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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

SPRAY REPULSIF IR200

Product type 19

Ethyl butylacetylaminopropionate
(Further referred to as IR3535®)

Case Number in R4BP: BC-GP074783-18

Evaluating Competent Authority: France

Date: 24/08/2022

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Note to the reader

This consolidated PAR for the minor change application of the SPRAY REPULSIF IR200 product authorisation is based on the PAR of the reference product INSECT REPELLENT PUMP SPRAY LICE IR3535 20% evaluated by the Belgium Competent Authority, in which all necessary addenda have been included.

The SPC (in section 2.1 of the PAR) corresponds to the authorised uses in the frame of the minor application 2022.

In the following assessment report of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post-authorisation data…). The assessments related to the minor change 2022 of the product are at the end of each concerned section and are highlighted in grey.

History of the dossier

Application type	Ref MS	Case number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	BE	BC-PR013536-21	29/03/2017	Initial assessment of the reference product : Insect Repellent Pump Spray Lice IR3535 20%
NA-BBS	FR	BC-BF039835-45	04/07/2018	National authorisation of same biocidal product (Name of the product : SPRAY REPULSIF ANTIPOUX CHEVEUX)
NA-MAC	FR	BC-QN044792-19	06/03/2020	National application for major change : - Addition of intended uses (2.2.1) - Modification of the device delivering the required dose for the biocidal product - Change in the shelf life from 18 to 24 months - Replacement of the current came by SPRAY REPULSIF IR200 - Addition of trade names - Administrative changes

NA-MIC	FR	BC-FG069209-40	17/02/2022	National application for minor change : - Change in the shelf life from 18 to 24 months - Addition of a spray discharge device
NA-MIC	FR	BC-GP074783-18	24/08/2022	National application for minor change : - Change in the shelf life from 24 to 30 months

1 CONCLUSION

⇨ MINOR CHANGE 2022

The biocidal product SPRAY REPULSIF IR200 is a ready-to-use leave-on repellent (PT19) to be applied on clean and dried human hair, skin and clothes. It is intended to be used to repel human head-lice (*Pediculus humanus capitis*) only after a pediculicidal treatment and mosquitoes and ticks.

This minor change application consists in the change of the shelf-life from 24 to 30 months.

Conclusion of the physico-chemical and technical properties

New storage stability studies submitted shows that the product is stable after 30 months of storage at ambient temperature for all devices.

The shelf-life can be therefore extended to 30 months.

⇨ MINOR CHANGE 2021

The biocidal product SPRAY REPULSIF IR200 is a ready-to-use leave-on repellent (PT19) to be applied on clean and dried human hair, skin and clothes. It is intended to be used to repel human head-lice (*Pediculus humanus capitis*) only after a pediculicidal treatment and mosquitoes and ticks.

This minor change application consists in the change of the shelf-life from 18 to 24 months and the addition of a spray discharge device.

Conclusion of the physico-chemical and technical properties

New storage stability studies submitted shows that the product is stable after 24 months of storage at ambient temperature in the new system device.

The shelf-life can be therefore extended to 24 months and the addition of a spray discharge device with a 300 µL discharge rate is supported with sufficient data. .

➔ MAJOR CHANGE 2019

The biocidal product SPRAY REPULSIF IR200 is a as a ready-to-use leave-on repellent (PT19) to be applied on clean and dried human hair, the nape of the neck and behind ears. It is intended to be used to repel human head-lice (*Pediculus humanus capitis*) only after a pediculicidal treatment.

SPRAY REPULSIF IR200 is the new name of the product claimed in the frame of the major change. The initial product is SPRAY REPULSIF ANTIPOUX CHEVEUX.

SPRAY REPULSIF ANTIPOUX CHEVEUX is a same biocidal product as the reference product INSECT REPELLENT PUMP SPRAY LICE IR3535 20%.

This major change application consists in the addition of uses for non-professionals:

- Textile spraying to prevent re-infestation by head lice (intended use #2);

- Clothes spraying to repel mosquitoes (intended use #3) and ticks (intended use #5);

- Cutaneous spraying to repel mosquitoes (intended use #4) and ticks (intended use #6);

- Textile spraying to repel dust mites (intended use #7).

The change request also concerns the modification of the device delivering the dose required for the biocidal product, the increase in shelf life from 18 to 24 months, and administrative modifications.

Conclusion of the physico-chemical and technical properties

The product SPRAY REPULSIF IR200 is an AL – another liquid. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
The change of the device delivering the dose required (a new spray system of 100 and 250 mL) for the biocidal product was supported with sufficient data.

A new accelerated storage study was provided with the new system sprayer. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. **As the long term storage study is not yet available and the previous study is not acceptable after 24 months storage (loss of active substance >10%), the shelf life of the product is therefore kept at 18 months.**

Conclusion of Efficacy

French competent authorities (FR CA) considers that the elements presented, in the frame of the assessment of the major change application, are sufficient to demonstrate the efficacy of the product SPRAY REPULSIF IR200:

For intended use #3 :

- against mosquitoes (genus *Culex spp.* and *Aedes spp.*) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,

- against mosquitoes (genus *Anopheles spp.* and *Aedes spp.*) with a protection time of 3 hours when applied on skin at the application rate of 8 g product/m² under tropical conditions,

For intended use #4 :

- against mosquitoes (genus *Culex* spp. and *Aedes* spp.) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under temperate conditions during a protection time of 8 hours after application and up to 30 days after storage in a closed packaging (such as a plastic bag),
- against mosquitoes (genus *Anopheles* spp. and *Aedes* spp.) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under tropical conditions during a protection time of 8 hours after application and up to 30 days after storage in a closed packaging (such as a plastic bag),

For intended use #5 :

- against ticks (*Ixodes ricinus*) when applied on textile (cotton and polyester) at the application rate of 8.5 g product/m² under temperate conditions during a protection time of 6 hours after application and up to 7 days after storage in a closed packaging (such as a plastic bag).

