the complete qualitative and quantitative information on final composition of the biocidal single product, please refer to the confidential annex of this document.

2 Please delete as appropriate.

3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

2.1.2.4 Information on technical equivalence

The source of Ethyl butylacetylaminopropionate, IR3535® used for manufacture of the biocidal product matches the reference source which was defended for approval of the active substance.

2.1.2.5 Information on the substance(s) of concern

No substance of concern were identified in the formulation.
ES CA: see draft PAR confidential annex

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements[4]

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

Classification	
Hazard category	Eye irrit. 2
Hazard statement	H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P264: Wash … thoroughly after handling P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. P501: Dispose of content and / or its container as hazardous waste according to the regulations in force ").
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Mosquitoes repellent – spray to apply on human skin – General public

Product Type	PT19 – Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent

[4] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Target organism (including development stage)	Aedes spp. – Mosquitoes Culex spp. – Mosquitoes Anopheles spp. - Mosquitoes Development stage: Adults
Field of use	Outdoor and indoor use in well ventilated areas Only for use in temperate zones. This repellent is **not** authorized for tropical areas.
Application method(s)	Spraying with trigger spray. Apply sparingly and spread evenly a thin layer on the uncovered skin (face, hands, arms, legs and feet) to be protected. Spray directly on the exposed skin and distribute the liquid with the hand. Do not spray directly to the face.
Application rate(s) and frequency	Dose per application: 1.15 mg/cm²[5]. Application rate: • Adults: 52 spray pumps Maximum 2 applications/day. • Children 6-12y: 29 spray pumps Children: maximum 1 application/day. • Children 2-6y: 22 spray pumps Children: maximum 1 application/day. • Toddlers: 15 spray pumps Children: maximum 1 application/day. • Infants: 13 spray pumps Children: maximum 1 application/day. Protection time: • against mosquitoes: up to 6 hours
Category(ies) of users	General public.
Pack sizes and packaging material	HDPE, recycled HDPE and PET spray bottle (trigger spray) of the following volumes: 25, 50, 75, 80, 100, 120, 125, 150, 200, 250*, 500* and 1000* ml.

[5] See Section 3.2 for an explanation about the dose to be applied.
The pump releases a dose of 0.2 ml per spray burst. Please see annex 3.2 for further information

	(*These size/volume of the packaging will not authorised in Spain and article 37 according to BPR will be applied)

2.1.4.2 Use-specific instructions for use

- Apply and spread evenly on the skin areas to be protected. Do not spray directly on the face, but apply it with your hands, avoiding contact with eyes and mouth. Wash hands thoroughly after applying the product.
- Inform the registration holder if the treatment is ineffective.
- The use of the product with other repellent products is not recommended.
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.
- Adults: 52 spray pumps a day (10 on arm, 25 on leg, 6 on the face, 5 on hands and 6 on feet).
- Children 6-12y: 29 spray pumps a day (7 on arm, 16 on leg, 3 on the face, 3 on feet).
- Children 2-6y: 22 spray pumps a day (6 on arm, 11 on leg, 3 on the face, 2 on feet).
- Toddlers: 15 spray pumps a day (4 on arm, 7 on leg, 2 on the face, 2 on feet).
- Infants: 13 spray pumps a day (3 on arm, 6 on leg, 2 on the face, 2 on feet).
- Spray directly on the exposed skin and distribute the liquid with the hand. Do not spray the product directly on the face. Spray the product on your hands first if you want to protect your face. Wash your hands thoroughly after applying the product.
- Once the time of protection is over, properly wash the body area where the product has been applied.
- For adults, apply up to 2 times a day. Reapply when repellency wears off.
- For children, apply once a day. If necessary, consult your pediatrician.
- CHILDREN MUST NOT APPLY THIS PRODUCT BY THEMSELVES. An adult should apply the product on children. Do not apply on children's hands.
- Only for use in temperate zones. This repellent is not authorized for tropical areas. Please, consult your pharmacist or physician if you are planning to travel to areas with risk of vector-borne diseases in order to receive specific instructions for your protection.
- The instructions above should be followed. Nevertheless, in areas where there is a high risk of disease transmission through mosquito bites and under those circumstances where it is advised, the preventive measures dictated by the health authorities should be embraced.
- Do not throw the product on the ground, into a water course, into the sink or down the drain
- Avoid contact of the treated skin or clothes with food.
- Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption.

2.1.4.3 Use-specific risk mitigation measures

- Do not storage at temperatures above 30°C.

- Before use the product, read carefully the label. The instructions above should be followed.
- Do not inhale.
- Do not swallow. Avoid any direct or indirect contact with food and feed.
- Use in well ventilated areas.
- Avoid contact with eyes.
- Frequent application is unnecessary.
-
- Do not apply on children's hands.
- Keep out of reach of children.
- Keep the container upright.
- Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent.
- Do not use in people sensitive to its components.

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 directions for use.

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

See general directions 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 directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

See section 1.1.4.2

2.1.5.2 Risk mitigation measures

See section 1.1.4.3

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

- Causes serious eye irritation.

- IF IN EYES: rinse cautiously with water for several minutes.

- If medical advice is needed, have product container or label at hand.

- IF SWALLOWED: call a POISON CENTER or doctor if you feel unwell.
- Use for repellent purpose only. Once this purpose has been fulfilled, discard properly to avoid its release to the environment.

For environment:
- Use for repellent purpose only. Once this purpose has been fulfilled, discard properly to avoid its release to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations
Do not release to soil, ground, surface water or any kind of sewer.

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

Protect from frost.
Shelf-life: 30 months.

2.1.6 Other information

General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

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)
Spray bottle	25, 50, 75, 80, 100, 120, 125, 150, 200, 250*, 500* and 1000* ml	HDPE, recycled HDPE, PET	Cap of the bottle in LDPE	Non-professional	Yes

*These size/volume of the packaging will not authorised in Spain and article 37 according to BPR will be applied

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please, refer to section 3.1 (annex) for the reference list of the studies.

2.1.8.2 Access to documentation

Alcoholes Montplet S.L.U. has provided the letter of access of active substance IR3535 from owner data Merck KGaA. This letter of access covers the studies owned by Merck and other information that have been used for including Ethyl butylacetylaminopropionate in the Union list of approved active substances under the Biocidal Products Regulation.

2.2 Assessment of the biocidal product

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

Table 2. Intended Use # 1 – Mosquitoes and ticks repellent – spray to apply on human skin – General public

Product Type(s)	PT19
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Mosquitoes (development stage: adult): 8 hours of protection in temperate areas. Ticks (development stage: nymph): 9 hours of protection in temperate areas.
Field of use	Indoor and outdoor uses.
Application method(s)	Spraying with trigger spray.
Application rate(s) and frequency	Dose per application: 1.15 mg/cm²[6]. Adults: maximum 2 applications/day. Children: 1 application/day.
Category(ies) of user(s)	General public.
Pack sizes and packaging material	HDPE, recycled HDPE and PET spray bottle (trigger spray) of the following volumes: 50ml ; 75ml; 100 ml and 125ml

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Appearance - Physical state at 20 °C and 101.3 kPa - Colour at 20 °C and 101.3 kPa - Odour at 20 °C and 101.3 kPa	Visual	Montplet insect repellent IR3535 10%	Limpid liquid Light yellow a pleasant odour	C. Belussi, 2019, Study N° 2017/184AM
pH	CIPAC MT 75.3	Montplet insect repellent IR3535 10%	The pH at 20ºC of a dilution at 1% in water is 5.72.	C. Belussi, 2019, Study N° 2017/184AM
Acidity / alkalinity	Not relevant, pH value is not <4 or >10, so this test is not required for the formulation			
Relative density / bulk density	OECD Guideline 109	Montplet insect repellent IR3535 10%	The relative density of the formulation is 1.0361	C. Belussi, 2019, Study N° 2017/184AM

[6] See Section 3.7 for an explanation about the dose to be applied.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC method MT 46.3	Montplet insect repellent IR3535 10%	Storage accelerated stability for 18 weeks at 30°C: Appearance of the test item at initial time and after 18 weeks : Homogenous and clear liquid. Appearance of the packaging at initial time and after 18 weeks: - 100 ml white plastic (HDPE) bottle with spray pump Colour and odour of the product at initial time and after 18 weeks: - light yellow liquid with - characteristic odour of repellent Weight loss after 18 weeks: - 0.140% w/w Relative density at initial time and after 18 weeks: - T0: 1.0309 - T18: 1.0321 pH as is (20°C) at initial time and after 18 weeks: - T0: 5.60 - T18: 4.45 pH 1% (20°C) at initial time and after 18 weeks: - T0: 5.63 - T18: 4.52 Active substance content (IR3535) at initial time and after 18 weeks: - T0: 10.39% w/w - T18: 10.71% w/w (103.1% of T0)	Luana D'Annunzio, Study N° STULV21AA0564-1
Storage stability test – **long term storage at ambient temperature**	GIFAP monograph no. 17	Montplet insect repellent IR3535 10%	Storage stability test at 25°C/60% RH for 36 months: Appearance (physical state, colour and odour of the test item for T0;T6;T12;T18,	C. Belussi, 2021, Study N° 2017/184AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T24, T30, T36: - Limpid liquid light yellow with pleasant odour Appearance of the packaging for T0;T6;T12;T18, T24, T30, T36 : - White plastic bottle (HDPE) with trigger dispenser Weight loss at time: - T0 : - - T6 : 0.119% - T12 : 0.208% - T18 : 0.441% - T24 : 0.432% - T30 : 0.629% - T36 : 0.686% Relative density at time: - T0 : 1.0361 - T6 : 1.0374 - T12 : 1.0363 - T18 : 1.0373 - T24 : 1.0344 - T30 : 1.0372 - T36 : 1.0374 pH 1% (20°C) at time: - T0 : 5.72 - T6 : 5.24 - T12 : 4.85 - T18 : 4.52 - T24 : 4.46 - T30 : 4.25 - T36 : 4.09 Active substance content : - T0: 10.45% w/w - T6: 10.42% w/w (99.7% of T0) - T12: 10.19% w/w (97.5% of T0) - T18: 10.00% w/w (95.7% of T0) - T24 : 9.81% w/w (93.9% of T0) - T30 : 9.47% w/w (90.6% of T0) - T36 : 9.09% w/w (87.0% of T0) Valve clogging for T0; T6;	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T12; T18 : - No clogging Spray rate : - T0 : 0.2039 g (RSD=0.6%) - T6 : 0.2033 g (RSD=0.6%) - T12 : 0.2006 g (RSD=0.7%) - T18 : 0.2022 g (RSD =0.4%) - T24 : 0.2029 g (RSD= 1.0%) - T30 : 0.2024 g (RSD= 0.4%) - T36 : 0.1965 g (RSD= 0.6%) Spray pattern : - T0: Like a spray - T36 : Like a spray Particle size distribution - T0: Dv(50) = 87.62 µm - T36: will be available in the final report	
Storage stability test – **low temperature stability test for liquids**	Waiver	No testing is necessary as it is indicated on the product label that it should be protected from cold.		
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	No testing is necessary because the packaging is opaque and therefore protects the product from light.		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The effect of temperature higher than normal was assessed in the accelerated storage study. The product is protected from humidity thanks to its impermeable packaging.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual	Montplet insect repellent IR3535 10%	At initial time, the packaging was white plastic bottle (HDPE) with trigger dispenser and no variation has been observed. In addition, the formulation is stable. So no reactivity towards container has been raised by the laboratory.White plastic bottle (HDPE) with trigger	C. Belussi, 2019, Study N° 2017/184AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Wettability	Waiver	Not relevant for an trigger spray formulation.		
Suspensibility, spontaneity and dispersion stability	Waiver	Not relevant for an trigger spray formulation.		
Wet sieve analysis and dry sieve test	Waiver	Not relevant for an trigger spray formulation.		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver	Not relevant for an trigger spray formulation.		
Disintegration time	Waiver	Not relevant for an trigger spray formulation.		
Particle size distribution	CIPAC MT 187	Montplet insect repellent IR3535 10%	DV(50) = 87.62 µm	C. Belussi, 2019, Study N° 2017/184AM
Content of dust/fines, attrition, friability	Waiver	Not relevant for a trigger spray formulation		
Flowability/Pourability/Dustability	Waiver	Not relevant for a trigger spray formulation		
Burning rate — smoke generators	Waiver	Not relevant for a trigger spray formulation		
Burning completeness — smoke generators	Waiver	Not relevant for a trigger spray formulation		
Composition of smoke — smoke generators	Waiver	Not relevant for a trigger spray formulation		
Flowability/Pourability/Dustability	Waiver	Not relevant for a trigger spray formulation		
Discharge/spray rate	FEA 643	Montplet insect repellent IR3535 10%	0.2039 g (RSD=0.6%)	C. Belussi, 2019, Study N° 2017/184AM
Spraying pattern — aerosols	FEA 644	Montplet insect repellent IR3535 10%	Like a spray	C. Belussi, 2019, Study N° 2017/184AM
Valve clogging	According to FAO	Montplet insect repellent IR3535 10%	No clogging	C. Belussi, 2019, Study N° 2017/184AM
Physical compatibility	Waiver	Not relevant because the product is not intended to be used in combination with any other product.		
Chemical compatibility				
Degree of dissolution and dilution stability	Waiver	Not relevant for a trigger spray (PAE) formulation		
Surface tension	Wilhelmy plate method	100%, no dilution	The surface tension at 25ºC: 32.25 mN/m	A.Briz, Report No.: IN-01232/2020-2
Viscosity	Rotational viscosimeter	Montplet insect repellent IR3535 10%	Viscosity (20°)= 33.2 mPa.s Viscosity (40°C)= 20.2 mPa.s	MICROBIOS, 2019

Conclusion on the physical, chemical and technical properties of the product
For the biocidal product "Montplet insect repellent IR3535 10%", all the physico-chemical properties show no significant variation after 18 weeks at 30°C during the accelerated storage stability test. The study of storage stability at long-term storage shows the product is stable during 30 months

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived	None of the ingredients are classified as explosive substances.		
Flammable gases	Waived	The product is a liquid formulation.		
Flammable aerosols	Waived	The product is a liquid formulation.		
Oxidising gases	Waived	The product is a liquid formulation.		
Gases under pressure	Waived	The product is a liquid formulation.		
Flammable liquids	Waived	None of the ingredient contained in the product "Montplet insect repellent IR3535 10%" has flammable properties.		
Flammable solids	Waived	The product is a liquid formulation.		
Self-reactive substances and mixtures	Waived	None of the ingredients are thermally unstable liquid. The mixture cannot undergo a strongly exothermic decomposition.		
Pyrophoric liquids	Waived	None of the ingredients are classified as pyrophoric substances.		
Pyrophoric solids	Waived	The product is a liquid formulation.		
Self-heating substances and mixtures	Waived	The biocidal product or any of its components can self-heat by reaction with air and without power supply.		
Substances and mixtures which in contact with water emit flammable gases	Waived	None of the ingredients are classified as able to emit flammable gases in contact with water.		
Oxidising liquids	Waived	None of the ingredients are classified as oxidising substances.		
Oxidising solids	Waived	The product is a liquid formulation.		
Organic peroxides	Waived	None of the ingredients are classified as organic peroxides.		
Corrosive to metals	Manual of Test and Criteria 7th Ed. 2019, UNECE (ST/SG/AC. 10/11/Rev. 7), section 37.4.4.	Montplet insect repellent IR3535 10%	No corrosion attack was occurred on the 3 sets of specimens after 7 days of exposure at the tempera	Frank Rincón, 2021

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			ture of 55+/-1°C and the loss mass was lower than 0,01% for the 3 sets of specimens	
Auto-ignition temperatures of products (liquids and gases)	Waived	None of the ingredient contained in the product "Montplet insect repellent IR3535 10%" has flammable nor auto-ignition properties.		
Relative self-ignition temperature for solids	Waived	The product is a liquid formulation.		
Dust explosion hazard	Waived	The product is a liquid formulation.		

Conclusion on the physical hazards and respective characteristics of the product
For the product "Montplet insect repellent IR3535 10%" none of the physical hazard categories should be attributed at this product.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product Montplet Insect Repellent IR3535 10% 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**	**Precision**	**Reference**
					Range	Mean	RSD			
Ethyl butylacetylamino propionate *(active substance)*	HPLC-UV	Linearity: 5 calibration solutions Precision: 6 samples Accuracy: 3 different concentrations (50% – 150%),	Range= 5.0%w/w-15.0% w/w corresponding to experimental range 50.1%-150.3% of the theoretical value in the	The method proved to be specific: no peak of blank or placebo solution interfered	102.7 – 99.8%	101.2%	1.3 %	-	10.3 % w/w RSD = 1.1%	F. Abbiati, 2017, S-2017-02126 AM

		three levels, two preparation for each level	sample R^2= 0.9999	with that of the active ingredient						

Conclusion on the methods for detection and identificationof the product
The HPLC-UV method was developed and validated in compliance with the guidance document SANCO/3030/99 rev.4 (11/07/00) for the analysis of Ethyl butylacetylaminopropionate in the product "Montplet insect repellent IR3535 10%". This method was proven to have sufficient analytical qualities.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Product Type 19: Repellents and attractants (pest control).

According to the SPC submitted by the applicant, the product "Montplet insect repellent IR3535 10%" intended to be used by general public in temperate areas. It is applied as a spray directly on human skin.

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

According to the use claimed by the applicant:

- The product "Montplet insect repellent IR3535 10%" is intended to be used to repel insects on skin.
- The target organisms to be controlled are mosquitoes
- The organisms to be protected are humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering

MONTPLET INSECT REPELLENT IR3535 10% is intended to be used as an insect repellent to protect humans from mosquitoes (Aedes sp. ,Culex sp. and Anopheles sp.) by application on skin.

2.2.5.4 Mode of action, including time delay

The mode of action of IR3535® is not a passive masking of an attracting odour of a victim, but an active repellent effect as insects avoid entering regions with IR3535® vapours. According to the Competent Authority Report of Ethyl butylaceylaminopropionate (Belgium, 2014), the exact biochemical mode of action of IR3535® on insects is not well known yet, but it is most self-evident to assume that IR3535® has an olfactory-based effect.

2.2.5.5 Efficacy data

The applicant submitted 8 studies.

1) A lab test (336- 1916) with **insect repellent spray IR3535 10 % against Ixodes scapularis**

- The test system was based on EPA OPPTS 810.3700.
- The study was conducted with 10 human volunteers.
- The dose of application of the test item was 0,00115 g / cm².
- Enviromental conditions:
  Temperature: 19-26 ºC
  Relative humidity:31-52%
- Exposure started 15 minutes after application. Each volunteer tested 1 tick every 15 minutes.
-
- **This study is not accepted due to the differences in composition between the product Montplet insect repellent IR3535 10 % and the product tested.**

2) A field test (336- 1917) in two different habitats (Forest and Marsh/Pasture) with **insect repellent spray IR3535 10 % on Aedes melanimon (predominant species), Culex erythrothorax, Culex tarsalis, Culiseta incidens, Anopheles freeborni and Aedes vexans.**

- The test system was based on EPA OPPTS 810.3700
- The study was conducted with 10 human volunteers per habitat.
- The dose of application of the test item was 0,00115 g / cm².
- Enviromental conditions:
  Temperature: 19-25 ºC
  Relative humidity:24-39 %
- Exposure started 15 min (Forest) or 3 h and 15 min (Marsh/Pasture) after application and the exposure time was 1 min every 15 min.
- **This study is not accepted due to the differences in composition between the product Montplet insect repellent IR3535 10 % and the product tested.**

3) A field test (336-1921) with **insect repellent lotion IR3535 15 % against Ixodes ricinus.**

- The test system was based on EPA OPPTS 810.3700 Guideline
- The study was conducted with 11 human volunteers.
- The dose of application of the test item was 1 g / 600 cm², i.e. 1,67 mg/cm^2.
- Enviromental conditions:
  Temperature: 24,3±1,1 ºC
  Relative humidity:24,2±3,7 %
- Exposure started inmediately after application. 5 ticks were conducted at 30-min intervals, until a maximum of 10 hours.
- **This study is not accepted due to the differences in composition between the product Montplet insect repellent IR3535 10 % and the product tested.**

4) An arm-in-cage study (336-1922) with a product **with not reported composition against Aedes albopictus.**

- The test system was based on EPA OPPTS 810.3700 Guideline.

- The composition of the products tested was not reported.
- This study is not accepted.

5) An arm-in cage study (Study No. 1622) with the product Montplet insect repellent IR3535 10% against Aedes albopictus.

- The test system was based on the guideline WHO/HTM/NTD/WHOPES/2009.4
- The study was conducted with 3 human volunteers, 3 replicates. 9 tests.
- The dose of application of the test item was 0,00167 g / cm².
- Enviromental conditions:
  Temperature: 27 ±2 ºC
  Relative humidity: 65 ±10 %
- Exposure started 30 min after application and the exposure time was 3 min.
- Each test (control + test) was repeated every hour until proven inefficacy of the product (first bite confirmed by a second one in succession).

The study demonstrated the protection against Aedes albopictus and until 6 h afer application of the product Montplet insect repellent IR3535 10% on the skin with a dose 1,67 mg/cm2.

6) An arm-in cage study (1623e0513) with the product Montplet insect repellent IR3535 10% against Anopheles gambiae.

