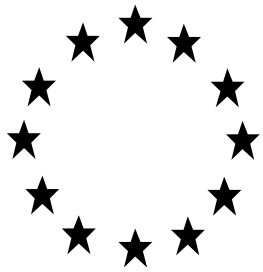
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Product name: ISDIN INSECT REPELLENT IR3535 30%

Trade name: ISDIN XTREM ANTIMOSQUITOS REPELENTE USO HUMANO

Product type 19

Ethyl butylacetylaminopropionate

Case Number in R4BP: BC-TP020608-19

Evaluating Competent Authority: Spain

October 2023

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

ISDIN INSECT REPELLENT IR3535 30% is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an AL formulation.

The formulation has shown to be stable under accelerated conditions (30°C during 18 weeks) and after storing at 20 ºC for 3 years. Thus a self-life of 3 years is granted. Due to the fact that the low temperature test has not been carried out the biocidal products have to be protected from frost.

Furthermore, it is not considered to be explosive, oxidising or pyrophoric. But the bridged result of flash point (32°C) from Montplet insect repellent IR3535 20% show that the product is flammable. So, according to CLP Regulation, it has to be categorized as flammable liquid cat.3 (H226).

The analytical methods provided are fully validated for the determination of the active substance Ethyl butylacetylaminopropionate, IR3535®.

Conclusion on efficacy

Efficacy data show that the product "Isdin insect repellent IR3535 30%" is able to repel *Aedes spp.* mosquitoes for 6 hours and *Anopheles* and *Culex spp.* mosquitoes for 7 hours after application of the product on the skin, in temperate and tropical areas.

Conclusion on human health

ISDIN INSECT REPELLENT IR3535 30%can be authorized following Art.19(1) of Regulation (EU) No 528/2012 as a ready-to-use repellent (PT19) in temperate areas and should only be applied once per day on uncovered parts of the face, hands, arms, legs and feet.

Tha applicant submits a human health risk assessment (HHRA) for ISDIN INSECT REPELLENT IR3535 30% in line with the latest agreements reached at UE level. This HHRA, as performed by the applicant, concludes that the biocidal product pose risk for human health with regard to the intended uses. For children below 6 year threre is risk, therefore its use will not be authorized for this subpopulations. ISDIN INSECT REPELLENT IR3535 30% should not be applied for children below 6 year. 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 assessment has been updated the assessment 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 (0.56 mg/cm²) obtained from the data from active substance's supplier, 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.

Environment

Based on this risk assessment and on available data, «Isdin Insect repellent IR3535 30%» should not cause any unacceptable risks to the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
ISDIN INSECT REPELLENT IR3535 30%	
ISDIN XTREM ANTIMOSQUITOS REPELENTE USO HUMANO	Spain

2.2.2.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratorios Montplet S.L.U
	Address	Via Trajana 53-59 08020 Barcelona Spain
Authorisation number	ES/APP(NA)-2023-19-00897	
Date of the authorisation	26/10/2023	
Expiry date of the authorisation	26/10/2033	

2.2.2.3 Manufacturer(s) of the product

Name of manufacturer	Laboratorios Montplet S.L.U
Address of manufacturer	Via Trajana 53-59 08020 Barcelona Spain
Location of manufacturing sites	Via Trajana 53-59 08020 Barcelona SPAIN

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

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Straβe 250, 64293 Darmstadt GERMANY
Location of manufacturing sites	Merck S.L.U. Poligono Merck 08100 Mollet de Valles Barcelona SPAIN

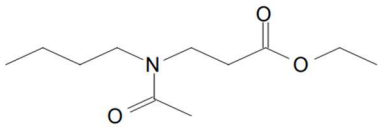
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	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 "ISDIN INSECT REPELLENT IR3535 30%" is not candidate for substitution in accordance with Article 10 of BPR.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (pure active substance%)	Content (technical active substance) (%)
Ethyl butylacetylaminopropionate, IR3535®	3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester	Active substance	52304-36-6	257-835-0	30.00	30.00

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

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family

Not relevant.

2.1.2.5 Information on technical equivalence

The source of substance is the same as was evaluated for inclusion in the Union list of approved active substances, therefore the technical equivalence is not relevant.

2.1.2.6 Information on the substance(s) of concern

No substance of concern were identified in the formulation.

2.1.2.7 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Flam. Liquid 3 Eye irrit. 2
Hazard statement	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 P103: Read label before use P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
Note	-

*ES CA will apply article 37 according to BPR in the authorisation of this product including in this section the P statements that are recommended and highly recommended according to the result of the risk assessment of the product and considering the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 March 2021).

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

Where relevant, an exact description of the authorised use	Ready-to-use insect repellent spray.
Target organism (including development stage)	Scientific name: *Culicidae* Common name: Mosquitoes *(Aedes spp., Culex spp., Anopheles spp)* Development stage: Adults
Field of use	Outdoor and indoor use in well ventilated areas This repellent is authorized for tropical areas.
Application method(s)	Spraying with trigger spray. Apply on the skin zones to be protected. Do not spray the product directly on the face. Apply the product over the body with the hand. Do not apply on children's hands. Frequent and repeated application of this product is unnecessary.
Application rate(s) and frequency	Dose per application: 0.56 mg/cm². - Adults: 5.11 g or aprox. 27 pump strokes - Children (6-<12 years): 2.83 g or aprox. 15 pump strokes **Do not use in children younger than 6 years old.** Frequency of application: Only one application/day Protection time against mosquitoes: **6 hours.** - up to 6 hours against *Aedes spp.* mosquitoes - up to 7 hours against *Culex spp. and Anopheles spp*. mosquitoes The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it. This product is **not intended to be reapplied**.
Category(ies) of users	General public (non-professional).
Pack sizes and packaging material	HDPE, recycled HDPE, PET of the following volumes: 50, 75, 100 and 125 ml.

2.1.4.2 Use-specific instructions for use

- Apply and spread evenly on the skin zones to protect (arms, hands, legs, feet and face).

  Adults: 27 spray pump a day (5 on arms, 12 on legs, 5 on the face, 1 on hands and 4 on feet)
  Children (6-<12 years): 15 spray pump a day (3 on arm, 8 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
- CHILDREN MUST NOT APPLY THIS PRODUCT. An adult should apply the product on children. Do not apply on children's hands.
- Do not use in children younger than 6 years. If necessary, consult your pediatrician.
- Frequent and repeated application of this product is unnecessary
- The use of the product with other repellent products is not recommended.
- If the product is to be used in combination with sunscreen, first apply the sunscreen and wait 30 minutes before applying the product.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.

2.1.4.3 Use-specific risk mitigation measures

- Always read the label and product information before use. Avoid breathing the spray.
- Use only outdoors or in well ventilated areas.
- Do not swallow.
- Avoid breathing vapours/spray.
- Do not use on children’s hands.
- For children of 6 to 12 years: the repellent must be applied by adults.
- Do not use near food and surfaces that may come into contact with food and feed or drinks for human consumption and animal feedingstuffs.
- Avoid contact of the treated skin with food and feed.
- Do not use near domestic animals.
- Do not use in people sensitive to its components.
- Keep the container upright.
- In natural water bodies, such as lakes or rivers, do not go swimming after application of the product.

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

- Read attached instructions before use.
- Apply the product sparingly and carefully to parts of the body that are not covered.
- Do not throw the product on the ground, into a water course, into the sink or down the drain
- Do not apply on clothes; divide the product evenly over the skin.

2.1.5.2 Risk mitigation measures

See section 2.1.4.2

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

IF SWALLOWED: Rinse mouth. Give something no drink, if exposed person is able to swallow. DO NOT induce vomiting**.**Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. Only the part of the skin that were not supposed to be exposed should be washed. If irritation occurs the skin should be washed and medical advice should be sought.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

- 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 should be deposited in separate collection containers according to the material of the containers.

-Unused product and other waste generated during the treatment must be deposited in the residual fraction or in the collecting facilities.

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

Protect from frost.
Store the product at temperatures lower than 30°C
Protect from direct sunlight
Shelf-life: 36 months.
Keep out of reach of children and non-target animals/pets.

2.1.6 Other information

Definition of non professional (general public): 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	50 ml; 75 ml; 100 ml; 125 ml	HDPE, PET, recycled HDPE and PET	Cap of the bottle in LDPE	Non-professional	Yes

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

The applicant Laboratorios Montplet S.L.U, has submit a letter of access (LoA) wich covers the studies owned by Merck KGaA and other information that have been used for including Ethyl butylacetylaminopropionate in the Union list of approved active substances under the Biocidal Products Regulation, and which are protected in accordance with Article 60 and 95 of the same ("Data").

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 repellent – spray to apply on human skin – General public

Product Type	PT19
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Mosquitoes (Culex spp, Aedes spp. and Anopheles spp.) Development stage: adult. Protection time against mosquitoes: • up to 6 hours against Aedes and Anopheles mosquitoes • up to 7 hours against Culex mosquitoes
Field of use	Indoor and outdoor uses.

Application method(s)	Spraying with trigger spray.
Application rate(s) and frequency	Dose per application: 0,56 mg/cm². 1 application/day.
Category(ies) of users	General public.
Pack sizes and packaging material	HDPE, recycled HDPE, PET spray bottle (trigger spray) of the following volumes: 50ml ; 75ml; 100 ml and 125ml.

2.2.2 Physical, chemical and technical properties

Please note the following data on physical, chemical and technical properties are directly bridged from the results obtained in the studies conducted on the formulation "Montplet insect repellent IR3535 30%". Indeed, this product has a similar composition to the product defended in this application which should not have any influence on the physical and chemical properties neither on the shelf-life duration. Please find the proposed waiver which compare both compositions in the section 3.7.2 of this dossier (Confidential annex).

Please find in the following table, the summary of the results obtained for physical and chemical 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 30%	Transparent liquid colourless a pleasant odour	C. Belussi, 2020
pH	CIPAC MT 75.3	Montplet insect repellent IR3535 30%	4.99 at 20 ±2ºC (dilution at 1% in water)	C. Belussi, 2020
Acidity	OECD 122	Montplet insect repellent IR3535 30%	0,034% +/- 0,004 (average result)	DETERMINATION OF PH AND ACIDITY, 2021.
Relative density	Internal method (OECD 109)	Montplet insect repellent IR3535 30%	0.9709 at 20 ºC	C. Belussi, 2020
Storage stability test – **accelerated storage**	CIPAC method MT 46.3	ISDIN insect repellent IR3535 30%	Time:18 weeks Tª: 30°C: Appearance of the test item at initial time and after 18 weeks: - Transparent liquid	A.Bonetti, 2020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Appearance of the packaging at initial time and after 18 weeks: - HDPE yellow spray bottle with a black spray dispenser Colour and odour of the product at initial time and after 18 weeks: - Colourless with pleasant odour Weight loss after 18 weeks: - 0.22% w/w Relative density at initial time and after 18 weeks: - T_0: 0.978 - T_{18w}: 0.979 pH 1% (20°C) at initial time and after 18 weeks: - T_0: 6.05 - T_{18w}: 5.06 Active substance content (IR3535): $[C]_0$ = 31.08% $[C]_f$ = 32.51% Δ[C] = +4.60% Conclusion: After 18 weeks at 30°C no significant variation in the test item and packaging appearance, weight loss, pH, relative density and active substance assay were observed.	
Storage stability test – **long term storage at ambient temperature**	CropLife International, Technical Monograph No. 17	Montplet insect repellent IR3535 30%	Time: 36 months Ta: 25°C/60% RH • Appearance (physical state, colour and odour of the test item for T_0;T_{6M};T_{12M};T_{18M};T_{24M};T_{30M} T_{36M}:	C. Belussi 2020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			- Transparent colorless liquid with pleasant odour • Weight loss at time: - T_0: - - T_{6M}: 0.25% - T_{12M}: 0.23% - T_{18M}: 0.82% - T_{24M}: 0.94% - T_{30M}: 1.50% - T_{36M}: 1.42% • Active substance content: $[C]_0$: 29.440% w/w $[C]_{6M}$: 29.526% w/w $\Delta[C]$: +0.29% $[C]_0$: 29.440% w/w $[C]_{12M}$: 29.826% w/w $\Delta[C]$: +1.31% $[C]_0$: 29.440% w/w $[C]_{18M}$: 29.500% w/w $\Delta[C]$: +0.20% $[C]_0$: 29.440% w/w $[C]_{24M}$: 29.592% w/w $\Delta[C]$: +0.52% $[C]_0$: 29.440% w/w $[C]_{30M}$: 29.775% w/w $\Delta[C]$: +1.14% $[C]_0$: 29.440% w/w $[C]_{36M}$: 28.747% w/w $\Delta[C]$: -2.35% Valve clogging for T_0; T_{6M}; T_{12M}; T_{18M}; T_{24M}; T_{30M}; T_{36M}: - No clogging Spray pattern T_0: Like a spray T_{36M}: Like a spray Particle size distribution T0: Dv(50) = 63.6 µm T36: Dv(50) = 72.93 µm	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			MMAD=72.04 µm %V 50 µm=21.56.	
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 frost.		
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	The packaging is a HDPE yellow spray bottle with a black spray dispenser. It can be considered opaque. However, as applicant's resquest the sentence "Protect from direct sunlight" has been added to the label			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The effect of temperature was assessed in the accelerated storage study and the results were acceptable. However, it has been added the sentence "Store the product at temperatures lower than 30°C" since it is the maximum temperature at which the stability has been assessed. 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 30%	No changes were observed in the HDPE orginal container after storing it for 18 weeks at 30 ºC	A.Bonetti, 2020
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 30%	D_V (50) = 63.6 µm	C. Belussi, 2020
Persistent foaming	Waiver	Not relevant for an trigger spray formulation.		
Flowability/Pourability/Dustability	Waiver	Not relevant for a trigger spray formulation		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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		
Discharge/spray rate	FEA 643	Montplet insect repellent IR3535 30%	0.16 g (RSD=27.6%)	C. Belussi, 2020
Spraying pattern — aerosols	FEA 644	Montplet insect repellent IR3535 30%	Like a spray	C. Belussi, 2020
Valve clogging	According to FAO	Montplet insect repellent IR3535 30%	No clogging	C. Belussi, 2020
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 formulation		
Surface tension	EU Method A.5	Montplet insect repellent IR3535 30%	31.12 mN/m	J. Jamilena, 2020
Viscosity	Rotational viscosimeter (dynamic)	Montplet insect repellent IR3535 30%	27.5 mPa.s at 20ºC 15.4 mPa.s at 40ºC	J. Palomar, 2019

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

The product "ISDIN INSECT REPELLENT IR3535 30%" is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a transparent liquid colourless with a pleasant odour.