For intended use #6 :

- against ticks (*Ixodes ricinus*) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,

For intended use #7 :

- against House Dust mites (*Dermatophagoïdes pteronyssinus*) up to 24 hours when applied on bed linen (cotton) at the application rate of 8.5 g product/m²,

Nevertheless, FR CA considers that the elements presented in the dossier are not sufficient to demonstrate the efficacy of the product SPRAY REPULSIF IR200 against human head lice (*Pediculus humanus capitis*) when applied on bed linen and/or cloth's surface (cotton and polyester) at the application rate of 10 g product/m² under temperate conditions (intended use #2). Indeed the efficacy tests provided present methodological biases (random behaviour of lice in controls, not attracted by the textile) and the test design is not relevant to derive a CPT.

Conclusion of risk characterisation for Human Health

For Intended use #4 (Spray for skin application to repel mosquitoes) :

- Temperate condition: The risk is unacceptable for adult and children considering two applications per day (as claimed by the applicant) but acceptable considering only one application.
- Tropical condition: The risk is unacceptable for adult and children of 12 years and more considering two applications per day (as claimed by the applicant) but acceptable for only one application. For children younger than 1 year to 6 years, the risk is unacceptable.

For intended use #5 (Spray to treat clothes against ticks):

- The risk is unacceptable for children younger than 1 year.

For intended use #6 (Spray for skin application to repel ticks)

- The risk is unacceptable for adult and children under 12 years considering two applications per day as claimed by the applicant but acceptable with only one application.

For other intended uses (intended uses #2, #3 and #7), risk is acceptable for adults and children in the conditions of uses specified in the SPC.

Combined exposure:

For Intended use #4 (Spray for skin application to repel mosquitoes) tropical conditions and Intended use #3 (Spray to treat clothes against mosquitoes)

- For combined treatment, the risk is acceptable for adults and children of 12 years and more but unacceptable for children under 12 years.

For Intended use #4 (Spray for skin application to repel mosquitoes) temperate conditions and Intended use #3 (Spray to treat clothes against mosquitoes)

- For combined treatment, the risk is acceptable for adults and children more than 12 years, but unacceptable for children under 12 years.

For Intended use #6 (Spray for skin application to repel ticks) and Intended use #5 (Spray to treat clothes against ticks):

- For combined treatment, the risk is unacceptable for adults and children.

Therefore, for combined treatment, RMM are proposed and specified in the SPC and summarized in the table below.

[IN FRANCE ONLY]

Given the risk of vector-borne diseases transmission in France, FR CA considers that SPRAY REPULSIF IR200 could be authorized for application on humans, with appropriate risk mitigation measures that limit human exposure, based on article 19(5). The following RMMs are considered as applicable in France:

- For adult: "apply on the face, neck, hands, ¾ arms, ½ legs"

- For children: "do not apply the product on hands of child" and "apply on the face, neck, ¾ arms and ½ legs"

For Intended use #4 (Spray for skin application to repel mosquitoes):

- Tropical condition: The risk is unacceptable for children from 6 to 12 years considering two applications per day (as claimed by the applicant) but acceptable considering only one application.

For Intended use #5 (Spray for clothes application to repel ticks):
- The risk is unacceptable for children younger than 1 year.

For other intended uses (intended uses #2, #3 and #6 and #7) , risk is acceptable for adults and children in the conditions of uses specified in the SPC.

Risk linked to combined uses (skin and clothes applications) are also assessed:

For Intended use #4 (Spray for skin application to repel mosquitoes) tropical conditions and Intended use #3 (Spray to treat clothes against mosquitoes):
- For combined treatment, the risk is acceptable for adults and children of 6 years and more considering only one application per day on skin.The risk is unacceptable for children younger than 6 years.

For Intended use #4 (Spray for skin application to repel mosquitoes) temperate conditions and Intended use #3 (Spray to treat clothes against mosquitoes):
- For combined treatment, the risk for children younger than 2 years is unacceptable.
- For combined treatment, the risk is acceptable for adults and children of 6 years and more considering only one application per day on skin.

For Intended use #6 (Spray for skin application to repel ticks) and Intended use #5 (Spray to treat clothes against ticks):
- For combined treatment, the risk is unacceptable for children younger than 6 years.

Therefore, for combined treatment, RMM are proposed and specified in the SPC and summarized in the table below.

Conclusion of risk for consumers via residues in food

As regards the intended uses of the product SPRAY REPULSIF IR200 on human skin, no dietary risk for adults and child is expected. Considering the biocidal product, the following RMMs are considered sufficient regarding assessment of indirect exposure via food:

- *Wash hands thoroughly after handling*
- *Do not apply the product on the hands of child*

Conclusion of risk characterisation for Environment

The levels of exposure for the non-target organisms of the aquatic compartment (STP, surface water and sediment) following the use of the product SPRAY REPULSIF on human skin, clothes or fabrics are lower than the threshold values for each compartment under the use conditions provided in the SPC.

Considering the profile of the active substance and the different uses described above, the predicted concentrations in the terrestrial compartment including groundwater are considered negligible under the use conditions provided in the SPC.

GENERAL CONCLUSION :

FR CA consider that the spray's number required to obtain the efficacy dose when the product is applied on clothes against mosquitoes and ticks with a bottle of 100 mL or when the product is applied on textiles against house dust mites with bottle of 100 and 250 mL is inapplicable. Consequently, these used are not authorized in France and commercial names that refer to theses uses are not authorized in application of article 69.2 and 72.3 of the BPR.

