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

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

(submitted by the evaluating Competent Authority)

PREDATOR JUNIOR. PROTECTOR COOL

Product type 19

IR3535 as included in the Union list of approved active substances

Case Number in R4BP: BC-NU020488-11

Evaluating Competent Authority: CZ

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1 CONCLUSION

Insect Repellent biocidal products Predator Junior and Protector Cool can be authorised according to Art. 19(1) of Regulation (EU) No 528/2012 as a ready-to-use repellents (PT19). For further details, see the relevant sections.

Physico-chemical properties and analytical methods
Predator Junior and Protector Cool can be used safely in terms of hazards due to their phys. chem. properties, provided the product is handled, stored and disposed of as specified in this assessment report. Therefore, there is no obstacle preventing the product authorisation regarding the identified hazards linked to their phys. chem. properties or required analytical methods.

Efficacy assessment
Predator Junior and Protector Cool demonstrated sufficient efficacy in WHO arm-in-cage tests against two species of mosquitoes (*Aedes aegypti* and *Culex pipiens quinquefasciatus*) and one tick species (*Ixodes ricinus*). Products are effective as a repellent against house mosquitoes and ticks for maximum protection times of 4 and 6 hours, respectively.

Risk assessment for human health
Predator Junior and Protector Cool can be used safely in terms of human health, provided the dosing and directions for use specified in this assessment report are followed. This ensures that no local or systemic effects should occur during or after the use of these products. Therefore, there is no obstacle preventing the product authorisation regarding human health.

Risk assessment for the environment
Predator Junior and Protector Cool are not considered to pose significant risks to the environment, providing that the dosing and directions for use specified in this assessment report are followed. There are no obstacles preventing the product authorization in regard to the protection of environmental health.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
PREDATOR JUNIOR. PROTECTOR COOL	Czech Republic

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Leroy Cosmetics s.r.o.
	Address	Nejdecká 600, 69144, Lednice
Authorisation number	CZ-0031370-0000	

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

Date of the authorisation	8.11.2023
Expiry date of the authorisation	8.11.2023

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Leroy Cosmetics s.r.o.
Address of manufacturer	Nejdecká 600, 69144, Lednice
Location of manufacturing sites	Lednice, Czech Republic

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

Active substance	IR3535
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strasse 250, F129/004, 64293, Darmstadt
Location of manufacturing sites	Darmstadt, Germany

2.1.2 Product (family) composition and formulation

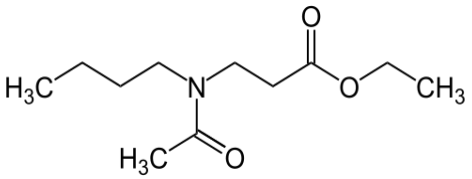
The product family consists of two biocidal products: Protector Cool (20 % w/w of the active substance IR3535) and Predator Junior (15 % w/w of the active substance IR3535).

NB: the full composition of the product is 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 3-[acetyl(butyl)amino] propanoate
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	
Minimum purity / content	99 % (w/w)
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance contained in the product is not a candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Information on technical equivalence

The active substance ethyl 3-[acetyl(butyl)amino] propanoate (IR3535) declared for the product authorisation is technically equivalent with the substance listed in the Union list of approved active substances under Regulation No. 528/2012.

2.1.2.4 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.5 Information on ED potential of co-formulants

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AE (liquid with propellant gases applied in a form of aerosol)

2.1.3 Hazard and precautionary statements[2]

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

Classification	
Hazard classes, category codes	Flam. Aerosol 1 Eye Irrit. 2
Hazard statement	H222 Flam. Aerosol 1 H319 Eye Irrit. 2
Labelling	
Signal words	Danger
Hazard statements	H222 Extremely flammable aerosol H280 Contains gas under pressure; may explode if heated. H319 Causes serious eye irritation
Precautionary statements	P102 Keep out from reach of children P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use. P260 Do not breathe spray. P273 Avoid release to the environment. P410+P412 Protect from sunlight. Do no expose to temperatures exceeding 50°C/ 122°F. P501 Dispose of contents to the hazardous waste collection point. Dispose of container to the municipal or sorted waste collection point.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description[3]

Table 1. Use # 1 – Application on skin and clothing

Product Type	PT19
Where relevant, an exact description of the authorised use	Application on skin and clothing from a distance 20-30 cm.
Target organism (including development stage)	Ticks (adults, nymphae), mosquitos (adults)
Field of use	Indoor and outdoor
Application method(s)	Spraying

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

3 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

Application rate(s) and frequency	**Protector Cool** (20% of the active substance): This product can be used once per day with the dosing of 7.31 g, 4.05 g and 2.99 g in adults, children from 6-12 years old and children from 2-6 years old, respectively. Effective as a repellent against mosquitoes and ticks with complete protection time of 6 hours at the above application rates of the product (one gram/one second) **Predator Junior** (15% of the active substance): This product can be used once per day with the dosing of 7.61 g, 4.21 g, 3.11 g, 2.19 g and 1.88 g in adults, children from 6-12 years old, children form 2-6 years old, toddlers (1-2 years old) and infants (6 moths to 1 year old). Effective as a repellent against house mosquitoes and ticks with complete protection time of 4 hours, at the application rates of the product (one gram/one second)
Category(ies) of users	Non-professional users
Pack sizes and packaging material	150 ml aluminium

2.1.4.2 Use-specific instructions for use[4]

See General directions for use

2.1.4.3 Use-specific risk mitigation measures

See General directions for use

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

See General 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

4 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5 General directions for use

2.1.5.1 Instructions for use[5]

The product can be applied directly onto the uncovered human skin from a distance of about 20-30 cm. Over face and neck, the product should be spread by hand. For children do not apply the product directly on hands.

2.1.5.2 Risk mitigation measures

Spray only in a direction away from your face. Do not inhale. The product can be applied directly onto the uncovered human skin from a distance of about 20-30 cm. Over the face and neck, the product should be spread by hand. Do not apply on sunburnt or damaged skin and near eyes and lips. For children, do not apply the product directly on hands.
Do not allow this product to reach aquatic environments, the sewer system or the ground. In case of bigger releases inform the authorities.

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

First aid measures: In case of unconsciousness, place the affected person into the recovery position, with the head slightly tilted backward. Make sure air passages are unhindered, never intentionally induce vomiting. If the affected person vomits, make sure they do not aspire vomit.
Inhalation: Remove patient to fresh air and ensure quiet and comfort for body. Do not let the patient get cold. If the problems do not recede, seek medical assistance/advice.
Eye contact: Flush with plenty of pure water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing for 10 minutes. In case of persistent inflammation, seek medical advice.
Swallowing: Rinse mouth with water provided the affected person is conscious. Do not induce vomiting; instantly seek medical help.

Person-related safety precautions: Prevent contact with source of ignition (fire, unshielded electrical bulbs). Ensure sufficient ventilation and prevent inhalation of gaseous products. Use protective equipment, in case of fire use protective clothing and self contained breathing apparatus.

Measures for environmental protection: Prevent from spreading or entering into the sewers, drains, ditches, streams or rivers. In case of bigger releases, inform the authorities.

Measures for cleaning/collecting: If possible, gather the spilled material together. Use a suitable sorbent to absorb the material (i.e., inert powdered material such as sand or lime). Place the spent sorbent in a suitable container for recovery or destroying according to the regional legislation.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Proposal for waste classification according to European waste catalogue and

5 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

hazardous waste list:
The product, its packaging and material contaminated with the product, must be disposed of as hazardous waste by passing to the licensed waste disposal site.
EWC: 20 01 19* Pesticides

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

Store the product in tightly closed original containers in upright position. Keep container closed when not in use. Store in a cool, dry and well-ventilated area away from incompatible substances (strongly oxidative agents), high temperature and sources of ignition. Keep away from food, drink, fresh water and feed. Storage temperature is from 0 to 30°C. Keep out of reach of children. No smoking. Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C.
Shelf-life: four and a half years

2.1.6 Other information

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	150 ml	aluminium	safety, plastic safety cap	Non-professionals	Yes

2.1.8 Documentation

See the active substance Assessment Report.

The applicant has submitted a Letter of access dated 09/10/2015.

2.2 Assessment of the biocidal product (family)

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

Table 2. Intended use # 1 – name of the use[6]

Product Type(s)	PT19
Where relevant, an exact description of the authorised use	Application on skin and clothing from a distance 20-30 cm.
Target organism (including development stage)	Ticks Mosquitoes
Field of use	Indoor and outdoor
Application method(s)	spraying
Application rate(s) and frequency	***Protector Cool*** (20% of the active substance): Adults and children older than 12 years max. 2 times per day, children of age between 2-12 years max. 1 times per day. The product is not intended for children younger 2 years. ***Predator Junior*** (15% of the active substance): Adults and children older than 3.5 years max. 2 times per day, for children younger than 3.5 years max. 1 times per day. The product is not intended for children younger 3 months.
Category(ies) of user(s)	Non-professionals
Pack sizes and packaging material	150 ml, aluminium

2.2.2 Physical, chemical and technical properties

Physico-chemical properties of the active substance were evaluated during the process of its inclusion in annex I of the BPD and their detailed description can be found in the CAR. The data can be used on behalf of the applicant based on the Letter of access from the data owner.

Related to the physico-chemical properties of the biocidal products Predator Junior and Protector Cool, the applicant submitted new long term stability Tests Report, or, where applicable, provided a waiver and/or justification. A brief overview of physico-chemical properties for both biocidal products and all justifications are given in the Table below.

Property	**Guideline and Method**	**Purity of the test substance (% w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual observation	BPs*	transparent liquid	Dušková, Š. 2016, 2021
Colour at 20 °C and 101.3 kPa	Visual observation	BP*	colourless	Dušková, Š. 2016, 2021
Odour at 20 °C and	Olfactory		menthol aroma	

6 Copy this section as many times as necessary (one table per use).

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
101.3 kPa	inspection	BP*		Dušková, Š. 2016, 2021
Acidity / alkalinity		BP*	Not necessary. Biocidal product pH is within the range 4-10 units. None of the components is acidic or alkaline.	
Relative density / bulk density		BP*	Not required for AE formulation types	
Storage stability test – **accelerated storage**	In accordance with ECHA Guidance Volume I: Parts A+B+C and Technical Monograph n°17, 2nd Edition Storage for 14 days at 54°C±2°C CIPAC: MT46.3	BP*	*15% of IR3535 (declared) (Predator Junior)* T(0) = 15.43 ± 0.44 % T (14d.) = 15.28 ± 0.46 % (both values in % w/w) Decrease of the AS content is 0.15% relative. *20% of IR3535 (declared) (Protector Cool)* T(0) = 20.61 ± 1.18 % T (14d.) = 20.60 ± 0.61 % (both values in % w/w) Decrease of the AS content is 0.01% relative. **<u>Conclusion:</u>** Statistically **non-significant decrease** of the AS content in both biocidal products was observed.	Dušková, Š. 2016, SZÚ
Storage stability test – **long term storage at ambient temperature**	In accordance with ECHA Guidance Volume I: Parts A+B+C and Technical Monograph n°17, 2nd Edition (GIFAP) Storage for 55 months under ambient conditions. For further details see	BP*	*15% of IR3535 (declared) (Predator Junior)* (T0) = 15.43 ± 0.44 % (T55m.) = 14.29 ± 0.55 % (both values in % w/w) Decrease of the AS content is **7.4 % relative**. **<u>Conclusion:</u>** This value 7.4 % relative for the biocidal product Predator Junior is within the tolerance interval given by the corresponding Guidance. For the product Protector Cool	Dušková, Š. 2021, SZÚ