There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30 ºC, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in the commercial packaging material. Its technical characteristics are acceptable for an AL formulation.

2.2.3 Physical hazards and respective characteristics

Please note the following data on flammable liquids hazard is directly bridged from the results obtained in the studies conducted on the formulations "Montplet insect repellent IR3535 20%". Indeed, the percentage of alcohol in the ISDIN INSECT REPELLENT IR3535 30% is lower than in the reference product (23.7% w/w in the " ISDIN INSECT REPELLENT IR3535 30%" vs. 33% w/w in the "Montplet insect repellent IR3535 20%"). The "Montplet insect repellent IR3535 20%" is therefore considered to be a worst-case product and its flash-point is expected to be higher than the one of the product defended in this dossier. Please find the proposed waiver comparing the composition of both products in the section 3.7.2 of this dossier (Confidential annex).

In the same way, please note the following data on auto-ignition properties is bridged from the study of Merck conducted on the product "Merck Insect Repellent IR3535 20%". This formulation has a similar composition of the product defended in this dossier. In addition, the Merck's formulation covers the Montplet formulation in terms of ethanol content. Please find the proposed waiver comparing the composition of both products in the section 3.7.1 of this dossier (Confidential annex).

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Explosives	Waived	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.		
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.		
Flammable liquids	ASTM method D-93	Montplet insect repellent IR3535 20%	Flash point value = 32°C	Laboratoire de analisis Dr. Echevarne, 2002
Flammable solids	Waived	The product is a liquid formulation.		
Self-reactive substances and mixtures	Waived	None of the ingredients are classified as self-reactive substances.		
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	None of the ingredients are classified as self-heating substances.		
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.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising solids	Waived	The product is a liquid formulation.		
Organic peroxides	Waived	None of the ingredients are classified as organic peroxides.		
Corrosive to metals	Test UNECE	Montplet insect repellent IR3535 30%	No corrosion attack was occurred after 7 days of exposure at the temperature of 55 ºC.	J.Abellá, 2021
Auto-ignition temperatures of products (liquids and gases)	EC A15 auto-ignition	Merck Insect Repellent IR3535 20%	Auto-ignition temperature = 440°C	J. Dornhagen, 2011
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
"ISDIN INSECT REPELLENT IR3535 30%" product (AL) is not considered to be explosive, as no chemical structures that have explosive properties are present in the formulation, The product has no oxidizing, and no organic peroxides properties. The conducted test complies with requirements for determining the flash point of flammable liquids (Pensky-Martens method). For the biocidal product "Isdin insect repellent IR3535 30% the results on flammable liquid study bridged from the "Montplet insect repellent IR3535 20%" formulation show a flash point value of of 32°C. This result is higher than 23°C and lower than 60°C, concluding the formulation should be classified as a flammable liquid category 3 according to the ECHA Guidance on the Application of the CLP Criteria.

2.2.4 Methods for detection and identification

Please note the following data on methods for detection and identification are directly bridged from the results obtained in the study conducted on the formulation "Montplet insect repellent IR3535 30%". Indeed, this product has a similar composition to the product defended in this application which should not have any influence on analytical methods. Please find the proposed waiver comparing the composition of both products in the section 3.7.2 of this dossier (Confidential annex).

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Reference**
					Range	Mean	RSD	
Ethyl butylacetylaminopropionate (IR3535® (active substance)	HPLC-UV	Linearity: 5 calibration solutions Precision: 6 samples Accuracy: 3 different concentrations (50% – 150%), three levels, two preparation for each level7	Range= 15.0%w/w - 45.0% w/w corresponding to experimental range 50% - 150% of the theoretical value in the sample y=68.6879 + 2672.3594x R^2= 0.9997	The method proved to be specific: no peak of blank or placebo solution interfered with that of the active ingredient	100.58 – 100.87%	100.81%	0.28%	F. Abbiati, 2017

Conclusion on the methods for detection and identificationof the product
For the biocidal product "ISDIN INSECT REPELLENT IR3535 30%" the HPLC-UV method bridged from the "Montplet insect repellent IR3535 30%" formulation 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. 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

The product "Isdin insect repellent IR3535 30%" is used as an insect repellent (against mosquitoes). It is applied as a spray directly on human skin. It is for non-professional use and can be applied indoors as well as outdoors. It gives protection up to 6 hours against *Aedes ssp.* and 7 hours against *Anopheles* and *Culex spp.* Under temperate and tropical areas.

Product Type 19: Repellents and attractants (pest control).
Products used to control harmful organisms (invertebrates such as mosquitoes), by repelling or attracting, including those that are used for human hygiene directly on the skin of humans.

According to the SPC submitted by the applicant, the product "ISDIN INSECT REPELLENT IR3535 30%" is intended to be used by general public in temperate and tropical areas whenever are substantiated by key studies and appropriate results were submitted for product authorisation.

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 ISDIN INSECT REPELLENT IR3535 30 % is intended to be used to repel mosquitoes 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

The product "Isdin insect repellent IR3535 30%" is intended to be used as an insect repellent to protect humans from mosquitoes (Aedes spp., Anopheles spp., and Culex spp.) (no killing action) by application on skin. No unacceptable suffering is therefore expected.
The efficacy of ISDIN INSECT REPELLENT IR3535 30 % has been demonstrated against mosquitoes.

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

Experimental data on the efficacy of the biocidal product against target organism(s)						
Field of use envisaged	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
-Applied on human skin (spraying) -For non-professional use. -In temperate and tropical areas.	ISDIN XTREM ANTIMOSQUITOS (containing 30% IR3535)	MOSQUITOES: -Aedes albopictus, -Anopheles gambiae, -Culex pipiens. Female, 5-7 days old. 12 hours before the test, the females were deprived of any blood meal.	Simulated-use trial ("arm in cage test"). ECHA "Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 4.0 - December 2021 – Guidelines for efficacy testing of mosquito repellents for human skin (WHO/HTM/NTD/WHOPES/2009.4), World Health Organization, 2009	"Arm in cage" method. Dose: 0.56mg/cm² of skin (i.e: 0,34g/600cm^2 forearm). 10 volunteers. Size of the cage = 64 000 cm³ (40*40*40 cm). Mosquito density = 100+/-2 females in the 64 L cages Mínimun landing rate for control: Aedes spp. 20 landings/minute Culex spp. 5 landings/minute Anopheles spp. 5 landings/minute Climatic conditions: - Temperature: 27 ° C + / - 2 ° C,	After application of the product at dose 0,56mg/cm^2 of skin, the protection time was: -Aedes albopictus 6hours, -Culex pipiens 7hours and -Anopheles gambiae 7hours. Temperate and tropical areas.	Serrano, B., 2022, Study No. 2742h/1121

				- Relative humidity of 75+/-5% - Exposure started 1 min after application. -Exposure time of the treated arm: 3 minutes. -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).		
Organisms to be protected: humans. **Method of application:** By spraying (sprays number unknown)control.	Repellent XTREM 30% IR3535 Spray Application	MOSQUITOES Species. **Aedes albopictus** Developmet stage: adults. Sex: female mosquitoes, Age: 5 to 7 days old, Starves: females were starved from blood-meal for 12 hours before testing.	Simulated used test: **Arm-in-cage study** **Example of test design:** Based on WHO/HTM/NTD/ WHOPES/2009.4; Guideline for efficacy testing of mosquito repellents for human skin.	Laboratory test. Arm-in-cage study Dose of product 1 g + 3% for 600 cm² Size of cage: 64000 cm3 (40 cm x 40 cm x 40 cm). **Test system:** - Temperature: 27 + 2°C - Relative humidity 65 + 10% - Doses tested: 1 g / 600 cm² - Light 700 lux	**OBSOLETE**	Serrano, B., 2013, Study No. 1623b/0513

		Number tested: 3 volunteers Number of replicates: single application per volunteer to human skin Number of mosquitoes: 200		Product applied on one forearm of each volunteer, the other untreated one being used as a control. 3 volunteers and 3 replicates. The trial began 30 minutes after the product had been applied. The duration of exposure of the forearms in the cage was 3 minutes for the test and for the control. The trial is stopped from 10 landings in 30 seconds or 2 bites. The same procedure was repeated every hour until 8 hours or inefficacy. Landings and bites were counted during each exposure time. Climatic conditions: temperature 27 + 2 °C; relative humidity 65 % + 10%		
Organisms to be protected: humans. **Method of application:** By spraying (sprays number	Repelente de insectos forte - 30% IR3535 + perfume herbal ifra. Ref. 24921 0.3%.	MOSQUITOES Species. **Anopheles gambiae**. Developmet stage: adults. Sex: female mosquitoes, Age: 5 to 7 days old,	Simulated used test: **Arm-in-cage study** **Example of test design:** Based on WHO/HTM/NTD/ WHOPES/2009.4; Guideline for efficacy testing of mosquito repellents for human skin.	Laboratory test. Arm-in-cage study. Dose of product 1 g + 3% for 600 cm² 3 volunteers and 3 replicates. Size of cage: 64000 cm3 (40 cm x 40 cm x 40 cm). **Test system:**	**OBSOLETE** The parfum quantity declared does not match with product formulation.	Serrano, B., 2013, Study No. 1623c/0513

unknown)control.	Spray Application	Starves: females were starved from blood-meal for 12 hours before testing. Number tested: 3 volunteers Number of replicates: single application per volunteer to human skin. Number of mosquitoes: 200		- Temperature: 27 + 2°C - Relative humidity 65 + 10% - Doses tested: 1 g / 600 cm² - Light 700 lux Product applied on one forearm of each volunteer, the other untreated one being used as a control. The trial began 30 minutes after the product had been applied. The duration of exposure of the forearms in the cage was 3 minutes for the test and for the control. The trial is stopped from 10 landings in 30 seconds or 2 bites. The same procedure was repeated every hour until 8 hours or inefficacy. Landings and bites were counted during each exposure time. Climatic conditions: temperature 27 ± 2 °C; relative humidity 65 % ± 10%		
Organisms to be protected: humans.	REPELENTE INSECTOS 30% 8P44L	MOSQUITOES Two species. **Aedes albopictus and Anopheles**	Simulated used test: **Arm-in-cage study** **Example of test design:**	Laboratory test. Arm-in-cage study. Dose of product 1 g + 3% for 600 cm²	**OBSOLETE**	Serrano, B., 2017, Study No. 2244/0817

Method of application: By spraying (sprays number unknown)control.		**gambiae.** Developmet stage: adults. Sex: female mosquitoes, Age: 5 to 7 days old, Starves: females were starved from blood-meal for 12 hours before testing. Number tested: 10 volunteers (five men and five women) Number of replicates: single application per volunteer to human skin. Number of mosquitoes: 100	Based on WHO/HTM/NTD/ WHOPES/2009.4; Guideline for efficacy testing of mosquito repellents for human skin.	10 volunteers and 3 replicates. Size of cage: 64000 cm3 (40 cm x 40 cm x 40 cm). **Test system:** **"tropical" climatic conditions** - Temperature: 32 + 2°C - Relative humidity 75 + 5% - Doses tested: 1 g / 600 cm² - Light 700 lux Product applied on one forearm of each volunteer, the other untreated one being used as a control. The trial began 1 minutes after the product had been applied. The duration of exposure of the forearms in the cage was 30 seconds for the control and 5 minutes for the test. After validation of the untreated control, the treated forearm was inserted. The trial was validated only if there are at least 10 arthropod touchdowns or 10 bites.The trial was stopped when one bite was observed and		

				confirmed by a second one in succession. The same procedure was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product. Landings and bites were counted during each exposure time. Climatic conditions: temperature 27 ± 2 °C; relative humidity 65 % ± 10%		
Organisms to be protected: humans.	Repelente de insectos forte M090713 – 30% IR 3535	MOSQUITOES **Anopheles gambiae.** Developmet stage: adults. Sex: female mosquitoes, Age: 5 to 7 days old, Starves: females were starved from blood-meal for 12 hours before testing. Number tested: 10 volunteers (five men and five women)	Simulated used test: **Arm-in-cage study** **Example of test design:** Based on WHO/HTM/NTD/ WHOPES/2009.4; Guideline for efficacy testing of mosquito repellents for human skin.	Laboratory test. Arm-in-cage study. Dose of product 1 g + 3% for 600 cm² 3 volunteers and 3 replicates. Size of cage: 64000 cm3 (40 cm x 40 cm x 40 cm). **Test system:** - Temperature: 25°C + 2° - Relative humidity 65% + 5% - Ventilation during the assays (30 m3/h). The trial began 30 minutes after application of the	**OBSOLETE**	Serrano, B., 2013, Study No. 1623d/0513

		Number of replicates: single application per volunteer to human skin. Number of mosquitoes: 100		product, the arm is introduced into the test cages. Each trial (control + test) was repeated every 60 minutes. The duration of exposure (control + test) of the forearms in the cage was 3 minutes. The trial is stopped from 10 landings in 30 seconds or 2 bites (5 for the untreated control). The time of protection is the time until there is a first bite followed by a second one. Climatic conditions in the cages during the trial: - Temperature: 27 + 2°C - Relative humidity 65 + 10% - Light 700 lux		
Organisms to be protected: humans. **<u>Method of application:</u>** Aerosol	EUS26-16-9N (lot# M17547) IR3535	TICKS **Ixodes Scapularis. (nymphal deer ticks)**	**Laboratory test.** **<u>Example of test design:</u>** EPA OPPTS 810.3700 guideline	10 volunteers TEST CONDITIONS Temperature, relative humidity and light intensity were recorded at approximately 1-hour intervals during the test.	**OBSOLETE**	Carroll, S.P., 2007, Doc. No 336-1914