Given the risk of vector-borne diseases transmission in France, the product SPRAY REPULSIF IR200 will be authorized for use on humans based on article 19(5) with appropriated risk mitigation measures. The following RMMs are considered as applicable in France:

- For adult: "apply on the face, neck, hands, ¾ arms, ½ legs"
- For children: "do not apply the product on hands of child" and "apply on the face, neck, ¾ arms and ½ legs"

FR CA considers that the product shall be authorized for the following new uses as summarized in the table below:

Target organisms	Application rates	Use conditions	EU only	FR only
Mosquitoes (Aedes spp, Culex spp) Adults	0.6 mg of product per cm² of fabric	Spray onto the textile Protection time: 8 hours in temperate conditions	- For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children and on their clothes.	- For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.
Mosquitoes (Aedes spp, Anopheles spp) Adults	0.6 mg of product per cm² of fabric	Spray directly the textile Protection time: 8 hours in tropical conditions	- For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes	- For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes for children younger than 6 years.
Mosquitoes (Aedes spp, Culex spp) Adults	0.6 mg of product per cm² of skin	Spray on skin Protection time: 4 hours in temperate conditions	- Apply only one time per day - Do not apply the product simultaneously on the skin of children and on their clothes. - For adult, do not apply the product on skin under clothes	- Apply only on head, arms, hands and legs. - For adult and children of 6 years and more, apply up to two times per day - For children younger than 6 years, apply one time per day - For children of 2 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day. Do not apply the product on skin under clothes. - Do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.
Mosquitoes (*Aedes spp, Anopheles spp)* Adults	0.8 mg of product per cm² of skin	Spray on skin Protection time: 3 hours in tropical conditions	- Apply only one time per day - Do not apply on children younger than 2 years - Do not apply the product simultaneously on the skin and on clothes.	- Apply only on head, arms, hands and legs. - For adult and children more than 12 years, apply up to two times per day - For children under 12 years, apply one time per day - For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes for children younger than 6 years. - For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product more than one time per day and do not apply on skin under clothes.

Ticks (*Ixodes ricinus*) Adults and nymphs	0.85 mg of product per cm² of fabric	Spray onto the textiles Protection time : 6 hours in temperate conditions	- Do not apply on clothes of children younger than 1 year - For treatment against ticks, do not apply the product simultaneously on the skin and on clothes.	- Do not apply on clothes of children younger than 1 year. - For treatment against ticks, do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.
	0.6 mg of product per cm² of skin :	Spray on skin Protection time : 4 hours in temperate conditions	- Apply only one time per day - For treatment against ticks, do not apply the product simultaneously on the skin and on clothes.	- Apply only on head, arms, hands and legs. - For adult and children of 6 years and more, apply up to two times per day - For children younger than 6 years, apply one time per day - For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day and do not apply the product on skin under clothes. - Do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.

2 ASSESSMENT REPORT

2.1 SUMMARY OF THE PRODUCT ASSESSMENT

1.1.1 Administrative information

1.1.1.1 *Identifier of the product*

Identifier[1]	**Country (if relevant)**
	- SPRAY RÉPULSIF ANTIPOUX CHEVEUX - LOTION ANTI-POUX - LOTION ANTI-POUX CHEVEUX - ABATOUT ANTI-POUX - REPUL'S ANTI-POUX - K-OVERT ANTI-POUX - K-OCIDE ANTI-POUX - VNM ANTI-POUX - SPRAY RÉPULSIF ANTIMOUSTIQUE PEAU - LOTION ANTI-MOUSTIQUE PEAU - SPRAY RÉPULSIF ANTIMOUSTIQUE PEAU – FAMILLE - LOTION ANTI-MOUSTIQUE PEAU – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU SPÉCIAL SPORT - ABATOUT ANTI-MOUSTIQUE - REPUL'S ANTI-MOUSTIQUE - K-OVERT ANTI-MOUSTIQUE - K-OCIDE ANTI-MOUSTIQUE - SPRAY RÉPULSIF ANTIMOUSTIQUE PEAU – TROPIQUE - LOTION ANTI-MOUSTIQUE PEAU – TROPIQUE - ABATOUT ANTI-MOUSTIQUE ZONE TROPICALE - REPUL'S ANTI-MOUSTIQUE ZONE TROPICALE - K-OVERT ANTI-MOUSTIQUE ZONE TROPICALE - K-OCIDE ANTI-MOUSTIQUE ZONE TROPICALE - VNM ANTI-MOUSTIQUE ZONE TROPICALE - RÉPULSIF CORPOREL SPÉCIAL TROPIQUE - SPRAY RÉPULSIF ANTIMOUSTIQUE VÊTEMENT - LOTION ANTI-MOUSTIQUE VÊTEMENT - SPRAY RÉPULSIF ANTIMOUSTIQUE VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTIMOUSTIQUE VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL SPORT - K-OCIDE ANTI-MOUSTIQUE VÊTEMENT - K-OVERT ANTI-MOUSTIQUE VÊTEMENT - ABATOUT ANTI-MOUSTIQUE VÊTEMENT - REPUL'S ANTI-MOUSTIQUE VÊTEMENT - VNM ANTI-MOUSTIQUE VÊTEMENT - CINQ SUR CINQ SPRAY ANTI-MOUSTIQUES VÊTEMENTS - INSECT ECRAN

Identifier[1]	**Country (if relevant)**
	- INSECT EXPERT - SPRAY RÉPULSIF ANTI-TIQUE VÊTEMENT - LOTION ANTI-TIQUE VÊTEMENT - SPRAY REPULSIF ANTI-TIQUE VÊTEMENT – FAMILLE - LOTION ANTI-TIQUE VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-TIQUE VÊTEMENT LONGUE DURÉE - LOTION ANTI-TIQUE VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE TEXTILE - LOTION ANTI-TIQUE TEXTILE - SPRAY RÉPULSIF ANTI-TIQUE TEXTILE – FAMILLE - LOTION ANTI-TIQUE TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-TIQUE TEXTILE LONGUE DURÉE - LOTION ANTI-TIQUE TEXTILE LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE VÊTEMENT SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-TIQUE VÊTEMENT SPÉCIAL SPORT - K-OCIDE ANTI-TIQUE VÊTEMENT - K-OVERT ANTI-TIQUE VÊTEMENT - ABATOUT ANTI-TIQUE VÊTEMENT - REPUL'S ANTI-TIQUE VÊTEMENT - VNM ANTI-TIQUE VÊTEMENT - SPRAY RÉPULSIF ANTI-TIQUE – PEAU - LOTION ANTI-TIQUE – PEAU - SPRAY RÉPULSIF ANTI-TIQUE - PEAU – FAMILLE - LOTION ANTI-TIQUE - PEAU – FAMILLE - ABATOUT ANTI-TIQUE - REPUL'S ANTI-TIQUE - K-OVERT ANTI-TIQUE - K-OCIDE ANTI-TIQUE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU – FAMILLE - K-OCIDE LOTION INSECTIFUGE - K-OVERT LOTION INSECTIFUGE - ABATOUT LOTION INSECTIFUGE - REPUL'S LOTION INSECTIFUGE - VNM LOTION INSECTIFUGE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT - LOTION ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE - VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE VÊTEMENT LONGUE DURÉE – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE LONGUE DURÉE