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	the Long term stability and shelf-life justifications below the Table.		(*20% of IR3535 declared)* read across was applied. This is considered to be fully acceptable due to the identical composition and content of all coformulants in the formulation. For further details related to the compositions of formulations see the Confidential annex. For further details related to the both biocidal products stability and shelf-life period confirmation see the Long term stability testing conclusion below the Table.	
Storage stability test – **low temperature stability test for liquids**		BP*	Not required. The product is not intended to be stored under refrigerated conditions and it is not considered that the active substance may crystallize.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		BPs*	Not relevant. Biocidal product is stored in non-transparent aluminium container, i.e. lightproof packaging.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		BPs*	Not relevant. The biocidal product is stored in aluminium container tightly closed with safety cap.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		BPs*	Visual inspection/assessment was done after the long term stability testing. After the storage period of 55 months the containers/vessels were opened and inspected in detail. No corrosion, damages or any other changes compared to the original containers before the formulation filling were observed.	Dušková, Š. 2021, SZÚ

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Wettability		BPs*	Not relevant. The product is neither a solid preparation, nor formulation to be dispersed in water. Biocidal product is ready-to-use repellent spray.	
Suspensibility, spontaneity and dispersion stability		BPs*	Not relevant. The product is neither wettable powder, aqueous suspension concentrate, water dispersible granules or powder, nor formulation forming suspensions on dilutions with water. The biocidal product is ready-to-use repellent spray. Moreover, the formulation was inspected in detail after 55 months of storage. Formulation was colourless and fully transparent liquid.	Dušková, Š. 2021, SZÚ
Wet sieve analysis and dry sieve test		BPs*	Not relevant. The product is neither wettable powder, suspension or dispersible concentrate, water dispersible or soluble granules or powder, aqueous capsule suspension, nor suspo-emulsion.	
Emulsifiability, re-emulsifiability and emulsion stability		BPs*	Not relevant. The preparation do not forms or maintains in a form of stable emulsion. The product is ready-to-use repellent spray.	
Disintegration time		BPs*	Not relevant. The product is not a soluble or dispersible tablet.	
Particle size distribution, content of dust/fines, attrition, friability		BPs*	Not relevant. The product is not a powder or granules.	
Persistent foaming		BPs*	Not relevant. The product contains pressurised gases and it is applied as aerosol. The product is not intended to be applied in water for use. The product is ready-to-use repellent spray.	
Flowability/Pourability/Dustability		BPs*	Not relevant. The product is neither suspension	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			concentrate, capsule suspension, nor emulsion. The product is ready-to-use repellent spray.	
Burning rate — smoke generators		BPs*	Not applicable. The product is not a smoke generator.	
Burning completeness — smoke generators		BPs*	Not applicable. The product is not a smoke generator.	
Composition of smoke — smoke generators		BPs*	Not applicable. The product is not a smoke generator.	
Spraying pattern — aerosols		BPs*	See the justification below the Table.	
Physical compatibility		BPs*	Not relevant. The product is not intended to be used or stored with any other products.	
Chemical compatibility		BPs*	Not relevant. The product is not intended to be used, stored or mixed with any other products.	
Degree of dissolution and dilution stability		BPs*	Not relevant. The product is neither soluble bag, tablet, nor solid to be diluted in water.	
Surface tension		BPs*	Not required for AE formulation types	
Viscosity		BPs*	Not required for AE formulation types	

*BPs = Refers to both biocidal products tested, i.e. Protector Cool (20 % w/w of the active substance IR3535) and Predator Junior (15 % w/w of the active substance IR3535). For further details related to the full composition of the biocidal products tested see the Confidential annex attached. For a dummy solution of the same composition the fraction of particles smaller than 5 µm was shown to be below 0.6 %. Hence, the respirable fraction is below 0.3 % and therefore it is assumed that the other 99.7 % precipitate in the upper airways and are taken in orally (see IR3535 Assessment Report). Letter of access to CAR was supplied.

Conclusion on the physical, chemical and technical properties of the product
Biocidal products Predator Junior and Protector Cool are an aerosol based products, formed from transparent and colourless liquid, with menthol aroma, and propellant gasses. Storage conditions: Light influence is avoided by using a lightproof packaging. There are no humidity effects expected in tightly closed package. Physical and chemical compatibility with any other products is not relevant. Both biocidal products are ready-to-use repellent formulations applied in the form of aerosols generated from the formulation filled in and supplied in the original commercial packaging, i.e. pressurised vessels fit for given purpose of the application. Products are not intended to be used,

stored or mixed with any other products, chemicals or any formulations.

Long term stability testing conclusion, justification, shelf-life:
The long term stability testing of the AS in the BP Predator Junior was performed in accordance with the requirements of ECHA Guidance Volume I: Parts A+B+C and related to the Technical Monograph No. 17, 2nd Edition. The pressure vessels were stored at the required temperature and storage conditions for 55 months. At the end of this period, the mass concentration of the AS IR3535 in the formulation was determined (04/06/2021) and compared with the mass concentration value of the AS in the BP at the beginning of the long-term stability tests (i.e. time T0, dated 26/09/2016, value measured within the accelerated stability testing under the same samples). The average decrease of the AS content taken from 9 parallel measurements of the mass concentration values IR 3535 in the BP Predator Junior after 55 months of storage was 7.4% relative compared to the initial AS mass concentration value. This value is within the tolerance interval given by the corresponding Guidance. The long term stability of the BP within the given storage period and under defined conditions was therefore confirmed. The four and half year shelf life of the biocidal product Predator Junior could be agreed. Taking into account the identical composition, with all coformulants included, of the biocidal product Protector Cool, read across for the BP Protector Cool from the BP Predator Junior for the equivalent shelf life confirmation is reasonable and could be applied. Both biocidal product were therefore found to be stable within the four and half year shelf life period.

Visual inspection and assessment of the products after long-term storage:
The weight change of the pressure vessels from T(0) to T (55 months) was less than 0.5%. The condition of the product packaging (150 ml pressure vessels with an approximate weight of 140 g) and the functionality of the aerosol dispenser after the long term stability tests remained unchanged. No leaks, corrosion or degradation of the packaging were visible. For visual comparison, a larger amount of the formulation from the pressure vessel was sampled and this liquid was compared with a fresh mixture used for the filling of the pressure vessels. No changes were observed. The liquid was still colourless with a characteristic odour of the original mixture.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test subst. % w/w	Results	Reference
Explosives			Based on the Guidance on the Application of the CLP Criteria, a mixture need not be classified for explosive properties provided that none of the substance/constituent in the mixture possesses explosives properties as well as there are no chemical groups present in the molecule of each constituent associated with potential explosive properties. However, relevant alerts are arising from the final formulation type and/or packaging. Biocidal product, as a final product to be marketed, is a liquid mixture with extremely flammable propellants under pressure in one application vessel/packaging, and is to be applied in the form of aerosol. These alerts are covered by relevant hazards and precautionary statements. See justifications and conclusions later.	
Flammable gases			Biocidal product contains flammable gases/propellants under pressure and is classified as extremely flammable. For further details, see the relevant section below, i.e. flammable aerosols. Classification related to the formulation type "aerosols" is applied.	
Flammable aerosols			Biocidal product contains flammable gases/propellants under pressure and ethanol in the liquid part of the mixture. Biocidal product is classified in accordance with relevant Chapters of the Guidance on the Application of the CLP Criteria, i.e. Chapter 2.3.4. Classification of aerosols, 2.3.4.1. Classification criteria, Annex I: 2.3.2.1., 2.3.2.2. Based on the general note for this formulation type AE, "Aerosols containing more than 1% flammable components…" (for further details related to the product's composition, see the Confidential Annex to the PAR), classification with H222 (AE Category 1) was applied.	
Oxidizing gases			None of the component of the product's mixture has oxidizing properties. Based on the Guidance on	

Property	Guideline and Method	Purity of the test subst. % w/w	Results	Reference
			the Application of the CLP Criteria, biocidal product is classified as formulation type "Aerosols."	
Gases under pressure			Biocidal product contains gases/propellants under pressure. Final product as marketed is a ready-to-use repellent spray in pressurized containers/vessels to be applied in the form of aerosol. Classification procedure as above. Relevant hazard and precautionary statements were applied. Label claims included.	
Flammable liquids			Biocidal product contains ethanol. Product is classified as extremely flammable. Classification procedure as mentioned above.	
Flammable solids			Not relevant. Product is not solid.	
Self-reactive substances and mixtures			There are no chemical groups present in the molecule of all constituents associated with self-reactive properties. Moreover, experiences in manufacture, handling and/or storage show that the product is known to be stable at room temperature for prolonged periods of time.	
Pyrophoric liquids			Biocidal product does not contain pyrophoric components.	
Pyrophoric solids			Not relevant. Product is not solid.	
Self-heating substances and mixtures			Biocidal product does not contain self-heating components and as a mixture is not self-heating. Moreover, substances bounded with this phenomenon are never used as aerosol contents.	
Substances and mixtures which in contact with water emit flammable gases			Product's mixture is not able to emit flammable gases in contact with water. It contains extremely flammable gases/propellants under pressure and is classified as extremely flammable as it is. Therefore, it is also scientifically not reasonable to deal with potential flammable gases emission.	
Oxidizing liquids			Not relevant. None of the components in the formulation have oxidizing properties.	
Oxidizing solids			Not relevant. Product is not solid.	
Organic peroxides			Biocidal product contain neither organic peroxides nor their precursors.	
Corrosive to metals			Biocidal product do not contain	Dušková, Š.

Property	Guideline and Method	Purity of the test subst. % w/w	Results	Reference
			components corrosive to metals. Visual inspection/assessment of the inner layer of the containers was done after the storage period of 55 months. Containers/vessels were opened and inspected in detail. No corrosion, damages or any other changes compared to the original containers/vessels were observed.	2021, SZÚ
Auto-ignition temperatures of products (liquids and gases)			Classification of the biocidal product as extremely flammable aerosol, Category 1, covered by hazard statement H222 and by relevant precautionary statements, makes these test on the auto-ignition temperature pointless. Biocidal product's classification was performed/done based on the composition of the final mixture and product's formulation type to be marketed and applied as AE in accordance with the relevant Chapters of the CLP Guidance.	
Relative self-ignition temperature for solids			Not relevant. Product is not solid.	
Dust explosion hazard			Not relevant. Product is not solid.	

Conclusion on the physical hazards and respective characteristics of the product

The classification of the product as extremely flammable is warranted by the content of propellant gases each classified as extremely flammable. For further details related to the product's composition, see the Confidential annex to the PAR. Biocidal product is not classified for explosive or oxidizing properties from the point of view of the individual constituents and/or co-formulants as mentioned within the relevant end-points above. Classification was performed in accordance with the Guidance on the Application of the CLP Criteria, Chapter 2.3.4. Classification of aerosols, 2.3.4.1. Classification criteria, Annex I: 2.3.2.1., 2.3.2.2. Based on the general note related to the classification of aerosols containing more than 1% flammable components, classification with H222 (i.e. AE, Category 1) could be done and was applied by default. Relevant hazards and precautionary statements covering risks given by the content of extremely flammable gasses/propellants under pressure are stated. Biocidal product supplied/marketed, to be used/applied in the form of aerosol, must be stored, handled and disposed accordingly. Label claims are stated.

2.2.4 Methods for detection and identification

Analytical methods are evaluated for the determination of the active substance (IR3535) in the biocidal products and in water only. See the final conclusion at the end of this Chapter.