Organisms to be protected: humans. **Method of application:** Aerosol	EUS26-16-9N (lot# M17547) 20% IR3535	MOSQUITOES in nature.	**Field study** **Example of test design:** EPA OPPTS 810.3700 guideline	10 volunteers TEST CONDITIONS Temperature, relative humidity and light intensity were recorded at approximately 1-hour intervals during efficacy testing. Mosquitoes were collected by subjects using mechanical aspirators. Identify in the laboratory by a technician. Exposures took place at 15 minutes intervals.	**OBSOLETE**	Carroll, S.P., 2007, Doc. No 336-1915
Organisms to be protected: humans. **Method of application:** By pump spraying or lotion	21229-10 21229-20 21229-30 21229-40 21229-50 21229-60 Compare several formulations but the exact composition are unknown.	TICKS **Ixodes ricinus. (nymphal ticks)**	**Laboratory study data** **Example of test design:** Guidelines of the Environmental Protection Agency (EPA) of the USA.	Dose of product: intended to apply 1.6 mg repellent per cm². 10 volunteers TEST CONDITIONS - Temperature: 24.3±1.1°C - Rel. humidity: 24.2±3.7% The forearm of a person was treated from the elbow to the wrist, leaving the lowest 5	**OBSOLETE**	Dippel, C. and Dautel, H., 2006, Doc No. 336-1921

				cm of the arm near the wrist untreated. The arm was held vertically and a tick was placed on the untreated area, 2 cm below the treated area. Ticks entering the treated skin and walking 2 cm in direction to the elbow were considered not repelled. Protection time was defined as the time until the first tick was not repelled		
Organisms to be protected: humans. **Method of application:** By spraying or lotion or roll-on.	TMT-002 TMT-003 TMT-004 TM-005 TM-006 Compare several formulations but the exact composition are unknown.	MOSQUITOES **Aedes Albopictus** Approx. 600 mosquitoes of a mixed population in terms of sex and age, meaning about 300"blood thirsty" female mosquitoes.	Simulated used test: **Arm-in-cage study** **Example of test design:** OPPTS 810.3700 guideline	Size of cage: 108000 cm3 (90cm x 30cm x 40cm). 10 volunteers TEST CONDITIONS - Temperature: 24 -26°C - Rel. humidity: 52 - 70% The test were stopped for each volunteer after receiving three bites within one test interval or within two subsequent test intervals.	**OBSOLETE**	Lüpkes, K.-H., 2011, Doc No. 336-1922

Conclusion on the efficacy of the product
The efficacy studies submitted demonstrate that: The product "ISDIN INSECT REPELLENT IR3535 30%" is efficient as a mosquito repellent (Aedes albopictus for 6 hours, Culex pipiens for 7 hours and Anopheles gambiae for 7 hours) in tropical and temperate areas when applied on skin at the application rate of 0,56 mg product / cm². The product "ISDIN INSECT REPELLENT IR3535 30%" is efficient as a mosquito repellent for 6 hours in tropical and temperate areas when applied on skin at the application rate of 0,56 mg product / cm².

2.2.5.6 Occurrence of resistance and resistance management

The following statement from the assessment report of the active substance applies to the product "ISDIN INSECT REPELLENT IR3535 30%": "as the active substance, IR3535, is a repellent (no killing action) and does not give rise to selection pressure, no resistance can be developed".

2.2.5.7 Known limitations

There are no known limitations to the product "ANTIMOSQUITOS ISDIN XTREM REPELENTE INSECTOS".

2.2.5.8 Evaluation of the label claims

The 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, to support a claim in temperate areas. For temperate areas, 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 "Isdin insect repellent IR3535 30%" against Aedes spp., Anopheles spp., and Culex spp. For 6 hours in temperate and tropical conditions.

The following product claims are supported with adequate data:

- 6 hours of protection against mosquitoes.
- 6 hours of protection against Aedes spp. mosquitoes.
- 7 hours of protection against Anopheles spp. and Culex spp. mosquitoes.

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

The product "isdin insect repellent ir3535 30%" 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 product ISDIN INSECT REPELLENT IR3535 30% is similar to this representative product. The main difference between ISDIN INSECT REPELLENT IR3535 30% and the representative product is the content of IR3535 which is 30% in ISDIN INSECT REPELLENT IR3535 30% and 20% in representative product. The other ingredients are the same in both products with slightly different contents. The main difference between «Montplet insect repellent IR3535 30%» and « ISDIN INSECT REPELLENT IR3535 30% » is the parfum

2.2.6.1 Assessment of effects on Human Health

An eye irritation study was conducted with a representative product, which contains 20% of IR3535.The applicant confirms that is identical to Montplet insect repellent IR3535 20% (see Confidential annex). 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

An acute dermal toxicity study was conducted with product which contains 30% of IR3535.The applicant confirms that is identical to Montplet insect repellent IR3535 30% (see Confidential annex) , the main difference between «Montplet insect repellent IR3535 30%» and «ISDIN INSECT REPELLENT IR3535 30%» is the parfum (see Confidential annex). So, ES CA accepts a read across .

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. 1272/2008~1221/2015 (CLP).

Skin corrosion and irritation

In product ISDIN INSECT REPELLENT IR3535 30% , there are no ingredient classified for their skin corrosion/irritation properties.
Testing on the product does not need to be conducted as synergistic effects between components are not expected.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin corrosive. Not skin irritant
Justification for the value/conclusion	Based on the classification of IR3535 and its respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	There are valid data available on each of the components in the product ISDIN INSECT REPELLENT IR3535 30% are sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the

	components are not expected. In the product, there are no ingredient classified for their skin corrosion/irritation properties.

Eye irritation

An eye irritation study was conducted with a representative product, which contains 20% of IR3535.The applicant confirms that is identical to Montplet insect repellent IR3535 20%. The report does not specify if the test complies with OECD norm 405. However, the methodology followed is equivalent to OECD norm 405 The report does not indicate if the study is generated according to the Good Laboratory Practices and and not establish any level for reliability. ES CA doesn't validate this test

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

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritant.
Justification for the value/conclusion	Based on the classification of the IR3535, the coformulants and, their respective content in the final formulation
Classification of the product according to CLP and DSD	Eye irritant, Category 2 - H319.

Data waiving	
Information requirement	Eye irritation study
Justification	ES CA does not validate the submitted test for not following the GLP criteria and for not establishing any level for reliability. So, the classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation),10% is the concentration triggering the classification of a skin irritant category 2 in a mixture. Therefore, based on the concentration of the active substance and co-formulants, the product ISDIN INSECT REPELLENT IR3535 30% is classified as Eye irritant. 2; H319 .

Respiratory tract irritation

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.

Data waiving	
Information requirement	Respiratory tract irritation.
Justification	The active substance IR3535 showed no irritant properties to the respiratory tract in animals or in humans.

	In product ISDIN INSECT REPELLENT IR3535 30% , there are no ingredient classified for their respiratory tract irritant properties.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on the classification of the IR3535 and the different co-formulants and, their respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin sensitisation study
Justification	Testing on the product does not need to be conducted if 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. Therefore, based on the classification of the active substance and coformulants, the product ISDIN INSECT REPELLENT IR3535 30% is not classified as skin sensitizer So this study does not need to be conducted. The parfum is classified skin sens 1; H317. However as the relevant components for skin sensitisation are well below of their concentration limits for elicitation, EUH208 must not be included.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the IR3535 and the different co-formulants and, their respective content in the final formulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No data on the respiratory sensitisation of the product ISDIN INSECT REPELLENT IR3535 30% has been submitted However, the biocidal product is not expected to have respiratory sensitizing properties since none of the components of the mixture shows respiratory sensitisation effects.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	None
Justification for the selected value	In product ISDIN INSECT REPELLENT IR3535 30% », there are no ingredient classified for their acute oral toxic properties and no synergistic effects between components are expected.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity studies
Justification	Acute oral toxicity studies for product ISDIN INSECT REPELLENT IR3535 30% have not been performed. There aren´t ingredient classified for their acute oral toxic properties. So, it is therefore proposed that the product ISDIN INSECT REPELLENT IR3535 30% , is not harmful by the oral route and will remain unclassified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	None
Justification for the selected value	In product ISDIN INSECT REPELLENT IR3535 30% » there are no ingredient classified for their acute inhalation potential and no synergistic effects between components are expected.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity studies
Justification	Acute inhalation toxicity studies for product ISDIN INSECT REPELLENT IR3535 30% have not been performed. There aren´t ingredient classified for their acute inhalation toxicity. The biocidal product can be considered as no toxic by the inhalation route according to Regulation (EC) Nº 1272/2008.

Acute toxicity by dermal route

A study was conducted with a representative product, which contains 30% of IR3535.The applicant confirms that It is Montplet insect repellent IR3535 30%. The main difference between «Montplet insect repellent IR3535 30%» and «ISDIN INSECT REPELLENT IR3535 30%» is the perfume (0.20 % w/w in both products) (see Confidential annex)

Test complies with OECD 402. The report indicate that the study is generated according to the Good Laboratory Practices and with a reability of 1.

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, RL: 1	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	Freli V. (2012) Study No.2012/1085 AMi (Report 70)

No human data available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 >2000 mg/kg bw
Justification for the selected value	Reliable study conducted on the product. This study showed that ISDIN INSECT REPELLENT IR3535 30% has a dermal LD50 >2000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute dermal toxicity studies
Justification	Acute dermal toxicity studies for product «Montplet insect repellent IR3535 30%» have been performed. ES CA accepts a read across. So ISDIN INSECT REPELLENT IR3535 30% is not acutely toxic dermal because your LD50 >2000 mg/kg bw according to Regulation (EC) Nº 1272/2008.

Information on dermal absorption

No study (*in vivo* or *in vitro*) has been performed with ISDIN INSECT REPELLENT IR3535 30% .

A read across with the dermal absorption value of 14% ,proposed in the study of Broschard *et al.*, 2013, 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 to be 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.
Since the composition of 30% IR3535 formulation of ISDIN INSECT REPELLENT IR3535 30% is comparable to the product tested in the dermal toxicokinetics/metabolism study, especially as concerns the content of organic solvents and emulsifiers/surfactants which may have an impact on the skin absorption, a separate skin absorption study with the biocidal product is not considered to be required. Instead, the skin absorption of 14% for IR3535® as decided in the Assessment Report far IR3535 can be applied to the 30% IR3535 farmulation of ISDIN INSECT REPELLENT IR3535 30% . Therefore, a dermal penetration of 14% could be used in the human exposure assessment of the biocidal product.

On the other hand, according to Guidance on Dermal Absorption (EFSA 2012) the rate of absorption is generally inversely related to the concentration of the active substance. For this reason, the skin absorption of IR3535 from the 30% IR3535 formulation of Isdin insect repellent IR3535 30% will be very likely lower than 14% therefore, the use of the skin absorption as derived in the dermal toxicokinetics/metabolism study represents a conservative approach.

However, taking into account that the read across with the dermal absorption value of 14% proposed in the study of Broschard *et al*., 2013 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 CS considers that at the renewal stage of the active substance, this value should be revised.

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 ISDIN INSECT REPELLENT IR3535 30%

Endocrine disrupting properties

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

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), the biocidal product contains one substance which is under assessment as potential endocrine disruptor in the frame of the Community Rolling Action Plan (CoRAP). However, this evaluation has not been finalised yet. If that substance is identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised. Please, refer to the confidential annex for more information

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

According to the formulation there is no other potential substance to be classified of concern for human risk with the exception of the active substance. For further details please refer to the Confidential Annex.

Available toxicological data relating to a mixture

No further studies on the toxicity of the product are required as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1272/2008 (CLP)

2.2.6.2 Exposure assessment

ISDIN INSECT REPELLENT IR3535 30% is intended to be applied as an insect repellent by spraying on human skin.

The exposure assessment submitted by the applicant is based on the Competent Authority Report (CAR) for IR3535. The representative product considered in the CAR for IR3535 was a water/ethanol-based 20% IR3535 formulation. 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 eCA (evaluating competent authority) has updated the assessment in order to include the latest agreements on this matter.

The exposure has been calculated with the efficacious dose (0.56 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.	no	Yes [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

For primary exposure (adult spraying on the skin), the most relevant route of exposure is the dermal route. During the application, inhalation exposure is possible during spraying. It was considered that the respirable particles will be absorbed via the lower airways and that the non-respirable particles will precipitate in the upper airways and be taken in orally. The particles above 5 µm are assumed to be taken in orally. The particles above 5 µm are assumed to be taken in orally (Technical Notes for Guidance on Human Exposure, Chapter 3.5.2 (page 247)). 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). Direct oral exposure is not considered to be relevant because of the repellent taste (bad palatability) of the active substace and since the product is not intended to be applied by children. Oral exposure can be precluded among adults with a minimum hygene standards.

For secondary exposure, dermal exposure is possible for an adults applying or spraying the product on children and herself/himself. Hand to mouth transfer is also possible for adults and children; nonetheless, the biocidal product is not intended to be applied on children's hands which reduces potential oral uptake of the dermally applied active substance. For inhalative exposure, the inhalation of volatilized residues after application is also relevant based on the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance.

It should be noticed that neither inhalation or oral exposure are expected to be significant routes of exposure; because of the small fraction of respirable particles and the bad palatability (bitterness) of the product which prevents repeated mouthing by small children. Therefore, these scenarios are unlikely and should be considered as worse cases.

In addition and in order to prevent any potential exposure, the following RMMs are considered:

i. "For children 6 to 12 years: The repellent must be applied by adults"

ii. "Do not apply to children's hands"

iii. "Keep out of reach of children"

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-professional
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-professional
2	Post-application Hand-mouth transfer	**Secondary exposure** Hand to mouth transfer Exposure route: oral	Non-professional General public
4.	Post-application Inhalation of volatilized residues	**Secondary exposure** Inhalation of volatilised residues after application (inhalative exposure) Exposure route: inhalation	Non-professional General public

Industrial exposure

The production of ISDIN INSECT REPELLENT IR3535 30% 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

ISDIN INSECT REPELLENT IR3535 30% will not be used by professional users. Neither primary nor secondary exposure can happen for this population.

Non-professional exposure

ISDIN INSECT REPELLENT IR3535 30% 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 and herself/himself (secondary exposure).

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

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

It is considered that the exposure of the person spraying the product is covered by the exposure to the product he applies on his skin. ISDIN INSECT REPELLENT IR3535 30% is applied directly to the intact skin of adults and 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. amount b.p. is the derived from the efficacy data (0.56 mg/cm²)

2. 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 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 childrens, in a worst case approach, the same skin exposure percentage as for adults, 55%, is considered to calculate the BS. In a worst case approach, it is 55% of the total body surface, 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. Although the applicant initially did not support the use of biocidal product for infants under 1 year of age, a human exposure assessment was still done.