- The test system was based on the guideline WHO/HTM/NTD/WHOPES/2009.4
- The study was conducted with 3 human volunteers, 3 replicates. 9 tests.
- The dose of application of the test item was 0,00167 g / cm².
- Enviromental conditions:
  Temperature: 27 ±2 ºC
  Relative humidity: 65 ±10 %
- Exposure started 30 min after application and the exposure time was 3 min.
- Each test (control + test) was repeated every hour until proven inefficacy of the product (first bite confirmed by a second one in succession).

The study demonstrated the protection against Aedes albopictus and Culex pipiens until 6 h afer application of the product Montplet insect repellent IR3535 10% on the skin with a dose 1,67 mg/cm2.

7) An arm-in cage study (2742c/1121) with the product Montplet insect repellent IR3535 10% against Aedes albopictus and Culex pipiens.

- The test system was based on the guideline WHO/HTM/NTD/WHOPES/2009.4
- The study was conducted with 10 human volunteers.
- The dose of application of the test item was 0,00167 g / cm².
- Enviromental conditions:
  Temperature: 25 ±2 ºC
  Relative humidity: 65 ±5 %
  Under an air extraction of 30 m^3/h
- Exposure started 1 min after application and the exposure time was 5 min.

- Each test (control + test) was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product (first bite confirmed by a second one in succession).

The study demonstrated the protection against Aedes albopictus and Culex pipiens until 6 h afer application of the product Montplet insect repellent IR3535 10% on the skin with a dose 1,67 mg/cm2.

8) An arm-in cage study (2742d/1121) with the product Montplet insect repellent IR3535 10% against Aedes albopictus, Culex pipiens and Anopheles gambiae.

- The test system was based on the guideline WHO/HTM/NTD/WHOPES/2009.4
- The study was conducted with 10 human volunteers.
- The dose of application of the test item was 0,00115 g / cm^2.
- Enviromental conditions:
  Temperature: 25 ±2 ºC
  Relative humidity: 65 ±5 %
  Under an air extraction of 30 m^3/h
- Exposure started 1 min after application and the exposure time was 5 min.
- Each test (control + test) was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product (first bite confirmed by a second one in succession).

The study demonstrated the protection against Aedes albopictus, Culex pipiens and Anopheles gambiae until 6 h afer application of the product Montplet insect repellent IR3535 10% on the skin with a dose 1,15 mg/cm2.

2.2.5.6 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**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Insect repellent spray IR3535 10%	*TICKS* *Ixodes scapularis*	Laboratory test	- Dose of product 1,15 mg/cm2 forearm. - 10 volunteers. - Exposure started 15 min after application. - 3 min exposure time, every 15 min. - Climatic conditions: Temperature 19-26 ºC Relative humidity 31-52 %	Protection time: 9 h in temperate conditions.	Carrol, S.P. (2006) Doc No. 336-1916 **Not accepted**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Insect repellent spray IR3535 10%	*MOSQUITOES* *Aedes melanimon (predominant species), Culex erythrothorax, Culex tarsalis, Culiseta incidens, Anopheles freeborni and Aedes vexans*	Field test	- 1,15 mg/cm2 forearm. - 10 volunteers in each area. - Exposure started 15 min (forest) or 3h 15 min (marsh/pasture) after application - 1 min exposure time, every 15 min until 14 hours - Climatic conditions: Temperature 19-25°C Relative humidity 24- 39%	Protection time: 8 hours in temperate conditions.	Carrol, S.P. (2006) Doc No. 336-1917 **Not accepted**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Insect Repellent Lotion/Pump spray (15% IR3535)	*TICKS* *Ixodes ricinus*	Laboratory test	- Dose 1g/600 cm2 - 11 volunteers. - Exposure started immediately after application. - 5 ticks were conducted at 30-min intervals, until a maximum of 10 hours. - Climatic conditions: Temperature 23,2-25,4 ºC Relative humidity 24,2±3,7 %	Protection time: 8 hours in temperate conditions.	Dippel, C. Dautel, H. (2006) Doc No. 336-1921 **Not accepted**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	TMT-003 **Not reported composition**	*MOSQUITOES* *Aedes albopictus*	Laboratory test. Arm-in-cage study.			Lüpkes, K.-H. (2011) Doc No. 336-1922

							Not accepted
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Montplet insect repellent IR3535 10%	*MOSQUITOES Aedes albopictus*	Laboratory test. Arm-in-cage study.	- Dose of product 1g/600 cm2 forearm. - 3 volunteer, 3 replicates. 9 tests. - Exposure started 30 min after application. - 3 min exposure time, every 60 min. - Climatic conditions: Temperature 27+2 ºC Relative humidity 65+10 %	Protection time: 6 hours in temperate conditions.	B. Serrano (2013) Study No. 1622 **Reliability 2 Supportive study**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Montplet insect repellent IR3535 10%	*MOSQUITOES Anpheles gambiae*	Laboratory test. Arm-in-cage study.	- Dose of product 1g/600 cm2 forearm. - 3 volunteer, 3 replicates. 9 tests. - Exposure started 30 min after application. - 3 min exposure time, every 60 min. - Climatic conditions: Temperature 27+2 ºC Relative humidity 65+10 %	Protection time: 6 hours in temperate conditions.	B. Serrano (2013) Report 1623e0513 **Reliability 2 Supportive study**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Montplet insect repellent IR3535 10%	*MOSQUITOES Aedes albopictus, Culex pipiens*	Laboratory test. Arm-in-cage study.	- Dose of product 1g/600 cm2 forearm. - 10 volunteers. - Exposure started 1 min after application. - 5 min exposure time, every hour until the first landing and then every 30 minutes. - Climatic conditions: Temperature 25+2 ºC Relative humidity 65+5 %	Protection time: 6 hours in temperate conditions.	B. Serrano (2021) Report 2742c/1121 **Reliability 2 Supportive study**
Repellent	- Spray - Applied on human skin -For consumers -In temperate areas	Montplet insect repellent IR3535 10%	*MOSQUITOES Aedes albopictus, Culex pipiens, Anopheles gambie*	Laboratory test. Arm-in-cage study.	- Dose of product 0,69 g/600 cm2 forearm. 1,15 mg/cm2 - 10 volunteers. - Exposure started 1 min after application. - 5 min exposure time, every hour until the first landing and then every 30 minutes. - Climatic conditions: Temperature 25+2 ºC Relative humidity 65+5 %	Protection time: 6 hours in temperate conditions.	B. Serrano (2021) Report 2742d/1121 **Reliability 1 Key study**

Conclusion on the efficacy of the product
The efficacy studies submitted demonstrates that: - The product MONTPLET INSECT REPELLENT IR3535 10% is efficient as a mosquito repellent (Aedes albopictus, Culex pipiens, Anopheles gambiae) for 6 hours in temperate conditions when applied on skin at the application rate of 1,67 mg product / cm². - The product MONTPLET INSECT REPELLENT IR3535 10% is efficient as a mosquito repellent (Aedes albopictus, Culex pipiens, Anopheles gambiae) for 6 hours in temperate conditions when applied on skin at the application rate of 1,15 mg product / cm². - The efficacy of the product MONTPLET INSECT REPELLENT IR3535 10% against ticks has not been proven. **- The product MONTPLET INSECT REPELLENT IR3535 10% is efficient as a mosquito repellent (Aedes spp., Culex spp., Anopheles spp.) for 6 hours in temperate conditions when applied on skin at the application rate of 1,15 mg product / cm². The efficacy of the product MONTPLET INSECT REPELLENT IR3535 10% against ticks has not been proven."**

2.2.5.7 Occurrence of resistance and resistance management

The following statement from the assessment report of the active substance applies to the product "Montplet insect repellent IR3535 10%": "as the active substance, IR3535, is a repellent (no killing action) and does not give rise to selection pressure, no resistance can be developed".

2.2.5.8 Known limitations

There are no known limitations to the product "Montplet insect repellent IR3535 10%".

2.2.5.9 Evaluation of the label claims

Efficacy against mosquitoes has been assessed with several mosquito species. According to the Guidance on BPR: Volume II (parts B+C), efficacy tests should be performed with Culex mosquitoes, as they are the most common in Europe and large mosquitoes. Testing should also be carried out with Aedes mosquitoes, as they are the most aggressive mosquitoes.
Efficacy studies have proven the efficacy of the product "Montplet insect repellent IR3535 10%" against both of these mosquito genera, and even against additional one, for at least 6 hours.

Therefore, the following product claims are supported with adequate data:

- 6 hours of protection against mosquitoes in temperate areas.

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

The product "Montplet insect repellent IR3535 10%" is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

The representative product considered in the Competent Authority Report (CAR) from Belgium finalised in the Standing committee on Biocidal Products at its meeting on March 13th, 2014 for IR3535 was a water/ethanol-based 20% IR3535 formulation.

The main difference between «Montplet insect repellent IR3535 10%» and the representative product is the content of IR3535 which is 10% in «Montplet insect repellent IR3535 10%». Another difference is the absence of denaturated alcohol in «Montplet insect repellent IR3535 10%». This ingredient is replaced by water. Other ingredients are very similar with slightly different contents.

2.2.6.1 Assessment of effects on Human Health

A skin compatibility study (human patch test) and a skin irritation study were conducted with product «Montplet insect repellent IR3535 10%».

An acute oral toxicity study and an acute dermal study were conducted respectively with product «Montplet insect repellent IR3535 20%» and «Montplet insect repellent IR3535 30%», considered as worst-case products and therefore covering the product «Montplet insect repellent IR3535 10%».

When no experimental toxicological data on the preparation (or on a product which composition is known and similar) was available, the toxicological classification for this mixture was carried out by using the conventional calculation method of the Regulation (EC) No. 1272/2008 (CLP).

Skin corrosion and irritation

The studies conducted with «Montplet insect repellent IR3535 10%» showed a good cutaneous compatibility or the absence of skin irritation.

In addition, in product «Montplet insect repellent IR3535 10%», most ingredients are not classified for their skin corrosion/irritation properties. Only one ingredient (8PRHL) is classified as skin irritant, category 2 and labelled with H315 as hazard statement. However, as its content in «Montplet insect repellent IR3535 10%» is lower than the trigger concentration for classification (10%), the mixture is not classified.
Testing on the product does not need to be conducted as synergistic effects between components are not expected.

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Episkin® (reconstructed human skin model), OECD 439, GLP, reliable	"Montplet insect repellent IR3535 10%"	Positive and negative controls demonstrated the efficacy of the assay	Not skin irritant	None	8/2.2.6.1/01

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Patch test, not to GLP, reliable	"Montplet insect repellent IR3535 10%"	10 volunteers, each being his own control. One spraying, then occlusive patch for 24h ± 5h	Two control times (15 min and 24 h). No reaction observed. Daily average irritation score = 0 at each time control. Good cutaneous compatibility.	8/2.2.6.1 /02

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant
Justification for the value/conclusion	Reliable study conducted on the product. In addition, considering the data sheet of the components of the product and information of C&L Inventory of ECHA, the skin irritation is not expected
Classification of the product according to CLP and DSD	Not classified

Eye irritation

A study was conducted with «Montplet insect repellent IR3535 20%» containing 20% of IR3535 which is an eye irritant substance. This study showed that «Montplet insect repellent IR3535 20%» is an eye irritant, category 2.

«Montplet insect repellent IR3535 20%» (20% w/w IR3535) is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» (10% w/w IR3535) and test results are therefore expected to cover «Montplet insect repellent IR3535 10%» as well.

In addition, according to the conventional calculation method of the Regulation (EC) No. 1272/2008 (CLP), 10% is the concentration triggering the classification of a skin irritant category 2 in a mixture. We would like to mention that the mayority of the components included in both products are the same.

As the content of IR3535 in «Montplet insect repellent IR3535 10%» is 10%, it was considered useless to conduct an eye irritation study.

Summary table of animal studies on serious eye damage and eye irritation

<table>
<tr><th>Method, Guideline GLP status, Reliability</th><th>Species, Strain, Sex, No/group</th><th>Test substance, Dose levels, Duration of exposure</th><th>Results</th><th>Remarks</th><th>Reference</th></tr>
<tr><td>Eye irritation equivalent to OECD n°405 EC criteria, not GLP, reliable</td><td>Rabbit, New Zealand white, male, 3</td><td>«Montplet insect repellent IR3535 20%», 0.1mL/eye no vehicle, no washing, observations for 21 days</td><td>Eye irritant
<table>
<tr><th></th><th>Rabbit 1</th><th>Rabbit 2</th><th>Rabbit 3</th><th>Mean</th></tr>
<tr><td>Corneal opacity</td><td>1.6</td><td>1.0</td><td>2.0</td><td>1.5</td></tr>
<tr><td>Iris damage</td><td>1.0</td><td>0.0</td><td>1.0</td><td>0.6</td></tr>
<tr><td>Conjuntival redness</td><td>3.0</td><td>2.0</td><td>3.0</td><td>2.6</td></tr>
<tr><td>Conjuntival oedema</td><td>2.0</td><td>2.6</td><td>3.0</td><td>2.5</td></tr>
</table></td><td>None</td><td>8/2.2.6.1 /03</td></tr>
</table>

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritant.
Justification for the value/conclusion	Reliable study conducted on a similar product, «Montplet insect repellent IR3535 20%». Please refer to the confidential annex, 3.7.2, for the composition of the «Montplet insect repellent IR3535 20%» product. Indeed, the «Montplet insect repellent IR3535 20%» is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» and test results are therefore expected to cover the «Montplet insect repellent IR3535 10%» as well. In addition, the rest of components for both products are very similar and a read across can be accepted.
Classification of the product according to CLP and DSD	Eye irritant, Category 2 - Hazard statement H319.

Respiratory tract irritation

The active substance IR3535 showed no irritant properties to the respiratory tract in animals or in humans.
In product «Montplet insect repellent IR3535 10%», there are no ingredient classified for their respiratory tract irritant properties.
Therefore, the mixture is not classified.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No ingredient classified.
Classification of the product according to CLP and DSD	Not classified.

Recommendations on ventilation or avoiding breathing in spray should be included in the product labels of spray formulations.

Skin sensitization

In product «Montplet insect repellent IR3535 10%», most ingredients are not classified for their skin sensitization properties. The composition of this product has been slightly changed by eliminating a co-formulant that contained a substance classified as sensitizing. Now, only the perfume is classified as skin sensitzer, category 1 and labelled with H317 as hazard statement. However the perfume ingredient is a mixture and as its components in «Montplet insect repellent IR3535 10%» are lower than the trigger concentration for classification (1%), the mixture is not classified (please see confidential PAR).

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	Conventional calculation method of the Regulation (EC) No. 1272/2008 (CLP).
Classification of the product according to CLP and DSD	

Respiratory sensitization (ADS)

The active substance IR3535 showed no sensitising properties to the respiratory tract in animals or in humans.
In product «Montplet insect repellent IR3535 10%», there are no ingredient classified for their respiratory tract sensitising properties and no synergistic effects between components are expected.
Therefore, the mixture is not classified.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No ingredient classified.
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity

Acute toxicity by oral route

A study was conducted with «Montplet insect repellent IR3535 20%» which contains 20% of IR3535 which is not acutely toxic via the oral route. This study showed that «Montplet insect repellent IR3535 20%» is not acutely toxic (oral LD50 >2000 mg/kg bw). «Montplet insect repellent IR3535 20%» (20% w/w IR3535) is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» (10% w/w IR3535). But the report does not specify if the test complies with OECD norm 423. However, the methodology followed is equivalent to OECD norm 423 The report does not indicate if the study is generated according to the Good Laboratory Practices and not establish any level for reliability . ES CA doesn't validate this test

So, the toxicological classification for this mixture has carried out by using the conventional calculation method of the Regulation (EC) No. 1272/2008~1221/2015 (CLP).

In product «Montplet insect repellent IR3535 10%», there are no components classified for their acute oral toxic properties and no synergistic effects between components are expected.

Therefore, the mixture is not classified.

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute toxic class method, equivalent to OECD 423, EC B1ter, not GLP, reliable	Rat, Sprague Dawley, 3 males and 3 females	«Montplet insect repellent IR3535 20%», no vehicle, 2000 mg/kg bw, gavage	None	>2000 mg/kg bw	None	8/2.2.6.1 /04

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 > 2000 mg/kg bw
Justification for the selected value	There are no components classified for their acute oral toxic properties and no synergistic effects between components are expected. Therefore, the mixture is not classified. Although it has not been considered, additionally, reliable study conducted on a similar product, «Montplet insect repellent IR3535 20%» with more active substance concentration. Please refer to the confidential annex, 3.7.2, for the composition of the «Montplet insect repellent IR3535 20%» product. Indeed, the «Montplet insect repellent IR3535 20%» is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» and test results are therefore expected to cover the «Montplet insect repellent IR3535 10%» as well.
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	None.
Justification for the selected value	None of the ingredient is classified for acute inhalation toxicity and no synergistic effects between components are expected.

Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by dermal route

An acute toxicity study by the dermal route was conducted with «Montplet insect repellent IR3535 30%». This study showed that «Montplet insect repellent IR3535 30%» is not acutely toxic (dermal LD50 >2000 mg/kg bw). «Montplet insect repellent IR3535 30%» (30% w/w IR3535) is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» (10% w/w IR3535) and test results are therefore expected to cover «Montplet insect repellent IR3535 10%» as well.

In product «Montplet insect repellent IR3535 10%», there are no ingredients classified for their acute dermal toxic properties and no synergistic effects between components are expected.

Therefore, the mixture is not classified.

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute dermal toxicity, OECD 402, GLP, reliable	Rat, SD, 5 males and 5 females	«Montplet insect repellent IR3535 30%», no vehicle, 2000 mg/kg bw, 10% of total body surface	None	>2000 mg/kg bw	None	8/2.2.6.1 /05

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 >2000 mg/kg bw
Justification for the selected value	Reliable study conducted on a similar product, «Montplet insect repellent IR3535 30%». Please refer to the confidential annex, 3.7.2, for the composition of the «Montplet insect repellent IR3535 30%» product. Indeed, the «Montplet insect repellent IR3535 30%» is considered a worst-case product compared to «Montplet insect repellent IR3535 10%» and test results are therefore expected to cover the «Montplet insect repellent IR3535 10%» as well.
Classification of the product according to CLP and DSD	Not classified.

Information on dermal absorption

No study (*in vivo* or *in vitro*) has been performed with Montplet Insect repellent IR3535 10%.

A read across with the dermal absorption value of 14%, proposed in the study of Dekant, 2010, has been proposed by the applicant. The results of this study have been summarized in the CAR of active substance and were assessed for the approval of IR3535® 5 male and 5 female volunteers sprayed approx. 3g of a formulation containing 20% IR3535 onto hands, arms, feet, legs, neck, face (50% of total body area) and showered 12 hours after application. The total amount of IR3535® and its metabolite IR3535®-free acid excreted with the urine over a period of 48 hours presented 13.3% of the dermal dose of IR3535® applied. Since IR3535® is rapidly and extensively metabolized and as IR3535®- free acid has a low molecular weight and high water solubility, it is expected that urinary excretion of IR3535®-free acid and IR3535® represents the total extent of absorption of IR3535® in humans and a distribution to organs and issues is considered tobe negligible. The data of this study suggest that most absorption takes place in the first 6 hours after application with no further evidence of absorption beyond this time point. Based on these findings, a dermal absorption of 14 % is also valid for an exposure of 24 hours.

This value could be used in the human exposure assessment of the biocidal product taking into account that it has been widely used by other Member States in the evaluation of IR3535 repellent biocide products. ES CA accepts this value for risk assessment. Nevertheless, ES CA considers that at the renewal stage of the active substance, this value should be revised because the content of organic solvents and emulsifiers/surfactants which may have an impact on the skin absorption.

Therefore, a dermal penetration of 14% could be used in the human exposure assessment of the biocidal product (please, see confidential PAR in order to see more information regarding the acceptation about this read across).

Value used in the Risk Assessment – Dermal absorption	
Substances	IR3535®
Value	14%
Justification for the selected value	Worst case value reported in CAR

Data waiving	
Information requirement	Dermal absorption
Justification	Dermal penetration rate of 14% is established by the CAR of IR3535 for the human heatlh exposure assessment and the subsequent risk characterisation. This data can be extrapolated to the used of the product Montplet Insect repellent IR3535 20%

Endocrine disrupting properties

According to the CAR for Ethyl butylacetylaminopropionate (IR3535®) there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting assessment of co-formulants is mandatory according to the article 19. Pending

a standardized procedure is made available at EU level, the following sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product:

Substance identified as ED under the BPR:
https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

Substance identified as ED under the PPPR:
https://ec.europa.eu/food/sites/food/files/pesticides_ppp_app-proc_cfs_database-201501.xlsx
ECHA Candidate List of substances of very high concern for Authorisation:
https://echa.europa.eu/candidate-list-table

ECHA's Endocrine disruptor assessment list
https://echa.europa.eu/ed-assessment

EU Community rolling action plan (CoRAP)
https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), the biocidal product does not contain any substance which is under assessment as potential endocrine disruptor

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

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

Available toxicological data relating to a mixture

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

Other
Not relevant.

2.2.6.2 Exposure assessment

MONTPLET INSECT REPELLENT IR3535 10% is intended to be applied as an insect repellent by spraying on human skin.