Identifier[1]	**Country (if relevant)**
	- LOTION ANTI-MOUSTIQUE ANTI-TIQUE TEXTILE LONGUE DURÉE – FAMILLE - K-OCIDE VÊTEMENT - K-OVERT VÊTEMENT - ABATOUT VÊTEMENT - REPUL'S VÊTEMENT - VNM VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE PEAU & TEXTILE LONGUE DURÉE - K-OCIDE REPULSIF TOTAL CORPS ET TEXTILE - K-OVERT REPULSIF TOTAL CORPS ET TEXTILE - ABATOUT REPULSIF TOTAL CORPS ET TEXTILE - REPUL'S REPULSIF TOTAL CORPS ET TEXTILE - VNM REPULSIF TOTAL CORPS ET TEXTILE - RÉPULSIF CORPOREL ANTI-TIQUES - RÉPULSIF CORPOREL ANTI-MOUSTIQUES - RÉPULSIF CORPOREL MOUSTIQUES SPÉCIAL VÊTEMENTS - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & VÊTEMENT - LOTION ANTI-MOUSTIQUE PEAU & VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE PEAU & VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE PEAU & VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & TEXTILE - LOTION ANTI-MOUSTIQUE PEAU & TEXTILE - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & TEXTILE – FAMILLE - LOTION ANTI-MOUSTIQUE PEAU & TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE PEAU & TEXTILE LONGUE DURÉE - LOTION ANTI-MOUSTIQUE PEAU & TEXTILE LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL SPORT - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL RANDO LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE VÊTEMENT SPÉCIAL SPORT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT - LOTION ANTI-TIQUE PEAU & VÊTEMENT - SPRAY REPULSIF ANTI-TIQUE PEAU & VÊTEMENT – FAMILLE

Identifier[1]	**Country (if relevant)**
	- LOTION ANTI-TIQUE PEAU & VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT LONGUE DURÉE - LOTION ANTI-TIQUE PEAU & VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & TEXTILE - LOTION ANTI-TIQUE PEAU & TEXTILE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & TEXTILE – FAMILLE - LOTION ANTI-TIQUE PEAU & TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & TEXTILE LONGUE DURÉE - LOTION ANTI-TIQUE PEAU & TEXTILE LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE PEAU ET VÊTEMENTS SPÉCIAL CO - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT SPÉCIAL SPORT - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT SPÉCIAL RANDO LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE PEAU & VÊTEMENT SPÉCIAL SPORT LONGUE DURÉE - SPRAY RÉPULSIF ANTIMOUSTIQUE CORPOREL - LOTION ANTI-MOUSTIQUE CORPOREL - SPRAY RÉPULSIF ANTIMOUSTIQUE CORPOREL – FAMILLE - LOTION ANTI-MOUSTIQUE CORPOREL – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL SPÉCIAL RANDO - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL SPÉCIAL SPORT - SPRAY RÉPULSIF ANTIMOUSTIQUE CORPOREL – TROPIQUE - LOTION ANTI-MOUSTIQUE CORPOREL – TROPIQUE - SPRAY RÉPULSIF ANTI-TIQUE – CORPOREL - LOTION ANTI-TIQUE – CORPOREL - SPRAY RÉPULSIF ANTI-TIQUE - CORPOREL – FAMILLE - LOTION ANTI-TIQUE - CORPOREL – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE – FAMILLE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE LONGUE DURÉE - LOTION ANTI-MOUSTIQUE ANTI-TIQUE CORPOREL & TEXTILE LONGUE DURÉE

Identifier[1]	Country (if relevant)
	- LOTION ANTI-MOUSTIQUE CORPOREL & VÊTEMENT - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL & VÊTEMENT – FAMILLE - LOTION ANTI-MOUSTIQUE CORPOREL & VÊTEMENT – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL & VÊTEMENT LONGUE DURÉE - LOTION ANTI-MOUSTIQUE CORPOREL & VÊTEMENT LONGUE DURÉE - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL & TEXTILE - LOTION ANTI-MOUSTIQUE CORPOREL & TEXTILE - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL & TEXTILE – FAMILLE - LOTION ANTI-MOUSTIQUE CORPOREL & TEXTILE – FAMILLE - SPRAY RÉPULSIF ANTI-MOUSTIQUE CORPOREL & TEXTILE LONGUE DURÉE - LOTION ANTI-MOUSTIQUE CORPOREL & TEXTILE LONGUE DURÉE - SPRAY RÉPULSIF ANTI-TIQUE CORPOREL & VÊTEMENT - LOTION ANTI-TIQUE CORPOREL & VÊTEMENT - INSECT ECRAN VÊTEMENTS ET TISSUS - CINQ SUR CINQ SPRAY TISSUS - POUXIT RÉPULSIF - POUXIT RÉPULSIF 48H - POUXIT RÉPULSIF LONGUE DURÉE

1.1.1.2 *Authorisation holder*

Name and address of the authorisation holder	**Name**	ENVIROTECH
	Address	638 Maisonneuve 42320 ST-CHRISTO-EN-JAREZ France
Authorisation number	FR-2018-0046	
Date of the authorisation	04/07/2018	
Expiry date of the authorisation	06/04/2027	

1.1.1.3 *Manufacturer(s) of the products*

Name of manufacturer	MERCK KGaA
Address of manufacturer	Frankfurter strasse 250 64293 Darmstadt Germany
Location of manufacturing sites	Frankfurter strasse 250 64293 Darmstadt Germany

Name of manufacturer	Fabrication Chimique Ardéchoise
Address of manufacturer	1041 Chemin de la digue du Rhône

	07300 Tournon sur Rhône France
Location of manufacturing sites	1041 Chemin de la digue du Rhône 07300 Tournon sur Rhône France

Name of manufacturer	SAS SPRING
Address of manufacturer	ZI du Bois de Leuze 4 rue Blaise Pascal 13310 Saint Martin de Crau France
Location of manufacturing sites	ZI du Bois de Leuze 4 rue Blaise Pascal 13310 Saint Martin de Crau France