2.2.4.1 Analytical methods for the active substance in the biocidal product

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. AS)	**Method**	**Fortification range / Number of measurements**	**Linearity for each 5 point calibration prepared**	**Specificity**	**Validation parameters:** *Accuracy (as recovery) **Precision (as rel. std. deviation of repeatability) Values in % relative. For 15 and 20% w/w AS**			**LOQ (AS) LOD (AS)**	**Reference**
					*Range	*Avg.	**RSD		
AS *IR 3535*	GC-FID	3 samples 3-times repeated measure-ments per sample	R^2=0.99+ Linear for proposed concentrations of AS IR3535.	below the Table	***20%*** 95.5-111.5 **15%** 98.3-106.7	***20%*** 103.1 **15%** 102.9	***20%*** 5.9 **15%** 2.9	**LOQ** 0.3 % **LOD** 0.1 %	Dušková, Š., 2016, SZÚ
Identification of the active substance was made via the retention time using AS standard supplied with Certificate of analysis. All the control chromatograms generally have no peaks above the chromatographic background and the spiked/fortified samples chromatograms contain only the analyte peak of interest, i.e. for AS, at the relevant retention time. No interfering peaks were observed. All peaks were well defined and symmetrical, evaluated and described.									

Description of the analytical method and quality assurance, conclusion:
The determination of the AS IR 3535 in the samples was performed by GC-FID on a DB-5ms UI 30 m x 0.25 mm x 0.25 µm column. The method was developed and validated by the laboratory. In order to verify the repeatability and overall quality assurance of the analytical method used, the samples were measured under repeatability conditions, i.e. on one day, by one operator and per one calibration. To support the overall QC reliability of the method used the samples were measured on another day, by an independent calibration and by different operator. All AS mass concentration values measured were compatible under the definition of metrological compatibility (VIM3). It is possible to conclude on an adequate and sufficient precision, i.e. repeatability, as well as on accuracy covered by recovery, of the analytical method used. Taking into account the setting up and the possibilities of the method itself, all values of the AS measured can be attributed with the corresponding and satisfactory informative value for the given purpose. The tightness of the values measured to the values declared by the applicant further supports the sufficient trueness. The method is suitable for the given purpose of the determination.

2.2.4.2 Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Analytical methods for water									
Analyte (type of analyte e.g. AS)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**LOQ LOD**	**Reference**
					Range	Avg	RSD		
Active substance	HPLC–MS/MS Internal standard: phenacetin 100-1000x dilution	Not given	R^2-values of the calibration curves were >0.99 (5-9 points), calibration matrix matched standards	Specificity was provided using selective MS-MS detector in SIM mode.	**			**LOQ** (urine) 3 µg/L (IR3535) 2 µg/L (free acid) **LOD** (urine) 0.6 µg/L (IR3535) 0.4 µg/L (free acid)	T. H. Broschard, A. M. Bohlmann, S. Konietzny, U. M. D. Schauer, W. Dekant 2013: Biotransformation and toxicokinetics of the insect repellent IR3535® in male and female human subjects after dermal exposure. *Toxicology Letters*, 218, 246–252.*

*The method was developed for the determination of the IR3535 and its metabolites in urine and blood plasma. According to its parameters (LOD, LOQ), the method is suitable also for the determination of IR3535 in water (PNEC-water value is 100 µg/L).
**Phenacetin was used as an internal standard to eliminate loss of the analytes during the sample preparation phase.

Conclusion on the methods for the detection and identification of the product
For the determination of the IR3535 in the formulation GC-FID method was developed. For the determination of the IR3535 in water HPLC-MS/MS method can be used based on the LoA. According to the active substance Assessment report, analytical methods for residue analysis in soil are not required as significant residues in soil can be excluded, thus no method for residues in soil is need. Analytical methods for residue analysis in the air are not required. Product spray applications involve large droplets which are not respirable. Analytical methods for residue analysis in body fluids and tissues are not required. No product components are classified as toxic. Analytical methods for residue analysis in foods and feeding stuff are not required. The product is not used in manner which may cause contact with such material. Apart from the active substance the product contains no substance of concern for the environment.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Predator Junior and Protector Cool are a self pressurised aerosol designed to protect humans by repelling of ticks and mosquitoes insects. The efficacy of the product is ensured by the content of the active ingredient IR3535. The efficacy of IR3535 was assessed during the review program under biocidal directive and is described in detail in the relevant section Assessment Report for IR3535.

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

Mosquitoes (*Aedes aegypti*), adults.
Mosquitoes (*Culex pipiens quinquefasciatus*), adults.

Ticks (*Ixodes ricinus*), adults and nymphae
Protection of human, including children and people with sensitive skin.

2.2.5.3 Effects on target organisms, including unacceptable suffering:

The products has a repellent effect on target organisms. IR3535 acts mainly via the vapour phase. The mode of action of IR3535 is an active repellent effect to prevent insects to enter places with IR3535 vapours.

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. 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.
The active substance is an activity modulator of insect olfactory receptors (ORs) of the yellow fever mosquito *Aedes aegypti* (due to strong inhibition of *AaOR8* and *AaOR2* receptors). For detailed information see e.g.:

Bohbot J.D., Dickens J.C. 2010. Insect Repellents: Modulators of Mosquito Odorant Receptor Activity. *PLoS ONE* 5(8): e12138.
Bohbot J. D., Dickens J. C. 2012. Odorant receptor modulation: ternary paradigm for mode of action of insect repellents. *Neuropharmacology*, 62, 2086-2095.
Debboun, M., Frances, S. P., Strickman, D. 2015. *Insect Repellents Handbook*, 2nd Ed., CRC Press, Boca Raton, 2015.

2.2.5.5 Efficacy data

The applicant has submitted six studies by IUCLID in support of the efficacy of Protector Cool and Predator Junior as a repellent for use against mosquitoes and ticks.
CZ CA evaluated these studies, considers two relating to mosquitoes and one relating to ticks to be acceptable in support of the product authorisation. The additional three studies are supplementary evidence (Rettich 2009, 2011 and 2016).
A summary of the studies from the 2017 is presented in the following table. Methods based on WHO arm-in-cage test was applied for the efficacy testing against target organisms in these tests. Qualitative and quantitative information on the composition of the liquid (15% and 20% IR3535) used in the efficacy test Rettich 2017 are submitted in the confidential annex. The liquid is to be applied at an application rate of 0.5 ml per forearm (cca 600cm^2 skin). This is approximately equivalent to 0.167 mg IR3535 per cm^2 skin (liquid with 20% IR3535) and 0.125 mg IR3535 per cm^2 skin (liquid with 15% IR3535).

For ethical reasons, field test were not requested and arm-in-cage tests are considered as sufficient.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Repellent (PT 19)	Skin/clothing	*IR3535 (15% and 20 %)*	*Ixodes ricinus* (female adults and nymphaea)	Fall-off test	Predator junior and Protector cool applied on human skin, 0.5 ml of the liquid (propellant gases are not included) per forearm. The ticks were placed to the treated skin 1,2,3,4 and 6 hours after the product application.	Application of 0.5 ml of both products to human forearm skin. It resulted in 4 and 6 hours repellent effect after the application Predator junior and Protector cool, respectively (≥ 90% repellence during the claimed efficacy period).	*Rettich, F. Expertizní zpráva, Exp. Č. 171246, NRL CEM, SZÚ Praha, 2017.*
Repellent (PT19)	Skin/clothing	*IR3535 (15 and 20 %)*	*Aedes aegypti* Female adults Bora-Bora strain	Number of bites per min.	Predator junior and Protector cool applied on human skin, 0.5 ml of the liquid per forearm. The repellent effect was tested 1,2,3,4 and 6 hours after the product application.	Sufficient repellent effect (mean complete protection time) was found to be 4 hours for Predator junior and 6 hours for Protector cool.	*Rettich, F. Expertizní zpráva, Exp. Č. 171246, NRL CEM, SZÚ Praha, 2017.*

Repellent (PT19)	Skin/clothing	*IR3535 (15 % and 20%)*	*Culex pipiens quinquefasciatus* Female adults Hyderabad strain	Number of bites per min.	Predator junior and Protector cool applied on human skin, 0.5 ml of the liquid per forearm. The repellent effect was tested 1,2,3,4 and 6 hours after the product application.	Sufficient repellent effect (mean complete protection) was found to be 5 and 6 hours for Predator junior and Protector cool, respectively.	*Rettich, F. Expertizní zpráva č.: 171246. NRL CEM, SZÚ Praha, 2017.*

Conclusion on the efficacy of the product
Application of 0.5 ml of the product (with 15 and 20 % of the active substance) to human forearm skin indicate repellent effect for ticks at least 4 hours after the product application. For applied dose 0.5 ml sufficient repellent effect for *Aedes* sp. mosquitoes was found to be at least 4 hours for the product with 15 % and 6 hours with 20 % of the active substance. Application of 0.5 ml of the product (with 15 and 20 % of the active substance) cause sufficient repellent effect for *Culex* sp. mosquitoes for 5 hours for the product with 15% and 6 hours with 20 % of the active substance. In conclusion, products Predator Junior and Protector Cool are effective as a repellent against house mosquitoes and ticks for maximum protection times of 4 and 6 hours respectively.

2.2.5.6 Occurrence of resistance and resistance management

As the efficacy is due to the active ingredient, evaluation of resistance and its possible development is only relevant for IR3535. Development of resistance to IR3535 is not known. Due to the repellent action of the active substance, insects are only repelled, not killed. Therefore there is no selection pressure and resistance is not likely to develop. No management strategy is necessary.

2.2.5.7 Known limitations

Factors such as ambient temperature, humidity and sweating may influence the efficacy. No other limitations on efficacy, undesirable or unintended side effects are known.

2.2.5.8 Evaluation of the label claims

The following label claim are justified:
Repells mosquitoes (*Aedes* sp.and *Culex* sp.) minimally for 4 hours for Predator Junior and 6 hours for Protector Cool.
Repells ticks minimally for 4 hours for Predator Junior and 6 hours for Protector Cool.

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

The product will not be used with other products.

2.2.6 Risk assessment for human health

As the products contain no substance of concern risk assessment of both products rests in calculating the exposure and comparing the result with the AEL for the active substance.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Study report	Product with 15 % of active substance 15% of IR3535 Aerosol	Frosh-Klingman test*, according to the Cosmetic Product Test Guideline for the Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997 Adult volunteers, 23-56 years old, male and female.	Primary dermal irritation index (PDII) mean value = 0 (no irritation) Primary dermal irritation index (PDII) max. value = 0 (no irritation)	*Rulcová J. Skin tolerance test for children up to 3 years of age (Test kožní tolerance pro děti do 3 let věku). Protokol č. 3/2009. Centrum estetické dermatologie Syncare Plus s.r.o. Brno, 2008.*

* Frosh-Klingman test (repeated epicutaneous plaster test with occlusion): Occlusive plaster with 0.10 ml of the product was applied on the upper part of the volar surface of the arm. The product was applied on the plaster surface - the 1st day for 24 hours, and the 2nd-5th day for 6 hours. The product was applied underneath of the plaster. After each taking off the plaster, skin irritation was evaluated and the plaster was substituted. Index of skin irritation was evaluated on the end of the test, and 5 and 10 days after test termination.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Without visible skin reaction.
Justification for the value/conclusion	The product (15% of IR3535) application does not lead to skin corrosion or irritation. The study results are reliable only for low concentrated member of the product family (Predator Junior).
Classification of the product according to	No classification according to CLP and DSD.

CLP and DSD	

Data waiving	
Information requirement	Study is not required
Justification	No component of the product (both family members, Protector Cool and Predator Junior) is classified for this endpoint.