At the time of submission, neither the Commission implementing Decision (EU) 2018/1477 nor the Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure for harmonizing the assessment of human exposure to repellents (18 January 2018) were available. The assesment has been updated in order to include the latest agreements on this matter.
The exposure has been calculated with the efficacious dose (1.15 mg/cm²) obtained from the data from active substance's supplier.

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	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Oral	n.a.	n.a.	No[1]	n.a.	n.a.	Yes	n.a.

n.a.: not applicable

1- For primary exposure, direct oral exposure is not considered to be relevant since the product is not intended to be applied by children and oral exposure can be precluded among adults with a minimum hygene standards. Despite the latter, the non respirable particles might precipitate in the upper ways and be taken orally. However, since the inhalation absorption considered is a 100%, and no refinement between respirable and non respirable fraction is performed (due to the lack of data), this exposure should be covered.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application Spraying	**Primary exposure** Spraying on the skin Exposure route: dermal and inhalation	Non professionals
2	Post-application Adult treating or handling children	**Secondary exposure** An adult applying or spraying the product on children and herself/himself Exposure route: dermal and inhalation	Non professionals
3	Post-application Hand to mouth	**Secondary exposure** Hand to mouth transfer Exposure route: oral	Non professionals (general public)
4.	Post-application Inhalation of volatilized residues	**Secondary exposure** Inhalation of volatilized residues after application indoors Exposure route: inhalation	Non professionals (general public)

Industrial exposure

Not applicable. The production of «Montplet insect repellent IR3535 10%» is automated and the modelling of exposure and risk assessment/risk characterisation during this production should be addressed under other EU legislation and not repeated here, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for ethyl butylacetylaminopropionate (IR3535) which is an existing biocidal active substance within the EU.

Professional exposure

Not applicable. Montplet insect repellent IR3535 10%» will not be used by professional users. Neither primary nor secondary exposure is expected for this population.

Professional exposure

«Montplet insect repellent IR3535 10%» will not be used by professional people. Neither primary nor secondary exposure can happen for this population.

Non-professional exposure

«Montplet insect repellent IR3535 10%» will be used by non-professional people. Primary and secondary exposure can happen for this population.
The following exposure scenarios are considered:

Scenario 1: Adult spraying on the skin (primary exposure). Scenario 2: Adult applying the product on children (secondary exposure).

Scenario [1] Adult spraying on the skin (primary exposure)

Description of Scenario [1] Adult spraying on the skin (primary exposure)
«Montplet insect repellent IR3535 10%» is applied by an adult directly to the intact skin of infants, toddlers or children. Indoor and outdoor applications are possible. Exposure is expected to happen via the dermal and inhalation routes. The amount of product applied will be considered for the dermal exposure evaluation. The exposure by dermal route can be calculated according to the following equation: $$PDE = \frac{Dp \times C_{IR3535} \times BS \times DA \times N}{100 \times 100 \times BW}$$ where: PDE Potential dermal exposure (mg/kg b.w./day) D_p Dose of product applied on skin (mg/cm²) C_{IR3535} Concentration of substance in product (%) BS Body surface exposed to the product (cm²) (more information below) DA Dermal absorption (%) N Number of product application per day (/day) BW Body weight (kg) The following data is being considered: 1. Percentage of body surface to be treated: For adults, in line with the ECHA Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)", it is considered that 55% of the total body surface remains uncovered and is treated with repellent, it will be used to calculate the BS. Indeed, it is assumed that during the whole season (mid-term exposure within a year) a short-sleeved shirt (i.e. T-shirt) and shorts are worn. The product is not sprayed directly on the face, but applied with hands, avoiding contact

Description of Scenario [1] Adult spraying on the skin (primary exposure)

with mouth and eyes. The hands should be washed after applying the product, but their surface is included nevertheless in the applied surface area.

For infants, toddlers and children, in line with the ECHA Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)", it is considered that 55% of the total body surface remains uncovered and is treated with repellent, it will be used to calculate the BS. Indeed, it is assumed that during the whole season (mid-term exposure within a year) a short-sleeved shirt (i.e. T-shirt) and shorts are worn.The55% of the total body surface is considered, including the hands, that is used even though the hands of infants, toddlers and children are not exposed to the repellent. Indeed, they will not apply the product themselves and the adults should not apply the product to children's hands. Exposure of **infants (<12 months old), toddlers (1 to <2 years old) and children (2 to <6 years old** as well as **6 to <12 years old)** will be assessed separately.

2. Anthropometric data

The body weights, surface areas and inhalation rates from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations.
It should also be noticed that frequent and repeated application is unnecessary. Once the time protection has ended (6-9 hours of efficacy), it is recommended to properly wash the body area where the product has been applied.

For inhalation exposure, the model used is "Consumer spraying and dusting model 2" from TNsG Part 2, p. 197. For a hand-held trigger spray, the 75th percentile value for the inhaled amount is 10.5 mg/m^3.

	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		10%
	Number of applications per day		1 (for infant, toddler, child from 2 to 12 years old) 2 (for adults)
	Body weight #	Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg
		Adult	60 kg
Inhalation	Use duration $		4 min
	Inhalation rate, short-term #	Infant	0.84 m^3/h
		Toddler	1.26 m^3/h
		Child - 2 to <6 years old	1.26 m^3/h
		Child - 6 to <12 years old	1.32 m^3/h

Description of Scenario [1] Adult spraying on the skin (primary exposure)			
		Adult	1.25 m^3/h
	Inhalation uptake £		100%
Dermal	Dose of product applied on the skin ¤		1.15 mg/cm²
	Dermal uptake		14%4
	55% ¥ of the total body surface area #	Infant	2 255 cm²
		Toddler	2 640 cm²
		Child - 2 to <6 years old	3 740 cm²
		Child - 6 to <12 years old	5 060 cm²
		Adult	9 130 cm²

¤ A dose rate of 0.69g/600cm², i.e. 1.15 mg/cm², is considered on the basis of the data confirmed by Merck. Please refer to the section 3.7.
$ time during which the spraying takes place, i.e. the use duration, from Human exposure to biocidal products (TNsG, part 2 (June 2002), page 256.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products
¥ from ECHA Recommendation no. 11 - Proposal for harmonising the assessment of human exposure to repellents (PT19)
£ According to the Technical Notes for Guidance on Human Exposure - 2002, Chapter 2.2.3 (page 247) only half of the particles smaller than 5 µm in diameter are respirable for humans. The fraction of particles smaller than 5 µm is probably low in «Montplet insect repellent IR3535 10%».
In the absence of data about the particle size distribution in the product «Montplet insect repellent IR3535 10%», the systemic exposure to IR3535 is calculated as if only from inhalation even if a great part is from the oral route. This has no impact on the final exposure level as the inhalation and the oral absorption rates are both 100%.

Calculations for Scenario [1]

Dermal exposure:

The table below is summarizing the calculation performed with the dose rate of 1.15mg/cm²:

Population group (application)	Treated body surface area cm^2	Body weight (kg)	Applied product[1] (g)	Applied active substance (g)	Absorbed active substance (g)	Estimated dermal uptake (mg a.s./kg bw/day)
Adult (2)	9130	60	21	2.10	0.294	4.90
Adult (1)	9130	60	10.5	1.05	0.147	2.45
Children (6 to <12 years-old) (1)	5060	23.9	5.82	0.58	0.081	3.41
Children (2 to <6 years-old) (1)	3740	15.6	4.30	0.43	0.060	3.86
Toddler (1)	2640	10	3.04	0.30	0.043	4.25
Infant (1)	2255	8	2.59	0.26	0.036	4.54

[1] BS x D_p x N /1000

Inhalation exposure:
The table below is summarizing the calculation performed with the inhaled product amount of 10.5 mg product/m^3. The applicant provides no data on the particle size distribution therefore it is assumed that the entire amount is inhaled. Since the absorption rate considered is 100%, this assessment should be conservative enough to cover any potential oral exposure per deglution of the non-respirable fraction.

Population group (application)	Inhaled product per hour (mg/h)	Inhaled product during one application (mg)	Inhaled active substance (mg)	Body weight (kg)	Estimated inhalation uptake (mg a.s./kg bw/day)
Adult (2)	13.125	0.875	0.175	60	0.003
Adult (1)	13.125	0.875	0.0875	60	0.0015
Children (6 to <12 years-old) (1)	13.86	0.924	0.0924	23.9	0.0039
Children (2 to <6 years-old) (1)	13.23	0.882	0.0882	15.6	0.0057
Toddler (1)	13.23	0.882	0.0882	10	0.0088
Infant (1)	8.82	0.588	0.0588	8	0.0074

Summary table: systemic exposure from non-professional uses – Scenario 1

Exposure scenario	Tier/ PPE	Estimated inhalation uptake (mg/kg bw/day)	Estimated dermal uptake (mg/kg bw/day)	Estimated oral uptake (mg/kg bw/day)	Estimated total uptake (mg/kg bw/day)
Scenario [1]	1 / No PPE	Adult: 0.0015 for one application 0.003 for two applications Child (6-12): 0.0039 Child (2-6): 0.0057 Toddler: 0.0088 Infant: 0.0074	Adult: 2.45 for one application 4.90 for two applications Child (6-12): 3.41 Child (2-6): 3.86 Toddler: 4.25 Infant: 4.54	Part of inhalation uptake (not detailed)	Adult: 2.45 for one application 4.90 for two applications Child (6-12): 3.41 Child (2-6): 3.87 Toddler: 4.26 Infant: 4.55

Further information and considerations on scenario [1]
None.

Scenario [2] Adult applying the product on children and herself/himself

Description of Scenario [2] Adult applying the product on children		
A worst case is considered with an adult applying the product on three children and his/herself. The body weight and inhalation rate from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations. Exposure is expected to happen via the dermal and inhalation routes. Only hands of the adult can be exposed via the dermal route since the product is not intended to be applied on any child's hands. Regarding inhalation exposure, the time of spraying takes into account 5 times 4 minutes and one application per day. The model used is "Consumer spraying and dusting model 2" from TNsG Part 2, p. 197. For a hand-held trigger spray, the 75th percentile value for the inhaled amount is 10.5 mg/m^3. HTM exposure can be precluded in adults. Only inhalation exposure will be taken into account.		
	Parameters	Value
Tier 1	Concentration of a.s. in the product (no dilution)	10%
	Number of applications per person per day	1 for infant, toddler and children from 2 to 12 years old 2 for adult
	Number of treatments per day	5 (once on three children and twice on himself/herself)
	Use duration $	4 min
	Adult - inhalation rate, short-term #	1.25 m^3/h

	Adult – palms of both hands - surface area #	410 cm²
	Inhalation uptake	100%
	Oral uptake	100%
	Adult – body weight #	60 kg

$ time during which the spraying takes place, i.e. the use duration, from Human exposure to biocidal products (TNsG, part 2 (June 2002), page 256.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [2]

Dermal exposure

This is covered by the general dermal exposure of an adult when treating himself/herself (detailed in scenario 1).

Inhalation exposure
The indicative default value of 10.5 mg product/m^3 is considered for inhalation exposure when a hand-held trigger spray is used.

Exposure of the adult treating two children and himself/herself to the product during spraying for 5 times 4 min is calculated according to the inhalation rate:

Adult : 10.5 mg/m^3 x 5 x 4 min x 1.25 m^3/ 60 min = 4.375 mg product per application

According to the Technical Notes for Guidance on Human Exposure - 2002, Chapter 2.2.3 (page 247) only half of the particles smaller than 5 µm in diameter are respirable for humans. The fraction of particles smaller than 5 µm is probably low in «Montplet insect repellent IR3535 10%».
In a worst-case approach, if the absence of data about the particle size distribution in the product «Montplet insect repellent IR3535 10%» is considered, the systemic exposure to IR3535 is calculated as if only from inhalation even if a great part is from the oral route. This has no impact on the final exposure level as the inhalation and oral absorption rates are 100%.

Based on one application per day, on the concentration of IR3535 in the product and on 100% absorption, the exposure from inhaled product is:

Adult: 4.375 x 1 x 10% x 100% = 0.44 mg IR3535/day

Inhalation exposure in mg/kg bw/day:
Adult: 0.44 / 60 = 0.0073 mg IR3535/kg bw/day

Summary table: systemic exposure from non-professional uses – Scenario 2

Exposure scenario	Tier /PPE	Estimated inhalation uptake (mg/kg bw/day)	Estimated dermal uptake (mg/kg bw/day)	Estimated oral uptake (mg/kg bw/day)	Estimated total uptake (mg/kg bw/day)
Scenario [2]	1 / no PPE	Adult: 0.0073	4.90 (for two applications per day from scenario 1)	Included in inhalation intake	Adult: 4.91

Further information and considerations on scenario [2]
None.

Combined scenarios
Only adults may be concerned by this combined scenario. Inhalation from scenario 2 covers inhalation from scenario 1 (no addition). As a consequence, exposure under scenario 2 is identical to exposure under combined scenarios 1, 2.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios [1,2]	0.0073	4.90	Included in inhalation intake	4.91

Exposure of the general public

The general public can be exposed under secondary exposure scenarios after application of «Montplet insect repellent IR3535 10%».
Those scenarios are:

Scenario 3: Hand to mouth transfer.
Scenario 4: Inhalation of volatilized residues after application indoors.

Scenario [3] Hand to mouth transfer

Description of Scenario [3] Hand to mouth transfer
Hand to mouth transfer might be possible for small children. However, it is recommended not to apply the product on the hands of children. The bitterness of the product should prevent repeated mouthing due to bad palatability. Anyway, no deterrent agent is included in the composition so the HTM exposure possibility cannot be ruled out. Indoor and outdoor applications are possible. A reverse reference scenario is considered to determine how much IR3535 anyone can be exposed to after oral exposure without exceeding the refence dose (AEL of 5 mg/kg bw/day). According to TNsG 2002 (Part 2, section 5.2, page 274), the surface of the fingers of an

adult represents approximately 4% of the treated dermal surface (not covered by clothes, *i.e*. including head, hands, arms, legs and feet). For a child (or infant or toddler), this surface of possible contact with the mouth represents 10% of the treated dermal surface. The same ratio is considered for infants, toddlers and children whose treated surface also includes the trunk; for them a 10% ratio represents a worst case.
The body weights and inhalation rates from the ECHA Recommendation no. 14 (Default human factor values for use in exposure assessments for biocidal products) will be used for exposure calculations.
Exposure is expected to happen via the oral route only. This is consistent with the TM IV 2010 agreement not to sum up the two routes (oral and dermal) in small children.

	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		10%
	Dose of product applied on the skin ¤		1.15 mg/cm²
	Dose of product per application∞	Infant	2.59 g
		Toddler	3.04 g
		Child - 2 to <6 years old	4.30 g
		Child - 6 to <12 years old	5.82 g
		Adult	10.5 g
	Number of applications per day		1 (for infant, toddler, child from 2 to 12 years old) 2 for adult
	Surface ratio between fingers and the treated surface area $		10% (child from 2 to 12 years old, toddler, infant) 4% (adult)
	Oral uptake		100%
	Body weight #	Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg
		Adult	60 kg

¤ A dose rate of 0.69g/600cm², i.e. 1.15 mg/cm², is considered on the basis of the data confirmed by Merck. Please refer to the section 3.7.
∞ Please refer to scenario 1 for dose of product per application (=BS x D_p /1000, where the BS correspond to 55% of the total body surface of the corresponding population group and D_p is the dose of product applied on skin)
$ from TNsG 2002, Part 2 section 5.2, page 274.
# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [3]

Oral exposure

The external total oral dose of product is calculated per application:

User category	ADULT	CHILD (6-12y)	CHILD (2-6y)	TODDLER	INFANT
Amount / application [mg active substance/application]	1049,95	581,9	430,1	303,6	259,325
Body weight [kg]	60	23,9	15,6	10	8
Oral absorption	100	100	100	100	100
Factor for oral intake by hand-mouth transfer	4	8	8	8	8

Oral systemic exposure via hand-mouth transfer mg/kg bw	0,70	1,95	2,21	2,43	2,59

For the values calculated above, the maximum number of applications before reaching the AEL could be calculated :

AEL (mg/kg bw /d)	5	5	5	5	5
Number of time of application b,p before exceeding the AEL via hand-mouth transfer	7,14	2,57	2,27	2,06	1,93

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/application)**	**Estimated dermal uptake (mg/kg bw/application)**	**Estimated oral uptake (mg/kg bw/application)**	**Estimated total uptake (mg/kg bw/application)**
Scenario [3]	1 / no PPE	Not applicable	Not applicable	Adult: 0.70 Child (6-12): 1.95 Child (2-6): 2.21 Toddler: 2.43 Infant: 2.59	Adult: 0.70 Child (6-12): 1.95 Child (2-6): 2.21 Toddler: 2.43 Infant: 2.59

Further information and considerations on scenario [3]
None.

Scenario [4] Inhalation of volatilized residues after application indoors

Description of Scenario [4] Inhalation of volatilized residues after application indoors
For this secondary exposure scenario, inhalation of volatilized residues after indoor application is considered possible. This scenario is included with completeness purposes, since the product is only authorised in well- ventilated indoor areas. The applicant initially submitted an assessment is based on the assumption (in TNsG 2002 part 3, page 50) that the airborne concentration of IR3535 will not exceed 1% of the saturated vapour concentration (SVC). Anyway, since the SVC could exceed the 1% value, the opinion 13 of the HEEG as been taken into account. An updated assessment based on ConsExpo: inhalation of vapour,

instantaneous release as a worst case has been included.			
	Parameters		Value
Tier 1	Molecular weight of IR3535		215.29 g/mol
	Vapour pressure of IR3535		0.15 Pa at 20°C, equivalent to $1.5x10^{-3}$ mbar
	Atmospheric pressure		1013 mbar
	Exposure duration (residential time)ɖ		18 hours per day
	Ventilation rate		0.6 /h
	Room volume		20 m3
	Temperature		25 ºC
	Parameters for each sub-population	Adult	1.25 m^3/d
		Product amount	10499,5 mg
		Body weight	60 kg
		Child - 6 to <12 years old	1.32 m^3/d
		Product amount	5819 mg
		Body weight	23,9 kg
		Child - 2 to <6 years old	1.26 m^3/d
		Product amount	4301 mg
		Body weight	15,6 kg
		Toddler	1.26 m^3/d
		Product amount	3036 mg
		Body weight	10 kg
		Infant	0.84 m^3/d
		Product amount	2593,25 mg
		Body weight	8 kg
	Inhalation uptake		100%

ɖ from TNsG, part 3 (June 2002), page 50. Generally the exposure is considered to last 24 hours. However, the applicant proposes an 18 hour exposure. Since it is unreasonable to expect that anyway will be exposed during 24 hours, so an 18 hours exposure is deemed acceptable

from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [4]

Inhalation of volatilized residues after application is relevant considering the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance (value above 1):

$$\frac{0.328 \times\ 215.29 \times 0.15}{5} = 2.12$$

See annex 3.2. for ConsExpo calculations.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario [4]	1 / no PPE	Adult: 1.82 Child (6-12): 2.68 Child (2-6): 2.89 Toddler: 3.16 Infant: 2.94	Not applicable	Not applicable	Adult: 1.82 Child (6-12): 2.68 Child (2-6): 2.89 Toddler: 3.16 Infant: 2.94

Further information and considerations on scenario [4]
Even if based on a worst case basis an SVC approach is deemed inadequate, the continuous exposure during 18 hours is considered quite conservative.
Also, it is generally agreed that the inhalation route is excluded due to the use outdoors, and because use indoors takes place in the summer in situations where there is a high ventilation rate. It should be noticed that the product is only intended to be used in well ventilated facilities.Kindly notice that the product is **only authorised indoors in well ventilated areas.**
For the sake of completeness, the SVC calculations are included below. From the calculations below if can be concluded that the exposure outdoors and in well ventilated areas is negligible:
The saturated vapour concentration (SVC) is calculated using the following equations:
SVC [ppm] = [vp (substance) x 10^6] / atmospheric pressure
= (0.0015 x 10^6) / 1013
= 1.48 ppm

SVC [mg/m^3] = SVC [ppm] x (molecular weight / 24.04)
= 1.48 x (215.29 / 24.04)
= 13.25 mg/m^3

The airborne concentration is: 13.25 mg/m^3 x 1% = 0.13 mg/m^3

Inhalation exposure in mg/kg bw/day:
The inhalation rate for long-term exposure is taken into account as the possible exposure time is defined as up to 18 h (conservative assessment).

The systemic dose from inhalation is:
airborne concentration x exposure duration x respiration rate / body weight,
which corresponds to:

Adult: (0.13 mg/m^3) x (18 h/24 h) x (16 m^3/day) / 60 kg = 0.026 mg/kg bw/day
Child (6-12): (0.13 mg/m^3) x (18 h/24 h) x (12 m^3/day) / 23.9 kg = 0.049 mg/kg bw/day
Child (2-6): (0.13 mg/m^3) x (18 h/24 h) x (10.1 m^3/day) / 15.6 kg = 0.063 mg/kg bw/day

Toddler: (0.13 mg/m^3) x (18 h/24 h) x (8 m^3/day) / 10 kg = 0.078 mg/kg bw/day
Infant: (0.13 mg/m^3) x (18 h/24 h) x (5.4 m^3/day) / 8 kg = 0.066 mg/kg bw/day

The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of a parent treating three children are negligible compared to primary (dermal) exposure. Therefore, is not considered on the combined assessment.