Name of manufacturer	Pacome
Address of manufacturer	Lot N°17 La Ziza 98890 Paita Nouvelle Calédonie
Location of manufacturing sites	Lot N°17 La Ziza 98890 Paita Nouvelle Calédonie

1.1.1.4 *Manufacturer(s) of the active substance(s)*

Active substance	Ethyl butylacetylaminopropionate (IR3535®)
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strasse 250 64293 Darmstadt GERMANY
Location of manufacturing sites	Merck S.L.U. Poligono Merck 08100 Mollet del Valles Spain

Active substance	Ethyl butylacetylaminopropionate (IR3535®)
Name of manufacturer	Merck S.L.U.
Address of manufacturer	Calle Maria de Molina, 40 28006 Madrid SPAIN
Location of manufacturing sites	Merck S.L.U. Poligono Merck 08100 Mollet del Valles Spain

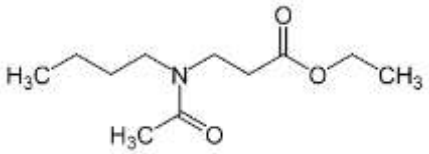
1.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

1.1.2.1 *Identity of the active substance*

Main constituent(s)	
ISO name	IR3535®, Ethyl butylacetylaminopropionate
IUPAC or EC name	ethyl 3-[N-acetyl-N-butyl] aminopropionate
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	

1.1.2.2 *Candidate(s) for substitution*

The active substance IR3535 is not a candidate for substitution.

1.1.2.3 *Qualitative and quantitative information on the composition of the biocidal product[2]*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
IR3535®	ethyl 3-[N-acetyl-N-butyl] aminopropionate	Active substance (technical)	52304-36-6	257-835-0	20.0 Purity: ≥ 99%

1.1.2.4 *Information on technical equivalence*

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not needed, since the manufacturer is the same as included in the Union list of approved active substances.

1.1.2.5 *Type of formulation*

AL – Any other liquid

1.1.3 Hazard and precautionary statements[3]

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

Classification	
Hazard category	Flammable liquid, category 3 Eye irritation, category 2
Hazard statement	H226: flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: flammable liquid and vapour H319: Causes serious eye irritation

Classification	
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P264 Wash … thoroughly after handling P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
Note	

1.1.4 Authorised use(s)

1.1.4.1 *Use description*

Table 1. Use # 1 – Spray to repel human head lice (general public)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Pediculidae Human Head louse (*Pediculus humanus capitis*) Adults
Field of use	Indoor
Application method(s)	Spraying
Application rate(s) and frequency	Adults: up to 1.05 g product per application; Children from 0 to 11 years old: 0.5g per application - Ready-to-use (no dilution needed) - RTU leave-on product Timing: Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used to prevent reinfestation with human head lice (Pediculus humanus capitis) only after a pediculicidal treatment. Reapply after washing the hair and at the latest after 2 days. Dose per application: • Adults: up to 1.05 g product per application. • Children from 0 to 11 years old: 0.5g hubs per application - Product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day:

	- For pump spray (100mL) : o Adults and children >12 years: 11 sprays, 1 to 3 times a day o Children (1 to <12 years): 5 sprays, 1 to 3 times a day o Infants (<1 year): 5 sprays, 1 to 2 times a day - For trigger spray (250 mL) : o Adults : 2 sprays, 1 to 3 times a day o Children (1 to <12 years): 1 spray, 1 to 3 times a day o Infants (<1 year): 1 spray, 1 to 2 times a day When the biocidal product is applied to children under 11 years old, the product should be applied by an adult
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

1.1.4.1.1 Use-specific instructions for use

- Ensure that no lice are present. First use a pediculicide.
- Evenly apply the product on clean and dry or towel dried hair close to the scalp and take care to first treat the nape of the neck and behind the ears. Then spray on the totality of hair like a lacquer. Make sure that the scalp and hair are sufficiently moistened.
- The application must be repeated after washing the hair.
- The product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day:
    - For pump spray (100mL – 100µL per spray):
        - Adults and children >12 years: 11 sprays, 1 to 3 times a day
        - Children (1 to <12 years): 5 sprays, 1 to 3 times a day
        - Infants (<1 year): 5 sprays, 1 to 2 times a day
    - For pump spray (100mL – 300µL per spray):
        - Adults and children >12 years: 4 sprays, 1 to 3 times a day
        - Children (1 to <12 years): 2 sprays, 1 to 3 times a day
        - Infants (<1 year): 2 sprays, 1 to 2 times a day
    - For trigger spray (250mL):
        - Adults and children >12 years: 2 sprays, 1 to 3 times a day
        - Children (1 to <12 years) : 1 spray, 1 to 3 times a day
        - Infants (<1 year): 1 spray, 1 to 2 times a day
- For continued protection: Reapply at the latest after 2 days on cleaned and dry or towel dried hair. Reapply earlier, if the hair was in contact with water (like after rain or swimming) until there is no longer a risk of infestation.

1.1.4.1.2 Use-specific risk mitigation measures

- Do not spray into the face or apply to eye area.

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

-

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

-

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

-

1.1.4.2 *Use description*

Table 2. Use # 2 – Spray to be applied on clothes to repel mosquitoes (temperate conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism (including development stage)	*Aedes spp.* *Culex spp.* Development stage: adults
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles
Application rate(s) and frequency	0.6 mg of product per cm² of fabric Protection time: 8 hours (in temperate conditions and tropicale conditions), even after up to 30 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100 and 250mL HDPE bottle (with sprayer)

1.1.4.2.1 Use-specific instructions for use

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).

- Retreat after water exposure without exceeding the maximal recommended application number.

Number of sprays:

- 100 mL bottle (300µL per spray): Apply the following number of sprays to the front of clothing:
  - For adults and children > 12 years old: 6 per part body, 3 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children from 2 to 12 years old: 2 to 3 per part body, 1 to 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children under 1 to 2 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

- 250 mL bottle: Apply the following number of sprays to the front of clothing:
  - For adults and children > 12 years old: 4 per part body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children from 2 to 12 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children under 1 to 2 years old: 1 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
-

1.1.4.2.2 Use-specific risk mitigation measures

EU only:
For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes.