3. 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.
Once the time protection has ended (8-12 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/m³.			
	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		30%
	Number of applications per day		1 (for adults, infant, toddler, child from 2 to 12 years old)
	Body weight #	Adult	60 kg
		Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg
Inhalation	Use duration $		4 min
	Inhalation rate, short-term #	Adult	1.25 m³/h
		Infant	0.84 m³/h
		Toddler	1.26 m³/h
		Child - 2 to <6 years old	1.26 m³/h
		Child - 6 to <12 years old	1.32 m³/h
	Inhalation uptake £		100%
Dermal	Dose of product applied on the skin ¤		0.56 mg/cm²
	Dermal uptake		14%
	55% ¥ of the total body surface area #	Adult	9 130 cm²
		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

¤ A dose rate of 0.56 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 «Isdin insect repellent IR3535 30%».
In the absence of data about the particle size distribution in the product «Isdin insect repellent IR3535 30%», 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 0.56mg/cm²:

Population group (application)	**Treated body surface area cm²**	**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 (1)	9130	60	5.11	1.53	0.21	3.85
Children (6 to <12 years-old) (1)	5060	23.9	2.83	0.85	0.19	4.98
Children (2 to <6 years-old) (1)	3740	15.6	2.09	0.63	0.09	5.64
Toddler (1)	2640	10	1.48	0.44	0.06	6.21
Infant (1)	2255	8	1.26	0.38	0.05	6.63

[1] BS (55% of the total body surface area) x dose rate (1.67mg/cm²); $BS \times D_p / 1000$

Inhalation exposure:
The table below is summarizing the calculation performed with the inhaled product amount of 10.5 mg product/m³:

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 (1)	13.16	0.877	0.263	60	0.004
Children (6 to <12 years-old) (1)	13.90	0.926	0.278	23.9	0.012
Children (2 to <6 years-old) (1)	13.26	0.884	0.256	15.6	0.017
Toddler (1)	13.26	0.884	0.265	10	0.026
Infant (1)	8.84	0.590	0.177	8	0.022

Total exposure

Summary table: systemic exposure from non-professional uses					
Exposure scenario		**Estimated inhalation uptake [mg/kg bw d][1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [1]	Adult / 1 spray application/ day	0.004	3. 58	.	**3. 58**
Scenario [1]	Children (6-12 years) / 1 spray application/day	0.012	4.98	.	**4.99**
Scenario [1]	Children (2-6 years) / 1 spray application/day	0.017	5.64	-	**5.66**
Scenario [1]	Toddler (1-2 years) / 1 spray application/day	0.026	6.21	-	**6.24**
Scenario [1]	Infant (< 1 year) / 1 spray application/day	0.022	6.63	-	**6.65**

[1] Part of inhalation uptake (not detailed)

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 and herself/himself		
A worst case is considered with an adult applying the product on two children and herself/himself. 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. The dermal exposure of the adult is considered to be covered by the general dermal exposure from scenario 1. Regarding inhalation exposure, the time of spraying takes into account 3 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.		
	Parameters	Value
Tier 1	Concentration of a.s. in the product (no dilution)	30%

	Number of applications per person per day	1
	Number of treated person per day	3 (two children and herself/himself)
	Use duration $	4 min
	Adult - inhalation rate, short-term #	1.25 m^3/h
	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 3 times 4 min is calculated according to the inhalation rate:

Adult : 10.5 mg/m^3 x 3 x 4 min x 1.25 m^3/ 60 min = 2.625 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 ISDIN INSECT REPELLENT IR3535 30%.

In a worst-case approach, if the absence of data about the particle size distribution in the product ISDIN INSECT REPELLENT IR3535 30% 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: 2.625 x 30% x 100% = 0.7875 mg IR3535/day

Inhalation exposure in mg/kg bw/day:

Adult: 0.7875 / 60 = 0.01312 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	0.01312	3.57 (from scenario 1)	Included in inhalation intake	3.59

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]	0.01312	3.57	Included in inhalation intake	3.59

Exposure of the general public

The general public can be exposed under secondary exposure scenarios after application of ISDIN INSECT REPELLENT IR3535 30%.

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
Indoor and outdoor applications are possible. 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. 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.

	Parameters		Value
Tier 1	Concentration of a.s. in the product (no dilution)		30%
	Dose of product applied on the skin ¤		0.56 mg/cm²
	Dose of product per application∞	Adult	5.11 g
		Infant	1.26 g
		Toddler	1.48 g
		Child - 2 to <6 years old	2.09 g
		Child - 6 to <12 years old	2.83 g
	Number of applications per day		1 (for adults, infant, toddler, child from 2 to 12 years old)
	Surface ratio between fingers and the treated surface area $		4% (adults) 10% (child, toddler, infant)
	Oral uptake		100%
	Body weight #	Adult	60 kg
		Infant	8 kg
		Toddler	10 kg
		Child - 2 to <6 years old	15.6 kg
		Child - 6 to <12 years old	23.9 kg

¤ A dose rate of 0.56 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	Value				
	Adult	**Children (6-12 years)**	**Children (2-6 years)**	**Toddler (1-2 years)**	**Infant (< 1 year)**
Amount of active substance/application [mg/application]	1533.84	850.08	628.32	443.52	378.84
Body weight [kg]	60	23.9	15.6	10	60
Oral absorption	100	100	100	100	100
Factor for oral intake by hand-mouth transfer	4	10	10	10	10
Oral systemic exposure via hand-mouth transfer mg/kg bw	**1.02**	**3.56**	**4.03**	**4.44**	**4.74**

Total exposure

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d] [1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [3]	Adult Tier 1/ no PPE	Not applicable	Not applicable	1.02	**1.02**
Scenario [3]	Children (6-12 years) Tier 1/ no PPE	Not applicable	Not applicable	3.56	**3.56**
Scenario [3]	Children (2-6 years) Tier 1/ no PPE	Not applicable	Not applicable	4.03	**4.03**
Scenario [3]	Toddler (1-2 years) Tier 1/ no PPE	Not applicable	Not applicable	4.44	**4.44**
Scenario [3]	Infant (< 1 years) Tier 1/ no PPE	Not applicable	Not applicable	4.74	**4.74**

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 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).
The calculation of the SVC is done on the basis of the physico-chemical properties of IR3535 (from the CAR issued in September 2013).
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 used for the human exposure scenario are provided in the table below:

	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
	Residential time $			24 hours per day
	Room volume			20 m^3
	Temperature			25 ºC
	Parameters for each sub-population[2]	Adult	Inhalation rate	1.25 m^3/h
			Product amount	5112.80 mg
			Body weight	60 kg
		Child - 6 to <12 years old	Inhalation rate	1.32 m^3/h
			Product amount	2833.6 mg
			Body weight	23,9 kg
		Child - 2 to <6 years old	Inhalation rate	1.26 m^3/h
			Product amount	2094.4 mg
			Body weight	15,6 kg
		Toddler	Inhalation rate	1.26 m^3/h
			Product amount	1478.4 mg
			Body weight	10 kg
		Infant	Inhalation rate	0.84 m^3/h
			Product amount	1262.8 mg
			Body weight	8 kg

# from ECHA Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products
$ from TNsG, part 3 (June 2002), page 50.

Calculations for Scenario [4]

Inhalation exposure

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):

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

The result of this equation is superior to 1 which means that the inhalation exposure could not be considered as negligible. So this scenario was assessed using ConsExpo exposure to vapour – instantaneous release.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d] [1]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d] [1]**	**Estimated total uptake [mg/kg bw d]**
For IR3535®					
Scenario [4]	Adult Tier 1/ no PPE	2.66	Not applicable	Not applicable	**2.66**
Scenario [4]	Children (6-12 years) Tier 1/ no PPE	3.91	Not applicable	Not applicable	**3.91**
Scenario [4]	Children (2-6 years) Tier 1/ no PPE	4.22	Not applicable	Not applicable	**4.22**
Scenario [4]	Toddler (1-2 years) Tier 1/ no PPE	4.63	Not applicable	Not applicable	**4.63**
Scenario [4]	Infant (<1 years) Tier 1/ no PPE	3.31	Not applicable	Not applicable	**3.31**

See annex 3.2. for ConsExpo calculations.

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 24 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 24 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 (16 m^3/day) / 60 kg = 0.035 mg/kg bw/day

Child (6-12): (0.13 mg/m^3) x (12 m^3/day) / 23.9 kg = 0.066 mg/kg bw/day

Child (2-6): (0.13 mg/m^3) x (10.1 m^3/day) / 15.6 kg = 0.088 mg/kg bw/day

Toddler: (0.13 mg/m^3) x (8 m^3/day) / 10 kg = 0.11 mg/kg bw/day

Infant: (0.13 mg/m^3) x (5.4 m^3/day) / 8 kg = 0.088 mg/kg bw/day

The exposure to volatized residues is considered negligible.
The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of an adult applying the product on two children and herself/himself 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)[1]**	**Estimated total uptake (mg/kg bw/day)**
Scenarios [1a, 1b and 2]	Adult: 0.004+0.013= 0.0175	Adult: 3.58	Included in inhalation uptake	Adult: 3.59

1 Included in inhalation uptake

The exposure by inhalation of volatilized residues after application and the combined inhalative and oral exposure of an adult applying the product on two children and herself/himself 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 indoors in well ventilated areas or outdoors.

Monitoring data

There are no monitoring data with «Isdin insect repellent IR3535 20%».

Dietary exposure

ISDIN INSECT REPELLENT IR3535 30% 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) = 0.56 (value given by the efficacy)
C	Concentration of a.s. in the BP (%) = 30 %
Hfood contact	Hand surface in contact with food (cm^2). (default value) 196.8 cm^2 for infant (<1 year old). 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) 8 kg for infant (<1 year old) 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

Infant Exp_{cons} =
0.56 mg/cm^2 x 30% x 196.8 cm^2 x 100% x 10% / 8 kg = 0.41 mg/kg bw/d

Toddler Exp_{cons} =
0.56 mg/cm^2 x 30% x 230.4 cm^2 x 100% x 10% / 10 kg = 0.39 mg/kg bw/d

Children 2-6 years old Exp_{cons} =
0.56 mg/ cm^2 x 30% x 330.9 cm^2 x 100% x 10% / 15.6 kg = 0.36 mg/kg bw/d

Children 6-12 year old Exp_{cons} =
0.56 mg/ cm^2 x 30% x 427.8 cm^2 x 100% x 10%/ 23.9 kg = 0.31/kg bw/d

Adult Exp_{cons} =
0.56 mg/ cm^2 x 30% x 410 cm^2 x 50% x 10% / 60 kg = 0.06 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 «Isdin insect repellent IR3535 30%».

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

Not relevant for «Isdin insect repellent IR3535 30%» product.

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

Not relevant for «Isdin insect repellent IR3535 30%» product.

Information of non-biocidal use of the active substance

No different use as biocidal PT19 is known for IR3535

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 «ISDIN INSECT REPELLENT IR3535 30%» 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.

Aggregated exposure

No aggregated exposure is foreseen.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier /PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1 1 application/day	Non Professionals	Adult	Tier 1/No PPE	3.58
		Children (6-12 years)		4.99
		Children (2-6 years)		5.66

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier /PPE**	**Estimated total uptake (mg/kg bw/d)**
		Toddler (1-2 years)		6.24
		Infant (<1 year)		6.55
Scenario 2 An adult applying on two children and himself	Non professionals	Adult	Tier 1/No PPE	3. 59
Scenario 3 Hand to mouth 1 aplication/day	Non professinals – General public	Adult	Tier 1/No PPE	1.02
		Children (6-12 years)		3.56
		Children (2-6 years)		4.03
		Toddler (1-2 years)		4.44
		Infant (<1 year)		4.74
Scenario 4 Inhalation residues volatil	Non professinals – General public	Adult	Tier 1/No PPE	2.66
		Children (6-12 years)		3.91
		Children (2-6 years)		4.22
		Toddler (1-2 years)		4.68
		Infant (<1 year)		3.31

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	1) 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

[1] Factor 10 for both intra-species and interspecies differences. No extrapolation factor for duration is needed, as the overall NOAEL is derived from a repeated 28d-oral toxicity study and a teratogenicity study.
The derivation of an ADI or an ARfD is not applicable as no residues in food/feed are expected.
No derivation of a local AEC is set in IR3535's CAR based on it is not justified a risk characterisation for local effects.

Maximum residue limits or equivalent
No data available, not relevant.

Risk for industrial users
No relevant, the product is intended to be applied by non-professional users.

Risk for professional users
No relevant, the product is intended to be applied by non-professional users.

Risk for non-professional users

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)	Exposed group	Estimated uptake (mg/kg bw/day)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 Non professinals	1	1) 300 2) 500	5	Adult	3.58	72	**yes**
				Children (6-12 years)	4.99	99	**yes**
				Children (2-6 years)	5.66	113	**no**
				Toddler (1-2 years)	6.24	125	**no**
				Infant (<1 year)	6.55	133	**no**
Scenario 2 Non professionals	1	1) 300 2) 500	5	Adult	3. 59	72	**yes**
Scenario 3 Non professionals (Public general)	1	1) 300 2) 500	5	Adult	1.02	*	Yes (see below)
				Children (6-12 years)	3.56		
				Children (2-6 years)	4.03		
				Toddler (1-2 years)	4.44		
				Infant (<1 year)	4.74		
Scenario 4 Non professionals	1	1) 300 2) 500	5	Adult	2.66	53	**yes**
				Children (6-12 years)	3.91	78	**yes**
				Children (2-6 years)	4.22	84	**yes**

(Public general)				Toddler (1-2 years)	4.68	92	**yes**
				Infant (<1 year)	3.31	66	**yes**

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

Reverse reference scenario	Adult	Child (6-2)	Child (2-6)	Toddler	Infant
Oral systemic exposure via hand-mouth transfer mg/kg bw	1.02	3.56	4.03	4.44	4.74
AEL (mg/kg bw /d)	5	5	5	5	5
Oral systemic exposure/AEL Number of time of application b,p before exceeding the AEL via hand-mouth transfer	4,89	1,41	1,24	1,13	1,06

* For scenario 3, a reverse reference scenario is considered calculating the maximum number of applications which would allow to reach the reference dose:
Adult: 5 / 1.02 = 5 applications
Child (6-12): 5 / 3.56 = 1 applications
Child (2-6): 5 / 4.03 = 1 applications
Toddler: 5 / 4.44 = 1 applications
Infant: 5 / 4.74 = 1 applications

As a conclusion for scenario 3, it is recommended that one adult will not apply on more than 5 people (including himself/herself). Actually, he/she is expected not to apply over more than three people (*i.e.* one time himself/herself + two 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 of 0.56 mg/cm² ISDIN INSECT REPELLENT IR3535 30%.