Combined scenarios

According to the CAR for IR3535 issued in September 2013 by the Belgian authorities (page 20 of 89), it was agreed not to sum up exposure from the oral route (from hand to mouth, scenario 3) and exposure from the dermal route (primary exposure, evaluated under scenario 1).
Combination of scenarios from non-professional exposure and general public are presented:

- For adults, combination of scenarios 1 and 2. The inhalation exposure calculated under scenario 2 replaces this calculated under scenario 1. Actually scenario 2 takes into account the multiplication of the number of people to apply the product on to calculate the inhalation exposure.
- For infants, toddlers and children, they are not concerned by scenario 2.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenarios [1a, 1b and 2]	Adult: 0.0073+0.026= 0.011	Adult: 4.90	Included in inhalation uptake	Adult: 4.91

The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of a parent treating three children are negligible compared to primary (dermal) exposure. Scenario 4 not combined since it is considered an overestimation. As already indicated, it is generally agreed that the inhalation route is excluded due to the use outdoors, and because use indoors takes place in the summer in situations where there is a high ventilation rate. It should be noticed that the product is only intended to be used in well ventilated facilities or outdoors.

Monitoring data

There are no monitoring data with «Montplet insect repellent IR3535 10%».

Dietary exposure

Montplet insect repellent IR3535 10% can be applied directly on the skin. The product is applied using hands palms on different parts of the body (hands, arms, head, legs and feet). Human exposure to IR3535 via food is considered to be relevant because IR3535 may be transferred from the treated hands to the food.

Considering that the exposure to repellent residues via food is not negligible, a scenario to estimate the dietary exposure and risk via food is included. This scenarios was agreed on at the ARTFood meeting in november 2019 (WGV/2019 HH).

Assumptions

- The application rate, expressed as mg of BP per cm^2 of treated skin (mg product/cm^2), is considered to estimate the exposure.
- The default values of hand surface that can be in contact with food is expressed as % of the treated body surface. This is equivalent to 100% of hand surface areas for toddler and children, and 50% of hands surface area for adults (Recommendations no. 11 and 14 of the BPC Ad hoc WGHE)
- Transfer factor from hand to food: 50% (adult) and 100% (toddler and children) (default values
- Exposure of all intended age groups
- The frequency of hand contact with food should not be included in the calculation.

Refinement

- A retention factor of 10% after rinsing can be used to refine exposure if hands are washed after application (default values)

Dietary exposure via food

EXp_{cons} = ApplRate * C * Hfood contact * TF (*RF)/ bw

Where:

EXp_{cons}	Dietary exposure (mg a.s./kg bw/d)
ApplRate	Application rate (mg product/cm^2) = 1.5 (value given by the efficacy)
C	Concentration of a.s. in the BP (%) = 10 %
Hfood contact	Hand surface in contact with food (cm^2). (default value) 230.4 cm^2 for toddler (1-2 years old). 330.9 cm^2 for children (2-6 years old). 427.8 cm^2 for children (6-12 years old). 410 cm^2 for adults.
TF	% of biocide residue transferred from hands surface to food (default value). 50 % (adult). 100% (toddler and children).
RF	% of biocide residue retained after hands washing = 10% (default value)
bw	Body weight (kg) (default value) 10 kg for toddler (1-2 years old) 15.6 kg for children (2-6 years old) 23.9 kg for children (6-12 years old) 60 kg for adults

Toddler Exp_{cons} = 1.5 mg/cm^2 x 10% x 230.4 cm^2 x 100% x 10% ÷ 10 kg
= 0.0.34 mg/kg bw/d

Children 2-6 years old Exp_{cons} = 1.5 mg/ cm^2 x 10% x 330.9 cm^2 x 100% x 10% ÷ 15.6 kg
= 0.31 mg/kg bw/d

Children 6-12 year old Exp_{cons} = 1.5 mg/ cm^2 x 10% x 427.8 cm^2 x 100% x 10%÷ 23.9 kg
= 0.26 mg/kg bw/d

Adult Exp_{cons} = 1.5 mg/ cm^2 x 10% x 410 cm^2 x 50% x 10% ÷ 60 kg
= 0.05 mg/kg bw/d

the following precautionary advices are recommended:

- "Avoid contact of the treated skin or clothes with food."
- "Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption"

Information of non-biocidal use of the active substance

IR3535 is only used as a biocide.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

No livestock exposure is foreseen from the use of «Montplet insect repellent IR3535 10%».

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

Not relevant for «Montplet insect repellent IR3535 10%» product.

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

Not relevant for «Montplet insect repellent IR3535 10%» product.

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

During production of the active substance, the whole reaction process (including the loading of raw materials) is carried out in a closed device. Potential human exposure is only possible during loading and cleaning/service processes. Any handling related to these processes are carried out using personal protection measures adapted to each task (up to full personal protection for special cleaning and service tasks).
Formulation of the active substance to produce «Montplet insect repellent IR3535 10%» is done in modern formulation plants equipped with fully automated equipment. The workers involved in the formulation tasks are trained professional people who usually wear the adequate PPE (according to the task) and their exposure should be negligible.

Summary of exposure assessment

Scenarios and values to be used in risk assessment

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake (mg/kg bw/day)
1.	Non professionals	1 / no PPE	mg/kg bw/day: Adult: 4.90 Child (6-12): 3.41 Child (2-6): 3.87 Toddler: 4.26 Infant: 4.55
2.	Non professionals	1 / no PPE	mg/kg bw/day: Adult: 4.91
3.	Non professionals – General public	1 / no PPE	mg/kg bw/application: Adult: 0.70 Child (6-12): 1.95 Child (2-6): 2.21 Toddler: 2.43 Infant: 2.59
4.	Non professionals – General public	1 / no PPE	mg/kg bw/day: Adult: 1.82 Child (6-12): 2.68 Child (2-6): 2.89 Toddler: 3.16 Infant: 2.94

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day
AELmedium-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day
AELlong-term	1) Rabbit, oral, developmental toxicity study. 2) Rabbit, oral, 28-day toxicity study.	1) NOAEL = 300 mg/kg bw/d 2) NOAEL = 500 mg/kg bw/d	100	100%	5 mg/kg bw/day

The derivation of an ADI or an ARfD is not applicable as no residues in food/feed are expected.
Risk characterisation for local effects of IR3535 is not justified and the derivation of a local AEC is not needed.

Maximum residue limits or equivalent

Not applicable.

Risk for industrial users

Not applicable. «Montplet insect repellent IR3535 10%» will not be used by industrial users.

Risk for professional users

Not applicable. «Montplet insect repellent IR3535 10%» will not be used by professional users.

Risk for non-professional users and for the general public

Non-professional users and the general public are gathered in one section for the risk characterisation because people from one population can also be in the other population.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL (mg/kg bw/d)	Estimated uptake	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1	1	1) 300 2) 500	5	mg/kg bw/day: Adult: 4.90 Child (6-12): 3.41 Child (2-6): 3.87 Toddler: 4.26 Infant: 4.55	 Adult: 98.05 Child (6-12): 68.2 Child (2-6): 77.3 Toddler: 85.2 Infant: 90.9	Yes
Scenario 2	1	1) 300 2) 500	5	mg/kg bw/day: Adult: 4.91	 Adult: 98.14	Yes
Scenario 3	1	1) 300 2) 500	5	mg/kg bw/application: Adult: 0.7 Child (6-12): 2.44 Child (2-6): 2.76 Toddler: 3.04 Infant: 3.24	*	Yes (see below)
Scenario 4	1	1) 300 2) 500	5	mg/kg bw/day: Adult: 0.026 Child (6-12): 0.049 Child (2-6): 0.063	Adult: 0.52 Child (6-12): 0.98 Child (2-6):	Yes

				Toddler: 0.078 Infant: 0.066	1.26 Toddler: 1.56 Infant: 1.32	

* For scenario 3, a reverse reference scenario is considered calculating the maximum number of applications which would allow to reach the reference dose:

User category	**ADULT**	**CHILD (6-12y)**	**CHILD (2-6y)**	**TODDLER**	**INFANT**
Amount / application [mg active substance/application]	1049,95	581,9	430,1	303,6	259,325
Body weight [kg]	60	23,9	15,6	10	8
Oral absorption	100	100	100	100	100
Factor for oral intake by hand-mouth transfer	4	8	8	8	8
Oral systemic exposure via hand-mouth transfer mg/kg bw	0,70	1,95	2,21	2,43	2,59

For the values calculated above, the maximum number of applications before reaching the AEL could be calculated :

AEL (mg/kg bw /d)	5	5	5	5	5
Number of time of application b,p before exceeding the AEL via hand-mouth transfer	7,14	2,57	2,27	2,06	1,93

As a conclusion for scenario 3, it is recommended that one adult will not apply on more than 7 people (including himself/herself). Actually, he/she is expected not to apply over more than five people (*i.e.* two times himself/herself + three children). No risk via this scenario is expected for adults.
As infants, toddlers and children will be treated once per day, no risk is expected via the oral route further to hand to mouth exposure after application of «Montplet insect repellent IR3535 10%».

The risk is acceptable for **adults** under all the possible scenarios (1, 2, 3 or 4) if two applications are done on the 55% of the body surface area at the dose of 1.15mg/cm² «Montplet insect repellent IR3535 10%» per application and if one application is done up to three children.
The risk is acceptable for **infants, toddlers and children** under all the possible scenarios (1, 3 or 4) if one application is done on the 55% of the body surface area at the dose of 1.15mg/cm² «Montplet insect repellent IR3535 10%» per application.

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)**
1 + 2	1	1) 300 2) 500	5	Adult: 4.91	98.14	Yes

As the exposure by inhalation of volatilized residues after application (scenario 4) and the combined inhalative and oral exposure of a parent treating three children (scenario 2) are

negligible compared to primary (dermal) exposure (from scenario 1), the combination of scenarios led to similar or slightly higher total uptake. The risk is still acceptable for each combination.

Local effects

Qualitative risk characterization for local effects is required only when the biocidal product is classified for local effects, and triggers classification of the product according to the CLP criteria.
The qualitative risk characterization for MONTPLET INSECT REPELLENT IR3535 10% is performed following the stepwise approach described in the Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017. This assessment covers non-professional users and general public.

1. Local hazard description: The active substance IR3535 is classified as Eye irrit.2; H319.
   The product MONTPLET INSECT REPELLENT IR3535 10% USO HUMANO is classified as Eye irritant. 2
2. Assignment of hazard categories: Low

Hazard category	Relevant local effect	Precautionary statements	Equivalent CLP hazard classification
Low	Irritant to eye	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.	H319

3. Identification of the exposure scenarios

See section 2.2.6.2

4. Acceptability or non-acceptability of the risks

Support for acceptable risk	Support for non-acceptable risk
Reversible effect	Operational and organisational rmms not applicable
Used with low frequency: Warm seasons	Potential children exposure due to hand to eye contact
High ventilation expected, due to its use outdoors and during summer season, where a high ventilated rate is expected indoors	
Proper instructions for use, indicating not to spray directly to the face and apply the product on the hand of adults, minimising the hand to eye contact	
Children are not expected to apply the product by themselves.	

5. Conclusion:

Effects	Frequency and durantion of potential exposures	Degree of potential exposure under best practice conditions	Relevant RMMs
Eye irrit. 2, H319	Less than one hour per day	Outdoor or indoor in warm season (i.e. efficiently ventilated facilities) spray use	Labelling, instructions for use that minimise exposure or possible health effects. The product shall not be sprayed directly to the face, adults will extend the product with their bare hands, and hands will be immediately washed. The product shall not be applied on the hands of children.

The risk of local irritation is acceptable under the terms established in the instrutions of use.

Conclusion
MONTPLET INSECT REPELLENT IR3535 10% does not post any unacceptable risk when it is used following the instructions. See authorized uses for further information.

«Montplet insect repellent IR3535 10%» containing 10% IR3535 can be used one time per day on infants, toddlers, children and two times adults with an acceptable risk.

It is important that the hands of infants, toddlers and children are not treated to limit the hand to mouth ingestion. The bitterness of the product will also prevent the oral ingestion.

Risk for consumers via residues in food

Not applicable.

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

There are no substances of concern in «Montplet insect repellent IR3535 10%».

2.2.7 Risk assessment for animal health

Not applicable. «Montplet insect repellent IR3535 10%» is not used on animals and no residues are expected.

2.2.8 Risk assessment for the environment

ESCA:
Please notice that the environmental risk assessment is reported as provided by the applicant. The ES CA position is presented in grey boxes when is needed.

For the product Insect Repellent for children no new studies or additional information for the environment have been provided. The active substance contained in this product is the same as evaluated in the CAR for IR3535® and therefore no new data/information on

the active substance is required.

This environmental risk assessment was carried out for the biocidal product «Montplet Insect repellent IR3535 10%». This product is an insect repellent (PT19) against mosquitoes containing 10% IR3535 (ethyl butylacetylaminopropionate). The repellent is for use by non-professionnals and is applied as a spray directly to the human skin. It can be used indoors as well as outdoors.

A complete assessment report is available for the active substance IR3535 (AR, March 2014). However, as «Montplet Insect repellent IR3535 10%» differs somewhat in composition and use from the product reprenseted in the IR3535 AR, the risk for the environment was assessed here anew for «Montplet Insect repellent IR3535 10%». «Montplet Insect repellent IR3535 10%» characteristics that were not covered in the IR3535 AR include:

- Swimming after product application is a scenario that is not covered in the IR3535 AR. Swimming after product application is not restricted for «Montplet Insect repellent IR3535 10%» and this scenario will therefore be taken into account in this risk assessment.

- The ESD for PT19 was not yet published when the IR3535 risk assessment was performed. Environmental risk was previously assessed based on a PT1 (human hygiene) scenario. As the more complete scenario for PT19 is now available, «Montplet Insect repellent IR3535 10%»'s risk assessment will be based on the ESD for PT19.

This environmental risk assessment is based on the information provided in the assessment report for IR3535 (March 2014), including its documents IIb and IIc (provided by the applicant), as well as the "Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and evaluation (Parts B+C), Version 2.0" (October 2017) and the "Emission Scenario Document for Product Type 19, Repellents and attractants" (May 2015).

IR3535 forms a known metabolite in water but its ecotoxicity and degradation are covered by the data provided on IR3535 as transformation to the metabolite is very rapid. No SOCs relevant for environmental assessment were identified in the formulation.

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

Under the CLP classification, the active substance IR3535 is classified as Eye Irrit 2 and the biocidal product «Montplet Insect repellent IR3535 10%» is classified as Eye Irrit 2 and Flam Liq 3. However neither the active substance nor the biocidal product are classified for environmental hazards.

Further Ecotoxicological studies

Product emission to the environment is assumed to mainly affect the STP compartment (via showering) and the aquatic compartment (via swimming in outdoor waterbodies). Acute toxicity studies were carried out for both these compartments in the IR3535 risk assessment and the following endpoints are listed in the active substance AR :

Summary table of effects on aquatic species (most sensitive species of each group)					
Group	**Species**	**Time-scale**	**Endpoint**	**Toxicity**	**Reference**
Fish	Zebra (*Brachydanio rerio*)	96h	LC_{50}	> 100 mg ai/L	AR, 2014
Invertebrates	*Daphnia magna*	48h	EC_{50}	> 100 mg ai/L	
Algae	*Desmodesmus subspicatus*	72h	E_bC_{50} E_rC_{50}	> 100 mg ai/L > 100 mg ai/L	
Microorganisms	*Activated sludge*	3h	EC_{20} EC_{50} EC_{80}	> 1000 mg ai/L > 1000 mg ai/L > 1000 mg ai/L	

Acute toxicity studies carried out on aquatic organisms (Brachydanio rerio, Daphnia magna and Desmodesmus subspicatus) did not indicate a toxic effect of IR3535 and the active substance is therefore not considered toxic for the aquatic environment.

Toxicity in the STP compartment was assessed by observing the inhibition of respiration of sludge microorganisms after 3 hours of contact with the active substance. No inhibitory effect was recorded and IR3535 is not considered toxic for sludge microorganisms.

No studies were carried out in the IR3535 AR for long term aquatic toxicity, marine species or the sediment compartment. Long term aquatic tests were left out because no acute toxicity was recorded for the aquatic compartment. Marine species were not tested because no toxicity was recorded for freshwater species and the marine compartment is not expected to receive any major emissions. As endpoints for these compartments are absent, assessment factors of 1000 for the freshwater compartment and 10 000 for the marine compartment were used. And since not toxicity studies were carried out for the sediment compartment either, the PNECsed was derived from the PNECwater via the equilibrium partitioning method.

No ecotoxicity studies were carried out for the soil or air compartment in the IR3535 AR. Based on product use, emissions to the soil compartment are expected to be negligible. PNECsoil for the assessment of «Montplet Insect repellent IR3535 10%» was calculated (with EUSES) through the equilibrium partitioning method based on aquatic toxicity data (BPR Guid., Vol. IV Env. Parts B+C, 2017 – p.147). As the active substance has a very low volatility, the air compartment is not expected to be at risk. No PNEC was thus calculated for this compartment.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	IR3535 is not considered toxic for the two main receiving compartments (STP compartment and aquatic compartment).
Justification for the value/conclusion	Acute toxicity studies were carried out on fish (Brachydanio rerio), *Daphnia magna*, algae (Desmodesmus subspicatus) and activated sludge but no toxic effects were observed.

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

Data waiving	
Information requirement	-
Justification	No data available. Product use and ecotoxicological studies do not suggest possible effects on other specific species.

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

Data waiving	
Information requirement	-
Justification	No data available. Product use is not expected to pose a risk to non-target organisms. Indeed, the product is applied to human skin which no non-target animals should be in contact with.

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

Data waiving	
Information requirement	-
Justification	No data available. During product use, ingestion by non-target organisms is not expected to occur as the biocidal product is a repellent applied to human skin.

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

Data waiving	
Information requirement	-
Justification	No data available. No secondary ecological effects are expected as the biocidal product is a repellent applied to human skin.

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

Based on the product use, the main entry routes into the environment are the STP compartment (through showering after product application) and the aquatic compartment (through swimming in surface waterbodies). Secondary emission from the STP compartment is expected to affect the aquatic compartments via effluents to surface water and the terrestrial compartments via sludge application to agricultural soil. These secondary emissions are expected to be minor as 99% biodegradation was measured in the STP compartment (AR, 2014).

In the case of emission through swimming, only closed water bodies (lakes, ponds, reservoirs) are considered as a worst-case scenario. Secondary emission from the freshwater compartment is therefore expected to only impact the freshwater sediment. Major impact to the sediment is however not expected as IR3535 remains mainly in the water phase.

The atmosphere compartment is not expected to be affected as IR3535 has low volatility.

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

Data waiving	
Information requirement	-
Justification	No data available.

Leaching behaviour (ADS)

Data waiving	
Information requirement	-
Justification	No data available. Risk is not expected for the terrestrial compartment as IR3535 was 99% degraded in the STP.

Testing for distribution and dissipation in soil (ADS)

Distribution

Summary table of the adsorption/desorption in soils								
Method, Guideline, GLP status, Reliability	**Sediment type**	**Adsorbed AS [%]**	**K_a (l/kg)**	**K_{aoc} (l/kg)**	**K_d K_{doc} K_a/K_d (l/kg)**	**Kf**	**l/n**	**Reference**
	Freshwater	-	9.516	475.25	K_d: 40.4 K_{doc}: 1136 K_a/K_d: 0.236	-	-	AR, 2014

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	K_{OC} = 475.25 l/kg
Justification for the value/conclusion	Based on the adsorption/desorption test, a mean (arithmetic) K_{OC} of 475.25 l/kg was determined. DT_{50} in soil was not determined. Only limited exposure is expected for the terrestrial compartment as IR3535 is mainly emitted to STP where it is degraded up to 99%.

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

Dissipation

Summary table on half lives in water and sediments				
Compartment /process	**DT_{50} measured in test**	**DT_{50} at 12°C**	**Rate constant at 12°C**	**Reference**
Freshwater – aerobic degradation	6.79-8.41 d (20°C)	12.88-15.59 d		AR, 2014

The aerobic water/sediment degradation study from the IR3535 AR indicates that the active substance remains mainly in the water phase. No half-life for the sediment could therefore be determined.

In the water phase, IR3535 is degraded first into its free-acid, which is in its turn degraded. IR3535 degrades rapidly into its metabolite. The subsequent degradation of the free-acid knows two phases: a lag phase, during which degradation is slow, and a rapid ultimate biodegradation phase.

Summary table of identified metabolites /transformation- or reaction products in water and sediments				
Compartment	**Metabolite/transformation- or reaction product**	**DT_{50} measured in test**	**DT_{50} at 12°C**	**Reference**
Freshwater – aerobic degradation	Free acid (lag phase)	86.1-110 d (20°C)	163.29-208.61d	AR, 2014
Freshwater – aerobic degradation	Free acid (phase 2, rapid)	4.47-5.68 d (20°C)	8.48-10.77 d	

Conclusion used in Risk Assessment – distribution and dissipation in water and sediment	
Value/conclusion	IR3535 and its free-acid metabolite should not be classified as persistent.
Justification for the value/conclusion	IR3535 remains mainly in the water phase, where it degrades rapidly into its free-acid (DT50 (12°C) = 12.88-15.95 days, which is below the P-criterion of 40 days). The free-acid is then ultimately degraded in two phases: a lag phase (DT50 (12°C) = 163.29-208.61 days) and a rapid phase (DT50 (12°C) = 8.48-10.77 days). These two phases (lag and rapid) are combined together for the P-criterion evaluation and overall DT50 values do not indicate that IR3535 is persistent.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	-
Justification	Emission of IR3535 to air is unlikely as its vapour pressure is low. IR3535's half-life is 13.16 hours due to reaction with OH-radicals. No

	accumulation and long range transport in air is therefore expected.