Eye irritation

Data waiving	
Information requirement	study is not required
Justification	Due to high content of the active substance (> 10 %) the product is classified with Eye Irrit. 2; H319 (see *Guidance on the Application of the CLP Criteria*, ECHA, 2015). Non-active components of the product classified for this endpoint, menthol (0.4 %; Eye Dam. 1; H318) and denatonium benzoate (0.01 %; Eye Irrit. 2; H319), do not contribute to the classification of the product.

Respiratory tract irritation

Data waiving	
Information requirement	study is not required
Justification	No respiration tract irritation effect is noted for the active substance. The product is not classified for respiratory tract irritation. Non-active components of the product classified for this endpoint, menthol (0.4 %; STOT SE3; H335) and denatonium benzoate (0.01 %; STOT SE3; H335) do not contribute to the classification of the product.

Skin sensitization

Data waiving	
Information requirement	study is not required
Justification	No skin sensitisation effect is noted for all product components. The product is not classified for this endpoint.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	study is not required
Justification	No respiration tract sensitisation effect is noted for any product component. The product is not classified for this endpoint.

Acute toxicity

Acute toxicity by oral route

No study on acute toxicity of the product is provided by the applicant. According to the BPR, if the toxicity of the product can be extrapolated form that of individual components no studies are required. The product contains no substance of concern for human health, none of its components is suspected of synergistic effects or potentiation of the active substance toxicity. Therefore, the acute toxicity profile of the product is determined by that of the active substance. As the active substance is not classified for acute toxicity it follows that the product is not classified either. The relevant endpoints for the active substance are provided. N-acetyl-3-N-n-butylaminopropionic acid (IR3535-free acid), main metabolite, is rapidly formed and degraded, hence covered by toxicity tests on IR3535.

Data waiving	
Information requirement	study is not required
Justification	The active substance is not classified for oral acute toxicity. Non-active components of the product classified for this endpoint, menthol (0.4 %; Acute toxicity, Oral (Category 5); H302) and denatonium benzoate (0.01 %; Acute toxicity, Oral (Category 4); H302) do not contribute to the classification of the product.

Acute toxicity by inhalation

Data waiving	
Information requirement	study is not required
Justification	No product components are classified as toxic via inhalation route. In addition, the spray application of the product involve large droplets which are not respirable (according to the active substance Assessment Report aerosol droplets of the dummy product are large and tend to sediment rapidly). Furthermore, according to *Technical Notes to the Guideline on Human Exposure*, 2002, part 2, the inhalation route is considered as irrelevant for the risk assessment of the product as it is used outdoors or when there is sufficient ventilation rate indoors (e.g. in the summer). For the active substance this issue is covered in the relevant sections of the Assessment Report for IR3535.

Acute toxicity by dermal route

Data waiving	
Information requirement	study is not required
Justification	No product components are classified for dermal acute toxicity. For the active substance this issue is covered in the relevant sections of the Assessment Report for IR3535.

Information on dermal absorption

Data waiving	
Information requirement	
Justification	For 20% aqueous solution of IR3535 (dummy solution) dermal absorption was 14 % (according to the active substance Assessment Report). This value is acceptable also for the product, because of the similar composition (20% a.s. in water/ethnol) of the product and the dummy solution and the product does not contain any surfactants or dermal absorption enhancing substances.

Published experimental study of dermal application of approx. 3 g of a formulation containing 20% IR3535 (ethanol: 35 %, water 31.5%) found skin penetration rate of IR3535 13.3%. However, used model solution contains also some components enhancing dermal absorption: Polyethylene glycol 400 (5 %), PPG-15 stearyl ether (1 %), Polyethylene glycol 1500 (4 %), PVP/VA W-735 (1 %) and Polysorbate 20 (1.5 %). Determined penetration rate of 13.3 % for IR3535 can thus reasonably be considered as a worst-case value for skin absorption.

T. H. Broschard, A. M. Bohlmann, S. Konietzny, U. M. D. Schauer, W. Dekant 2013: Biotransformation and toxicokinetics of the insect repellent IR3535® in male and female human subjects after dermal exposure. *Toxicology Letters*, 218, 246–252

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

No product components are classified as toxic. No non-active substance can be classified as a substance of concern. Hence the product contains no substace of concern for human health, none of its componets is suspected of synergistic effects or potentiation of the active substance toxicity.

Available toxicological data relating to a mixture

No product components are classified as toxic. No non-active component is considered as substance of concern.

Other

Neither the active substance nor any coformulants are classified for carcinogenicity, teratogenicity or mutagenicity.

2.2.6.2 Exposure assessment

The exposure calculations are performed for Protector Cool (20 % w/w) and Predator Junior (15%), which is also water/ethanol-based product.

The products are self-pressurized aerosols applied directly onto uncovered skin and /or onto the clothing through which a part can penetrate to the skin. Thus, systemic exposure is due primarily to dermal route of exposure. Exposure via oral route is prevented with presence of bittering agent (denatonium benzoate) in the product formulation. Exposure via inhalation is unlikely. In the Assessment Report for IR3535 it is stated that the aerosol droplets of the dummy product are large and tend to sediment rapidly. According to

Technical Notes to the Guideline on Human Exposure, 2002 (part 2, p. 272) the inhalation route is excluded due to the use outdoors, and because use indoors only takes place in the summer in situations where there is a high ventilation rate. On these grounds, the inhalation exposure to aerosol sprays is also considered to be negligible.

Possible secondary (indirect) routes of exposure are: hand to mouth transfer for small children, a parent/adult applying (spraying) the product on children and herself/himself and an inhalation of volatilized residues after application indoors.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Product application	Application of the product onto skin	Non-professionals
2.	Secondary exposure	Hand to mouth transfer.	Non-professionals
3.	Secondary exposure	A parent/adult applying (spraying) the product on children and herself/himself.	Non-professionals
4.	Secondary exposure	Inhalation of volatilized residues after application indoors.	Non-professionals

Industrial exposure

The product is intended for use by non-professionals only. Industrial users can be exposed to the products or its ingredients during the product formulation. This stage is higly automated, performed primarily in closed systems and by operators using suitable PPE. Furthermore, the product is formulated in the Czech Republic, where risk due to occupational exposure is covered by relevant legislative abidance by which is enforced by relevant inspection bodies.

Professional exposure

The product is intended for use by non-professionals only. Professional use is not envisaged. If a professional decides to use the product in their job, then they are assumed to follow the instructions for the non-professional. Such use is assumed to be of low frequency and considered as covered by the non-professional use.

Non-professional exposure

The product is to be used by non-professionals as consumer product. It is applied on the uncovered parts of the body, to intact skin of adults and children or to the clothing. The following application frequency was recommended by the applicant:
Protector Cool (20% of a.s.): Adults and children older than 12 years max. 2 times per day, children of age between 2-12 years max. once per day. The product is not intended for children younger 2 years.
Predator Junior (15% of a.s.): Adults and children older than 3.5 years max. 2 times per day, for children younger than 3.5 years max. once per day.
The product should not be applied near eyes, lips and damaged (e.g. sunburnt) skin. For children, application of the product directly on hands is prohibited.
The non-professional user can be dermally exposed using the product. The vapour pressure of IR3535 is 0.15 Pa at 20 ºC, therefore respiratory exposure can potentially occur. However, due to the high ventilation rate indoors and the use outdoors, the inhalation exposure is not envisaged. The product can be applied indoors and outdoors. Exposure via hand to mouth contact is also possible for small children. In the IR3535 Assessment Report it is stated that hand to mouth transfer is not considered to be a significant route of exposure because of addition of bittering agent, preventing repeated mouthing of the product by children. Furthermore, a restriction do not apply the product to children's hands is included in the IR3535 Assessment Report.
The applicant has no measured values for dermal exposure. Therefore, the minimum tested efficacious dose is proposed to be used for exposure calculation. For comparison the UK Proforma approach is used to calculate the maximum safe doses for both products.

Scenario [1] Application of the product on skin

Description of Scenario [1]

UK proforma approach:

Table 1: Systemic dermal exposure when insect repellent containing 20% of the a.s. is applied to skin for relevant user groups listed (UK PROFORMA for AEL of 5 mg/kg)					
	Adult	**Child (6 to < 12 years)**	**Child (2 to < 6 years)**	**Toddler (1 to <2 years)**	**Infant (6 to < 12 months)**
Body weight	60 kg	23.9 kg	15.6 kg	10 kg	8 kg
Total body surface (cm^2)	16600	9200	6800	4800	4100
Exposed area of skin where insect repellent applied (cm^2) (55% of area)	9130	5060	3740	2640	2255
Amount of product (a.s.) to be applied (g)	10.7 (2.14)	4.27 (0.85)	2.79 (0.56)	1.79 (0.36)	1.43 (0.29)
Amount of product [a.s.] to be applied per cm^2 of skin (mg/cm^2)	1.17 [0.23]	0.84 [0.17]	0.74 [0.15]	0.67 [0.13]	0.54 [0.11]
Amount of a.s. on skin surface (mg)	2140	850	560	360	288
Dermal penetration	14%	14%	14%	14%	14%
Systemic dermal dose (mg/kg bw/day)	**4.99**	**4.98**	**5.02**	**5.04**	**5.04**

Table1a: Systemic dermal exposure when insect repellent containing 15 % of the a.s. is applied to skin for relevant user groups listed (UK PROFORMA for AEL of 5 mg/kg)					
	Adult	**Child (6 to < 12 years)**	**Child (2 to < 6 years)**	**Toddler (1 to <2 years)**	**Infant (6 to < 12 months)**
Body weight	60 kg	23.9 kg	15.6 kg	10 kg	8 kg
Total body surface (cm^2)	16600	9200	6800	4800	4100
Exposed area of skin where insect repellent applied	9130	5060	3740	2640	2255

(cm^2) (55% of area)					
Amount of product (a.s.) to be applied (g)	14.3 (2.14)	5.68 (0.85)	3.71 (0.56)	2.39 (0.36)	1.91 (0.29)
Amount of product [a.s.] to be applied per cm^2 of skin (mg/cm^2)	1.56 [0.23]	1.12 [0.17]	0.99 [0.15]	0.90 [0.13]	0.85 [0.11]
Amount of a.s. on skin surface (mg)	2140	850	560	360	288
Dermal penetration	14%	14%	14%	14%	14%
Systemic dermal dose (mg/kg bw/day)	**4.99**	**4.98**	**5.02**	**5.04**	**5.04**

CZCA calculated the exposure using UK Pro-forma approach. This gives maximum amount of the products/a.s. that can be safely applied per day. The amount of the active substance per unit skin area (cm2) provided above (Table 1 and 1a) is directly comparable with the efficacious dose determined in the section on efficacy above.

The efficacious doses for Protector Cool (20% a.s.) and Predator Junior corresponds to 0.16 mg a.s./cm^2 and 0.125 mg a.s/cm^2, respectively. Thus, the efficacious dose for Protector Cool is lower than the highest safe doses for adults (0.23 mg a.s./cm^2) and children from 6 years old (0.17 mg a.s./cm^2). The efficacious dose for Predator Junior is lower than the highest dose for all the age groups apart from the infant.

Scenario [2] Hand to mouth transfer

Description of Scenario [2]
Exposure via hand to mouth contact is irrelevant if bittering agent (denatonium benzoate) is present in the product formulation and/or direct application of the product on children hands is prohibited in the *Directions for use* of the product. This is the case for Protector Cool and Predator Junior. Therefore, the secondary exposure via hand to mouth contact is not calculated.