The risk is acceptable for **adults** and **children 6-12 years** under all the possible scenarios (1, 2, 3 or 4) if one application is done on the 55% of the body surface area at the dose of of 0.56 mg/cm² ISDIN INSECT REPELLENT IR3535 30% per application.
,
The risk is unacceptable for **children 2-6 years**, **toddlers** and **infants** under the possible scenario 1 one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² ISDIN INSECT REPELLENT IR3535 30% per application.

The risk is unacceptable for under scenario 1 and acceptable under scenarios 2, 3 and 4 if one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² «Isdin insect repellent IR3535 30%» per application.

The risk is acceptable for adults and children 6-12 years if one application is done on the 55% of the body surface area at the dose of 0.56 mg/cm² ISDIN INSECT REPELLENT IR3535 30% per application. This product will not be authorised for infants.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL	AEL (mg/kg bw/d)	Estimated uptake	Estimated uptake/ AEL (%)	Accept-able

		(mg/kg bw/d)		(mg/kg bw/d)		(yes/ no)
1 + 2	1	1) 300 2) 500	5	Adult:	72	yes

The combined inhalative and oral exposure of an adult applying on two children and herself/himself (scenario 2) are negligible compared to primary (dermal) exposure (from scenario 1). Also, the inhalation of volatised residures should not be combined, since the exposure is calculated for indoor application whilst the product is already authorised only in indoors in well ventilated areas.

No combined scenarios are foreseen.

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 ISDIN INSECT REPELLENT IR3535 30% 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 ISDIN INSECT REPELLENT IR3535 30% is classified as Eye irritant. 2.
2. Assignment of hazard categories: Low

- **Qualitative risk assessment for local effects**

Hazard			Exposure						Relevant RMM & PPE	Risk
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Rough degree of exposure** **Degree of potential exposure under best practice conditions**		**Conclusion of risk**
Low	Eye Irrit. 2, H319	IR3535 (30%)	19	General public: adults and children	Application: (Scenarios 1 and 2) See section 2.2.6.2	Skin Eye (splashes, hand to eye transfer)	4 min/day, 90 days/year (summer season when mosquitoes infestations are common) Less than one hour per da	< 5 mg/ kg bw /d Outdoor or indoor in warm season (i.e. efficiently ventilated facilities) spray use	***RMM*** - 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. - Labelling as eye irritant - Do not spray into the eyes or apply to eye area	***Acceptable*** + reversible effect. + low likelihood for exposure of eyes. + used with low frequency + short actual exposure. + High ventilation expected, due to its use outdoors and during summer season, where a high ventilated rate

									- An adult should apply the product to children below 12 years of age - Do not use on children's hands - Limit the exposure per day to the maximum number of spray-pulses claimed in the label for each human group. - Washing hands after use. - Instructions for use	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 **non-acceptable** Operational and organisational RMMs not applicable Potential children exposure due to hand to eye contact

Taking into account the appropriate risk mitigation measures considered above, an acceptable risk is expected for local effects (Eye irritation 2) derived from the application of ISDIN INSECT REPELLENT IR3535 30%.

ISDIN INSECT REPELLENT IR3535 30% pose an unacceptable risk for non-professional users.

Authorization of the product is requested, since its use in the period that is intended to be applied (summer time in which mosquitoes proliferate) and the possible effects that mosquitoes can cause in the population (infections, diseases, ...) should be considered much more serious effects compared to the risk to human health arising from the use of the biocidal product in accordance with the proposed conditions of use as follows:

Application rate: 0.56 mg/cm^2. The pump releases a dose of 0.1949 ml (0.1866 g) per spray burst (Applicant data). Please see annex 3.2 for further information

Adults: 5.11 g or aprox. 27 pump strokes

Children (6<12 years): 2.83 g or aprox. 15 pump strokes

Frequency of application: Only one application

Therefore, safe uses are identified for ISDIN INSECT REPELLENT IR3535 30% for adult and children 6-12 years when the product is applied once per day. There is no safe use for children 2-6 years, toddlerinfants. The product should not be applied on child below 1 year old.

This argument is based on article 19.5 of the BPR regulation that states that "*Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met*."

With regard to the potential risk observed, under systemic effects, an acceptable risk is considered at scenario 1 and 2 for adults, childrens. In addition, combined scenarios 1+2 shows acceptable exposure for adults. In view of that and considering the risk mitigation measures mentioned on local effects section, an acceptable risk might be expected by the use of the product on for adults, childrens skin and an unacceptable risk might be expected by the use of the product on infant skin.

There is no concern for indirect secondary exposure for adults and children from the use of the biocidal product as a Repellent PT19. Exposure via hand-to-mouth transfer is of minor concern when the product is used as intended (not to be applied to children's hands), and inhalation of volatilized residues after application is limited. Secondary exposure for a adult

applying (spraying) the product on two children and herself/himself is minor compared to primary dermal exposure.

Proper use, i.e. use in compliance with correct and complete conditions on the label, of ISDIN INSECT REPELLENT IR3535 30% is considered safe for adults and children.

The following RMM are required:

- Use repellent safely. Always read the label and product information before use.
- Suitable for children older than 6 year. Keep out of reach of children. Avoid breathing vapours/spray. Use only outdoors or in a well-ventilated area.
- ONLY apply to uncovered parts of the arms, hands, legs, feet and face. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes.
- Do not spray into the eyes or apply to eye area.
- An adult should apply the product to children below 12 years of age.
- Do not use on children's hands. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing.
- Maximum number of applications per day: once for adults and children above 1 year old. Product can be used only for children older than 6 year.
- Avoid contact with synthetic materials. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non-visible part of clothes before use.
- Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

ISDIN INSECT REPELLENT IR3535 30% containing 30% IR3535 can be used one time per day on children 6-12 years and adults.

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

Conclusion

ISDIN INSECT REPELLENT IR3535 30% poses an unacceptable risk for children 2-6 years, toddler and infant users.

Risk for consumers via residues in food

Not relevant, the product is not intended to be applied on food nor feedstuff.

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

There are no substances of concern
Not relevant, the product is not intended to be applied with other biocidal products

2.2.7 Risk assessment for animal health

Not applicable. ISDIN INSECT REPELLENT IR3535 30% 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 ISDIN INSECT REPELLENT IR3535 30% 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 «Isdin Insect repellent IR3535 30%». This product is an insect repellent (PT19) against mosquitoes and ticks containing 30% 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 «Isdin Insect repellent IR3535 30%» differs somewhat in composition and use from the product reprenseted in the IR3535 AR, the risk for the environment was assessed here anew for «Isdin Insect repellent IR3535 30%». The product characteristics that were not covered in the IR3535 AR include:

- The concentration in active substance in the biocidal product. The IR3535 AR was performed considering a maximal active substance concentration of 20%. «Isdin Insect repellent IR3535 30%», however, is composed of 30% IR3535 and is therefore not covered by that scenario.

- Swimming after product application is a scenario that is not covered in the IR3535 AR. Swimming after product application is not restricted for «Isdin Insect repellent IR3535 30%» 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, «Isdin Insect repellent IR3535 30%»'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 «Isdin Insect repellent IR3535 30%» 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 no toxicity studies were carried out for the sediment compartment either, the $PNEC_{sed}$ was derived from the $PNEC_{water}$ 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. $PNEC_{soil}$ for the assessment of «Isdin Insect repellent IR3535 30%» 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)	163.29-208.61 d	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 (DT_{50} (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 (DT_{50} (12°C) = 163.29-208.61 days) and a rapid phase (DT_{50} (12°C) = 8.48-10.77 days). These two phases (lag and rapid) are combined together for the P-criterion evaluation and overall DT_{50} 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:

Assessment of the ED properties of the active substance:

The biocidal product contains Ethyl butylacetylaminopropionate (IR3535®)
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.

Assessment of the ED properties of non-active substances (co-formulants):

A screening assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product Isdin insect repellent IR3535 30% has been performed according to the instructions described in the document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants). Based on existing knowledge and reasonably available scientific information, four co-formulants triggered an alert for ED property (see confidential annex). However, a conclusion has not yet been agreed for these substances and they are still identified as potential EDs. Based on this information, the ES CA considers that the authorisation of the biocidal product

ISDIN INSECT REPELLENT IR3535 30% can proceed. In future, the conclusion of the product could be reconsidered if the conclusion of the ED status of any of these substances would has been agreed

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:
"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

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 agrees 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	300	g/kg	30% a.s.
$Qform_{appl}$	Consumption per application	1.67	mg/cm²	Data from efficacy studies
$AREA_{skin}$	Treated area of human skin	10 660	cm²	ESD for PT19 and TAB Environment (ENV 172)
N_{appl}	Number of applications per day	3	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, an application rate of 1 g/600 cm², i.e. 1.67 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 on children, but considering adults is a worst-case scenario, since the area of skin and the maximal number of daily applications are higher for adults than for children.

The number of product applications per day (N_{appl}) was set to 3, as it is the maximum 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 :

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

$Elocal_{STP}$

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

$= 10\ 000 * 3 * 1.67 * 10\ 660 * 300 * 0.2 * 1 * 0.5 * 10^{-9}$

$= 16.02$ kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	16.02	-

ESCA:

Currently the AREAskin has changed.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.

According to the efficacy studies, the application rate is 0,56 mg product / cm^2 and three applications per day as a worst case.

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

$= 10\ 000 * 3 * 0.56 * 9.130 * 300 * 0.2 * 1 * 0.5 * 10^{-9} = 4.60$ kg/d

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Waste water	4.60	/

Since the new value obtained is lower than the value obtained by the applicant, the risk to the environment is covered by the assessment performed by the applicant, so no more calculations are needed.

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	300	g/kg	30% a.s.
$Qform_{appl}$	Consumption per application	1.67	mg/cm²	Data from efficacy studies
$AREA_{skin}$	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 and 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 ($Elocal_{water}$):

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

$$= 1500 * 1 * 1.67 * 10\,660 * 300 * 0.1 * 1 * 10^{-9}$$

$$= 0.801 \text{ kg/day}$$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Freshwater	0.801	-

ES CA:
Currently the AREAskin has changed.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.

According to the efficacy studies, the application rate is 0,56 mg product / cm^2.

$Elocal_{water}$=

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

$= 1500 * 1 * 0.56 * 9130 * 300 * 0.1 * 1 * 10^{-9} = 0.23$ kg/d

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Local water	0.23	/

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 «Isdin Insect repellent IR3535 30%» 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:
The applicant has only considered TIER 2 in the evaluation, where 99% degradation in STP and the remaining 1% enters the water compartment is taken into consideration. So for 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 and the 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

Input parameters of the IR3535 AR to calculate PEC values :

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)	0.084	Pa	-
Water solubility (at 12°C)	6.24×10^3	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)	2.91 x 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.

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	8.01 x 10^{-2}	8.01 x 10^{-3}	8.9 x 10^{-2}	8.01 x 10^{-4}	8.9 x 10^{-3}	-	-	-
Scenario 2	-	0.168	1.87	-	-	-	-	-

ES CA:
New PEC values have been calculated by ES CA.

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 ($C_{local,inf}$) :

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

= 16.02 * 10^6 / 2 x 10^6

= 8.01 mg/l

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

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

= 8.01 * 0.01

= 8.01 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	16.02	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	3	-	Applicant's data
Consumption per application	17.8	g	Output ($Qform_{appl}$ * $AREA_{skin}$)
Active substance in product	30	%	-

- **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.

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	0.801	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 ($Clocal_{water, 91d}$):

$Clocal_{water, 91d}$

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

$= 10^3 * 0.801 * 91 / 435\,000$

$= 0.168$ 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 * 0.168 * 1000

= 1.87 mg/kg

Input parameters for calculating the local PEC_{sed}				
Input		**Value**	**Unit**	**Remarks**
$PEC_{local,water}$	Concentration in surface water during emission episode	0.168	mg/l	Calculated via EUSES
RHO_{susp}	Bulk density of suspended matter	1150	kg/m³	Standard value from BPR Guid. Vol. IV Env. parts B+C – p.53
$K_{susp,water}$	Suspended matter-water partitioning coefficient	12.8	m³/m³	Calculated via EUSES

ES CA: this values has been recalculated using the Elocalwater obtained above

(Elocalwater= 2.3x10^{-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	$Elocal_{water}$	0.23	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

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

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

Resulting local concentrations in the waterbody		
Compartment	**Local concentration ($Clocal_{compartment}$) [mg/L]**	**Remarks**
Surface water – after 1 day	5.28x10^{-4}	/
Surface water – after 91 days	4.81x10^{-2}	(without considering possible degradation)

ES:
PEC values obtained:

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	2.3 x 10^{-2}	2.3 x 10^{-3}	2.56 x 10^{-2}	-	-	-	-	-
Scenario 2	-	0.048	0.53	-	-	-	-	-

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.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	$< 8.03 \times 10^{-3}$
Scenario 2	-

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.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1	$< 8.01 \times 10^{-2}$	$< 8.01 \times 10^{-2}$	$< 8.01 \times 10^{-2}$	$< 8.01 \times 10^{-2}$
Scenario 2	< 1.68	< 1.68	-	-

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. In these conditions, the risk is

unacceptable for freshwater and sediments. Further refinements and/or risk mitigation measures would be necessary to make this risk acceptable.

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: PEC/PNEC values obtained:

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{stp}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sediment}$**	**PEC/PNEC$_{soil}$**
Scenario 1	< 2.3 x 10^{-4}	< 2.3 x 10^{-2}	< 2.3 x 10^{-2}	-
Scenario 2	< 0.48	< 0.48	-	-

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 with the conclusion given by the applicant.

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

Two scenarios were considered in this risk assessment. No unacceptable risk was identified for scenario 1, i.e. when emissions occur following the showering/bathing of the users.

For scenario 2, i.e. when the emissions occur through outdoor swimming in surface water bodies, the risk for surface water and sediments is unacceptable.

The overall risk for the environment is thus not acceptable. Further refinements and/or risk mitigation measures should be applied to make this risk acceptable.

ES CA do not agree with the conclusion given by the applicant.

Based on this risk assessment and on available data, «Isdin Insect repellent IR3535 30%» should not cause any unacceptable risks to the environement.