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)

Data waiving	
Information requirement	-
Justification	No data available. The product is sprayed on human skin so a risk for overspray is not expected.

Endocrine disruption

ES CA: see Draft PAR confidential annex

PNEC derivation

- **STP compartment :**

The PNEC value for the STP compartment was calculated via EUSES and by applying an assessment factor of 100 (BPR Guid. Vol. IV Env. parts B+C – p. 137).

STP compartment PNEC value (mg/l)
$PNEC_{STP}$
> 10

- **Aquatic compartments :**

The PNEC values for the various aquatic compartments were calculated via EUSES.

Summary of the aquatic compartment PNEC values (mg/l)			
$PNEC_{water}$	**$PNEC_{sed}$**	**$PNEC_{seawater}$**	**$PNEC_{seased}$**
> 0.1	> 1.11	> 0.01	> 0.111

- **Terrestrial compartments :**

The PNEC value for the soil compartment was calculated via EUSES. The PNEC value used for the groundwater compartment is a trigger value for pesticides of 0.1 µg/L (BPR Guid. Vol. IV Env. part B+C – p.97)

Summary of the terrestrial compartment PNEC values	
$PNEC_{soil}$	**$PNEC_{groundwater}$**
> 0.85 mg/kg	0.1 µg/L

- **Air compartment :**

No PNEC value was calculated for the air compartment as it is not considered relevant in this risk assessment.

ES CA:

ES CA do not agree with the PNEC for STP indicated by the applicant. as it is stated in the CAR of the active substance IR3535:

"According to the TGD on Risk Assessment (Table 17, p.109), the PNEC for micro-organisms in a STP is derived by dividing the EC50 from a respiration inhibition test (OECD 209) by a factor of 100 or by dividing the NOEC from a respiration inhibition test by 10. 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. PNECmicro-organisms (STP) = 100 mg/l"

Thus, the PNEC for the STP is 100 mg/l.

For the sediment compartment, there are also no toxicity data available. The $PNEC_{sediment}$ was calculated based on equilibrium partitioning method and $PNEC_{water}$.

No terrestrial toxicity tests were performed for IR3535®. Due to the method of application directly on the skin only limited and very local emissions to the soil are expected. IR3535® is not likely to become accumulated in the soil in large amounts. $PNEC_{soil}$ has been calculated based on the equilibrium partitioning method.

The physicochemical properties of IR3535® do not suggest that this substance will pose a risk to the atmospheric environment. Therefore no PNECs were calculated for this compartment.

The low BCF values suggest that IR3535® has a low bioaccumulation potential. Therefore the risk of secondary poisoning via ingestion of contaminated food (eg. earthworms or fish) by birds or mammals is also low and no avian dietary tests were required.

Sumary of PNEC values:

Summary of PNEC values for the active substance	
Compartment	**PNEC value**
$PNEC_{aquatic}$	> 0.1 mg/l
$PNEC_{sediment}$	> 1.11 mg/kg wwt
$PNEC_{micro\text{-}organisms\ (STP)}$	100 mg/l
$PNEC_{soil}$	> 0.85 mg/kg wwt
$PNEC_{saltwater}$	> 0.01 mg/l
$PNEC_{marine\text{-}sediment}$	> 0.111 mg/kg wwt

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 19

Assessed scenarios	*Scenario 1*: Removal through showering and bathing of humans *Scenario 2*: Release to surface waterbodies through swimming
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015
Approach	*Scenario 1*: Average consumption *Scenario 2*: Average consumption
Distribution in the environment	Calculated via : - the EUSES program (EUSES 2.1.2) - the "Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and evaluation (Parts B+C), Version 2.0", October 2017
Groundwater simulation	-
Confidential Annexes	-
Life cycle steps assessed	The "removal of product" step of the product life cycle was assessed for both scenarii

ESCA:
ES CA gree with the two scenarios presened by the applicant.

Emission estimation

Product emission to the environment can occur during the product use (application, service life and removal).

In line with the approach taken in the IR3535 AR (2014), the main emission to the environment is expected to take place during the product removal. After application of the repellent to human skin, product removal can occur through (1) showering or bathing and (2) when swimming in outdoor surface waters. These are the two scenarios that will be taken into account in this risk assessment.

Emission during product application to human skin can also occur as a fraction of the spray can hit the floor or the ground at application. However the TM IV 2013 stated that these emissions are negligible and they are therefore not considered as relevant emission pathways.

The ESD for PT19 also considers emissions during product service life as irrelevant because of IR3535's low volatility.

Scenario 1: Removal through showering and bathing of humans

The first emission pathway is the removal of the insect repellent during showering/bathing of humans. This emission will directly affect sewage treatment plants (STP). Emissions to the STP compartment will then indirectly affect the aquatic compartment (including sediments) via STP effluent. Following the IR3535 AR (2014), virtually no IR3535 is expected to occur in the STP dry sludge so the soil and groundwater compartments are not expected to be affected by sludge application to agricultural soil. Finally, the air compartment is not expected to be affected due to IR3535's low volatility.

Product emission to the STP compartment was determined via the equation presented in the ESD for PT19. The paramaters in the following table were used as input :

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 1: Removal through showering and bathing of humans				
N_{local}	Number of inhabitants feeding one sewage treatment plant	10 000	-	Default value from ESD
$Cform_{weight}$	Active substance in the product	100	g/kg	10% a.s.
$Qform_{appl}$	Consumption per application	1.15	mg/cm²	Data from efficacy studies of Merck[7]
$AREA_{skin}$	Treated area of human skin	10 660	cm²	ESD for PT19 and TAB Environment (ENV 172)
N_{appl}	Number of applications per day	2	d^{-1}	Applicant's data
F_{water}	Fraction released to wastewater	1	-	Worst-case value from ESD
F_{inh}	Fraction of inhabitants using a repellent product	0.2	-	Default value in ESD for use as repellent on human skin
F_{penetr}	Market share of repellent	0.5	-	Default value from ESD

In line with the efficacy studies from Merck, an application rate of 1.15 mg/cm² is used. According to the ESD for PT19 and to the TAB Environment (ENV 172), the treated skin area to be considered for a standard adult person is 10 660 cm². The product can also be applied once a day on children, but considering adults is a worst-case scenario, since the maximal number of daily applications and the area of skin for adults are higher than for children.

The number of product applications per day (N_{appl}) is set to 2, since it is the maximum allowed for adults, as indicated in the authorised uses section.

The fraction of product that is released to the wastewater (F_{water}) will vary depending on the amount of product that evaporates from the skin or that is dermally absorbed. IR3535 has low volatility and is thus not expected to evaporate. The IR3535 AR indicates that a fraction of the active substance can be dermally absorbed. However, a worst-case scenario was considered here and F_{water} was set to 1 (indicating that the entirety of the product is released to the wastewater).

The following equation from the ESD for PT19 was used to calculate the product emission to the STP compartment :

[7] Please refer to the section 3.7 for the justification.

Local emission rate to wastewater ($Elocal_{STP}$):

$Elocal_{STP}$

$= N_{local} * N_{appl} * Qform_{appl} * AREA_{skin} * Cform_{weight} * F_{inh} * F_{water} * F_{penetr} * 10^{-9}$

$= 10\ 000 * 2 * 1.15 * 10\ 660 * 100 * 0.2 * 1 * 0.5 * 10^{-9}$

$= 2.45$ kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.45	-

ESCA:

We disagree with the value used for AREAskin by the applicant.

Taken into account WGV2018 agreement on treated skin surface:
TAB ENV v2.0 entry **ENV 172** - Refinement of risk assessment PT19: reduction of treated skin surface area and taking into account dermal adsorption
The WG agreed to apply the new value of the HEAdoc recommendation of January 2018 for the treated skin area, i.e. 55% of 16600 cm^2 (= 9130 cm^2), since this could be considered as a mean value taking into account the different skin areas for women, men and children.

$Elocal_{STP} = N_{local} * N_{appl} * Qform_{appl} * AREA_{skin} * Cform_{weight} * F_{inh} * F_{water} * F_{penetr} * 10^{-9}$

$= 10\ 000 * 2 * 1.15 * 9.130 * 100 * 0.2 * 1 * 0.5 * 10^{-9} = 2.10$ kg/d

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Waste water	2.10	/

Scenario 2: Release to surface waterbodies through swimming

The second emission pathway is removal of the insect repellent through swimming in outdoor surface waters. As opposed to the first scenario, product release through outdoor swimming will bypass the STP compartment and be directly released to surface waterbodies.

As proposed by the ESD for PT19, only ponds, lakes and reservoirs are considered in this scenario. Indeed, they represent a worst-case scenario as dilution is expected to occur when swimming in flowing waters (freshwater rivers or coastal areas). The only affected

compartments will therefore be the freshwater compartment and its corresponding sediment compartment.

Product emission to the freshwater compartment was determined via the equation presented in the ESD for PT19. The paramaters in the following table were used as input :

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 2: Release to surface waterbodies through swimming				
$N_{swimmers}$	Daily number of swimmers	1500	-	Default value from ESD
F_{swim}	Fraction of swimmers using the repellent product	0.1	-	Default value from ESD for product authorization
N_{appl}	Number of applications per day	1	d^{-1}	Default value from ESD
$F_{waterbody}$	Fraction released to surface water body	1	-	Default value from ESD
$Cform_{weight}$	Active substance in the product	100	g/kg	10% a.s.
$Qform_{appl}$	Consumption per application	1.15	mg/cm²	Data from efficacy studies of Merck
$AREA_{skin}$	Treated area of human skin	10 660	cm²	ESD for PT19 and TAB Environment (ENV 172)

The same values were used for the variable paramaters as in the first scenario (consumption per application, treated area of human skin, fraction of product released to surface water body), except for the number of product applications before release. As stated in the ESD for PT19, repellent application is only expected to occur once before swimming.

The following equation from the ESD for PT19 was used to calculate the product emission to the freshwater compartment :

Local emission rate to surface water ($Elocal_{water}$):

$Elocal_{water}$

$= N_{swimmer} * N_{appl} * Qform_{appl} * AREA_{skin} * Cform_{weight} * F_{swim} * F_{waterbody} * 10^{-9}$

$= 1500 * 1 * 1.15 * 10\ 660 * 100 * 0.1 * 1 * 10^{-9}$

$= 0.184$ kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Freshwater	0.184	-

ES CA:
ES CA do not agree with the AREAskin used for the risk assessment. When repellent products are used when swimming, one could assume the swimmer applies the product to the full body surface. So, ES CA consider as AREAskin:

$AREA_{skin}$ = 16600 cm²

$Elocal_{water}$=

= $N_{swimmer}$ * N_{appl} * $Qform_{appl}$ * $AREA_{skin}$ * $Cform_{weight}$ * F_{swim} * $F_{waterbody}$ * 10^{-9}

= 1500 * 1 * 1.15 * 16 600 * 100 * 0.1 * 1 * 10^{-9} = 0.286 kg/d

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Local water	2.86x10^{-1}	/

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	yes	yes	yes	no	yes	yes	-
Scenario 2	yes	Yes	no	no	no	no	no	no	-

The compartments receiving product emission vary between the two scenarios. The air compartment is not expected to be affected in either scenario due to IR3535's low volatility.

In the case of product release through showering/bathing (scenario 1), the main receiving compartment is the STP as product is washed off into wastewater. From there on, indirect emissions can occur from the STP to the freshwater compartment (via STP effluents) and to the soil compartment (via STP sludge application to agricultural soil). In the first case, freshwater sediments as well as the marine compartment can then be affected. In the second, product release can occur from the soil and affect the groundwater compartment.

In the case of product release through outdoor swimming (scenario 2), the main receiving compartment is the freshwater as the product is washed off into ponds, lakes or reservoirs. Freshwater and its corresponding sediment compartment are the only affected compartments. Indeed, product emission bypasses the STP compartment and, due to dilution effects, emissions to rivers or the marine compartment are considered covered by the lakes, ponds etc. as a worst-case.

The EUSES program was used for calculating certain parts of the product distribution in the environment. The following data extracted from the IR3535 AR served as input paramaters in EUSES :

Input parameters (only set values) for calculating the fate and distribution in

the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	215.29	g/mol	-
Melting point	-90	°C	-
Boiling point	300	°C	-
Vapour pressure (at 20°C)	0.15	Pa	-
Water solubility (at 20°C)	7×10^4	mg/l	-
Log Octanol/water partition coefficient	1.7	Log 10	-
Organic carbon/water partition coefficient (Koc)	475.25	l/kg	-
Biodegradability	Not readily biodegradable	-	Not readily biodegradable according to two "ready tests". However, an STP simulation test indicated > 99% elimination after 28 days.
Henry's law constant (at 20°C)	4.613×10^{-4}	$Pa.m^3/mol$	-
Use or bypass STP (local marine assessment)	Use STP	-	As indicated in the BPR Guid. Vol. IV Env. Parts B+C (2017) – p.107, for substances that are for private or public use (versus industrial use) it can be assumed that the degree of treatment in a biological STP corresponds to the inland scenario.

In the case of scenario 1, the product can be redistributed into secondary compartments after entering the STP compartment. In the first tier approach of the IR3535 AR, IR3535 is regarded as non-biodegradable and the entirety of the product emission to the STP compartement is redistributed into the secondary compartments. With this approach, IR3535 failed to pass the environmental risk assessment in the IR3535 AR. The risk was therefore evaluated once again with a second tier approach, where active substace biodegradation was taken into account. Indeed, 99% of IR3535 elimination was measured in a STP simulation test and this value was therefore used for the second tier approach (as agreed at the TM IV 2010).

As the risk assessment for IR3535 failed for a first tier approach and since «Montplet Insect repellent IR3535 10%» has a higher risk level (due to a higher concentration in active substance), it was decided to directly apply the second tier approach of the IR3535 AR (2014). Biodegradation in the STP was therefore set at 99% and the remaining 1% enters the water compartment. The final redistribution from the STP compartment is indicated in the following table :

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario 2	
Air	0	-	Emissions to air are considered negligible due to the low vapour pressure of the active substance (0.15 Pa) (AR, 2014)

Water	1	-	AR, 2014
Sludge	0	-	
Degraded in STP	99	-	Based on the STP simulation test (AR, 2014)

ESCA:
In scenario 1, the product applied is removed from the body through showering or bathing. The wastewater from washing is then removed to the municipal waste water treatment plant, after which the effluent is emitted to the surface water where it can expose both fresh water and fresh water sediments. Exposure to other compartments is not considered relevant.
In scenario 2, the applied product is removed from the body directly to the surface water through swimming, where it can expose both fresh water and fresh water sediments. Exposure to other compartments is not considered relevant.

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	no	no	no
Scenario 2	yes	Yes	No	no	no	no	no	no	no

In the CAR for IR3535®, calculations according to EUSES are available for the distribution in the STP, which in this case is only relevant for scenario 1. As a worst-case assessment the distribution presented in the CAR is taken over for the assumption that there is no degradation.

Calculated fate and distribution in the STP				
Compartment	**Percentage [%]**			**Remarks**
	Scenario 1 TIER 1	**Scenario 1 TIER 2**	**Scenario 2**	
Air	0.000547	0	Not relevant	
Water	99	1		
Sludge	1	0		
Degraded in STP	1.000547	99		

The applicant has only consider the TIER 2 in the evaluation, 99% degradation in STP is taken into consideration. **ES CA** agree with this evaluation. Nevertheles, Spain has calculated the values for TIER 1.

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	1.23×10^{-2}	1.23×10^{-3}	1.36×10^{-2}	1.23×10^{-4}	1.36×10^{-3}	-	-	-
Scenario 2	-	0.038	0.43	-	-	-	-	-

Scenario 1: Removal through showering and bathing of humans

- **PEC in STP by direct product release to STP:**

The PEC_{STP} was calculated following the BPR Guid. Vol. IV Env. Parts B+C (2017) – p. 72. The following equations and input values were used :

Concentration in untreated water ($C_{local,inf}$) :

$$Clocal,\inf = \frac{Elocal,water \times 10^6}{EFFLUENTstp}$$

= 2.45 * 10^6 / 2 x 10^6

= 1.23 mg/l

Concentration of substance in the STP effluent ($C_{local,eff}$ = PEC_{STP}) :

$$Clocal,eff = Clocal,\inf \times Fstp,water$$

= 1.23 * 0.01

= 1.23 x 10^{-2} mg/l

Input parameters for calculating PEC_{STP}				
Input		**Value**	**Unit**	**Remarks**
$E_{local,water}$	Local emission rate to (waste) water during episode	2.45	kg/day	Calculated in previous step
$EFFLUENT_{STP}$	Effluent discharge rate of STP	2 x 10^6	l/day	Default value in Guidance
$F_{STP,water}$	Fraction of emission directed to water by STP	0.01	-	Calculated in previous step

EUSES 2.1.2 does not have a scenario for PT19. However, as stated in the IR3535 AR, scenarios for PT1 (human hygiene products) are quite similar to the repellent in use and manner of application. When applying the scenario for PT1 (aerosol spray) in EUSES with the following input values, the same PEC_{STP} value was obtained as via the manual calculations above :

EUSES input parameters – Aerosol spray scenario			
Input	**Value**	**Unit**	**Remarks**
Fraction of inhabitants using the product	0.2	-	Default value from ESD
Number of applications	2	-	Applicant's data
Consumption per application	12.26	g	Output ($Qform_{appl}$ * $AREA_{skin}$)
Active substance in product	10	%	-

- **PEC in freshwater / freshwater sediment / seawater / seawater sediment, by release from STP:**

The EUSES program automatically calculates the PEC values for these compartments. This data was therefore taken from the EUSES outputs.

- **PEC in soil / groundwater, by release from STP:**

In view of the redistribution in the STP compartment, no IR3535 is expected to accumulate in the STP dry sludge. The soil and groundwater compartments are therefore not expected to be affected and no PEC_{soil} or PEC_{GW} were calculated.

ES CA:

In the CAR for IR3535®, calculations according to EUSES are available for the distribution in the STP, which in this case is only relevant for scenario 1. As a worst-case assessment the distribution presented in the CAR is taken over for the assumption that there is no degradation.

Calculated fate and distribution in the STP				
Compartment	**Percentage [%]**			**Remarks**
	Scenario 1 TIER 1	**Scenario 1 TIER 2**	**Scenario 2**	
Air	0.000547	0	Not relevant	
Water	99	1		
Sludge	1	0		
Degraded in STP	1.000547	99		

The applicant has only consider the TIER 2 in the evaluation, 99% degradation in STP is taken into consideration. **ES CA** agree with this evaluation. Nevertheles, Spain has calculated the values for TIER 1.

PEC values			
		PEC_{STP}	**PEC_{water}**
		[mg/m^3]	[mg/l]
Scenario 1	TIER 1	1.04	$1.04x10^{-1}$
	TIER 2	$1.05x10^{-2}$	$1.05x10^{-3}$

Scenario 2: Release to surface waterbodies through swimming

There are no options in the EUSES program to run the outdoors swimming scenario. Therefore both PEC values were estimated by following the ECHA guidances.

- **PEC in freshwater by direct product release to surface waterbodies:**

The PEC_{water} was estimated based on equations indicated in the ESD for PT19. The following data was used as input paramaters:

Input parameters for calculating the local PEC_{water}			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: Release to surface waterbodies through swimming			

$Elocal_{water}$	Local emission rate to surface water body	0.184	kg/day	Output from previous emission estimation
$V_{waterbody}$	Volume of water body	435 000	m^3	Default value from ESD
$T_{emission}$	Number of emission days	91	days	Product use only takes place during 3 months of peak bug season (as proposed in ESD)

As a first tier approach, the PEC_{water} corresponds to the $Clocal_{water}$. The following equation was therefore used to estimate PEC_{water} :

Local concentration in water body over 91 days ($Clocal_{water, 91d}$):

$Clocal_{water, 91d}$

$= 10^3 * Elocal_{water} * T_{emission} / V_{waterbody}$

$= 10^3 * 0.184 * 91 / 435\,000$

$= 0.038$ mg/L

- **PEC in freshwater sediment by release from freshwater:**

This PEC was obtained by following the methods in the BPR Guid.Vol. IV Env. parts B+C – p.84, where the PEC_{sed} can be estimated via the following equation and input paramaters:

$$PEClocal, sed = \frac{Ksusp, wat}{RHOsusp} \times PEClocal, water \times 1000$$

$= 12.8 / 1150 * 0.038 * 1000$

$= 0.43$ mg/kg

Input parameters for calculating the local PEC_{sed}				
Input		**Value**	**Unit**	**Remarks**
$PEC_{local,water}$	Concentration in surface water during emission episode	0.038	mg/l	Calculated via EUSES
RHO_{susp}	Bulk density of suspended matter	1150	kg/m^3	Standard value from BPR Guid. Vol. IV Env. parts B+C – p.53
$K_{susp,water}$	Suspended matter-water partitioning coefficient	12.8	m^3/m^3	Calculated via EUSES

ES CA: this values has been recalculated using the Elocalwater obtained above (Elocalwater= $2.86x10^{-1}$ kg/d):

As a first TIER evaluation concentrations are calculated for emission periods of 1 day and 91 days, without taking into account possible degradation progresses, which represents the worst-case.