Scenario [3] Parent/adult applying (spraying) the product on children and herself /himself

Description of Scenario [3]
As the applied products are expected to be rubbed over the skin of children by adults with bare hands, the oral route will also be important for adults in this case. This scenario is not included either in *Technical Notes to the Guidance on Human Exposure* or *Biocides Human Health Exposure Methodology* According to IR3535 Assessment Report, if bittering agent is present in the product

formulation, no oral exposure is proposed in adults applying the product on children.

Scenario [4] Inhalation of volatilized residues

Description of Scenario [4]
According to the IR3535 *Assessment Report* (p. 19) this scenario is relevant, however, calculation procedure is not described there. A screening test calculated according to the HEEG Opinion 13: *Assessment of Inhalation Exposure of Volatilised Biocide Active Substance* (p. 2) give value 2.12, this is higher than threshold value = 1; hence inhalation exposure should be included in the risk assessment. However, according to *Technical Notes to the Guideline on Human Exposure*, 2002 (part 2, p. 272) the inhalation route is excluded due to the use outdoors, and because use indoors only takes place in the summer in situations where there is a high ventilation rate. Hence no inhalation exposure is proposed.

Exposure of the general public

See Non-professionals exposure

Combined exposure scenario

As scenarios 2,3,4 are redundant due to the reasons stated in the corresponding sections the combined exposure is equivalent to the exposure calculated for scenario 1.

Monitoring data

No data.

Dietary exposure

Human exposure to IR3535 via food is not considered to be relevant because IR3535 is not used for and/or during food production, or in rooms where food is produced, processed or stored. This is also the case for feeding stuffs.

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

No contact of drinking water, foods or feeding stuffs with the product is proposed. No contact of drinking water, foods or feeding stuffs with the product is proposed. The product will not be used in rooms where food is produced, processed or stored. According to *Instructions for the use* the product should not be in contact with foods and feeding stuffs. According to *Instructions for the use* the product should not be in contact with foods and feeding stuffs.

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

No contact of drinking water, foods or feeding stuffs with the product is proposed. The product will not be used in rooms where food is produced, processed or stored. According

to *Instructions for the use* the product should not be in contact with foods and feeding stuffs.

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

Industrial users can be exposed to the products or its ingredients during the product formulation. This stage is highly automated, performed primarily in closed systems and by operators using suitable PPE. Furthermore, the product is formulated in the Czech Republic, where risk due to occupational exposure is covered by relevant legislative abidance by which is enforced by relevant inspection bodies.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) mg/kg bw/d	AF*	Correction for oral absorption**	Value mg/kg bw/d
AELshort-term	IR3535 Assessment Report	500	100	no	5
AELmedium-term	IR3535 Assessment Report	500	100	no	5
AELlong-term	IR3535 Assessment Report	500	100	no	5
ARfD	IR3535 Assessment Report				Not applicable
ADI	IR3535 Assessment Report				Not applicable

*** Default AF value included in the IR3535 Assessment Report.**

** Oral absorption: 100 %

Risk for professional users

The product is intended for use by non-professionals only. Professional use is not envisaged. If a professional decides to use the product in their job, then they are assumed to follow the instructions for the non-professional. Such use is assumed to be of low frequency and considered as cover by the non-professional use.

Risk for non-professional users

Systemic effects

CZCA calculated the exposure using UK Pro-forma approach. This gives maximum amount of the products/a.s. that can be safely applied per day. The amount of the active substance per unit skin area (cm^2) provided above (table 1 and 1a) is directly comparable with the efficacious dose determined in the section on efficacy above.

The efficacious doses for Protector Cool (20% a.s.) and Predator Junior (15% a.s.) corresponds to 0.16 mg a.s./cm^2 and 0.125 mg a.s/cm^2, respectively. Thus, the efficacious dose for Protector Cool is lower than the highest safe doses for adults (0.23 mg a.s./cm^2) and children from 6 years old (0.17 mg a.s./cm^2). The efficacious dose for Predator Junior is lower than the highest dose for all the age groups.

Table1 Risk characterization for efficacious dose of Protector Cool for AEL of 5 mg/kg)

	Adult	**Child (6 to < 12 years)**	**Child (2 to < 6 years)**	**Toddler (1 to <2 years)**	**Infant (6 to < 12 months)**
Body weight	60 kg	23.9 kg	15.6 kg	10 kg	8 kg
Exposed area of skin where insect repellent applied (cm^2) (55% of area)	9130	5060	3740	2640	2255
The efficacious amount of a.s. to be applied per cm^2 of skin (mg/cm^2)	0.16	0.16	0.16	0.16	0.16
Amount of product/a.s. on skin surface (mg)	7305/1461	4045/809	2990/598	2110/422	1805/361
Dermal penetration	14%	14%	14%	14%	14%
Systemic dermal dose (mg/kg bw/day)	3.41	4.74	5.36	5.91	6.31
% AEL	68.2	94.8	107	**118**	**126**

Table1a Risk characterization for efficacious dose of Predator Junior for AEL of 5 mg/kg					
	Adult	**Child (6 to < 12 years)**	**Child (2 to < 6 years)**	**Toddler (1 to <2 years)**	**Infant (6 to < 12 months)**
Body weight	60 kg	23.9 kg	15.6 kg	10 kg	8 kg
Exposed area of skin where insect repellent applied (cm^2) (55% of area)	9130	5060	3740	2640	2255
The efficacious amount of a.s. to be applied per cm^2 of skin (mg/cm^2)	0.13	0.13	0.13	0.13	0.13
Amount of product/a.s. on skin surface (mg)	7606/1141	4213/632	3113/467	2193/329	1879/282
Dermal penetration	14%	14%	14%	14%	14%
Systemic dermal dose (mg/kg bw/day)	2.66	3.70	4.18	4.62	4.93
% AEL	53.2	74.0	83.6	92.4	98.6

Local effects
The product is classified with H319 Eye Irrit. 2A. Accidental contact of the product with eyes cannot be excluded (e.g. during application on face). Hence, according to the *Directions for the use*, the product should not be applied near eyes and lips.

Conclusion

Protector Cool (20 % of IR3535). The efficacious product doses are 7.31, 4.05, 2.99 g can be applied once per day onto adults, the child 6 to 12 years, and the child 2 to 6 years respectively. For the child 2- 6 years the applied dose exceeds the AEL by 7% w/w. This exceedance can be mitigated by restrictions on label for use by children over child 2 to 6 years old will be required: these shall include the phrases communicating that the product shall not be applied to hands of children 2-6 years old. With this restriction RMS considers use in children 2-6 years old as sufficiently safe.

Predator Junior (15 % of IR3535). The efficacious product doses are 7.61, 4.21, 3.11, 2.19 and 1.88 g can be applied once per day onto adults, the child 6 to 12 years, and the child 2 to 6 years, Toddler (1 to <2 years) and Infant (6 to < 12 moths)**,** respectively.

Risk for the general public

See Risk for non-professional users

Risk for consumers via residues in food

According to *Instructions for the use* the product will not be used in rooms where food is produced, processed or stored and will not be in contact with foods and feeding stuffs.

2.2.7 Risk assessment for animal health

The product will be used only for humans. In addition, according to the IR3535 Assessment Report the active substance is not toxic for higher animals.

2.2.8 Environmental risk assessment

The eco-toxicological profile of Protector Cool and Predator Junior is determined by the content of the active component IR3535. The product contains no other eco-toxicologically relevant substances. Thus, risk characterization for the environment is based on the environmental exposure and effects of the active ingredient IR3535. This compound is used in insect repellents (PT19) that are applied on uncovered human skin. Products containing IR3535 will be used indoors and outdoors. The main emission pathways to the environment are assumed to be due to bathing/showering of treated people (direct emissions to STP) and due to release from treated skin during swimming (direct emissions to surface water). Based on the physico-chemical properties, it is expected that the emissions will primarily affect the aquatic compartment.

2.2.8.1 Effect assessment (environment)

The ecotoxicological profile of the biocidal products Predator Junior and Protector Cool is driven by the content of the active substance IR3535, which is not classified as toxic for the environment according to the rules laid down in Reg. (EC) 1272/2008 (CLP). The product contains no other ecotoxicologically relevant substances. Synergistic effects among the components are not expected.
The effect values determined for the active compound were taken from the Assessment Report on IR3535.
According to the Assessment Report on the active substance, IR3535® does not meet any of the criteria for Persistent, Bioaccumulative and Toxic (PBT) substances or the very Persistent, very Bioaccumulative (vPvB) category. IR3535® is not carcinogenic, mutagenic or teratogenic. No indication or data for IR3535® are available that indicate potential endocrine disruptive properties.

Summary of the effect values (taken from the Assessment Report)

Summary of the effect values (taken from Assessment Report]	
Endpoint (species)	**Effect value**
LC50-96h (Zebra fish)	>100 mg a.s./L
EC50-48h (Daphnia magna)	>100 mg a.s./L
E_bC50 (D. subspicatus) E_rC50 (D. subspicatus)	>100 mg a.s./L >100 mg a.s./L
EC20 (microorganisms) EC50 (microorganisms) EC80 (microorganisms)	>1000 mg a.s./L >1000 mg a.s./L >1000 mg a.s./L

Classification of the active substance IR3535

Active substance	**Classification**	***Readily biodegradable (yes/no)***	***Concentration in the product***
IR3535	-	no	Protector Cool: 20% Predator Junior: 15%

Further Ecotoxicological studies

No further data is available. The data on the active substances provides sufficient information.

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

The product is applied to skin only. It can enter i) STP *via* bathing/showering of treated people and ii) surface water due to release from treated skin during swimming. Direct emissions to the environment are considered as disperse both in space and time, and therefore rather negligible. No ingredient of the product is considered of concern for the environment. Therefore, no further study is needed for this product.

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

Please refer to the subsection *Fate and distribution in exposed environmental compartments* under 2.2.8.2.

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

No data is available. The fate of the components in the product is covered by the data provided for the active substance (Assessment report).

Testing for distribution and dissipation in soil (ADS)

According to the Assessment Report of the active substance IR3535, only limited and local emissions to soil are expected due to the method of application directly on skin. IR3535 is not likely to become accumulated in soil in large amounts and contamination due to sludge application to agricultural soil is proposed to be negligible.

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

The product contains only one active substance and no substance of concern. Risk assessment is thus covered in the relevant sections of the IR3535 Assessment Report. No direct emissions of the active substance to water are proposed. According to the

Assessment Report of active substance IR3535, the two main indirect emission pathways to the environment are assumed to be as follows:

1) showing/bathing + washing the garments
2) swimming in surface water bodies.

In the first case, emissions to the water are *via* STP. Related experimental data are available in the active substance Assessment Report.

Testing for distribution and dissipation in air (ADS)

IR3535 is a liquid with low vapour pressure (0.15 Pa at 20°C), which presumes negligible emissions to air during product application. Furthermore, the half-life of IR3535 in air is short (13.16 hours, Assessment report) due to the fast reaction of the active substance with OH-radicals. Thus, accumulation of IR3535 in air and long-range transport are unlikely. Similarly, secondary emissions to the air are also expected to be negligible due to the low volatility (Henry's Law constant value of 4.61 x 10^{-4} Pa m^3 mol^{-1}) of IR3535.

Physico-chemical characteristics and half-life of IR3535 in air

Physico-chemical characteristics and half-life of IR3535 in air			
Parameter	**Value**	**Unit**	**Remarks**
Molecular weight	215.29	g/mol	Assessment Report (IR3535)
Melting point	-90	°C	Assessment Report (IR3535)
Boiling point	300	°C	Assessment Report (IR3535)
Vapour pressure at 20°C	0.15	Pa	Assessment Report (IR3535)
Henry's Law Constant (20 °C)	$4.613 \cdot 10^{-4}$	Pa/m3/mol	Assessment Report (IR3535)
$DT50_{air}$ (OH radicals)	13.16	h	Assessment Report (IR3535)

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)

The product is applied directly to human skin. Direct emissions to outdoor air are considered to be negligible.