In France only:
For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.

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

-

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

-

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

-

1.1.4.3 *Use description*

Table 3. Use # 3 – Spray to be applied on clothes to repel mosquitoes (tropical conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism (including development stage)	*Aedes spp.* *Anopheles spp.* Development stage: adults
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles
Application rate(s) and frequency	0.6 mg of product per cm² of fabric Protection time: 8 hours (tropical conditions), even after up to 30 days of storage of the treated cloth (before being worn). Reapply after each washing or use of the treated cloth in a closed packaging (such as a plastic bag).
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	250mL HDPE bottle (with sprayer)

1.1.4.3.1 Use-specific instructions for use

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).
- Retreat after water exposure without exceeding the maximal recommended application number.

Number of sprays:

- 100 mL bottle (300µL per spray): Apply the following number of sprays to the front of clothing:
  - For adults and children > 12 years old: 6 per part body, 3 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children from 2 to 12 years old: 2 to 3 per part body, 1 to 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children under 1 to 2 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

- 250 mL bottle: Apply the following number of sprays to the front of clothing:
  - For adults and children > 12 years old: 4 per part body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children from 2 to 12 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children under 1 to 2 years old: 1 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

-

1.1.4.3.2 Use-specific risk mitigation measures

EU only:
For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes.

In France only:
For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.

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

-

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

-

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

-

1.1.4.4 *Use description*

Table 4. Use # 4 – Spray for skin application to repel mosquitoes (temperate conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Aedes spp.* *Culex spp.* Development stage: adults
Field of use	Skin application
Application method(s)	Spraying Spray directly on skin
Application rate(s) and frequency	Application rate in temperate conditions: 0,6 mg of product per cm² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

1.1.4.4.1 Use-specific instructions for use

- Wash hands thoroughly after handling
- Do not apply the product on the hands of child under 12 years.
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:
Number of sprays (100ml – 100 µL per spray):
- Adult and children >12 years old: apply 7 sprays to the head, 1 spray on the neck, 6 sprays per arm, 2 sprays per hand, 13 sprays per leg and 3 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 3 sprays to the head, 1 spray on the neck, 3 sprays per arm, 1 spray per hand, 7 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 3 sprays per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (100ml – 300 µL per spray):
- Adult and children >12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 5 sprays per leg and 1 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray on the neck, 1 sprays per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm and 1 spray per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 3 sprays per leg and 1 spray per foot, once a day.
- Children from 6 to <12 years old: apply 2 sprays per arm and 2 sprays per leg, once a day.
- Children from 2 to <6 years old: apply 1 spray for both arms and 1 spray per leg, once a day.
- Children 1 to <2 years old: apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 2 sprays for the body, once a day.

In France only:
Number of sprays (100ml – 100 µL per spray)):
- Adult and children >12 years old: apply 7 sprays to the head, 5 sprays per arm, 2 spray per hand and 8 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 3 sprays to the head and per arm, and 4 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 3 sprays to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and per leg, once a day.

Number of sprays (100ml – 300 µL per spray)):
- Adult and children >12 years old: apply 2 sprays to the head, 2 sprays per arm, 1 spray per hand and 3 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head and per arm, and 2 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 1 spray for the body, once a day.

1.1.4.4.2 Use-specific risk mitigation measures

- When the biocidal product is applied to children under 12 years, the product should be applied by an adult
- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area

EU only:
- Temperate condition:
  - Apply only one time per day.
  - Do not apply the product simultaneously on the skin of children under 12 years and on their clothes.
  - For adult and children more than 12 years, do not apply the product on skin under clothes.

In France only:
- Apply only on head, arms, hands and legs.
- For adult and children of 6 years and more, apply up to two times per day.
- For children younger than 6 years, apply one time per day.
- For children of 2 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day. Do not apply the product on skin under clothes.

- Do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.

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

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

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

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1.1.4.5 *Use description*

Table 5. Use # 5 – Spray for skin application to repel mosquitoes (tropical conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Aedes spp.* *Anopheles spp.* Development stage: adults
Field of use	Skin application
Application method(s)	Spraying Spray directly on skin
Application rate(s) and frequency	Application rate in tropical conditions: 0,8 mg of product per cm² of skin Protection time: 3 hours in tropical conditions
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

1.1.4.5.1 Use-specific instructions for use

- Wash hands thoroughly after handling - Do not apply the product on the hands of child under 12 years. - In case of a concomitant use of the product with sunscreen, first apply the

sunscreen and wait 20 minutes before the application of the product.
- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:
Number of sprays (100ml – 100µL per spray):
- Adult and children >12 years old: apply 9 sprays to the head, 1 spray to the neck, 8 sprays per arm, 3 sprays per hand, 18 sprays per leg and 4 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 4 sprays to the head, 2 sprays on the neck, 4 sprays per arm, 1 spray per hand, 9 sprays per leg and 2 sprays per foot, once a day.
- Children from 2 to <6 years old: apply 4 sprays to the head, 2 sprays on the neck, 3 sprays per arm, 1 spray per hand, 6 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 4 sprays per leg and 1 spray per foot, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 3 sprays per leg and 1 spray per foot, once a day.

Number of sprays (100ml – 300 µL per spray):
- Adult and children >12 years old: apply 3 sprays to the head, 1 spray to the neck, 3 sprays per arm, 1 spray per hand, 6 sprays per leg and 2 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 3 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per leg and 1 spray per foot, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm, 1 spray per leg and 1 spray per foot, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 2 sprays to the head, 1 spray to the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.
- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand, and 2 sprays per leg, once a day.
- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray per arm and 2 sprays per leg, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray for both arms and 1 spray per leg, once a day.
- Infants <1 year old: apply 4 sprays for the body, once a day.

In France only:
Number of sprays (100ml- 100µL per spray):
- Adult and children >12 years old: Apply 9 sprays to the head, 7 sprays per arm, 3 sprays per hand and 11 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 4 sprays to the head and per arm, and 5 sprays per leg, once daily.
- Children from 2 to <6 years old: Apply 4 sprays to the head, 3 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and 2 sprays per leg, once a day.