Input parameters for calculating surface water concentration				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Release of repellents used on human skin due to swimming activities in surface water bodies				
Local emission to surface water body	$Elocal_{water}$	$2.86x10^{-1}$	kg/d	O (Intermediate calculation)
Volume of water body	$V_{waterbody}$	435 000	m³	D
Number of emission days TIER 1	$T_{emission,\ 1d}$	1	D	D
Number of emission days TIER 2	$T_{emission,\ 91d}$	91	D	D
Number of emission events	$N_{emission,\ 91d}$	91	[-]	D

$$Clocal_{water,1d} = \frac{Elocal_{water} \times T_{emission,1d}}{V_{waterbody}}$$

$$Clocal_{water,91d} = \frac{Elocal_{water} \times T_{emission,91d}}{V_{waterbody}}$$

Resulting local concentrations in the waterbody		
Compartment	**Local concentration ($Clocal_{compartment}$) [kg/m³]**	**Remarks**
Surface water – after 1 day	$6.58x10^{-7}$	/
Surface water – after 91 days	$5.99x10^{-5}$	(without considering possible degradation)

ES CA: Summary of PEC values:

Summary table on calculated PEC values			
		PEC_{STP}	**PEC_{water}**
		[mg/m³]	[mg/l]
Scenario 1	TIER 1	1.04	$1.04x10^{-1}$
	TIER 2	$1.05x10^{-2}$	$1.05x10^{-3}$
Scenario 2	Day 1	n/a	$6.58x10^{-4}$
	Day 91	n/a	$5.99x10^{-2}$

Neither for scenario 1, nor for scenario 2, calculations were made for the sediment, since the $PNEC_{sediment}$ was determined through the EPM-method. This means that the risk assessment for water is applicable for the sediment as well.

Primary and secondary poisoning

As stated in the IR3535 AR, poisoning is not considered relevant. Primary poisoning should not occur as product use does not result in direct exposure for birds and mammals. Risk through secondary poisoning is also low since IR3535 has a low potential for bioaccumulation (with Log P_{OW} = 1.7) and a low potential for bioconcentration in the food chain (BCF_{fish} = 5.6 l/kg and $BCF_{earthworm}$ = 1.44 kg/kg).

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:
Product emission to air is not considered relevant due to IR3535's low vapour pressure (0.15 Pa at 20°C). No risk is therefore expected for the air compartment.

ES CA agrees

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	< 1.23 x 10^{-3}
Scenario 2	-

ESCA:

Summary table on calculated PEC/PNEC values		
		PEC/PNEC$_{STP}$
Scenario 1	TIER 1	1.04x10^{-2}
	TIER 2	1.05x10^{-4}
Scenario 2	Day 1	Not relevant
	Day 91	Not relevant

Conclusion:
In the case of scenario 1, the entire fraction of the applied product is emitted to the STP compartment. However, the IR3535 AR indicated 99% of active substance elimination during an STP simulation test and scenario 1 has an acceptable PEC/PNEC ratio. No unacceptable risk was therefore identified for microorganisms.

In the case of scenario 2, no emissions are expected towards the STP compartment.

ESCA:
ES CA agrees with the conclussions given bay the applicant

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1	< 1.23 x 10^{-2}	< 1.23 x 10^{-2}	< 1.23 x 10^{-2}	< 1.23 x 10^{-2}
Scenario 2	< 0.38	< 0.38	-	-

Conclusion:

In the case of scenario 1, the aquatic compartment is not the main receiving compartment. Only a fraction of the active substance is emitted to the freshwater compartment (1%) since 99% is degraded in the STP compartment. For the fraction that is emitted in the freshwater compartment, the PEC/PNEC ratio indicates no unacceptable

risks for freshwater organisms. The freshwater PEC/PNEC ratio also covers the freshwater sediment and marine compartments (no toxicity data is available for the sediment and marine compartments and the PNECS were calculated based on the equilibrium partitioning method).

In the case of scenario 2, product emission is only considered for lakes/ponds/reservoirs so only the freshwater compartments are concerned. Freshwater is the main receiving compartment for this scenario as a worst-case scenario considers that the entire fraction of product applied is released to freshwater through swimming. However the PEC/PNEC ratios for aquatic organisms and the corresponding data for sediments dwelling organisms do not indicate any unacceptable risk.

ES CA:

Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{water}$
Scenario 1	TIER 1	**1.04**
	TIER 2	$1.05x10^{-2}$
Scenario 2	Day 1	$6.58x10^{-3}$
	Day 91	$5.99x10^{-1}$

Neither for scenario 1, nor for scenario 2, calculations were made for the sediment, since the $PNEC_{sediment}$ was determined through the EPM-method. This means that the risk assessment for water is applicable for the sediment as well.

For the scenario 1, when considering the worst-case assessment, tier 1, where no elimination from the STP is taken into account, then an unacceptable risk for the surface water is calculated. However when considering the TIER 2, where 99 % elimination from the STP is considered, no unacceptable risk is calculated.
For the scenario 2, no adverse effects are expected, neither at day 1 nor at day 91, without considering degradation in the surface water.

Conclusion:
No adverse effect for the aquatic compartment is expected

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	-
Scenario 2	-

Conclusion:
In the case of scenario 1, the soil compartment is not expected to be affected by secondary exposure as no IR3535 accumulates in the dry sludge.

In the case of scenario 2, no emissions are expected to the soil compartment.

Groundwater

Calculated PEC/PNEC values	
	$PEC/PNEC_{gw}$
Scenario 1	-
Scenario 2	-

Conclusion:
In the case of scenario 1, since no product enters the soil compartment, no risk is expected for the groundwater compartment either.

In the case of scenario 2, no emission is expected to the groundwater compartment.

ES CA: this compartment is not relevant.

Primary and secondary poisoning

As stated in the IR3535 AR, poisoning is not considered relevant. Primary poisoning should not occur as product use does not result in direct exposure for birds and mammals. Risk through secondary poisoning is also low since IR3535 has a low potential for bioaccumulation (with Log P_{OW} = 1.7) and a low potential for bioconcentration in the food chain (BCF_{fish} = 5.6 l/kg and $BCF_{earthworm}$ = 1.44 kg/kg).

ES CA agrees

Overall conclusion on the risk assessment for the environment of the product
Based on this risk assessment and on available data, «Montplet Insect repellent IR3535 10%» should not cause any unacceptable risks to the environement.

ES CA agrees with the conclussions.

2.2.9 Measures to protect man, animals and the environment

ESCA see SPC

2.2.10 Assessment of a combination of biocidal products

Not relevant. The formulation is not intended to be used in combination with any other biocidal product.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES[8]

3.1 List of studies for the biocidal product

Section No. of IUCLID / Section of PAR	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data Protection (Yes/No)	Owner
3	[redacted]	2019	MicroBios – Viscosity – Rotational Viscosimeters MicroBios No report number provided Non GLP	Yes	Alcoholes Montplet, S.A.
3	[redacted]	2019	Control of critical parameters under stability conditions Eurofins Biolab S.r.l. Report no. 2017/184 AM GLP; Unpublished	Yes	Alcoholes Montplet, S.A.
3	[redacted]	2021	SHELF-LIFE STABILITY STUDY AT 25°C/60%RH FOR 3 YEARS ON THE TEST ITEM "INSECT REPELLENT FOR CHILDREN" - Laboratorios Montplet Report no. 2017/184AM GLP; Yes	Yes	Alcoholes Montplet, S.A.
3	[redacted]	2017	ACCELERATED STABILITIES STUDY ON THE TEST ITEM "INSECT REPELLENT FOR CHILDREN" Eurofins Biolab S.r.l. Report no. STULV21AA0564-1 GLP; Prov. Cert. 13/09/2021	Yes	Alcoholes Montplet, S.A.
3	[redacted]	2021	DETERMINATION OF CORROSION BEHAVIOUR TO METALS Laboratorios Montplet	Yes	Laboratorios Montplet,

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

			Report no. RD-D21-09		S.L.U.
3	[redacted]	2020	DETERMINATION OF THE SURFACE TENSION (SFT) OF A LIQUID. WILHELMY PLATE METHOD. Leitat. Report no. IN-01232-2020-2; Unpublished.	Yes	Laboratorios Montplet, S.L.U.
5	[redacted]	2017	Validation of an HPLC-UV method for the quantification of the ethyl butylacetylaminopropionate (IR3535) Active Ingredient in the test item "Montplet Insect Repellent IR3535 20%" Eurofins Biolab S.r.l. S-2017-02128 AM GLP; Unpublished	Yes	Alcoholes Montplet, S.A.
6	[redacted]	2006	Evaluation of the repellency of 6 products against the European Sheep Tick, Ixodes ricinus, on human volunteers according to the EPA guidelines IS Insect Services GmbH Report No. BD21229TickRep Doc Nº 336-1921 Unpublished	Yes	[redacted]
6	[redacted]	2011	Repellent Efficacy of Six Repellent Formulations on Human Arms against Mosquitoes BioGenius GmbH Report No. BIO057a-11 Doc Nº 336-1922 Unpublished	Yes	[redacted]
6	[redacted]	2006	Test of Personal Insect Repellents: Study EMD 004.1 - Replacement for MRID 4699003	Yes	[redacted]
6	[redacted]	2006	Test of Personal Insect Repellents: Study EMD-003.1 - Replacement for MRID 46979001 Carroll-Loye Biological Research Doc N°336-1916/2006 Unpublished	Yes	[redacted]
8 / 2.2.6.1	[redacted]	2013a	Determination of the in vitro skin irritation to child insect repellent Montplet, by the method of reconstructed human epidermis ETYCA RESEARCH Report no. 85 Non GLP; Unpublished Study No. 13-15964-L	Yes	Alcoholes Montplet, S.A.
8 / 2.2.6.1	[redacted]	2013b	Verification of skin compatibility in man of an insect repellent after making a unique application on patch (Patch-test)	Yes	Alcoholes Montplet,

			ETYCA RESEARCH Report no. 83 Non GLP; Unpublished Study No. 13-16002-M		S.A.
8 / 2.2.6.1	[redacted]	2002a	EYE IRRITATION TEST (3) Analytical Laboratory Dr. Echevarne Report no. 81 Non GLP; Unpublished Study No.A8113	Yes	Alcoholes Montplet, S.A.
8 / 2.2.6.1	[redacted]	2002b	ACUTE ORAL TOXICITY STUDY Analytical Laboratory Dr. Echevarne Report no. 71 Non GLP; Unpublished Study No.A8113	Yes	Alcoholes Montplet, S.A.
8 / 2.2.6.1	[redacted]	2012	Acute dermal toxicity on repelente insectos forte Montplet Eurofins Biolab S.r.l. Report 70 Non GLP; Unpublished Study No.2012/1085 AMi	Yes	Alcoholes Montplet, S.A.

3.2 Output tables from exposure assessment tools

3.2.1 Risk assessment for human health

BC-KK020575-39-Exposure calculation.x

Scenario 1.a - **Dermal exposure**

User category	ADULT	CHILD (6-12y)	CHILD (2-6y)	TODDLER	INFANT	Comments
Amount / application [mg active substance/application]	1049,95	581,9	430,1	303,6	259,325	Information form General data sheet
Number of application/ day (as recommended by the applicant)	2	1	1	1	1	Information form General data sheet
Dermal absorption value (%)	14	14	14	14	14	Information form General data sheet
Body weight [kg]	60	23,9	15,6	10	8	Information form General data sheet
Internal dose (mg / kg bw /d)	4,90	3,41	3,86	4,25	4,54	Calculation : amount/application (a.s.) x number of application/day *
AEL (mg/kg bw /d)	5,00	5,00	5,00	5,00	5,00	Data on active substance
RCR (Exposure / AEL)	0,98	0,68	0,77	0,85	0,91	Calculation
RCR (%)	98,00	68,17	77,20	85,01	90,76	Calculation
n* strokes 10%	7,499642857	4,156428571	3,072142857	2,168571429	1,852321429	
	14,99928571					

Total exposure (dermal + inhalation)	**4,9027**	**3,4125**	**3,8655**	**4,2592**	**4,5455**
AEL	5	5	5	5	5
RCR	98,05366667	68,24970711	77,31051282	85,1844	90,91075

Scenario 1.b - Inhalation exposure

User category	ADULT	CHILD (6-12y)	CHILD (2-6y)	TODDLER	INFANT	Comments
Indicative value for inhalation (mg/m3)	10,5	10,5	10,5	10,5	10,5	Default value from the model "Consumer spraying and dusting model 2 - Hand-held trigger spray" Biocide Human Health Exposure
inhalation rate	1,25	1,32	1,26	1,26	0,84	Information form General data sheet
% of active substance in the product	10	10	10	10	10	Information form General data sheet
Number of application /day	2	1	1	1	1	Information form General data sheet
Spray duration (hour)	0,066666667	0,066666667	0,066666667	0,066666667	0,066666667	4min (expert judgement based on CAR ir3535) /6
inhalation absorption (%)	100	100	100	100	100	Information form General data sheet
Oral absorption (%)	100	100	100	100	100	Information form General data sheet
% of inhalation fraction	100	100	100	100	100	IR3535 is calculated as if only from
% of oral fraction	100	100	100	100	100	
Body Weight (kg)	60	23,9	15,6	10	8	Information form General data sheet
Inhaled active substances (mg/day-	0,175	0,0924	0,0882	0,0882	0,0588	calculation : Calculation : amount/application (a.s.) x number of application/day * dermal absorption /100 / body weight
inhalation systemic exposure	0,0029	0,0039	0,0057	0,0088	0,0074	calculation :
total systemic exposure	0,003	0,004	0,006	0,009	0,007	
AEL (mg/kg bw /d)	5	5	5	5	5	Data on active substance
RCR (Exposure / AEL)	0,000583333	0,000773222	0,001130769	0,001764	0,00147	Calculation
RCR (%)	0,06	0,08	0,11	0,18	0,15	Calculation

TIER 1: Calculation including the trunk as a body part to be treated

Dermal and oral exposure	Child 2-6 yo	Child 6-12 yo	Children from 12-18 y.o.	Adult treating 2 children
Concentration IR3535 (% w/w)	10	10	10	10
AELdermal (mg a.s./kg bw/day)	5	5	5	5
Body weight (kg)	15,6	23,9	60	60
Dermal absorption (%)	14	14	14	14
Amount of spray exposed to reach AEL (mg product /day) [HTM= oral exposure + dermal exposure] mg of INSECT REPELLENT/kg bw/day	239	239	287	287
Amount of spray* Body weight	3736	5723	17202	17202
Amount of BP in a single spray spot (mg)	150	150	150	150
Number of sprays	25	38	115	115
Efficacy dose (1 g/600 cm2)	0,0016	0,0016	0,0016	0,0016
Area of skin that can be treated with product in one day [cm2]	2334,7	3576,9	10751,3	10660,0
Body surface (cm2) including the trunk. (For children from 2 to 6 y.o. hands are excluded)	6470	8772	15780	820
Number of applications	0,4	0,4	0,7	13,0
% skin that can be treated	36	41	68	1300

3.2.2 Risk assessment for the environment (output tables from Euses)

3.2.3 Risk assessment for the environment (output tables from Euses)

Scenario 1

STUDY

STUDY IDENTIFICATION

Study name	Montplet_IR3535 spray 10%	S
Study description	Montplet_IR3535 spray 10%	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	EDE51891	S

DEFAULTS
DEFAULT IDENTIFICATION

General name	Standard Euses 2.1		D
Description	According to TGDs		D

CHARACTERISTICS OF COMPARTMENTS
GENERAL

Density of solid phase	2.5	[kg.l-1]	D
Density of water phase	1	[kg.l-1]	D
Density of air phase	1.3E-03	[kg.l-1]	D
Environmental temperature	12	[oC]	D
Standard temperature for Vp and Sol	25	[oC]	D
Temperature correction method	Temperature correction for local distribution		D
Constant of Junge equation	0.01	[Pa.m]	D
Surface area of aerosol particles	0.01	[m2.m-3]	D
Gas constant (8.314)	8.314	[Pa.m3.mol-1.K-1]	D

SUSPENDED MATTER

Volume fraction solids in suspended matter	0.1	[m3.m-3]	D
Volume fraction water in suspended matter	0.9	[m3.m-3]	D
Weight fraction of organic carbon in suspended matter	0.1	[kg.kg-1]	D
Bulk density of suspended matter	1.15E+03	[kgwwt.m-3]	O
Conversion factor wet-dry suspened matter	4.6 [kgwwt.kgdwt-1]		O

SEDIMENT

Volume fraction solids in sediment	0.2	[m3.m-3]	D
Volume fraction water in sediment	0.8	[m3.m-3]	D
Weight fraction of organic carbon in sediment	0.05	[kg.kg-1]	D

SOIL

Volume fraction solids in soil	0.6	[m3.m-3]	D
Volume fraction water in soil	0.2	[m3.m-3]	D
Volume fraction air in soil	0.2	[m3.m-3]	D
Weight fraction of organic carbon in soil	0.02	[kg.kg-1]	D
Weight fraction of organic matter in soil	0.034	[kg.kg-1]	O
Bulk density of soil	1.7E+03	[kgwwt.m-3]	O
Conversion factor wet-dry soil	1.13 [kgwwt.kgdwt-1]		O

STP SLUDGE

Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D

DEGRADATION AND TRANSFORMATION RATES

Rate constant for abiotic degradation in STP	0	[d-1]	D
Rate constant for abiotic degradation in bulk sediment	0	[d-1] (12[oC])	D
Rate constant for anaerobic biodegradation in sediment	0	[d-1] (12[oC])	D
Fraction of sediment compartment that is aerated	0.1	[m3.m-3]	D
Concentration of OH-radicals in atmosphere	5E+05	[molec.cm-3]	D
Rate constant for abiotic degradation in bulk soil	0	[d-1] (12[oC])	D

RELEASE ESTIMATION

Fraction of EU production volume for region	100	[%]	D
Fraction of EU tonnage for region (private use)	10	[%]	D
Fraction connected to sewer systems	80	[%]	D

SEWAGE TREATMENT

GENERAL

Number of inhabitants feeding one STP	1E+04	[eq]	D
Sewage flow	200	[l.eq-1.d-1]	D
Effluent discharge rate of local STP	2E+06	[l.d-1]	O
Temperature correction for STP degradation	No		D
Temperature of air above aeration tank	15	[oC]	D
Temperature of water in aeration tank	15	[oC]	D
Height of air column above STP	10	[m]	D
Number of inhabitants of region	2E+07	[eq]	D
Number of inhabitants of continental system	3.5E+08	[eq]	O
Windspeed in the system	3	[m.s-1]	D

RAW SEWAGE

Mass of O2 binding material per person per day	54	[g.eq-1.d-1]	D
Dry weight solids produced per person per day	0.09	[kg.eq-1.d-1]	D
Density solids in raw sewage	1.5	[kg.l-1]	D
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D

PRIMARY SETTLER

Depth of primary settler	4	[m]	D
Hydraulic retention time of primary settler	2	[hr]	D
Density suspended and settled solids in primary settler	1.5	[kg.l-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D

ACTIVATED SLUDGE TANK

Depth of aeration tank	3	[m]	D
Density solids of activated sludge	1.3	[kg.l-1]	D
Concentration solids of activated sludge	4	[kg.m-3]	D
Steady state O2 concentration in activated sludge	2E-03	[kg.m-3]	D
Mode of aeration	Surface		D
Aeration rate of bubble aeration	1.31E-05	[m3.s-1.eq-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Sludge loading rate	0.15	[kg.kg-1.d-1]	D
Hydraulic retention time in aerator (9-box STP)	6.9	[hr]	O
Hydraulic retention time in aerator (6-box STP)	10.8	[hr]	O
Sludge retention time of aeration tank	9.2	[d]	O

SOLIDS-LIQUIDS SEPARATOR

Depth of solids-liquid separator	3	[m]	D
Density suspended and settled solids in solids-liquid separator	1.3	[kg.l-1]	D
Concentration solids in effluent	30	[mg.l-1]	D
Hydraulic retention time of solids-liquid separator	6	[hr]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D

LOCAL DISTRIBUTION

AIR AND SURFACE WATER

Concentration in air at source strength 1 [kg.d-1]	2.78E-04	[mg.m-3]	D
Standard deposition flux of aerosol-bound compounds	0.01	[mg.m-2.d-1]	D
Standard deposition flux of gaseous compounds	5E-04	[mg.m-2.d-1]	O
Suspended solids concentration in STP effluent water	15	[mg.l-1]	D
Dilution factor (rivers)	10	[-]	D
Flow rate of the river	1.8E+04	[m3.d-1]	D
Calculate dilution from river flow rate	No		D
Dilution factor (coastal areas)	100	[-]	D