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

The product is not intended to be used as an insecticide, acaricide or for the control of arthropods (PT18). It will be applied directly on human skin, emissions to the air are therefore considered to be negligible. A study to assess risk to bees and non-target arthropods are therefore deemed unnecessary.

2.2.8.2 Fate and distribution in the environment

According to the Assessment Report, the vapour pressure of IR3535 is low (0.15 Pa at 20 °C), which implies low emissions and exposure concentrations in the atmosphere. The half-life of IR3535 in air was calculated to be 13.16 hours due to reaction with OH-radicals (24-hr day). Thus, accumulation of IR3535 in air and long-range transport are unlikely. Secondary emissions to air also are improbable. IR3535 has a Henry's Law constant value of 4.61 x 10^{-4} Pa m^3 mol^{-1}, which indicates that volatilization from surface water is not expected to be an important process. In an aerobic water/sediment degradation study, IR3535 was shown to remain mainly in the water phase. There it was first rapidly degraded to its free acid, after which this metabolite ultimately degraded after a lag phase (see IR3535 Assessment Report). IR3535 is a liquid at room temperature and the solubility in water is 70 g/L (at 20 °C). The log Kow is 1.7 (at 23-24°C) indicating that IR3535 has a low potential for bioaccumulation or accumulation in sediment. IR3535 is not considered to be readily biodegradable.
The products Protector Cool and Predator Junior are intended to be applied as repellents (PT19) directly on human skin. In the current Emission Scenario Document for Product Type 19 – Repellents and attractants (2015), two emission scenarios are proposed:
1. Removal through showering and bathing of humans as well as washing of garments.
2. Release to surface water bodies through swimming.

The relevant receiving compartments were therefore identified to be as follows:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	No	No	No	No	No

2.2.8.3 Exposure assessment

The products are intended to be applied as repellents (PT19) directly on human skin. In the current *Emission Scenario Document for Product Type 19 – Repellents and attractants* (2015), two emission scenarios are proposed:

General information

Assessed PT	*PT 19*
Assessed emission scenarios	*Scenario 1: Bathing and showering of humans and washing of garments* *Scenario 2: Release to surface water bodies 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 based on:* - *Guidance on BPR (Volume IV Environment, Part B + C, 2017)* - *Emission mission Scenario Document for Product Type 19 – Repellents and attractants, May 2015* - *EUSES Model (SimpleTreat4.0)*
Groundwater simulation	*Not performed*
Confidential Annexes	*No*
Life cycle steps assessed	*Scenario 1: Bathing and showering of humans and washing of garments* *Production: No* *Formulation No* *Use: Yes* *Service life: No* *Scenario 2: Release to surface water bodies through swimming* *Production: No* *Formulation: No* *Use: Yes* *Service life: No*
Remarks	

Emission estimation

The product will be applied directly on human skin. The main emission pathway to the environment is assumed to be indirect through bathing/showering of treated humans (direct emission to wastewater, Scenario 1) and through swimming (direct emission to surface water, Scenario 2). In Scenario 1, the sewage treatment plants are the primary recipients of the emissions, whereas surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for remnants *via* sewage treatment plant effluents and sewage sludge applications, respectively.

The calculation of environmental emissions for the products in question is based on the *Emission Scenario document for Product Type 19 (2015)* concerning repellents and attractants and the Guidance on BPR (Volume IV Part B + C, 2017). For calculations, the content of 20% of the active substance in the product Protector Cool and the content of 15% of a.s. in the product Predator Junior were considered. The application rate was driven by the efficacy data where the efficacious doses for Protector Cool (20% a.s.) and Predator Junior corresponds to 0.16 mg a.s./cm^2 and 0.125 mg a.s/cm^2, respectively. These efficacious doses correspond to the consumption of the product of 0.80 mg/cm^2 and 0.83 mg/cm^2, respectively. The number of applications was set to 1 following the risk

characterization in human health assessment (Section 2.2.6, part Conclusion). In the Tier 1 assessment, fractions released to air and dermally absorbed were set to 0, assuming that the whole fraction of the applied product is emitted to (waste)water.

Emission scenario for calculating the release of repellents used on human skin and garments based on the average consumption (Emission scenario document, PT 19)

a) Scenario 1 (Removal through showering and bathing of humans as well as washing of garments) – products Protector Cool and Predator Junior

Input parameters for calculating the local emission (based on average consumption)				
Scenario 1: Removal through showering and bathing of humans as well as washing of garments				
Products: Protector Cool (20% of a.s.), Predator Junior (15% of a.s.) Tier 1				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Number of inhabitants feeding one sewage treatment plant	N_{local}	1000	cap	default
Active substance in the product	$Cform_{weight}$ (Protector Cool) $Cform_{weight}$ (Predator Junior)	200 150	$g.kg^{-1}$ $g.kg^{-1}$	
Consumption (of the product) per application	$Qform_{appl}$ (Protector Cool) $Qform_{appl}$ (Predator Junior)	0.80 0.83	$mg.cm^{-2}$ $mg.cm^{-2}$	See Efficacy data
Number of applications per day	N_{appl}	1	d^{-1}	See Human health assessment
Treated area of human skin	$AREA_{skin}$	10 660	cm^2	head + arms + hands + legs+ feet
Fraction released to air	F_{air}	0	-	
Fraction dermally adsorbed	F_{skin}	0	-	
Fraction released to wastewater	F_{water}	1	-	
Fraction of inhabitants using a	F_{inh}	0.2	-	default

repellent product				
Market share of repellent	F_{penetr}	0.5	-	default
Specific density of the product	RHO_{form}	1000	$kg.m^{-3}$	default

b) Scenario 2 (Removal through showering and bathing of humans as well as washing of garments) - products Protector Cool and Predator Junior

According to Assessment Report, the DT50 (12°C) of IR3535® in water/sediment degradation study reached 15.95 days in water, which corresponds to the degradation rate constant of 4.4E-02 d^{-1}. This k_{deg} was used in Scenario 2 for calculating Clocalwater,91d-ref (i.e., the concentration in surface water arising from release of the active compound IR3535 from treated human skin during swimming including biodegradation in water).

Input parameters for calculating the local emission (based on average consumption)				
Scenario 2: Release to surface water bodies through swimming				
Products: Protector Cool (20% of a.s.), Predator Junior (15% a.s.) Tier 1				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Daily number of swimmers	$N_{swimmer}$	1500	-	default
Fraction of swimmers using the repellent product	F_{swim}	0.1	-	default (for product authorization)
Number of applications per day	N_{appl}	1	d^{-1}	default
Fraction released to surface water body	$F_{waterbody}$	1	-	default
Active substance in the product	$Cform_{weight}$ (Protector Cool) $Cform_{weight}$ (Predator Junior)	200 150	$g.kg^{-1}$ $g.kg^{-1}$	
Consumption (of the product) per application	$Qfrom_{appl}$ (Protector Cool) $Qfrom_{appl}$ (Predator Junior)	0.80 0.83	$mg.cm^{-2}$ $mg.cm^{-2}$	See Efficacy data
Treated area of human skin	$AREA_{skin}$	10 660	cm^2	head + arms + hands + legs+ feet
Specific density of the product	RHO_{form}	1 000	$kg.m^{-3}$	default
Volume of water body	$V_{waterbodz}$	435 000	m^3	default

First order rate constant for biodegradation in surface water	$Kdeg_{water}$	0.044	d^{-1}	Calculated from DT50 value (water/sediment study, Assessment Report)
Number of emission days (emission period of 1 day)	$T_{emission, 1d}$	1	d	default
Number of emission days (emission period of 91 days)	$T_{emission, 91d}$	91	d	default
Number of emission events	$N_{emission, 91d}$	91	-	default

The corresponding local emission rates, i.e., $Elocal_{water}$ ($kg.d^{-1}$) for Scenario 1 (bathing/washing) and Scenario 2 (swimming) and the two products in question (Protector Cool and Predator Junior) are presented below.

Local emission rates			
Scenario	**Product**	**$Elocal_{water}$**	**Units**
Scenario 1 Removal through showering and bathing of humans as well as washing of garments	Protector Cool (20%) Predator Junior (15%)	1.706 1.327	$kg.d^{-1}$ $kg.d^{-1}$
Scenario 2 Release to surface water bodies through swimming	Protector Cool (20%) Predator Junior (15%)	0.256 0.199	$kg.d^{-1}$ $kg.d^{-1}$

Predicted environmental concentrations (PEC)

Emissions of IR3535 will only reach the local STP in scenario 1 when topically applied products are removed from human skin by washing/showering. Typically, the PEC_{STP} can be considered as being either the $Clocal_{inf}$ or $Clocal_{eff}$ value, representing either the concentration of compound in untreated wastewater or the concentration of compound in STP effluent. In situations where release of a chemical into drains is intermittent, the use of $Clocal_{inf}$ is more appropriate for PEC_{STP} but the alternative is true in the case of daily release ($Clocal_{eff}$ should be used to represent PEC_{STP}). Although topical application of IR3535-based repellents may be considered seasonal (with a $T_{emission}$ value of 91 d used in swimming emission assessment to reflect "peak bug season"), as exposure will be continuous over this 91-day period, the discharge is not considered intermittent. Therefore, $Clocal_{eff}$ has been chosen to act as PEC_{STP}.

The $Clocal_{infl}$ was calculated in accordance with the Guidance on BPR (Volume IV, 2017) as:

$$Clocal_{\inf} = \frac{Elocal_{water} * 10^6}{EFFLUENT_{stp}} \quad \text{and} \quad Clocal_{eff} = Clocal_{\inf} * Fstp_{water}$$

Where:
$Clocal_{inf}$ = concentration in untreated wastewater (in mg l^{-1})
$Clocal_{eff}$ = concentration of substance in the STP effluent or PEC_{STP} (in mg l^{-1})
$EFFLUENT_{stp}$ = (2,000,000 l d^{-1}; default value)
$Elocal_{water}$ = local emission to (waste) water during episode (in kg d^{-1})
$Fstp_{water}$ = fraction emission directed to water by STP

Computer modelling using SimpleTreat v4.0 (integrated in EUSES) was undertaken to predict the behavior of IR3535 reaching an STP. Fraction emission directed to water by STP was calculated using the following input parameters and the data on the active substance IR3535 taken from the Assessment report on IR3535. The active compound IR3535 was shown two fail the criteria for being classified as readily biodegradable, and therefore it is considered to be inherently biodegradable (Assessment Report). Therefore, in Tier 1, the rate constant for STP was set to 0 (Guidance on BPR, Volume IV, Part B + C, 2017 – Notes on Table 4). In Tier 2, the STP rate constant was modified following the results of the STP-simulation test that showed elimination of up to 99 % after 28 days (Assessment Report).

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	Purity 99.8 %
Vapour pressure (at 20 °C)	0.15 ± 0.01	Pa	Purity 99.8 %
Water solubility (at 20 °C)	70 000	mg/l	Non buffered water
Log Octanol/water partition coefficient	1.7	Log 10	23-24 °C, HPLC method
Henry's Law Constant (at 20 °C)	4.613 x 10^{-4}	$Pa/m^3/mol$	
Rate constant for STP (OECD 303)	0 (Tier 1) 3; (Tier 2)	h^{-1}	Tier 1: No biodegradation Tier2: STP simulation experiment (OECD 303, 99% elimination within 28 days)
DT50 (hydrolysis in water)	866.13 = 36.08	h d	
DT50 (photolysis in water)	0	d^{-1}	No photolysis observed in water
DT50 (biodegradation in surface water)	15.59	d	
DT50 (soil)	-	-	Not determined

The results of the modelling describing the behavior of IR3535 in STP are presented below for Tier 1 and Tier 2 assessments.