Number of sprays (100ml – 300µL per spray):
- Adult and children >12 years old: Apply 3 sprays to the head, 2 sprays per arm, 1 spray per hand and 4 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 2 sprays to the head, 1 spray per arm, and 2 sprays per leg, once daily.
- Children from 2 to <6 years old: Apply 2 sprays to the head, 1 spray per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 2 sprays to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 1 spray for the body, once a day.

1.1.4.5.2 Use-specific risk mitigation measures

- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area.
- When the biocidal product is applied to children, the product should be applied by an adult.

EU only:
- Apply only one time per day.
- Do not apply on children younger than 6 years.
- Do not apply the product simultaneously on the skin of children under 12 years and on their clothes.
- For adult and children more than 12 years, do not apply the product on skin under clothes.

In France only:
- Apply only on head, arms, hands and legs.
- For adult and children more than 12 years, apply up to two times per day.
- For children under 12 years, apply one time per day.
- For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes for children younger than 6 years.
- For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product more than one time per day and do not apply on skin under clothes.

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

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

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

1.1.4.6 *Use description*

Table 6. Use # 6 – Spray to be applied on clothes to repel ticks

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against ticks.
Target organism (including development stage)	Hard ticks *Ixodes ricinus* Development stage: adults and nymphs
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles
Application rate(s) and frequency	0.85 mg of product per cm² of fabric Protection time (in temperate conditions) during 6 hours even after 7 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100 and 250mL HDPE bottle (with sprayer)

1.1.4.6.1 Use-specific instructions for use

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag). - Retreat after water exposure without exceeding the maximal recommended application number. Number of sprays: - 100 mL bottle (300 µL per spray): Apply the following number of sprays to the front of clothing: - For adults and children > 12 years old: 9 per shirt body, 4 per leg, 2 per sleeve. Repeat on the back of the clothes.

- For children from 2 to 12 years old: 3-5 per shirt body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
- For children under 1 to 2 years old : 2 per shirt body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

- 250 mL bottle: Apply the following number of sprays to the front of clothing:
  - For adults and children > 12 years old: 6 per shirt body, 3 per leg, 2 per sleeve. Repeat on the back of the clothes.
  - For children from 2 to 12 years old: 2-3 per shirt body, 1-2 per leg, 1 per sleeve. Repeat on the back of the clothes.
  - For children under 1 to 2 years old : 1-2 per shirt body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
-

1.1.4.6.2 Use-specific risk mitigation measures

EU only:
- Do not apply on clothes of children younger than 1 year.
- For treatment against ticks, do not apply the product simultaneously on the skin of children under 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

In France only:
- Do not apply on clothes of children younger than 1 year.
- Do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

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

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

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

1.1.4.7 *Use description*

Table 5. Use # 5 – Spray for skin application to repel ticks

Product Type	PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Hard ticks *Ixodes ricinus* Development stage: adults and nymphs
Field of use	Skin application
Application method(s)	Spraying Spray for skin application to repel ticks
Application rate(s) and frequency	0,6 mg of product per cm² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

1.1.4.7.1 Use-specific instructions for use

- Wash hands thoroughly after handling
- Do not apply the product on the hands of child
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:
Number of sprays (100ml– 100 µL per spray):
- Adult and children >12 years old: apply 7 sprays to the head, 1 spray on the neck, 6 sprays per arm, 2 sprays per hand, 13 sprays per leg and 3 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 3 sprays to the head, 1 spray on the neck, 3 sprays per arm, 1 spray per hand, 7 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 3 sprays per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (100ml – 300 µL per spray):
- Adult and children >12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 5 sprays per leg and 1 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray on the neck, 1 sprays per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm and 1 spray per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 3 sprays per leg and 1 spray per foot, once a day.
- Children from 6 to <12 years old: apply 2 sprays per arm and 2 sprays per leg, once a day.
- Children from 2 to <6 years old: apply 1 spray for both arms and 1 spray per leg, once a day.
- Children 1 to <2 years old: apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 2 sprays for the body, once a day.

In France only:
Number of sprays (100ml– 100 µL per spray):
- Adult and children >12 years old: apply 7 sprays to the head, 5 sprays per arm, 2 spray per hand and 8 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 3 sprays to the head and per arm, and 4 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 3 sprays to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and per leg, once a day.

Number of sprays (100ml – 300 µL per spray)):
- Adult and children >12 years old: apply 2 sprays to the head, 2 sprays per arm, 1 spray per hand and 3 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head and per arm, and 2 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):
- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 1 spray for the body, once a day.

1.1.4.7.2 Use-specific risk mitigation measures

- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area.

- When the biocidal product is applied to children under 12 years, the product should be applied by an adult.

EU only:

- Apply only one time per day. Do not apply the product simultaneously on the skin of children under 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

In France only:

- Apply only on head, arms, hands and legs.
- For adult and children of 6 years and more, apply up to two times per day.
- For children younger than 6 years, apply one time per day.
- For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day and do not apply the product on skin under clothes.
- Do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.

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

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

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

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1.1.5 General directions for use

1.1.5.1 *Instructions for use*[4]

- Always read the label or leaflet before use and follow all the instructions provided.
- Respect the recommended application doses.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can lower it.
- The spraying device should be oriented at 10-20 cm toward the surface to be treated.
- The user should inform the registration holder if the treatment is ineffective.
- The use of the product with other repellent products is not recommended.

1.1.5.2 *Risk mitigation measures*

- Do not spray close to the eyes.
- Use in well-ventilated areas.

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

- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.
- Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- If medical advice is needed, have product container or label at hand.