SOIL

Mixing depth of grassland soil	0.1	[m]	D
Dry sludge application rate on agricultural soil	5E+03	[kg.ha-1.yr-1]	D
Dry sludge application rate on grassland	1000	[kg.ha-1.yr-1]	D
Averaging time soil (for terrestrial ecosystem)	30	[d]	D
Averaging time agricultural soil	180	[d]	D
Averaging time grassland	180	[d]	D
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Mixing depth agricultural soil	0.2	[m]	D
Fraction of rain water infiltrating soil	0.25	[-]	D
Average annual precipitation	700	[mm.yr-1]	D

REGIONAL AND CONTINENTAL DISTRIBUTION			
CONFIGURATION			
Fraction of direct regional emissions to seawater	1	[%]	D
Fraction of direct continental emissions to seawater	0	[%]	D
Fraction of regional STP effluent to seawater	0	[%]	D
Fraction of continental STP effluent to seawater	0	[%]	D
Fraction of flow from continental rivers to regional rivers	0.034	[-]	D
Fraction of flow from continental rivers to regional sea	0	[-]	D
Fraction of flow from continental rivers to continental sea	0.966	[-]	O
Number of inhabitants of region	2E+07	[eq]	D
Number of inhabitants in the EU	3.7E+08	[eq]	D
Number of inhabitants of continental system	3.5E+08	[eq]	O
AREAS			
REGIONAL			
Area (land+rivers) of regional system	4E+04	[km2]	D
Area fraction of freshwater, region (excl. sea)	0.03	[-]	D
Area fraction of natural soil, region (excl. sea)	0.27	[-]	D
Area fraction of agricultural soil, region (excl. sea)	0.6	[-]	D
Area fraction of industrial/urban soil, region (excl. sea)	0.1	[-]	D
Length of regional seawater	40	[km]	D
Width of regional seawater	10	[km]	D
Area of regional seawater	400	[km2]	O
Area (land+rivers+sea) of regional system	4.04E+04	[km2]	O
Area fraction of freshwater, region (total)	0.0297	[-]	O
Area fraction of seawater, region (total)	9.9E-03	[-]	O
Area fraction of natural soil, region (total)	0.267	[-]	O
Area fraction of agricultural soil, region (total)	0.594	[-]	O
Area fraction of industrial/urban soil, region (total)	0.099	[-]	O
CONTINENTAL			
Total area of EU (continent+region, incl. sea)	7.04E+06	[km2]	D
Area (land+rivers+sea) of continental system	7E+06	[km2]	O
Area (land+rivers) of continental system	3.5E+06	[km2]	O
Area fraction of freshwater, continent (excl. sea)	0.03	[-]	D
Area fraction of natural soil, continent (excl. sea)	0.27	[-]	D
Area fraction of agricultural soil, continent (excl. sea)	0.6	[-]	D
Area fraction of industrial/urban soil, continent (excl. sea)	0.1	[-]	D
Area fraction of freshwater, continent (total)	0.015	[-]	O
Area fraction of seawater, continent (total)	0.5	[-]	D
Area fraction of natural soil, continent (total)	0.135	[-]	O
Area fraction of agricultural soil, continent (total)	0.3	[-]	O
Area fraction of industrial/urban soil, continent (total)	0.05	[-]	O
MODERATE			
Area of moderate system (incl.continent,region)	8.5E+07	[km2]	D
Area of moderate system (excl.continent, region)	7.8E+07	[km2]	O
Area fraction of water, moderate system	0.5	[-]	D
ARCTIC			
Area of arctic system	4.25E+07	[km2]	D
Area fraction of water, arctic system	0.6	[-]	D
TROPIC			
Area of tropic system	1.275E+08	[km2]	D
Area fraction of water, tropic system	0.7	[-]	D
TEMPERATURE			
Environmental temperature, regional scale	12	[oC]	D
Environmental temperature, continental scale	12	[oC]	D
Environmental temperature, moderate scale	12	[oC]	D
Environmental temperature, arctic scale	-10	[oC]	D
Environmental temperature, tropic scale	25	[oC]	D
Enthalpy of vaporisation	50	[kJ.mol-1]	D
Enthalpy of solution	10	[kJ.mol-1]	D

MASS TRANSFER			
Air-film PMTC (air-water interface)	3.92E-03	[m.s-1]	O
Water-film PMTC (air-water interface)	4.72E-06	[m.s-1]	O
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
PMTC, soil side of air-soil interface	3.95E-10	[m.s-1]	O
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Water-film PMTC (sediment-water interface)	2.78E-06	[m.s-1]	D
Pore water PMTC (sediment-water interface)	2.78E-08	[m.s-1]	D
AIR			
GENERAL			
Atmospheric mixing height	1000	[m]	D
Windspeed in the system	3	[m.s-1]	D
Aerosol deposition velocity	1E-03	[m.s-1]	D
Aerosol collection efficiency	2E+05	[-]	D
RAIN			
Average precipitation, regional system	700	[mm.yr-1]	D
Average precipitation, continental system	700	[mm.yr-1]	D
Average precipitation, moderate system	700	[mm.yr-1]	D
Average precipitation, arctic system	250	[mm.yr-1]	D
Average precipitation, tropic system	1.3E+03	[mm.yr-1]	D
RESIDENCE TIMES			
Residence time of air, regional	0.687	[d]	O
Residence time of air, continental	9.05	[d]	O
Residence time of air, moderate	30.2	[d]	O
Residence time of air, arctic	22.3	[d]	O
Residence time of air, tropic	38.6	[d]	O
WATER			
DEPTH			
Water depth of freshwater, regional system	3	[m]	D
Water depth of seawater, regional system	10	[m]	D
Water depth of freshwater, continental system	3	[m]	D
Water depth of seawater, continental system	200	[m]	D
Water depth, moderate system	1000	[m]	D
Water depth, arctic system	1000	[m]	D
Water depth, tropic system	1000	[m]	D
SUSPENDED SOLIDS			
Suspended solids conc. freshwater, regional	15	[mg.l-1]	D
Suspended solids conc. seawater, regional	5	[mg.l-1]	D
Suspended solids conc. freshwater, continental	15	[mg.l-1]	D
Suspended solids conc. seawater, continental	5	[mg.l-1]	D
Suspended solids conc. seawater, moderate	5	[mg.l-1]	D
Suspended solids conc. seawater, arctic	5	[mg.l-1]	D
Suspended solids conc. seawater, tropic	5	[mg.l-1]	D
Concentration solids in effluent, regional	30	[mg.l-1]	D
Concentration solids in effluent, continental	30	[mg.l-1]	D
Concentration biota	1	[mgwwt.l-1]	D
RESIDENCE TIMES			
Residence time of freshwater, regional	43.3	[d]	O
Residence time of seawater, regional	4.64	[d]	O
Residence time of freshwater, continental	172	[d]	O
Residence time of seawater, continental	365	[d]	O
Residence time of water, moderate	2.69E+03	[d]	O
Residence time of water, arctic	5.84E+03	[d]	O
Residence time of water, tropic	1.09E+04	[d]	O
SEDIMENT			
DEPTH			
Sediment mixing depth	0.03	[m]	D

SUSPENDED SOLIDS			
(Biogenic) prod. susp. solids in freshwater, reg	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, reg	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in freshwater, cont	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, cont	5	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, moderate	1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, arctic	1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, tropic	1	[g.m-2.yr-1]	D
SEDIMENTATION RATES			
Settling velocity of suspended solids	2.5	[m.d-1]	D
Net sedimentation rate, freshwater, regional	2.8	[mm.yr-1]	O
Net sedimentation rate, seawater, regional	1.53	[mm.yr-1]	O
Net sedimentation rate, freshwater, continental	2.75	[mm.yr-1]	O
Net sedimentation rate, seawater, continental	6.69E-03	[mm.yr-1]	O
Net sedimentation rate, moderate	2.8E-03	[mm.yr-1]	O
Net sedimentation rate, arctic	2E-03	[mm.yr-1]	O
Net sedimentation rate, tropic	2E-03	[mm.yr-1]	O
SOIL			
GENERAL			
Fraction of rain water infiltrating soil	0.25	[-]	D
Fraction of rain water running off soil	0.25	[-]	D
DEPTH			
Chemical-dependent soil depth	No		D
Mixing depth natural soil	0.05	[m]	D
Mixing depth agricultural soil	0.2	[m]	D
Mixing depth industrial/urban soil	0.05	[m]	D
Mixing depth of soil, moderate system	0.05	[m]	D
Mixing depth of soil, arctic system	0.05	[m]	D
Mixing depth of soil, tropic system	0.05	[m]	D
EROSION			
Soil erosion rate, regional system	0.03	[mm.yr-1]	D
Soil erosion rate, continental system	0.03	[mm.yr-1]	D
Soil erosion rate, moderate system	0.03	[mm.yr-1]	D
Soil erosion rate, arctic system	0.03	[mm.yr-1]	D
Soil erosion rate, tropic system	0.03	[mm.yr-1]	D
CHARACTERISTICS OF PLANTS, WORMS AND CATTLE			
PLANTS			
Volume fraction of water in plant tissue	0.65	[m3.m-3]	D
Volume fraction of lipids in plant tissue	0.01	[m3.m-3]	D
Volume fraction of air in plant tissue	0.3	[m3.m-3]	D
Correction for differences between plant lipids and octanol	0.95	[-]	D
Bulk density of plant tissue (wet weight)	0.7	[kg.l-1]	D
Rate constant for metabolism in plants	0	[d-1]	D
Rate constant for photolysis in plants	0	[d-1]	D
Leaf surface area	5	[m2]	D
Conductance	1E-03	[m.s-1]	D
Shoot volume	2	[l]	D
Rate constant for dilution by growth	0.035	[d-1]	D
Transpiration stream	1	[l.d-1]	D
WORMS			
Volume fraction of water inside a worm	0.84	[m3.m-3]	D
Volume fraction of lipids inside a worm	0.012	[m3.m-3]	D
Density of earthworms	1	[kgwwt.l-1]	D
Fraction of gut loading in worm	0.1	[kg.kg-1]	D
CATTLE			
Daily intake for cattle of grass (dryweight)	16.9	[kg.d-1]	D
Conversion factor grass from dryweight to wetweight	4	[kg.kg-1]	D
Daily intake of soil (dryweight)	0.41	[kg.d-1]	D
Daily inhalation rate for cattle	122	[m3.d-1]	D
Daily intake of drinking water for cattle	55	[l.d-1]	D

SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	IR3535		S
Description			D
CAS-No			D
EC-notification no.			D
EINECS no.			D
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	215.29	[g.mol-1]	S
Melting point	-90	[oC]	S
Boiling point	300	[oC]	S
Vapour pressure at test temperature	0.15	[Pa]	S
Temperature at which vapour pressure was measured	20	[oC]	S
Vapour pressure at 25 [oC]	0.212	[Pa]	O
Octanol-water partition coefficient	1.7	[log10]	S
Water solubility at test temperature	7E+04	[mg.l-1]	S
Temperature at which solubility was measured	20	[oC]	S
Water solubility at 25 [oC]	7.5E+04	[mg.l-1]	O
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Chemical class for Koc-QSAR	Non-hydrophobics (default QSAR)		D
Organic carbon-water partition coefficient	475.25	[l.kg-1]	S
Solids-water partition coefficient in soil	9.5	[l.kg-1]	O
Solids-water partition coefficient in sediment	23.8	[l.kg-1]	O
Solids-water partition coefficient suspended matter	47.5	[l.kg-1]	O
Solids-water partition coefficient in raw sewage sludge	143	[l.kg-1]	O
Solids-water partition coefficient in settled sewage sludge	143	[l.kg-1]	O
Solids-water partition coefficient in activated sewage sludge	176	[l.kg-1]	O
Solids-water partition coefficient in effluent sewage sludge	176	[l.kg-1]	O
Soil-water partition coefficient	14.5	[m3.m-3]	O
Suspended matter-water partition coefficient	12.8	[m3.m-3]	O
Sediment-water partition coefficient	12.7	[m3.m-3]	O
AIR-WATER			
Environmental temperature	12	[oC]	D
Water solubility at environmental temperature	6.24E+04	[mg.l-1]	O
Vapour pressure at environmental temperature	0.0843	[Pa]	O
Sub-cooled liquid vapour pressure	0.0843	[Pa]	O
Fraction of chemical associated with aerosol particles	1.18E-03	[-]	O
Henry's law constant at test temparature	4.613E-04	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
Henry's law constant at 25 [oC]	6.08E-04	[Pa.m3.mol-1]	O
Henry's law constant at enviromental temparature	2.91E-04	[Pa.m3.mol-1]	O
Air-water partitioning coefficient	1.23E-07	[m3.m-3]	O
BIOCONCENTRATION FACTORS			
PREDATOR EXPOSURE			
Bioconcentration factor for earthworms	1.44	[l.kgwwt-1]	O
HUMAN AND PREDATOR EXPOSURE			
Bioconcentration factor for fish	5.56	[l.kgwwt-1]	O
QSAR valid for calculation of BCF-Fish	Yes		O
Biomagnification factor in fish	1	[-]	O
Biomagnification factor in predator	1	[-]	O
HUMAN EXPOSURE			
Partition coefficient between leaves and air	8.65E+06	[m3.m-3]	O
Partition coefficient between plant tissue and water	1.06	[m3.m-3]	O
Transpiration-stream concentration factor	0.782	[-]	O
Bioaccumulation factor for meat	1.26E-06	[d.kg-1]	O
Bioaccumulation factor for milk	7.94E-06	[d.kg-1]	O
Purification factor for surface water	1	[-]	O

DEGRADATION AND TRANSFORMATION RATES
CHARACTARIZATION

Characterization of biodegradability	Not biodegradable		S
STP			
Degradation calculation method in STP	First order, standard OECD/EU tests		D
Rate constant for biodegradation in STP	0	[d-1]	O
Total rate constant for degradation in STP	0	[d-1]	O
Maximum growth rate of specific microorganisms	2	[d-1]	D
Half saturation concentration	0.5	[g.m-3]	D
WATER/SEDIMENT			
WATER			
Rate constant for hydrolysis in surface water	6.93E-07	[d-1] (12[oC])	O
Rate constant for photolysis in surface water	6.93E-07	[d-1]	O
Rate constant for biodegradation in surface water	0	[d-1] (12[oC])	O
Total rate constant for degradation in bulk surface water	1.39E-06	[d-1] (12[oC])	O
Rate constant for biodegradation in saltwater	0	[d-1] (12[oC])	O
Total rate constant for degradation in bulk saltwater	1.39E-06	[d-1] (12[oC])	O
SEDIMENT			
Rate constant for biodegradation in aerated sediment	6.93E-07	[d-1] (12[oC])	O
Total rate constant for degradation in bulk sediment	6.93E-08	[d-1] (12[oC])	O
AIR			
Specific degradation rate constant with OH-radicals	0	[cm3.molec-1.s-1]	D
Rate constant for degradation in air	0	[d-1]	O
SOIL			
Rate constant for biodegradation in bulk soil	6.93E-07	[d-1] (12[oC])	O
Total rate constant for degradation in bulk soil	6.93E-07	[d-1] (12[oC])	O
REMOVAL RATE CONSTANTS SOIL			
Total rate constant for degradation in bulk soil	6.93E-07	[d-1] (12[oC])	O
Rate constant for volatilisation from agricultural soil	3.76E-06	[d-1]	O
Rate constant for leaching from agricultural soil	1.66E-04	[d-1]	O
Total rate constant for removal from agricultural top soil	1.7E-04	[d-1]	O
Rate constant for volatilisation from grassland soil	7.52E-06	[d-1]	O
Rate constant for leaching from grassland soil	3.32E-04	[d-1]	O
Total rate constant for removal from grassland top soil	3.4E-04	[d-1]	O
Rate constant for volatilisation from industrial soil	1.5E-05	[d-1]	O
Rate constant for leaching from industrial soil	6.63E-04	[d-1]	O
Total rate constant for removal from industrial soil	6.79E-04	[d-1]	O

RELEASE ESTIMATION
BIOCIDE SCENARIO INPUT DATA

Usage/production title	Showering / bathing		S
Scenario choice for biocides	(1) Human Hygiene		S

PRIVATE USE

Emission scenario	Local wastewater emission		
(ELocalWater)	S		

INTERMEDIATE RESULTS
RELEASE FRACTIONS AND EMISSION DAYS
PRIVATE USE
APPLICATION

Use tonnage or application data	Application data		S
Tonnage of substance in Europe	0	[tonnes.yr-1]	O
Regional tonnage of substance	0	[tonnes.yr-1]	O
Type of private human hygiene product	Deodorants, aerosol		S
Fraction of inhabitants using the product	0.2	[-]	O
Number of applications	2	[d-1]	S
Consumption per application	12.259	[g]	S
Daily consumption per inhabitant	4.9	[ml.d-1]	O
Active substance in product	100	[g.kg-1]	S
Number of emission days per year	365	[-]	O
Local emission to wastewater during episode	2.4518	[kg.d-1]	S

DEFAULTS

Fraction of EU production volume for region	10	[%]	D
Fraction of the local main source	2E-03	[-]	D
Fraction released to wastewater	1	[-]	D
Number of emission days, private use	365	[d]	D
Specific density of product	1000	[kg.m-3]	D
Penetration factor of disinfectant	0.5	[-]	D

REGIONAL AND CONTINENTAL RELEASES
PRIVATE USE
REGIONAL

Regional release to air	0	[kg.d-1]	O
Regional release to wastewater	0	[kg.d-1]	O
Regional release to surface water	0	[kg.d-1]	O
Regional release to industrial soil	0	[kg.d-1]	O
Regional release to agricultural soil	0	[kg.d-1]	O

CONTINENTAL

Continental release to air	0	[kg.d-1]	O
Continental release to wastewater	0	[kg.d-1]	O
Continental release to surface water	0	[kg.d-1]	O
Continental release to industrial soil	0	[kg.d-1]	O
Continental release to agricultural soil	0	[kg.d-1]	O

REGIONAL AND CONTINENTAL TOTAL EMISSIONS

Total regional emission to air	0	[kg.d-1]	O
Total regional emission to wastewater	0	[kg.d-1]	O
Total regional emission to surface water	0	[kg.d-1]	O
Total regional emission to industrial soil	0	[kg.d-1]	O
Total regional emission to agricultural soil	0	[kg.d-1]	O
Total continental emission to air	0	[kg.d-1]	O
Total continental emission to wastewater	0	[kg.d-1]	O
Total continental emission to surface water	0	[kg.d-1]	O
Total continental emission to industrial soil	0	[kg.d-1]	O
Total continental emission to agricultural soil	0	[kg.d-1]	O

LOCAL
[PRIVATE USE]

Local emission to air during episode	0	[kg.d-1]	O
Emission to air calculated by special scenario	Yes		O
Local emission to wastewater during episode	2.4518	[kg.d-1]	S
Emission to water calculated by special scenario	Yes		O
Specific biocides scenario available	Yes		D
Show this step in further calculations	Yes		O
Intermittent release	No		D

DISTRIBUTION			
SEWAGE TREATMENT			
CONTINENTAL			
Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O
REGIONAL			
Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O
[PRIVATE USE]			
INPUT AND CONFIGURATION [PRIVATE USE]			
INPUT			
Use or bypass STP (local freshwater assessment)	Use STP		D
Use or bypass STP (local marine assessment)	Use STP		S
Local emission to wastewater during episode	2.4518	[kg.d-1]	S
Concentration in untreated wastewater	1.23	[mg.l-1]	O
Local emission entering the STP	2.45	[kg.d-1]	O
CONFIGURATION			
Type of local STP	With primary settler (9-box)		D
Number of inhabitants feeding this STP	1E+04	[eq]	O
Effluent discharge rate of this STP	2E+06	[l.d-1]	O
Calculate dilution from river flow rate	No		O
Flow rate of the river	1.8E+04	[m3.d-1]	O
Dilution factor (rivers)	10	[-]	O
Dilution factor (coastal areas)	100	[-]	O
OUTPUT [PRIVATE USE]			
Fraction of emission directed to air by STP	0	[%]	S
Fraction of emission directed to water by STP	1	[%]	S
Fraction of emission directed to sludge by STP	0	[%]	S
Fraction of the emission degraded in STP	99	[%]	S
Total of fractions	100	[%]	O
Local indirect emission to air from STP during episode	0	[kg.d-1]	O
Concentration in untreated wastewater	1.23	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent	0.0123	[mg.l-1]	O
Concentration in effluent exceeds solubility	No		O
Concentration in dry sewage sludge	0	[mg.kg-1]	O
PEC for micro-organisms in the STP	0.0123	[mg.l-1]	O
REGIONAL, CONTINENTAL AND GLOBAL DISTRIBUTION			
PECS			
REGIONAL			
Regional PEC in surface water (total)	0	[mg.l-1]	O
Regional PEC in seawater (total)	0	[mg.l-1]	O
Regional PEC in surface water (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Regional PEC in seawater (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Regional PEC in air (total)	0	[mg.m-3]	O
Regional PEC in agricultural soil (total)	0	[mg.kgwwt-1]	O
Regional PEC in pore water of agricultural soils	0	[mg.l-1]	O
Regional PEC in natural soil (total)	0	[mg.kgwwt-1]	O
Regional PEC in industrial soil (total)	0	[mg.kgwwt-1]	O
Regional PEC in sediment (total)	0	[mg.kgwwt-1]	O
Regional PEC in seawater sediment (total)	0	[mg.kgwwt-1]	O