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

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

3.1 List of studies for the biocidal product

Section No.	[redacted]	[redacted]	Title Source Report GLP; Doc. No. (laboratory) No. (un)published	Data Protection (Yes/No)	Owner
3	[redacted]	[redacted]	MicroBios – Viscosity – Rotational Viscosimeters MicroBios No report number provided Non GLP	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)

3	[redacted]	[redacted]	Determination of the surface tension (SFT) of a liquid.	Yes	Laboratorios Montplet SLU (Former Alcoholes Montplet, S.A.)
3	[redacted]	[redacted]	Control of critical parameters under stability conditions Eurofins Biolab S.r.l. Report no. 2017/201 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
3	[redacted]	[redacted]	Study program 2017/201 AM - Shelf-Life stability study at 25°C/60%RH for 3 yeasrs on the test item "Montplet Insecte Repellent IR3535 30%" Eurofins Biolab S.r.l. Report no. 2017/201 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
3	[redacted]	[redacted]	Amendment to study program 2017/201 AM - Shelf-Life stability study at 25°C/60% RH for 3 years on the test item "Montplet Insect repellent IR3535 30%" Eurofins Biolab S.r.l. Report no. 2017/201 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
3	[redacted]	[redacted]	ACCELERATED STABILITY STUDY AT 30°C FOR 18 WEEKS ON THE TEST ITEM "ISDIN INSECT REPELLENT IR3535 20%" Eurofins Biolab S.r.l. Report no. 2019/166 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (Former Alcoholes Montplet, S.A.)
3	[redacted]	[redacted]	ACCELERATED STABILITY STUDY AT 30°C FOR 18 WEEKS ON THE TEST ITEM "MONTPLET INSECT REPELLENT IR3535 30%" Eurofins Biolab S.r.l. Report no. 2017/200 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
4	[redacted]	[redacted]	QUALITY CONTROL TEST REPORT Laboratorio de analisis DR. ECHEVARNE Report no. 3634437 Non GLP ; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
4	[redacted]	[redacted]	FINAL REPORT (1st Original of 3) Pump Spray IR 3535R 20 % Batch No.: SM-0-1-1/090211 AUTOIGNITION TEMPERATURE (LIQUIDS AND GASES) A.15 REPORT: 20110103.01 Study no 242-002 Unpublished	Yes	Merck
4	[redacted]	[redacted]	CORROSION TESTS ON S235JR STEEL AND ALUMINIUM 7075 IN INSECT REPELLENTS	Yes	Laboratorios Montplet, S.L.U.

5	[redacted]	[redacted]	Validation of an HLPC-UV method for the quantification of the ethyl butylacetylacminopropionate (IR3535) active ingredient in the test item "Montplet Insect Repellent IR3535 30%) Eurofins Biolab S.r.l. S-2017-02130 AM GLP; Unpublished	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
6	[redacted]	[redacted]	SIMULATED-USE TRIAL OF A SKIN MOSQUITO REPELLENT PRODUCT Trial against Aedes albopictus, Culex pipiens and Anopheles gambiae "REMPIB003 – ISDIN XTREM ANTIMOSQUITOS" Non GLP; Unpublished Study No. 2742h/1121	Yes	Laboratorios Montplet SLU
6	[redacted]	[redacted]	Laboratory assessment of a personal skin repellent against tropical mosquitoes T.E.C. Laboratory Report no. 1623c/0513 Non GLP; Unpublished Study number: 87	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
6	[redacted]	[redacted]	Laboratory assessment of a personal skin repellent against mosquitoes T.E.C. Laboratory Report no. 1623b/0513 Non GLP; Unpublished Study number: 79	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
6	[redacted]	[redacted]	Laboratory assessment of a personal skin repellent against mosquitoes - Trial against Aedes albopictus, Anopheles gambiae Report no. 2244/0817R T.E.C. Laboratory Non GLP; Unpublished Study number: 2244/0817	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
6	[redacted]	[redacted]	Laboratory assessment of a personal skin repellent against mosquitoes Anopheles gambiae T.E.C. Laboratory Report no. 1623d/0513 Non GLP; Unpublished study number: 133	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
6	[redacted]	[redacted]	Title: / Carroll-Loye Biological Research Doc N° 336-1915/2007 Unpublished	Yes	Merck
6	[redacted]	[redacted]	Title: / Carroll-Loye Biological Research Doc N°336-1914/2007 Unpublished	Yes	Merck

6	[redacted]	[redacted]	Title: 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 Unpublished Doc. No 336-1921	Yes	Merck
6	[redacted]	[redacted]	Repellent Efficacy of Six Repellent Formulations on Human Arms against Mosquitoes BioGenius GmbH Unpublished Doc. No 336-1922	Yes	Merck
8	[redacted]	[redacted]	SKIN IRRITATION TEST (3) Analytical Laboratory Dr. Echevarne Report no. 76 Non GLP; Unpublished Study No. A8113	Yes	Laboratorios Montplet SLU (Former Alcoholes Montplet, S.A.)
8	[redacted]	[redacted]	EYE IRRITATION TEST (3) Analytical Laboratory Dr. Echevarne Report no. 81 Non GLP; Unpublished Study No.A8113	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)
8	[redacted]	[redacted]	ACUTE ORAL TOXICITY STUDY Analytical Laboratory Dr. Echevarne Report no. 71 Non GLP; Unpublished Study No.A8113	Yes	Laboratorios Montplet SLU (Former Alcoholes Montplet, S.A.)
8	[redacted]	[redacted]	ACUTE DERMAL TOXICITY TEST – DL_{50} Analytical Laboratory Dr. Echevarne Report no. 77 Non GLP; Unpublished Study No.A8113	Yes	Laboratorios Montplet SLU (Former Alcoholes Montplet, S.A.)
8	[redacted]	[redacted]	Acute dermal toxicity on repelente insectos forte Montplet Eurofins Biolab S.r.l. Report 70 Non GLP; Unpublished Study No.2012/1085 AMi	Yes	Laboratorios Montplet SLU (former Alcoholes Montplet, S.A.)

3.2 Output tables from exposure assessment tools

3.2.1 Risk assessment for human health (output tables from Euses)

Scenario 1

STUDY
STUDY IDENTIFICATION

Study name	Isdin_IR3535 spray 30%	S
Study description	Isdin_IR3535 spray 30%	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	96DD57FB	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 D	[kg.kg-1]
Fraction of organic carbon in settled sewage sludge	0.3 D	[kg.kg-1]
Fraction of organic carbon in activated sewage sludge	0.37 D	[kg.kg-1]
Fraction of organic carbon in effluent sewage sludge	0.37 D	[kg.kg-1]
DEGRADATION AND TRANSFORMATION RATES		
Rate constant for abiotic degradation in STP	0 D	[d-1]
Rate constant for abiotic degradation in bulk sediment (12[oC])	0 D	[d-1]
Rate constant for anaerobic biodegradation in sediment (12[oC])	0 D	[d-1]
Fraction of sediment compartment that is aerated	0.1 D	[m3.m-3]
Concentration of OH-radicals in atmosphere	5E+05 D	[molec.cm-3]
Rate constant for abiotic degradation in bulk soil (12[oC])	0 D	[d-1]
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 D	[eq]
Sewage flow	200 D	[l.eq-1.d-1]
Effluent discharge rate of local STP	2E+06 O	[l.d-1]
Temperature correction for STP degradation	No D	
Temperature of air above aeration tank	15 D	[oC]
Temperature of water in aeration tank	15 D	[oC]
Height of air column above STP	10 D	[m]
Number of inhabitants of region	2E+07 D	[eq]
Number of inhabitants of continental system	3.5E+08 O	[eq]
Windspeed in the system	3 D	[m.s-1]

RAW SEWAGE		
Mass of O2 binding material per person per day	54 D	[g.eq-1.d-1]
Dry weight solids produced per person per day	0.09 D	[kg.eq-1.d-1]
Density solids in raw sewage	1.5 D	[kg.l-1]
Fraction of organic carbon in raw sewage sludge	0.3 D	[kg.kg-1]
PRIMARY SETTLER		
Depth of primary settler	4 D	[m]
Hydraulic retention time of primary settler	2 D	[hr]
Density suspended and settled solids in primary settler	1.5 D	[kg.l-1]
Fraction of organic carbon in settled sewage sludge	0.3 D	[kg.kg-1]
ACTIVATED SLUDGE TANK		
Depth of aeration tank	3 D	[m]
Density solids of activated sludge	1.3 D	[kg.l-1]
Concentration solids of activated sludge	4 D	[kg.m-3]
Steady state O2 concentration in activated sludge	2E-03 D	[kg.m-3]
Mode of aeration	Surface D	
Aeration rate of bubble aeration	1.31E-05 D	[m3.s-1.eq-1]
Fraction of organic carbon in activated sewage sludge	0.37 D	[kg.kg-1]
Sludge loading rate	0.15 D	[kg.kg-1.d-1]
Hydraulic retention time in aerator (9-box STP)	6.9 O	[hr]
Hydraulic retention time in aerator (6-box STP)	10.8 O	[hr]
Sludge retention time of aeration tank	9.2 O	[d]
SOLIDS-LIQUIDS SEPARATOR		
Depth of solids-liquid separator	3 D	[m]
Density suspended and settled solids in solids-liquid separator	1.3 D	[kg.l-1]
Concentration solids in effluent	30 D	[mg.l-1]
Hydraulic retention time of solids-liquid separator	6 D	[hr]
Fraction of organic carbon in effluent sewage sludge	0.37 D	[kg.kg-1]

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 D	[eq]
Number of inhabitants in the EU	3.7E+08 D	[eq]
Number of inhabitants of continental system	3.5E+08 O	[eq]

AREAS

REGIONAL

Area (land+rivers) of regional system	4E+04 D	[km2]
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 D	[km]
Width of regional seawater	10 D	[km]
Area of regional seawater	400 O	[km2]
Area (land+rivers+sea) of regional system	4.04E+04 O	[km2]
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 D	[km2]
Area (land+rivers+sea) of continental system	7E+06 O	[km2]
Area (land+rivers) of continental system	3.5E+06 O	[km2]
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 D	[km2]
Area of moderate system (excl.continent, region)	7.8E+07 O	[km2]
Area fraction of water, moderate system	0.5 D	[-]

ARCTIC

Area of arctic system	4.25E+07 D	[km2]
Area fraction of water, arctic system	0.6 D	[-]

TROPIC

Area of tropic system	1.275E+08 D	[km2]
Area fraction of water, tropic system	0.7 D	[-]

TEMPERATURE

Environmental temperature, regional scale	12 D	[oC]
Environmental temperature, continental scale	12 D	[oC]
Environmental temperature, moderate scale	12 D	[oC]
Environmental temperature, arctic scale	- 10 [oC]	D
Environmental temperature, tropic scale	25 D	[oC]
Enthalpy of vaporisation	50 D	[kJ.mol-1]
Enthalpy of solution	10 D	[kJ.mol-1]

MASS TRANSFER

Air-film PMTC (air-water interface)	3.92E-03 O	[m.s-1]
Water-film PMTC (air-water interface)	4.72E-06 O	[m.s-1]
PMTC, air side of air-soil interface	1.05E-03 O	[m.s-1]
PMTC, soil side of air-soil interface	3.95E-10 O	[m.s-1]
Soil-air PMTC (air-soil interface)	5.56E-06 D	[m.s-1]
Soil-water film PMTC (air-soil interface)	5.56E-10 D	[m.s-1]
Water-film PMTC (sediment-water interface)	2.78E-06 D	[m.s-1]
Pore water PMTC (sediment-water interface)	2.78E-08 D	[m.s-1]

AIR

GENERAL

Atmospheric mixing height	1000 D	[m]
Windspeed in the system	3 D	[m.s-1]
Aerosol deposition velocity	1E-03 D	[m.s-1]
Aerosol collection efficiency	2E+05 D	[-]

RAIN

Average precipitation, regional system	700 D	[mm.yr-1]
Average precipitation, continental system	700 D	[mm.yr-1]
Average precipitation, moderate system	700 D	[mm.yr-1]
Average precipitation, arctic system	250 D	[mm.yr-1]
Average precipitation, tropic system	1.3E+03 D	[mm.yr-1]

RESIDENCE TIMES

Residence time of air, regional	0.687 O	[d]
Residence time of air, continental	9.05 O	[d]
Residence time of air, moderate	30.2 O	[d]
Residence time of air, arctic	22.3 O	[d]
Residence time of air, tropic	38.6 O	[d]

WATER

DEPTH

Water depth of freshwater, regional system	3 D	[m]
Water depth of seawater, regional system	10 D	[m]
Water depth of freshwater, continental system	3 D	[m]
Water depth of seawater, continental system	200 D	[m]
Water depth, moderate system	1000 D	[m]
Water depth, arctic system	1000 D	[m]
Water depth, tropic system	1000 D	[m]

SUSPENDED SOLIDS

Suspended solids conc. freshwater, regional	15 D	[mg.l-1]
Suspended solids conc. seawater, regional	5 D	[mg.l-1]
Suspended solids conc. freshwater, continental	15 D	[mg.l-1]
Suspended solids conc. seawater, continental	5 D	[mg.l-1]
Suspended solids conc. seawater, moderate	5 D	[mg.l-1]
Suspended solids conc. seawater, arctic	5 D	[mg.l-1]
Suspended solids conc. seawater, tropic	5 D	[mg.l-1]
Concentration solids in effluent, regional	30 D	[mg.l-1]
Concentration solids in effluent, continental	30 D	[mg.l-1]
Concentration biota	1 D	[mgwwt.l-1]

RESIDENCE TIMES

Residence time of freshwater, regional	43.3 O	[d]
Residence time of seawater, regional	4.64 O	[d]
Residence time of freshwater, continental	172 O	[d]
Residence time of seawater, continental	365 O	[d]
Residence time of water, moderate	2.69E+03 O	[d]
Residence time of water, arctic	5.84E+03 O	[d]
Residence time of water, tropic	1.09E+04 O	[d]

SEDIMENT

DEPTH

Sediment mixing depth	0.03 D	[m]

SUSPENDED SOLIDS

(Biogenic) prod. susp. solids in freshwater, reg	10 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in seawater, reg	10 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in freshwater, cont	10 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in seawater, cont	5 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in water, moderate	1 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in water, arctic	1 D	[g.m-2.yr-1]
(Biogenic) prod. susp. solids in water, tropic	1 D	[g.m-2.yr-1]

SEDIMENTATION RATES

Settling velocity of suspended solids	2.5 D	[m.d-1]
Net sedimentation rate, freshwater, regional	2.8 O	[mm.yr-1]
Net sedimentation rate, seawater, regional	1.53 O	[mm.yr-1]
Net sedimentation rate, freshwater, continental	2.75 O	[mm.yr-1]
Net sedimentation rate, seawater, continental	6.69E-03 O	[mm.yr-1]
Net sedimentation rate, moderate	2.8E-03 O	[mm.yr-1]
Net sedimentation rate, arctic	2E-03 O	[mm.yr-1]
Net sedimentation rate, tropic	2E-03 O	[mm.yr-1]