Simple Treat 4.0 modelling describing the behavior of IR3535 in STP		
	IR 3535(%) Tier 1	**IR 3535(%) Tier 2**

Fraction of emission directed to air by STP ($Fstp_{air}$)	8.57E-04	9.07E-05
Fraction of emission directed to effluent by STP ($Fstp_{water}$)	94.22	2.725
Fraction of emission via primary settler	4.039	4.039
Fraction of emission via surplus sludge	1.745	0.051
Fraction of emission degraded in STP ($Fstp_{sludge}$)	0	93.18

The results on the distribution in STP corroborates the previous assumption that emissions of IR3535 as the active ingredients in the products Protector Cool and Predator Junior to air will generally be negligible.

The

PEC_{STP} (direct via scenario 1)

The resulting PEC_{STP} arising for the emissions covered by Scenario 1 (washing/showering) and Tier 1 and Tier 2 assessment are presented below. The highest PEC_{STP} was reported for Protector Cool in Tier 1 and reached 0.803 mg/L.

Calculation of PEC_{STP} for IR3535 resulting from scenario 1 emissions				
Scenario 1 **Product**	**Local emission rate to wastewater ($Elocal_{water}$, kg-d^{-1})**	**Concentration in non-treated wastewater, $Clocal_{infl}$ ($mg.L^{-1}$)**	**PEC for microorganisms in STP, $Clocal_{eff}$ ($mg.L^{-1}$) (Tier 1)**	**PEC for microorganisms in STP, $Clocal_{eff}$ ($mg.L^{-1}$) (Tier 2)**
Protector Cool	1.706	0.853	0.803	0.023
Predator Junior	1.327	6.64E-01	0.625	0.018

PEC_{SW} (indirect via scenario 1)

The corresponding PECsw (Scenario 1) was calculated according to:

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION}$$

Where
Clocal, eff - concentration of the substance in the STP effluent (mg/L)
Kp,susp - solids-water partition coefficient of suspended matter (L/kg)
SUSPwater - concentration of suspended matter in the river (default: 15 mg/L)
DILUTION – dilucation factor (default: 10)
Clocal, water - local concentration in surface water during emission episode (mg/L) = PECsw

Calculation of PEC_{sw} for IR3535 resulting from scenario 1 emissions				
Scenario 1 **Product**	**$Clocal_{eff}$ ($mg.L^{-1}$) (Tier 1)**	**$Clocal_{eff}$ ($mg.L^{-1}$) (Tier 2)**	**PECsw ($mg.L^{-1}$) (Tier 1)**	**PECsw ($mg.L^{-1}$) (Tier 2)**
Protector Cool	0.803	0.023	0.08	2.32E-03
Predator Junior	0.625	0.018	0.062	1.81E-03

PEC_{sw} (direct *via* scenario2)

For scenario 2, the corresponding local concentrations in water body, i.e., $Clocal_{water}$ (after 1d, over 91 days, and over 91 days including biodegradation) were calculated in accordance with the ESD (PT19) according to the equations presented below:

$$\mathbf{Clocal_{water,1d}} = Elocal_{water} * 10^3 * T_{emission,1d} / V_{waterbody}$$

$$\mathbf{Clocal_{water,91d}} = Elocal_{water} * 10^3 * T_{emission,91d} / V_{waterbody}$$

$$\mathbf{Clocal_{water,91d\text{-}ref}} = Clocal_{water,1d} * \{[1-(e^{-kdegwater * Temission,1d})^{Nemission,91d}] / [1-e^{-kdegwater * emission,1d}]\}$$

The first order rate constant for biodegradation in water was derived from the DT50 of 15.59 d determined for IR3535 in water/sediment study at 12°C (Assessment report). As a first-tier approach, the $PEC_{localwater}$ corresponds to $Clocal_{water,91d}$ and should be used for the risk assessment, representing the worst-case situation. The calculation of $Clocal_{water,91d\text{-}ref}$ value provides a refinement option considering degradation processes in the water body. Concentrations in surface water (Scenario 2) after one day, after 91 days (Tier 1), and after 91 days (refined, Tier 2) were calculated to be as follows:

Local concentrations in surface water PECsw values after 1, 91, and 91 (including biodegradation) days				
Scenario	**Product**	**Local concentration in water body after one day**	**Local concentration in water body over 91 days**	**Refined local concentration in water body over 91 days (including degradation)**
		$Clocal_{water,1d}$ ($mg.L^{-1}$)	**$Clocal_{water,91d}$ = PECsw (Tier 1)** ($mg.L^{-1}$)	**$Clocal_{water,91d\text{-}ref}$ = PECsw (Tier 2)** ($mg.L^{-1}$)
Scenario 2 Release to surface water bodies through swimming	Protector Cool (20%)	5.88E-04	0.054	0.013
	Predator Junior (15%)	4.58E-04	0.042	0.010

PEC_{sed} (Scenarios 1 and 2)

PEC_{sed} values were derived from PEC_{sw} (91d and 91d-refined) using the following equations:

$$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000$$

and

$$K_{comp\text{-}water} = Fair_{comp} \cdot K_{air\text{-}water} + Fwater_{comp} + Fsolid_{comp} \cdot \frac{Kp_{comp}}{1000} \cdot RHOsolid$$

$$with\ comp \in \{soil, susp, sed\}$$

and

$$Kp_{comp} = Foc_{comp} \cdot Koc$$

Where,
$K_{susp\text{-}water}$ is suspended matter-water partition coefficient (m^3/m^3)
RHO_{susp} is bulk density of wet suspended matter (1150 kg/m^3)
RHOsolid is density of the solid phase (2500 kg_{solid}/m_{solid}^3)
$F_{water\ susp}$ is volume fraction of water in susp. matter (0.9 m_{water}^3/m_{susp}^3)
$F_{solid\ susp}$ is volume fraction solids in susp. matter (0.1 m_{solid}^3/m_{susp}^3)
$F_{oc\ susp}$ is weight fraction organic carbon sediment solids (0.1 kg_{oc}/kg_{solid})
K_{oc} equals 475.25 L/kg (Assessment report)

Scenario	**Product**	**PECsed (Tier 1)**	**PECsed (Tier 2)**
		($mg.kg_{wwt}^{-1}$)	**($mg.kg_{wwt}^{-1}$)**
Scenario 1 Removal through showering and bathing of humans as well as washing of garments	Protector Cool (20%)	0.892	0.026
	Predator Junior (15%)	0.694	0.020
Scenario 2 Release to surface water bodies through swimming	Protector Cool (20%)	0.595	0.148
	Predator Junior (15%)	0.463	0.115

PEC_{sludge}
The concentration of IR3535 in sludge was calculated on the basis of IR3535 behavior in STP, where in Tier 1 assessment, no degradation in STP was proposed. For Tier 2 assessment, the results of the respiration inhibition study with activated sludge (99% degradation within 28 days) were taken into account.

Scenario	**Product**	**PECsludge (Tier 1)**	**PECsludge (Tier 2)**
		($mg.kg^{-1}$)	**($mg.kg^{-1}$)**

Scenario 1 Removal through showering and bathing of humans as well as washing of garments	Protector Cool (20%)	121.1	85.64
	Predator Junior (15%)	94.22	66.64
Scenario 2 Release to surface water bodies through swimming	Protector Cool (20%)	-	-
	Predator Junior (15%)	-	-

PEC$_{soil}$

The concentration of IR3535 in soil is proposed to be a result of sludge application to soil for 10 consecutive years in an amount of 5 000 kg/ha/y for agricultural soil and of 1 000 kg/ha/y for grassland. In line with the Guidance on BPR (Volume IV, Parts B + C, 2017), the concentrations in soil after the last sludge application were averaged over 30 or 180 days.

Scenario	**Product**	**PEC soil (Tier 1)**			**PEC soil (Tier 2)**		
		agrisoil 30d	**agrisoil 180d**	**grassland 180d**	**agrisoil 30d**	**agrisoil 180d**	**grassland 180d**
		(mg.kg$_{wwt}^{-1}$)			**(mg.kg$_{wwt}^{-1}$)**		
Scenario 1 Removal through showering and bathing of humans as well as washing of garments	Protector Cool (20%)	0.288	0.241	0.091	0.204	0.171	0.0605
	Predator Junior (15%)	0.224	0.188	0.071	0.159	0.133	0.05
Scenario 2 Release to surface water bodies through swimming	Protector Cool (20%)	-	-	-	-	-	-
	Predator Junior (15%)	-	-	-	-	-	-

Calculated PEC values

The summary of relevant PEC values is provided below.

Scenario Product	**PEC$_{STP}$**	**PEC$_{sw}$**	**PEC$_{sed}$**	**PEC$_{soil}$**	**PEC$_{GW}$** (groundwater under agricultural soil)
	[mg/L]	[mg/L]	[mg/kg$_{wwt}$]	[mg/kg$_{dwt}$]	[mg/L]

Scenario 1 (Protector Cool)	0.803 (Tier 1) 0.023 (Tier 2)	0.080 (Tier 1) 2.32E-03 (Tier 2)	0.892 (Tier 1) 0.0206 (Tier 2)	0.288[a]; 0.241[b]; 0.091[c] (Tier 1) 0.204[a]; 0.171[b]; 0.065[c] (Tier 2)	0.028 (Tier 1) 0.020 (Tier 2)
Scenario 1 (Predator Junior)	0.625 (Tier 1) 0.018 (Tier 2)	0.062 (Tier 1) 1.81E-03 (Tier 2)	0.694 (Tier 1) 0.02 (Tier 2)	0.224[a]; 0.188[b]; 0.071[c] (Tier 1) 0.159[a]; 0.133[b]; 0.005[c] (Tier 2)	0.022 (Tier 1) 0.016 (Tier 2)
Scenario 2 (Protector Cool)	-	0.054 (Tier 1) 0.013 (Tier 2)	0.595 (Tier 1) 0.148 (Tier 2)	–	–
Scenario 2 (Predator Junior)	–	0.042 (Tier 1) 0.010 (Tier 2)	0.463 (Tier 1) 0.115 (Tier 2)	–	–

[a] value for agricultural soil averaged over 30 days; [b] value for agricultural soil averaged over 180 days; [c] value for grassland soil averaged over 180 days

2.2.8.4 Risk characterization

PNEC values

The PNEC values for risk characterization were estimated according to the *Guidance on BPR (Volume IV, Part B+C, 2017)* from effect values using appropriate assessment factors ($PNEC_{water}$ and $PNEC_{STP}$) or equilibrium partitioning method ($PNEC_{sed}$ and $PNEC_{soil}$) as outlined below. $PNEC_{air}$ value was not calculated because no emissions to this compartment are proposed. The risk for the marine environment is supposed to be covered by the freshwater risk assessment.