CONTINENTAL			
Continental PEC in surface water (total)	0	[mg.l-1]	O
Continental PEC in seawater (total)	0	[mg.l-1]	O
Continental PEC in surface water (dissolved)	0	[mg.l-1]	O
Continental PEC in seawater (dissolved)	0	[mg.l-1]	O
Continental PEC in air (total)	0	[mg.m-3]	O
Continental PEC in agricultural soil (total)	0	[mg.kgwwt-1]	O
Continental PEC in pore water of agricultural soils	0	[mg.l-1]	O
Continental PEC in natural soil (total)	0	[mg.kgwwt-1]	O
Continental PEC in industrial soil (total)	0	[mg.kgwwt-1]	O
Continental PEC in sediment (total)	0	[mg.kgwwt-1]	O
Continental PEC in seawater sediment (total)	0	[mg.kgwwt-1]	O
GLOBAL: MODERATE			
Moderate PEC in water (total)	0	[mg.l-1]	O
Moderate PEC in water (dissolved)	0	[mg.l-1]	O
Moderate PEC in air (total)	0	[mg.m-3]	O
Moderate PEC in soil (total)	0	[mg.kgwwt-1]	O
Moderate PEC in sediment (total)	0	[mg.kgwwt-1]	O
GLOBAL: ARCTIC			
Arctic PEC in water (total)	0	[mg.l-1]	O
Arctic PEC in water (dissolved)	0	[mg.l-1]	O
Arctic PEC in air (total)	0	[mg.m-3]	O
Arctic PEC in soil (total)	0	[mg.kgwwt-1]	O
Arctic PEC in sediment (total)	0	[mg.kgwwt-1]	O
GLOBAL: TROPIC			
Tropic PEC in water (total)	0	[mg.l-1]	O
Tropic PEC in water (dissolved)	0	[mg.l-1]	O
Tropic PEC in air (total)	0	[mg.m-3]	O
Tropic PEC in soil (total)	0	[mg.kgwwt-1]	O
Tropic PEC in sediment (total)	0	[mg.kgwwt-1]	O
STEADY-STATE FRACTIONS			
REGIONAL			
Steady-state mass fraction in regional freshwater	??	[%]	O
Steady-state mass fraction in regional seawater	??	[%]	O
Steady-state mass fraction in regional air	??	[%]	O
Steady-state mass fraction in regional agricultural soil	??	[%]	O
Steady-state mass fraction in regional natural soil	??	[%]	O
Steady-state mass fraction in regional industrial soil	??	[%]	O
Steady-state mass fraction in regional freshwater sediment	??	[%]	O
Steady-state mass fraction in regional seawater sediment	??	[%]	O
CONTINENTAL			
Steady-state mass fraction in continental freshwater	??	[%]	O
Steady-state mass fraction in continental seawater	??	[%]	O
Steady-state mass fraction in continental air	??	[%]	O
Steady-state mass fraction in continental agricultural soil	??	[%]	O
Steady-state mass fraction in continental natural soil	??	[%]	O
Steady-state mass fraction in continental industrial soil	??	[%]	O
Steady-state mass fraction in continental freshwater sediment	??	[%]	O
Steady-state mass fraction in continental seawater sediment	??	[%]	O
GLOBAL: MODERATE			
Steady-state mass fraction in moderate water	??	[%]	O
Steady-state mass fraction in moderate air	??	[%]	O
Steady-state mass fraction in moderate soil	??	[%]	O
Steady-state mass fraction in moderate sediment	??	[%]	O
GLOBAL: ARCTIC			
Steady-state mass fraction in arctic water	??	[%]	O
Steady-state mass fraction in arctic air	??	[%]	O
Steady-state mass fraction in arctic soil	??	[%]	O
Steady-state mass fraction in arctic sediment	??	[%]	O

GLOBAL: TROPIC			
Steady-state mass fraction in tropic water	??	[%]	O
Steady-state mass fraction in tropic air	??	[%]	O
Steady-state mass fraction in tropic soil	??	[%]	O
Steady-state mass fraction in tropic sediment	??	[%]	O
STEADY-STATE MASSES			
REGIONAL			
Steady-state mass in regional freshwater	0	[kg]	O
Steady-state mass in regional seawater	0	[kg]	O
Steady-state mass in regional air	0	[kg]	O
Steady-state mass in regional agricultural soil	0	[kg]	O
Steady-state mass in regional natural soil	0	[kg]	O
Steady-state mass in regional industrial soil	0	[kg]	O
Steady-state mass in regional freshwater sediment	0	[kg]	O
Steady-state mass in regional seawater sediment	0	[kg]	O
CONTINENTAL			
Steady-state mass in continental freshwater	0	[kg]	O
Steady-state mass in continental seawater	0	[kg]	O
Steady-state mass in continental air	0	[kg]	O
Steady-state mass in continental agricultural soil	0	[kg]	O
Steady-state mass in continental natural soil	0	[kg]	O
Steady-state mass in continental industrial soil	0	[kg]	O
Steady-state mass in continental freshwater sediment	0	[kg]	O
Steady-state mass in continental seawater sediment	0	[kg]	O
GLOBAL: MODERATE			
Steady-state mass in moderate water	0	[kg]	O
Steady-state mass in moderate air	0	[kg]	O
Steady-state mass in moderate soil	0	[kg]	O
Steady-state mass in moderate sediment	0	[kg]	O
GLOBAL: ARCTIC			
Steady-state mass in arctic water	0	[kg]	O
Steady-state mass in arctic air	0	[kg]	O
Steady-state mass in arctic soil	0	[kg]	O
Steady-state mass in arctic sediment	0	[kg]	O
GLOBAL: TROPIC			
Steady-state mass in tropic water	0	[kg]	O
Steady-state mass in tropic air	0	[kg]	O
Steady-state mass in tropic soil	0	[kg]	O
Steady-state mass in tropic sediment	0	[kg]	O
LIFE CYCLE STEPS			
[PRIVATE USE]			
LOCAL CONCENTRATIONS AND DEPOSITIONS [PRIVATE USE]			
AIR			
Concentration in air during emission episode	0	[mg.m-3]	O
Annual average concentration in air, 100 m from point source	0	[mg.m-3]	O
Total deposition flux during emission episode	0	[mg.m-2.d-1]	O
Annual average total deposition flux	0	[mg.m-2.d-1]	O
WATER, SEDIMENT			
Concentration in surface water during emission episode (dissolved)	1.23E-03	[mg.l-1]	O
Concentration in surface water exceeds solubility	No		O
Annual average concentration in surface water (dissolved)	1.23E-03	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)	1.23E-04	[mg.l-1]	O
Annual average concentration in seawater (dissolved)	1.23E-04	[mg.l-1]	O
SOIL, GROUNDWATER			
Concentration in agric. soil averaged over 30 days	0	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days	0	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days	0	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)	??	[-]	O
Fraction of steady-state (grassland soil)	??	[-]	O

LOCAL PECS [PRIVATE USE]			
AIR			
Annual average local PEC in air (total)	0	[mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	1.23E-03	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	1.23E-03	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode	0.0136	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	1.23E-04	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	1.23E-04	[mg.l-1]	O
Local PEC in marine sediment during emission episode	1.36E-03	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	0	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	0	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	0	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	0	[mg.l-1]	O
Local PEC in pore water of grassland	0	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	0	[mg.l-1]	O

EXPOSURE
SECONDARY POISONING
SECONDARY POISONING [PRIVATE USE]

Concentration in fish for secondary poisoning (freshwater)	3.4E-03	[mg.kgwwt-1]	O
Concentration in earthworms from agricultural soil	0	[mg.kg-1]	O
Concentration in fish for secondary poisoning (marine)	3.4E-04	[mg.kgwwt-1]	O
Concentration in fish-eating marine top-predators	6.81E-05	[mg.kgwwt-1]	O

EFFECTS
INPUT OF EFFECTS DATA
MICRO-ORGANISMS

Test system	Respiration inhibition, EU Annex V C.11, OECD 209		D
EC50 for micro-organisms in a STP	??	[mg.l-1]	D
EC10 for micro-organisms in a STP	??	[mg.l-1]	D
NOEC for micro-organisms in a STP	??	[mg.l-1]	D

AQUATIC ORGANISMS
FRESH WATER
L(E)C50 SHORT-TERM TESTS

LC50 for fish	??	[mg.l-1]	D
L(E)C50 for Daphnia	??	[mg.l-1]	D
EC50 for algae	??	[mg.l-1]	D
LC50 for additional taxonomic group	??	[mg.l-1]	D
Aquatic species	other		D

NOEC LONG-TERM TESTS

NOEC for fish	??	[mg.l-1]	D
NOEC for Daphnia	??	[mg.l-1]	D
NOEC for algae	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D

MARINE
L(E)C50 SHORT-TERM TESTS

LC50 for fish (marine)	??	[mg.l-1]	D
L(E)C50 for crustaceans (marine)	??	[mg.l-1]	D
EC50 for algae (marine)	??	[mg.l-1]	D
LC50 for additional taxonomic group (marine)	??	[mg.l-1]	D
Marine species	other		D
LC50 for additional taxonomic group (marine)	??	[mg.l-1]	D
Marine species	other		D

NOEC LONG-TERM TESTS

NOEC for fish (marine)	??	[mg.l-1]	D
NOEC for crustaceans (marine)	??	[mg.l-1]	D
NOEC for algae (marine)	??	[mg.l-1]	D
NOEC for additional taxonomic group (marine)	??	[mg.l-1]	D
NOEC for additional taxonomic group (marine)	??	[mg.l-1]	D

FRESH WATER SEDIMENT
L(E)C50 SHORT-TERM TESTS

LC50 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

EC10/NOEC LONG-TERM TESTS

EC10 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

MARINE SEDIMENT
L(E)C50 SHORT-TERM TESTS

LC50 for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

EC10/NOEC LONG-TERM TESTS			
EC10 for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
TERRESTRIAL ORGANISMS			
L(E)C50 SHORT-TERM TESTS			
LC50 for plants	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
LC50 for earthworms	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
EC50 for microorganisms	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
LC50 for other terrestrial species	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC LONG-TERM TESTS			
NOEC for plants	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for earthworms	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for microorganisms	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for additional taxonomic group	??	[mg.kgwwt-1]	D
Terrestrial species	other		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for additional taxonomic group	??	[mg.kgwwt-1]	D
Terrestrial species	other		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
BIRDS			
LC50 in avian dietary study (5 days)	??	[mg.kg-1]	D
NOEC via food (birds)	??	[mg.kg-1]	D
NOAEL (birds)	??	[mg.kg-1.d-1]	D
Conversion factor NOAEL to NOEC (birds)	8	[kg.d.kg-1]	D
MAMMALS			
REPEATED DOSE			
ORAL			
Oral NOAEL (repdose)	??	[mg.kg-1.d-1]	D
Oral LOAEL (repdose)	??	[mg.kg-1.d-1]	D
Oral CED (repdose)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (repdose)	??	[mg.kg-1]	D
LOEC via food (repdose)	??	[mg.kg-1]	D
CED via food (repdose)	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory NOAEL (repdose)	??	[mg.m-3]	D
Inhalatory LOAEL (repdose)	??	[mg.m-3]	D
Inhalatory CED (repdose)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal NOAEL (repdose)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (repdose)	??	[mg.kg-1.d-1]	D
Dermal CED (repdose)	??	[mg.kg-1.d-1]	D

FERTILITY			
ORAL			
Oral NOAEL (fert)	??	[mg.kg-1.d-1]	D
Oral LOAEL (fert)	??	[mg.kg-1.d-1]	D
Oral CED (fert)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (fert)	??	[mg.kg-1]	D
LOEC via food (fert)	??	[mg.kg-1]	D
CED via food (fert)	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory NOAEL (fert)	??	[mg.m-3]	D
Inhalatory LOAEL (fert)	??	[mg.m-3]	D
Inhalatory CED (fert)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal NOAEL (fert)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (fert)	??	[mg.kg-1.d-1]	D
Dermal CED (fert)	??	[mg.kg-1.d-1]	D
MATERNAL-TOX			
ORAL			
Oral NOAEL (mattox)	??	[mg.kg-1.d-1]	D
Oral LOAEL (mattox)	??	[mg.kg-1.d-1]	D
Oral CED (mattox)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (mattox)	??	[mg.kg-1]	D
LOEC via food (mattox)	??	[mg.kg-1]	D
CED via food (mattox)	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory NOAEL (mattox)	??	[mg.m-3]	D
Inhalatory LOAEL (mattox)	??	[mg.m-3]	D
Inhalatory CED (mattox)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal NOAEL (mattox)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (mattox)	??	[mg.kg-1.d-1]	D
Dermal CED (mattox)	??	[mg.kg-1.d-1]	D
DEVELOPMENT-TOX			
ORAL			
Oral NOAEL (devtox)	??	[mg.kg-1.d-1]	D
Oral LOAEL (devtox)	??	[mg.kg-1.d-1]	D
Oral CED (devtox)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (devtox)	??	[mg.kg-1]	D
LOEC via food (devtox)	??	[mg.kg-1]	D
CED via food (devtox)	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory NOAEL (devtox)	??	[mg.m-3]	D
Inhalatory LOAEL (devtox)	??	[mg.m-3]	D
Inhalatory CED (devtox)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal NOAEL (devtox)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (devtox)	??	[mg.kg-1.d-1]	D
Dermal CED (devtox)	??	[mg.kg-1.d-1]	D

CARC (THRESHOLD)			
ORAL			
Oral NOAEL (carc)	??	[mg.kg-1.d-1]	D
Oral LOAEL (carc)	??	[mg.kg-1.d-1]	D
Oral CED (carc)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (carc)	??	[mg.kg-1]	D
LOEC via food (carc)	??	[mg.kg-1]	D
CED via food (carc)	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory NOAEL (carc)	??	[mg.m-3]	D
Inhalatory LOAEL (carc)	??	[mg.m-3]	D
Inhalatory CED (carc)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal NOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal CED (carc)	??	[mg.kg-1.d-1]	D
CARC (NON-THRESHOLD)			
ORAL			
Oral T25 for non-threshold effects	??	[mg.kg-1.d-1]	D
Oral CED for non-threshold effects	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
T25 via food for non-threshold effects	??	[mg.kgfood-1]	D
CED via food for non-threshold effects	??	[mg.kgfood-1]	D
INHALATORY			
Inhalatory T25 for non-threshold effects	??	[mg.m-3]	D
Inhalatory CED for non-threshold effects	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D
DERMAL			
Dermal T25 for non-threshold effects	??	[mg.kg-1.d-1]	D
Dermal CED for non-threshold effects	??	[mg.kg-1.d-1]	D
ACUTE			
Oral LD50	??	[mg.kg-1]	D
Oral Discriminatory Dose	??	[mg.kg-1]	D
Inhalatory LC50	??	[mg.m-3]	D
Dermal LD50	??	[mg.kg-1]	D
PREDATOR			
Duration of (sub-)chronic oral test	28 days		D
NOEC via food for secondary poisoning	??	[mg.kg-1]	O
Source for NOEC-via-food data	No data available, enter manually		S
BIO-AVAILIBILITY			
Bioavailability for oral uptake (oral to inhalation)	0.5	[-]	D
Bioavailability for oral uptake (oral to dermal)	1	[-]	D
Bioavailability for oral uptake (route to oral)	1	[-]	D
Bioavailability for inhalation (route from inhalation)	1	[-]	D
Bioavailability for inhalation (route to inhalation)	1	[-]	D
Bioavailability for dermal uptake (route from dermal)	1	[-]	O
Bioavailability for dermal uptake (route to dermal)	1	[-]	O
ENVIRONMENTAL EFFECTS ASSESSMENT			
ENVIRONMENTAL PNECS			
FRESH WATER			
Same taxonomic group for LC50 and NOEC	No		O
Toxicological data used for extrapolation to PNEC Aqua	100	[mg.l-1]	S
Assessment factor applied in extrapolation to PNEC Aqua	1000	[-]	S
PNEC for aquatic organisms	0.1	[mg.l-1]	O

INTERMITTENT RELEASES			
Toxicological data used for extrapolation to PNEC Aqua	??	[mg.l-1]	O
Assessment factor applied in extrapolation to PNEC Aqua	??	[-]	O
PNEC for aquatic organisms, intermittent releases	??	[mg.l-1]	O
STATISTICAL			
PNEC for aquatic organisms with statistical method	??	[mg.l-1]	D
MARINE			
Same taxonomic group for marine LC50 and NOEC	No		O
Toxicological data used for extrapolation to PNEC Marine	0.1	[mg.l-1]	S
Assessment factor applied in extrapolation to PNEC Marine	10	[-]	S
PNEC for marine organisms	0.01	[mg.l-1]	O
STATISTICAL			
PNEC for marine organisms with statistical method	??	[mg.l-1]	D
FRESH WATER SEDIMENT			
Toxicological data used for extrapolation to PNEC sediment (fresh)	??	[mg.kgwwt-1]	O
Assessment factor applied in extrapolation to PNEC sediment (fresh)	??	[-]	O
PNEC for fresh-water sediment organisms (from toxicological data)	??	[mg.kgwwt-1]	O
PNEC for fresh-water sediment organisms (equilibrium partitioning)	1.11	[mg.kgwwt-1]	O
Equilibrium partitioning used for PNEC in fresh-water sediment?	Yes		O
PNEC for fresh-water sediment, normalised to 10% o.c. (local)	1.11	[mg.kgwwt-1]	O
PNEC for fresh-water sediment, normalised to 5% o.c. (regional)	1.11	[mg.kgwwt-1]	O
MARINE SEDIMENT			
Toxicological data used for extrapolation to PNEC sediment (marine)	??	[mg.kgwwt-1]	O
Assessment factor applied in extrapolation to PNEC sediment (marine)	??	[-]	O
PNEC for marine sediment organisms (from toxicological data)	??	[mg.kgwwt-1]	O
PNEC for marine sediment organisms (equilibrium partitioning)	0.111	[mg.kgwwt-1]	O
Equilibrium partitioning used for PNEC in marine sediment?	Yes		O
PNEC for marine sediment, normalised to 10% o.c. (local)	0.111	[mg.kgwwt-1]	O
PNEC for marine sediment, normalised to 5% o.c. (regional)	0.111	[mg.kgwwt-1]	O
TERRESTRIAL			
Same taxonomic group for LC50 and NOEC	No		O
Toxicological data used for extrapolation to PNEC Terr	??	[mg.kgwwt-1]	O
Assessment factor applied in extrapolation to PNEC Terr	??	[-]	O
PNEC for terrestrial organisms (from toxicological data)	??	[mg.kgwwt-1]	O
PNEC for terrestrial organisms (equilibrium partitioning)	0.85	[mg.kgwwt-1]	O
Equilibrium partitioning used for PNEC in soil?	Yes		O
PNEC for terrestrial organisms	0.85	[mg.kgwwt-1]	O
STATISTICAL			
PNEC for terrestrial organisms with statistical method	??	[mg.kgwwt-1]	D
SECONDARY POISONING			
Toxicological data used for extrapolation to PNEC oral	??	[mg.kg-1]	O
Assessment factor applied in extrapolation to PNEC oral	??	[-]	O
PNEC for secondary poisoning of birds and mammals	??	[mg.kg-1]	O
STP			
Toxicological data used for extrapolation to PNEC micro	1000	[mg.l-1]	S
Assessment factor applied in extrapolation to PNEC micro	100	[-]	S
PNEC for micro-organisms in a STP	10	[mg.l-1]	O

RISK CHARACTERIZATION			
ENVIRONMENTAL EXPOSURE			
LOCAL			
RISK CHARACTERIZATION OF [PRIVATE USE]			
WATER			
RCR for the local fresh-water compartment	0.0123	[-]	O
Intermittent release	No		D
RCR for the local marine compartment	0.0123	[-]	O
RCR for the local fresh-water compartment, statistical method	??	[-]	O
RCR for the local marine compartment, statistical method	??	[-]	O
SEDIMENT			
RCR for the local fresh-water sediment compartment	0.0123	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the local marine sediment compartment	0.0123	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
SOIL			
RCR for the local soil compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the local soil compartment, statistical method	??	[-]	O
STP			
RCR for the sewage treatment plant	1.23E-03	[-]	O
PREDATORS			
RCR for fish-eating birds and mammals (fresh-water)	??	[-]	O
RCR for fish-eating birds and mammals (marine)	??	[-]	O
RCR for top predators (marine)	??	[-]	O
RCR for worm-eating birds and mammals	??	[-]	O
REGIONAL			
WATER			
RCR for the regional fresh-water compartment	0	[-]	O
RCR for the regional marine compartment	0	[-]	O
RCR for the regional fresh-water compartment, statistical method	??	[-]	O
RCR for the regional marine compartment, statistical method	??	[-]	O
SEDIMENT			
RCR for the regional fresh-water sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the regional marine sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
SOIL			
RCR for the regional soil compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the regional soil compartment, statistical method	??	[-]	O

3.3 New information on the active substance

Not relevant.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies

Please refer to the table summarizing the results obtained in efficacy studies in section 2.2.5. as well as to the IUCLID file.

3.6 Confidential annex

See confidential Annex.

3.7 Other

Not relevant.