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 D	[m]
Mixing depth agricultural soil	0.2 D	[m]
Mixing depth industrial/urban soil	0.05 D	[m]
Mixing depth of soil, moderate system	0.05 D	[m]
Mixing depth of soil, arctic system	0.05 D	[m]
Mixing depth of soil, tropic system	0.05 D	[m]
EROSION		
Soil erosion rate, regional system	0.03 D	[mm.yr-1]
Soil erosion rate, continental system	0.03 D	[mm.yr-1]
Soil erosion rate, moderate system	0.03 D	[mm.yr-1]
Soil erosion rate, arctic system	0.03 D	[mm.yr-1]
Soil erosion rate, tropic system	0.03 D	[mm.yr-1]
CHARACTERISTICS OF PLANTS, WORMS AND CATTLE		
PLANTS		
Volume fraction of water in plant tissue	0.65 D	[m3.m-3]
Volume fraction of lipids in plant tissue	0.01 D	[m3.m-3]
Volume fraction of air in plant tissue	0.3 D	[m3.m-3]
Correction for differences between plant lipids and octanol	0.95 D	[-]
Bulk density of plant tissue (wet weight)	0.7 D	[kg.l-1]
Rate constant for metabolism in plants	0 D	[d-1]
Rate constant for photolysis in plants	0 D	[d-1]
Leaf surface area	5 D	[m2]
Conductance	1E-03 D	[m.s-1]
Shoot volume	2 D	[l]
Rate constant for dilution by growth	0.035 D	[d-1]
Transpiration stream	1 D	[l.d-1]

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 D	[oC]
Water solubility at environmental temperature	6.24E+04 O	[mg.l-1]
Vapour pressure at environmental temperature	0.0843 O	[Pa]
Sub-cooled liquid vapour pressure	0.0843 O	[Pa]
Fraction of chemical associated with aerosol particles	1.18E-03 O	[-]
Henry's law constant at test temparature	4.613E-04 S	[Pa.m3.mol-1]
Temperature at which Henry's law constant was measured	20 S	[oC]
Henry's law constant at 25 [oC]	6.08E-04 O	[Pa.m3.mol-1]
Henry's law constant at enviromental temparature	2.91E-04 O	[Pa.m3.mol-1]
Air-water partitioning coefficient	1.23E-07 O	[m3.m-3]
BIOCONCENTRATION FACTORS PREDATOR EXPOSURE		
Bioconcentration factor for earthworms	1.44 O	[l.kgwwt-1]
HUMAN AND PREDATOR EXPOSURE		
Bioconcentration factor for fish	5.56 O	[l.kgwwt-1]
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 O	[m3.m-3]
Partition coefficient between plant tissue and water	1.06 O	[m3.m-3]
Transpiration-stream concentration factor	0.782 O	[-]
Bioaccumulation factor for meat	1.26E-06 O	[d.kg-1]
Bioaccumulation factor for milk	7.94E-06 O	[d.kg-1]
Purification factor for surface water	1 O	[-]
DEGRADATION AND TRANSFORMATION RATES CHARACTARIZATION		
Characterization of biodegradability	Not biodegradable S	

STP

Degradation calculation method in STP tests	First order, standard OECD/EU D	
Rate constant for biodegradation in STP	0	[d-1]
Total rate constant for degradation in STP	0	[d-1]
Maximum growth rate of specific microorganisms	2	[d-1]
Half saturation concentration	0.5	[g.m-3]

WATER/SEDIMENT

WATER

Rate constant for hydrolysis in surface water (12[oC])	6.93E-07	[d-1]
Rate constant for photolysis in surface water	6.93E-07	[d-1]
Rate constant for biodegradation in surface water (12[oC])	0	[d-1]
Total rate constant for degradation in bulk surface water (12[oC])	1.39E-06	[d-1]
Rate constant for biodegradation in saltwater (12[oC])	0	[d-1]
Total rate constant for degradation in bulk saltwater (12[oC])	1.39E-06	[d-1]

SEDIMENT

Rate constant for biodegradation in aerated sediment (12[oC])	6.93E-07	[d-1]
Total rate constant for degradation in bulk sediment (12[oC])	6.93E-08	[d-1]

AIR

Specific degradation rate constant with OH-radicals	0	[cm3.molec-1.s-1]
Rate constant for degradation in air	0	[d-1]

SOIL

Rate constant for biodegradation in bulk soil (12[oC])	6.93E-07	[d-1]
Total rate constant for degradation in bulk soil (12[oC])	6.93E-07	[d-1]

REMOVAL RATE CONSTANTS SOIL

Total rate constant for degradation in bulk soil (12[oC])	6.93E-07	[d-1]
Rate constant for volatilisation from agricultural soil	3.76E-06	[d-1]
Rate constant for leaching from agricultural soil	1.66E-04	[d-1]
Total rate constant for removal from agricultural top soil	1.7E-04	[d-1]
Rate constant for volatilisation from grassland soil	7.52E-06	[d-1]
Rate constant for leaching from grassland soil	3.32E-04	[d-1]
Total rate constant for removal from grassland top soil	3.4E-04	[d-1]
Rate constant for volatilisation from industrial soil	1.5E-05	[d-1]
Rate constant for leaching from industrial soil	6.63E-04	[d-1]
Total rate constant for removal from industrial soil	6.79E-04	[d-1]

RELEASE ESTIMATION
BIOCIDE SCENARIO INPUT DATA

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

PRIVATE USE

Emission scenario (ELocalWater)	Local wastewater emission 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 O	[tonnes.yr-1]
Regional tonnage of substance	0 O	[tonnes.yr-1]
Type of private human hygiene product	Deodorants, aerosol	S
Fraction of inhabitants using the product	0.2 O	[-]
Number of applications	3 S	[d-1]
Consumption per application	17.8 S	[g]
Daily consumption per inhabitant	10.7 O	[ml.d-1]
Active substance in product	300 S	[g.kg-1]
Number of emission days per year	365 O	[-]
Local emission to wastewater during episode	16.022 S	[kg.d-1]

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 D	[kg.m-3]
Penetration factor of disinfectant	0.5 D	[-]

REGIONAL AND CONTINENTAL RELEASES
PRIVATE USE
REGIONAL

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

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	16.022	[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 O	[kg.d-1]
Indirect emission to surface water	0 O	[kg.d-1]
Indirect emission to agricultural soil	0 O	[kg.d-1]
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 O	[kg.d-1]
Indirect emission to surface water	0 O	[kg.d-1]
Indirect emission to agricultural soil	0 O	[kg.d-1]
[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	16.022 S	[kg.d-1]
Concentration in untreated wastewater	8.01 O	[mg.l-1]
Local emission entering the STP	16 O	[kg.d-1]

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	8.01	[mg.l-1]
	O	
Concentration of chemical (total) in the STP-effluent	0.0801	[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	0.0801	[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 O	[mg.l-1]
Arctic PEC in water (dissolved)	0 O	[mg.l-1]
Arctic PEC in air (total)	0 O	[mg.m-3]
Arctic PEC in soil (total)	0 O	[mg.kgwwt-1]
Arctic PEC in sediment (total)	0 O	[mg.kgwwt-1]
GLOBAL: TROPIC		
Tropic PEC in water (total)	0 O	[mg.l-1]
Tropic PEC in water (dissolved)	0 O	[mg.l-1]
Tropic PEC in air (total)	0 O	[mg.m-3]
Tropic PEC in soil (total)	0 O	[mg.kgwwt-1]
Tropic PEC in sediment (total)	0 O	[mg.kgwwt-1]
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 O	[kg]
Steady-state mass in regional seawater	0 O	[kg]
Steady-state mass in regional air	0 O	[kg]
Steady-state mass in regional agricultural soil	0 O	[kg]
Steady-state mass in regional natural soil	0 O	[kg]
Steady-state mass in regional industrial soil	0 O	[kg]
Steady-state mass in regional freshwater sediment	0 O	[kg]
Steady-state mass in regional seawater sediment	0 O	[kg]

CONTINENTAL

Steady-state mass in continental freshwater	0 O	[kg]
Steady-state mass in continental seawater	0 O	[kg]
Steady-state mass in continental air	0 O	[kg]
Steady-state mass in continental agricultural soil	0 O	[kg]
Steady-state mass in continental natural soil	0 O	[kg]
Steady-state mass in continental industrial soil	0 O	[kg]
Steady-state mass in continental freshwater sediment	0 O	[kg]
Steady-state mass in continental seawater sediment	0 O	[kg]

GLOBAL: MODERATE

Steady-state mass in moderate water	0 O	[kg]
Steady-state mass in moderate air	0 O	[kg]
Steady-state mass in moderate soil	0 O	[kg]
Steady-state mass in moderate sediment	0 O	[kg]

GLOBAL: ARCTIC		
Steady-state mass in arctic water	0 O	[kg]
Steady-state mass in arctic air	0 O	[kg]
Steady-state mass in arctic soil	0 O	[kg]
Steady-state mass in arctic sediment	0 O	[kg]
GLOBAL: TROPIC		
Steady-state mass in tropic water	0 O	[kg]
Steady-state mass in tropic air	0 O	[kg]
Steady-state mass in tropic soil	0 O	[kg]
Steady-state mass in tropic sediment	0 O	[kg]
LIFE CYCLE STEPS		
[PRIVATE USE]		
LOCAL CONCENTRATIONS AND DEPOSITIONS [PRIVATE USE]		
AIR		
Concentration in air during emission episode	0 O	[mg.m-3]
Annual average concentration in air, 100 m from point source	0 O	[mg.m-3]
Total deposition flux during emission episode	0 O	[mg.m-2.d-1]
Annual average total deposition flux	0 O	[mg.m-2.d-1]
WATER, SEDIMENT		
Concentration in surface water during emission episode (dissolved)	8.01E-03 O	[mg.l-1]
Concentration in surface water exceeds solubility	No O	
Annual average concentration in surface water (dissolved)	8.01E-03 O	[mg.l-1]
Concentration in seawater during emission episode (dissolved)	8.01E-04 O	[mg.l-1]
Annual average concentration in seawater (dissolved)	8.01E-04 O	[mg.l-1]
SOIL, GROUNDWATER		
Concentration in agric. soil averaged over 30 days	0 O	[mg.kgwwt-1]
Concentration in agric. soil averaged over 180 days	0 O	[mg.kgwwt-1]
Concentration in grassland averaged over 180 days	0 O	[mg.kgwwt-1]
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 O	[mg.m-3]

WATER, SEDIMENT		
Local PEC in surface water during emission episode (dissolved)	8.01E-03	[mg.l-1]
Qualitative assessment might be needed (TGD Part II, 5.6)	No	
Annual average local PEC in surface water (dissolved)	8.01E-03	[mg.l-1]
Local PEC in fresh-water sediment during emission episode	0.089	[mg.kgwwt-1]
Local PEC in seawater during emission episode (dissolved)	8.01E-04	[mg.l-1]
Qualitative assessment might be needed (TGD Part II, 5.6)	No	
Annual average local PEC in seawater (dissolved)	8.01E-04	[mg.l-1]
Local PEC in marine sediment during emission episode	8.9E-03	[mg.kgwwt-1]
SOIL, GROUNDWATER		
Local PEC in agric. soil (total) averaged over 30 days	0	[mg.kgwwt-1]
Local PEC in agric. soil (total) averaged over 180 days	0	[mg.kgwwt-1]
Local PEC in grassland (total) averaged over 180 days	0	[mg.kgwwt-1]
Local PEC in pore water of agricultural soil	0	[mg.l-1]
Local PEC in pore water of grassland	0	[mg.l-1]
Local PEC in groundwater under agricultural soil	0	[mg.l-1]

EXPOSURE
SECONDARY POISONING
SECONDARY POISONING [PRIVATE USE]

Concentration in fish for secondary poisoning (freshwater)	0.0223	[mg.kgwwt-1]
	O	
Concentration in earthworms from agricultural soil	0	[mg.kg-1]
	O	
Concentration in fish for secondary poisoning (marine)	2.23E-03	[mg.kgwwt-1]
	O	
Concentration in fish-eating marine top-predators	4.45E-04	[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)	?? D	[mg.m-3]
Inhalatory LOAEL (mattox)	?? D	[mg.m-3]
Inhalatory CED (mattox)	?? D	[mg.m-3]
Correction factor for allometric scaling	1 D	[-]
DERMAL		
Dermal NOAEL (mattox)	?? D	[mg.kg-1.d-1]
Dermal LOAEL (mattox)	?? D	[mg.kg-1.d-1]
Dermal CED (mattox)	?? D	[mg.kg-1.d-1]
DEVELOPMENT-TOX		
ORAL		
Oral NOAEL (devtox)	?? D	[mg.kg-1.d-1]
Oral LOAEL (devtox)	?? D	[mg.kg-1.d-1]
Oral CED (devtox)	?? D	[mg.kg-1.d-1]
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks) D	
Conversion factor NOAEL to NOEC	10 O	[kg.d.kg-1]
NOEC via food (devtox)	?? D	[mg.kg-1]
LOEC via food (devtox)	?? D	[mg.kg-1]
CED via food (devtox)	?? D	[mg.kgfood-1]
INHALATORY		
Inhalatory NOAEL (devtox)	?? D	[mg.m-3]
Inhalatory LOAEL (devtox)	?? D	[mg.m-3]
Inhalatory CED (devtox)	?? D	[mg.m-3]
Correction factor for allometric scaling	1 D	[-]
DERMAL		
Dermal NOAEL (devtox)	?? D	[mg.kg-1.d-1]
Dermal LOAEL (devtox)	?? D	[mg.kg-1.d-1]
Dermal CED (devtox)	?? D	[mg.kg-1.d-1]

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	0.0801	[-]
Intermittent release	No	
RCR for the local marine compartment	0.0801	[-]
RCR for the local fresh-water compartment, statistical method	??	[-]
RCR for the local marine compartment, statistical method	??	[-]

SEDIMENT

RCR for the local fresh-water sediment compartment	0.0801	[-]
Extra factor 10 applied to PEC/PNEC	No	
RCR for the local marine sediment compartment	0.0801	[-]
Extra factor 10 applied to PEC/PNEC	No	

SOIL

RCR for the local soil compartment	0	[-]
Extra factor 10 applied to PEC/PNEC	No	
RCR for the local soil compartment, statistical method	??	[-]