PNEC$_{sed}$

PNEC$_{sed}$ was derived on a basis of the equilibrium partition method using the following equation and input values:

$$PNEC_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \cdot PNEC_{water} \cdot 1000$$

Where
PNECwater is predicted no effect concentration in water (0.1 mg/L)
RHOsusp is bulk density of sediment (1150 kg/m^3)
Ksusp-water is suspended matter-water partition coefficient (12.78 m^3/m^3)

PNEC$_{soil}$

PNEC$_{soil}$ was derived on a basis of the equilibrium partition method using the following equation and input values:

$$PNEC_{soil} = \frac{K_{soil-water}}{RHO_{soil}} \cdot PNEC_{water} \cdot 1000$$

Where
PNECwater is predicted no effect concentration in water (0.1 mg/L)
RHOsoil is bulk density of soil (1700 kg/m^3)
Ksoil-water is soil-water partition coefficient (14.46 m^3/m^3)

Summary of the PNEC values

Summary of PNEC values		
Compartment	**PNEC value**	**Remarks**
PNEC$_{STP}$	10 mg/l	(assessment factor of 100, Table 19 in Guidance on BPR, Volume IV, Parts B+C)
PNEC$_{SW}$	0.1 mg/l	(assessment factor of 1000; Table 18 in Guidance on BPR, Volume IV, Parts B+C))
PNEC$_{SED}$	1.11 mg/kg$_{wwt}$	(equilibrium partitioning method, see below)
PNEC$_{SOIL}$	0.85 mg/kg$_{wwt}$	(equilibrium partitioning method, see below)

Atmosphere

The vapor pressure of IR3535 is low (0.15 Pa at 20 °C), which results in low exposure to the atmosphere. Due to the method of application (directly on the human skin), no significant emissions to air are expected. The half-life of IR3535 in air was reported in the Assessment Report to be 13.16 hours due to reaction with OH-radicals. Thus, accumulation of IR3535 in air and long-range transport are unlikely. Secondary emissions to air are also improbable due to the low K$_{air-water}$ value (calculated) of 1.23E-07 m^3/m^3 and the low Henry's Law constant of 4.61 x 10^{-4} Pa m^3 mol^{-1}, which both indicate that volatilization from surface water is not expected to be an important process.

Conclusion: No risk due to emissions of the active substance to air is expected.

Sewage treatment plant (STP)

IR3535 is primarily emitted to the STP in Scenario 1. Therefore, the PEC/PNEC$_{stp}$ values were calculated for the STP compartment in Scenario 1 for the products Predator Cool and Predator Junior in Tier 1 and Tier 2 assessments. In neither case, the PEC/PNEC values exceeded 1 (see the table below).

The PEC/PNEC values for STP for the two products (Protector Cool, Protector Junior) and Scenario 1 – showering/bathing and washing, in Tier 1 and 2 assessments

Product Protector Cool (20%)	PEC/PNEC$_{stp}$
Scenario 1 (Tier 1)	0.08
Scenario 1 (Tier 2)	0.00
Product Predator Junior (15%)	PEC/PNECstp
Scenario 1 (Tier 1)	0.06
Scenario 1 (Tier 2)	0.00

Conclusion: For both Tier 1 and Tier 2 assessments, PEC/PNEC$_{STP}$ values are lower than 1 using PECs values calculated according to the Guidance on BPR, Volume IV, Parts B + C (2017).

Aquatic/sediment compartment

The active compound IR3535 is proposed to be inherently biodegradable (Assessment report). For Scenario 1 values of the PEC/PNEC ratios were calculated in both Tier 1 and Tier 2 assessments for water emitted from a STP to surface water. No biodegradation of the active substance (k=0 d^{-1}) for the Tier 1 and 95-99% degradation (k=3 h^{-1}) of the active substance for Tier 2 in the STP were proposed. For Scenario 2, no degradation (k=0 d^{-1}) of the active substance was considered in Tier 1 assessment, while inherent degradation (DT50 of 15.59 d at 12°C in water derived in the water/sediment biodegradation study) of the active substance was proposed in Tier 2 assessment. Emission to fresh water (Tier 1) is expected to be the worst-case. Therefore, risk for the marine environment is covered by the freshwater risk assessment.

For the sediment compartment, the PNEC$_{sed}$ value were derived on the basis of the partitioning equilibrium method. As both PEC$_{sed}$ and PNEC$_{sed}$ were derived using the same calculation to modify PEC$_{sw}$ and PNEC$_{sw}$, then the risks posed to sediment compartment (in the form of PEC/PNEC) are identical to those posed to surface waters.

Product Protector Cool (20%)	PEC/PNEC$_{sw}$	PEC/PNEC$_{sed}$
Scenario 1 (Tier 1)	0.80	0.80
Scenario 1 (Tier 2)	0.02	0.02
Scenario 2 (Tier 1)	0.54	0.54

Scenario 2 (Tier 2)	0.13	0.13
Product Predator Junior (15%)	$PEC/PNEC_{sw}$	$PEC/PNEC_{sed}$
Scenario 1 (Tier 1)	0.62	0.63
Scenarion 1 (Tier 2)	0.02	0.02
Scenario 2 (Tier 1)	0.42	0.42
Scenario 2 (Tier 2)	0.10	0.10

Conclusion: For both Scenario 1 and Scenario 2, the PEC/PNEC ratios calculated for the two products were below 1 in Tier 1 assessment for both surface water and sediment. Therefore, the application of the products is not expected to cause significant risks to the aquatic compartment.

Terrestrial compartment

Due to the method of application (directly on the human skin), no direct emissions to soil are expected. The active compound IR3535 can enter the soil environment *via* the application of contaminated sludge. For sludge application to agricultural soil, the application rate of 5,000 kg/ha dry weight per year was used. For grassland, the application rate of 1 000 kg/ha/yr was used. According to the active substance Assessment Report (p. 26), IR3535 is not likely to accumulate in the soil in large amounts, but no information concerning degradation of IR3535 in soil is available in this document. For Tier 1 assessment in Scenario 1, the worst-case scenario omitting degradation of the active substance in STP was therefore proposed and the half-life of IR3535 in soil was set to 300 days in accordance with Table 6 in the Guidance on BPR (Volume IV, Parts B + C, 2017). In Tier 2, the degradation in STP was taken into account, where according to the respiration inhibition test with activated sludge, 99% of IR3535 was degraded within 28 days (Assessment report).

Atmospheric deposition was considered negligible for the reasons specified above. No terrestrial toxicity tests results were available for IR3535 (Assessment report), and, therefore, the $PNEC_{soil}$ value (0.85 mg/kg_{wwt}) was calculated using the equilibrium partitioning method. The resulting PEC/PNEC values for soil for Tier 1 (no degradation in STP) and Tier 2 (IR3535 considered inherently biodegradable according to the Assessment Report) are reported. The PEC_{soil} value entering the calculation of PEC/PNEC ratio represents the highest concentration of IR3535 in soil that was observed for agricultural soil fertilized with sludge for 10 consecutive years and averaged over 30 days.

Product Protector Cool (20%)	$PEC/PNEC_{soil}$
Scenario 1 (Tier 1)	0.34
Scenario 1 (Tier 2)	0.24
Product Predator Junior (15%)	$PEC/PNEC_{soil}$
Scenario 1 (Tier 1)	0.26
Scenarion 1 (Tier 2)	0.19

Conclusion: No direct emissions of the active substance to soil are expected. According to the $PEC/PNEC_{soil}$ ratio calculated for two soil types, the risks due to sludge application to agricultural soil/grassland are considered to be negligible.

Groundwater

Due to the method of application (directly on the human skin), no direct emissions to groundwater are expected. Emissions of the active substance to groundwater may occur due to the application of sludge to soils. The calculated concentration of IR3535 in groundwater due to sludge application to agricultural soil resulted in PEC_{gw} values below 0.1 µg/L (the trigger value for pesticides in groundwater). In addition, no risks were identified for the soil compartment.
Conclusion: The PECgw were found to be below the trigger value of 0.1 µg/L, applied in the risk assessment of pesticides. In addition, no significant risk to the terrestrial compartment was identified due to sludge application on agricultural field/grassland.

Primary and secondary poisoning

Primary poisoning
None of the components of the product is classified as toxic. The product will be applied directly on human skin, no emissions to environment are proposed. Hence, primary poisoning due to direct exposure to this product is not expected.

Secondary poisoning
None of the components of the product is classified as toxic. The low values of $logK_{ow}$ (1.7) and BCF (5.56 L/kg) suggest that IR3535 has a low bioaccumulation potential (BMF = 1; Guidance on BPR, Volume IV, Parts B + C, 2017). The active substance interacts only with olfactory receptors of the target organisms, and it is not ingested. Hence, the risk of secondary exposure *via* ingestion of contaminated food (e.g., earthworms or fish) by birds or mammals is considered to be negligible.

Conclusion: Due to intended use of the products as repellents applied directly to human skin, the associated exposure patterns, and assumed low potential for bioaccumulation of the active substance IR3535 (Assessment report), primary and secondary poisoning are considered to be unlikely. The risks to birds and mammals are therefore considered to be relatively low and related PNECs are not presented.

Mixture toxicity

The product contains one active substance and no substance of concern. None of the product components is classified as toxic.

Overall conclusion on the risk assessment for the environment of the product
Based on the available data, it can be concluded that members of Protector Cool family, when used in accordance with the proposed label (WG/GA) complies with the environmental standards and will not cause unacceptable effects on the environment.

2.2.9 Measures to protect man, animals and the environment

The applicant did not include any risk mitigation measures for the environment in the proposed label (WG/GA) and in the *Pratical Use of Biocides* (PGB-PUB) drafts. Additional

risk mitigation measures are not required, considering that risks to the environment are acceptable for the intended use.

2.2.10 Assessment of a combination of biocidal products

The products contain single active substance and will not be used together with other products. The assessment of a combination of biocidal products is therefore not required.

3 ANNEXES[7]

3.1 List of studies for the biocidal product (family)

Dušková, Š., Test report dated 26/09/2016, Accelerated storage stability testing report Accelerated storage stability testing of the AS ethyl butylacetyl aminopropionate (IR3535) in the biocidal products Protector Cool and Predator Junior, CHPPL, SZÚ Praha, 2016.

Dušková, Š., Test report dated 04/06/2021, Long-term storage stability testing report Long-term storage stability testing of the AS IR3535 in the biocidal product Predator Junior stored for 55 months period at ambient temperature, CHPPL, SZÚ Praha, 2021.

Rettich, F. Certification of efficacy for repellents Predator junior and Protector cool against ticks Ixodes ricinus under laboratory conditions (Ověření účinnosti repelentů Predator junior a Protector cool proti klíšťatům Ixodes ricinus v laboratorních podmínkách) Expertizní zpráva, Exp. Č. 171246, NRL CEM, SZÚ Praha, 2017.

Rettich, F. Certification of efficacy for repellents Predator junior and Protector cool against mosquitoes Aedes aegypti under laboratory conditions (Ověření účinnosti repelentů Predator junior a Protector cool proti komárům Aedes aegypti v laboratorních podmínkách) Expertizní zpráva, Exp. Č. 171246, NRL CEM, SZÚ Praha, 2017.

Rettich, F. Certification of efficacy for repellents Predator junior and Protector cool against mosquitoes Culex sp. under laboratory conditions (Ověření účinnosti repelentů Predator junior a Protector cool proti komárům Culex sp. v laboratorních podmínkách). Expertizní zpráva č.: 171246. NRL CEM, SZÚ Praha, 2017.

Rulcová J. Skin tolerance test for children up to 3 years of age (Test kožní tolerance pro děti do 3 let věku). Protokol č. 3/2009. Centrum estetické dermatologie Syncare Plus s.r.o. Brno, 2008.

3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

See IR3535 Assessment Report.

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

3.4 Residue behaviour

See IR3535 Assessment Report.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[8]

See the attached IUCLID file.

3.6 Confidential annex

See the confidential file.

3.7 Other

Not given.

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