STP

RCR for the sewage treatment plant	8.01E-03	[-]

PREDATORS

RCR for fish-eating birds and mammals (fresh-water)	??	[-]
RCR for fish-eating birds and mammals (marine)	??	[-]
RCR for top predators (marine)	??	[-]
RCR for worm-eating birds and mammals	??	[-]

REGIONAL
WATER

RCR for the regional fresh-water compartment	0	[-]
RCR for the regional marine compartment	0	[-]
RCR for the regional fresh-water compartment, statistical method	??	[-]
RCR for the regional marine compartment, statistical method	??	[-]

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	

	ADULT	CHILD (6-12y)	CHILD (2-6y)	Toddler (1-2y)	Infant (-1y)	Source
Total body surface area [cm²]	16600	9200	6800	4800	4100	Recommendation 14 HEEG
Body weight [kg]	60	23,9	15,6	10	8	Recommendation 14 HEEG
Respiration rate [m³/air/hour] SHORT-TERM EXPOSURE VALUES FOR INHALATION	1,25	1,32	1,26	1,26	0,84	Recommendation 14 HEEG
Number of application/ day (as recommended by the applicant)	1	1	1	1	1	Applicant's data
Efficacy application rate [mg biocidal product/cm²]	0,56	0,56	0,56	0,56	0,56	Applicants data
55% of total body surface area [cm²]	9130	5060	3740	2640	2255	Recommendation 11 HEEG
Amount / application [mg biocidal product/application]	5112,80	2833,60	2094,40	1478,40	1262,80	Calculated : efficacy application rate * 55% of total body Surface area
% of active substance into the biocidal product	30	30	30	30	30	Applicants data
Amount / application [mg active substance/application]	1533,84	850,08	628,32	443,52	378,84	Calculated : Amount/application [mg biocidal product/application] x % of active substance into the biocidal product / 100
Dermal absorption value (%)	14	14	14	14	14	CAR
Inhalation absorption value (%)	100	100	100	100	100	Applicants data
Oral absorption value (%)	100	100	100	100	100	Applicants data

Scenario 1

ISDIN REPELENT INSECT IR3535 30%						
Task / Scenario :	**PT19 Adult spraying on the skin (primary exposure)**					
	Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)					
active substance	**IR3535**					
users		**ADULT**	**CHILD (6-12y)**	**CHILD (2-6y)**	**Toddler (1-2y)**	**Infant (-1y)**
	units					
Body weight	kg	60	23,9	15,6	10	8
Weight of fraction	%	30,00%	30,00%	30,00%	30,00%	30,00%
Dermal exposure						
application dose	mg/cm^2	0,56	0,56	0,56	0,56	0,56
Total body surface area	cm^2	16600	9200	6800	4800	4100
Total body surface area treated	%	55%	55%	55%	55%	55%
número aplicaciones	per day	1	1	1	1	1
Dermal absorption	%	14%	14%	14%	14%	14%
systemic dose via skin	**mg/kg bw/day**	**3,58**	**4,98**	**5,64**	**6,21**	**6,63**
Inhalation exposure						
indicative value	mg/m^3	10,50	10,50	10,50	10,50	10,50
inhalation rate	m^3/h	1,25	1,32	1,26	1,26	0,84
inhalation duration	min	4	4	4	4	4
events number	per day	1	1	1	1	1
inhalation absorption	%	100%	100%	100%	100%	100%
systemic inhaled dose	**mg/kg bw/day**	**0,004**	**0,012**	**0,017**	**0,026**	**0,022**
Dose						
systemic dose	mg/kg bw/day	**3,58**	**4,99**	**5,66**	**6,24**	**6,65**
AEL acute		5	5	5	5	5
% AEL	mg/kg bw/day	**71,67**	**99,82**	**113,11**	**124,71**	**133,04**

Scenario 2

ISDIN REPELENT INSECT IR3535 30%		
Task / Scenario :	**PT19 Adult applying the product on children and herself/himself (secondary exposure)**	
	Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)	
active substance	**IR3535**	
users		**ADULT**
	units	
Body weight	kg	60
Weight of fraction	%	30,00%
Dermal exposure	(scenario 1)	
application dose	mg/cm2	0,56
systemic dose via skin	**mg/kg bw/day**	**3,5790**
Inhalation exposure		
indicative value	mg/m3	10,50
inhalation rate	m3/h	1,25
inhalation duration	min	4
events number	per day	3
inhalation absorption	%	100%
systemic inhaled dose	**mg/kg bw/day**	**1,31E-02**
Dose		
systemic dose	mg/kg bw/day	**3,59**
AEL acute		5
% AEL	mg/kg bw/day	**72**

Scenario 3

	ISDIN REPELENT INSECT IR3535 30%					
Task / Scenario :		**PT19 Hand to mouth transfer (secondary exposure)**				
		Recommendation no. 11 "Proposal for harmonising the assessment of human exposure to repellents (PT19)				
active substance		**IR3535**				
users		**ADULT**	**CHILD (6-12y)**	**CHILD (2-6y)**	**Toddler (1-2y)**	**Infant (-1y)**
	units					
Body weight	kg	60	23,9	15,6	10	8
Weight of fraction	%	30,00%	30,00%	30,00%	30,00%	30,00%
Oral exposure						
application dose	mg/cm^2	0,56	0,56	0,56	0,56	0,56
Total surface area	cm^2	16600	9200	6800	4800	4100
		55%	55%	55%	55%	55%
Factor for oral intake by hand-mouth transfer	%	4%	10%	10%	10%	10%
events number	per day	1	1	1	1	1
Oral absorption	%	100%	100%	100%	100%	100%
systemic dose via skin	**mg/kg bw/day**	**1,02E+00**	**3,56E+00**	**4,03E+00**	**4,44E+00**	**4,74E+00**
Dose						
systemic dose	mg/kg bw/day	**1,02**	**3,56**	**4,03**	**4,44**	**4,74**
AEL acute		5	5	5	5	5
% AEL	mg/kg bw/day	**20,45**	**71,14**	**80,55**	**88,70**	**94,71**

Scenario 4

Adult		
Substance		
Name	IR3535	
CASNumber		
Molecular weight	215	g/mol
KOW		
Product		
Name	isdin insect repellent IR3535 30%	
Weight fraction substance	30	%
Population		
Name	Adult	
Body weight	60	kg
Scenario scenario 4 Adult		
Frequency		
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	24	hour
Product in pure form	No	
Molecular weight matrix		
The product is used in dilution	No	
Product amount	5.11E+03	mg
Weight fraction substance	30	%
Room volume	20	m^3
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	25	°C
Vapour pressure	0.15	Pa
Molecular weight	215	g/mol
Absorption model	Fixed fraction	
Absorption fraction	100	%
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario scenario 4 Adult		
Inhalation		
Mean event concentration	5.32	mg/m^3
Peak concentration (TWA 15 min)	13	mg/m^3
Mean concentration on day of exposure		
Year average concentration		
External event dose	2.66	mg/kg bw
External dose on day of exposure		
Internal event dose	2.66	mg/kg bw
Internal dose on day of exposure		
Internal year average dose		
Integrated		
Internal event dose	2,66	mg/kg bw
Internal dose on day of exposure		
Internal year average dose		
Exposure	2,66	mg/kg bw
AEL	5	mg/kg bw
RCR	53,2	

Child 6-12 yo		
Substance		
Name	IR3535	
CASNumber		
Molecular	215	g/mol
KOW		
Product		
Name	isdin insect repellent IR3535 30%	
Weight fraction	30	%
Population		
Name	Child 6-12	
Body	23.9	kg
Scenario scenario 4		
Frequency		
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure	24	hour
Product in	No	
Molecular weight		
The product is used in	No	
Product	2.83E+03	mg
Weight fraction	30	%
Room	20	m^3
Ventilation	0.6	per hour
Inhalation	1.32	m^3/hr
Limit concentration to	Yes	
Application temperatur	25	°C
Vapour	0.15	Pa
Molecular	215	g/mol
Absorption model	Fixed fraction	
Absorption	100	%
Dermal		
Exposure	n.a.	
Absorption	n.a.	
Oral		
Exposure	n.a.	
Absorption	n.a.	
Results for scenario		
Inhalation		
Mean event concentrati	2.95	mg/m^3
Peak concentrati	13	mg/m^3
Mean concentrati		
Year average		
External	3.91	mg/kg bw
External dose on day		
Internal	3.91	mg/kg bw
Internal dose on day		
Internal year		
Integrated		
Internal	3,91	mg/kg bw
Internal dose on day		
Internal year		
Exposure	3,91	mg/kg bw
AEL	5	mg/kg bw
RCR	78,2	

Child 2-6 yo		
Substance		
Name	IR3535	
CASNumber		
Molecular	215	g/mol
KOW		
Product		
Name	isdin insect repellent IR3535 30%	
Weight fraction	30	%
Population		
Name	Child 2-6	
Body	15.6	kg
Scenario scenario 4		
Frequency		
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure	24	hour
Product in	No	
Molecular weight		
The product is used in	No	
Product	2.09E+03	mg
Weight fraction	30	%
Room	20	m³
Ventilation	0.6	per hour
Inhalation	1.26	m³/hr
Limit concentration to	Yes	
Application temperatur	25	°C
Vapour	0.15	Pa
Molecular	215	g/mol
Absorption model	Fixed fraction	
Absorption	100	%
Dermal		
Exposure	n.a.	
Absorption	n.a.	
Oral		
Exposure	n.a.	
Absorption	n.a.	
Results for scenario		
Inhalation		
Mean event concentrati	2.18	mg/m³
Peak concentrati	13	mg/m³
Mean concentrati		
Year average		
External	4.22	mg/kg bw
External dose on day		
Internal	4.22	mg/kg bw
Internal dose on day		
Internal year		
Integrated		
Internal	4,22	mg/kg bw
Internal dose on day		
Internal year		
Exposure	4,22	mg/kg bw
AEL	5	mg/kg bw
RCR	84,4	

Toddler		
Substance		
Name	IR3535	
CASNumber		
Molecular	215	g/mol
KOW		
Product		
Name	isdin insect repellent IR3535 30%	
Weight fraction	30	%
Population		
Name	Toddler	
Body	10	kg
Scenario scenario 4		
Frequency		
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure	24	hour
Product in	No	
Molecular weight		
The product is used in	No	
Product	1.47E+03	mg
Weight fraction	30	%
Room	20	m³
Ventilation	0.6	per hour
Inhalation	1.26	m³/hr
Limit concentration to	Yes	
Application temperatur	25	°C
Vapour	0.15	Pa
Molecular	215	g/mol
Absorption model	Fixed fraction	
Absorption	100	%
Dermal		
Exposure	n.a.	
Absorption	n.a.	
Oral		
Exposure	n.a.	
Absorption	n.a.	
Results for scenario		
Inhalation		
Mean event concentrati	1.53	mg/m³
Peak concentrati	13	mg/m³
Mean concentrati		
Year average		
External	4.63	mg/kg bw
External dose on day		
Internal	4.63	mg/kg bw
Internal dose on day		
Internal year		
Integrated		
Internal	4,63	mg/kg bw
Internal dose on day		
Internal year		
Exposure	4,63	mg/kg bw
AEL	5	mg/kg bw
RCR	92,6	

Infant		
Substance		
Name	IR3535	
CASNumber		
Molecular	215	g/mol
KOW		
Product		
Name	isdin insect repellent IR3535 30%	
Weight fraction	30	%
Population		
Name	Infant	
Body	8	kg
Scenario scenario 4		
Frequency		
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure	24	hour
Product in	No	
Molecular weight		
The product is used in	No	
Product	1.26E+03	mg
Weight fraction	30	%
Room	20	m³
Ventilation	0.6	per hour
Inhalation	0.84	m³/hr
Limit concentration to	Yes	
Application temperatur	25	°C
Vapour	0.15	Pa
Molecular	215	g/mol
Absorption model	Fixed fraction	
Absorption	100	%
Dermal		
Exposure	n.a.	
Absorption	n.a.	
Oral		
Exposure	n.a.	
Absorption	n.a.	
Results for scenario		
Inhalation		
Mean event concentrati	1.31	mg/m³
Peak concentrati	13	mg/m³
Mean concentrati		
Year average		
External	3.31	mg/kg bw
External dose on day		
Internal	3.31	mg/kg bw
Internal dose on day		
Internal year		
Integrated		
Internal	3,31	mg/kg bw
Internal dose on day		
Internal year		
Exposure	3,31	mg/kg bw
AEL	5	mg/kg bw
RCR	66,2	

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

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

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 PAR Confidential

3.7 Other

3.7.1 Use of Merck's data

Data from active substance's supplier (Merck KGaA) has also been used for the Physical hazard "Auto-ignition" due to the same reasons. Please see the comparison of the formulas in the table below.

Components	Montplet's formula	Merck's formula
Water (7732-18-5)	33,25	31,50
Ethanol (64-17-5)	33,00	35,00
ETHYL BUTYLACETYLAMINOPROPIONATE (52304-36-6)	20,00	20,00
PEG-8(25322-68-3)	5,00	5,00
PEG-32(25322-68-3)	4,00	4,00
PPG-15 STEARYL ETHER (25231-21-4)	3,00	1,00
POLYSORBATE 20 (9005-64-5)	1,50	1,50
PARFUM	0,30	0,00
Film former PVP/VA copolymer	0,00	2,00
	100,00	100,00

3.7.2 Cross-references in the dossier

Validated analytical method, physical, chemical and technical properties, physical hazards; assessment of effects on Human Health; efficacy:

Please note the data on methods for detection and identification, physical and chemical properties are directly bridged from the results obtained in the study conducted on the formulation "Montplet insect repellent IR3535 30%". Indeed, this product has a similar composition to the product defended in this application which should not have any influence on analytical methods.

In order to compare the composition of both products „Isdin insect repellent IR3535 30%" and „Montplet insect repellent IR3535 30%" , please find both chemical compositions provided in the tables "Qualitative and quantitative information on the composition of" here below

Physical hazards and assessment of effects on Human Health:

The data for physical hazards properties are directly bridged from the results obtained in the study conducted on the formulation "Montplet insect repellent IR3535 20%". In order to compare the composition of both products, please also find the chemical composition of "Montplet insect repellent IR3535 20%" in the table here below.

Assessment of effects on Human Health:

Please note that some results used for the assessment of effects are directly bridged from studies conducted on the formulations "Montplet insect repellent IR3535 20%" and "Montplet insect repellent IR3535 30%". Their compositions are also provided in the tables below.