1.1.5.4 *Instructions for safe disposal of the product and its packaging*

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Keep out of reach of children

- Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.
- Advice on safe handling: Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.
- Environmental exposure controls: Do not let product enter drains.
- Shelf life : 30 months
- The product should not be stored at temperatures >40°C

1.1.6 Other information

Considering the importance of this active substance in vector control, the authorisation holder has to implement a monitoring of scientific literature toward the active substance IR3535. Results of this assessment must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA)

2.1.1 Packaging of the biocidal product

- **FIRST AUTHORISATION – 2017 (BE CA)**

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)
Bottle	≥25 mL - ≤250 mL	plastic: HDPE	pump head covered by a cap	non-professional	Yes

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

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)
Bottle	≥100 mL - ≤250 mL	HDPE	pump head covered by a cap *	non-professional	Yes

* A new spray system was proposed in the scope of major change 2019

- **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2021 (FR CA)**

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)
Bottle	≥100 mL - ≤250 mL	HDPE	pump head covered by a cap *	non-professional	Yes

* A new spray system for 100mL bottle (300µL per spray) was added in the scope of minor change 2021.

2.1.2 Documentation

2.1.2.1 Data submitted in relation to product application

- **FIRST AUTHORISATION – 2017 (BE CA)**

Please see §3.1 list of studies for the biocidal product.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

- Physico-chemical part

- An accelerated storage study in the new sprayer system of the product was provided.

- Efficacy

The following tests were submitted:

Mosquitoes

- An arm-in-cage study conducted with ten human volunteers with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535) applied on skin against two mosquito species *(Aedes aegypti* and *Culex quinquefasciatus)* in temperate conditions.
- An arm-in-cage study conducted with ten human volunteers with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535) applied on skin against two mosquito species *(Aedes albopictus* and *Anopheles gambiae)* in tropical conditions.
- Arm-in-cage studies conducted with ten human volunteers with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535) applied two types of fabric (cotton and polyester) three mosquito species (*Aedes aegypti*, *Aedes albopictus*, *Culex pipiens* and *Anopheles gambiae*).

Ticks

- Laboratory studies conducted with ten mice with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535) applied on mouse against adults and nymphs ticks (*Ixodes ricinus*) in temperate conditions.
- Laboratory studies conducted with ten mice with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535) applied on two type of fabric (cotton and polyester) on mouse against adults and nymphs ticks (*Ixodes ricinus*) in temperate conditions.

House dust mites

- A free-choice laboratory test was carried out with House Dust mites (*Dermatophagoïdes pteronyssinus*) with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535).

Human head lice

- Laboratory tests were carried out with human head lice (*Pediculus humanus capitis*) with the product "SPRAY IR3535 20% ANTI-POUX" (20% w/w IR3535).

➢ **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2021 (FR CA)**

• Physico-chemical part
- Chemical analyses and physical stability study during and after a storage after 30 months were provided (100ml & 250ml)
- Physical stability study during and after storage after 24 months (additional studies) was provided (100 mL bottle, 100 µL pump)
- An accelerated storage study in the new sprayer system of the product was provided (100ml bottle, new pump 300 µL)

➢ **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2022**

• Physico-chemical part
- Physical stability study during and after storage after 30 months (additional studies) was provided (100 mL bottle, 100 µL pump)

2.1.2.2 Access to documentation

➢ **FIRST AUTHORISATION – 2017 (BE CA)**

The applicant of this product is the same as the review programme participant for the active substance and is thus the owner of all data on the active substance.

➢ **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The authorization holder has a letter of access from Merck KGaA for the following data:

- The data package on the basis of which IR3535 was approved under the regulation 528/2012, through Commission Implementing Regulation 406/2014.
- The data package from the Product Assessment Report of the product Insect Repellent Spray Lice IR3535® 20% (Case number BC-PR013536-21), evaluated by Belgium.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

<table>
<tr><td>Product Type</td><td>PT19 – Repellents and attractants (Pest control)</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Evenly apply the product to the hair and take care to also treat the nape of the neck and behind the ear. For a single application of Insect Repellent Pump Spray IR3535® 20 %, 0.5 g product per application which is equivalent to 100 mg a.s. / application) is sufficient to treat the hair after having used a pediculicide. The application must be repeated after washing the hair. The biocidal product should only be applied by adults to children under 10 years.</td></tr>
<tr><td>Target organism (including development stage)</td><td><table><tr><th>Scientific name</th><th>Common name</th><th>Development stage</th></tr><tr><td>Pediculidae</td><td>Human head louse</td><td>Adult</td></tr></table></td></tr>
<tr><td>Field of use</td><td>Indoors in well ventilated areas</td></tr>
<tr><td>Application method(s)</td><td>Spraying</td></tr>
<tr><td>Application rate(s) and frequency</td><td>Dose: 0.5 mL
Dilution: 100%
Timing: Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used to prevent reinfestation with lice after a pediculicide treatment. It is usually applied once a day. The application must be repeated after washing of the hair.</td></tr>
<tr><td>Category(ies) of users</td><td>General public</td></tr>
<tr><td>Pack sizes and packaging material</td><td><table><tr><th>Type</th><th>Material</th><th>Size</th></tr><tr><td>Bottle</td><td>Plastic: HDPE</td><td>>25.0 - <250.0 mL</td></tr></table>
Note: Due to a technical issue with SPC-editor and IUCLID, the applicant wasn’t able to include the ≥ and ≤ symbols. The applied packaging should have been ‘larger or equal to 25 mL to smaller or equal to 250 mL’.</td></tr>
</table>

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Table 1. Intended use # 1 – Spray to repel human head lice (general public)[5]

<table>
<tr><td>Product Type(s)</td><td>PT19 – Repellents and attractants (Pest control)</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Repellent</td></tr>
<tr><td>Target organism (including development stage)</td><td>
<table>
<tr><th>Scientific name</th><th>Common name</th><th>Development stage</th></tr>
<tr><td>Pediculidae</td><td>Human head louse</td><td>Adults</td></tr>
</table>
</td></tr>
<tr><td>Field of use</td><td>Indoors in well ventilated areas.

Ready to use repellent product to prevent reinfestation with human head lice (Pediculus humanus capitis) only after a pediculicidal treatment.

It is to be applied on hair, the nape of the neck and behind the ears.</td></tr>
<tr><td>Application method(s)</td><td>Spraying: The ready to use product is a pump spray which is sprayed directly onto the hair.</td></tr>
<tr><td>Application rate(s) and frequency</td><td>RTU leave-on product.

Timing:
SPRAY REPULSIF IR200 is intended to be used to prevent reinfestation with human head lice (Pediculus humanus capitis) only after a pediculicidal treatment.

Reapply after washing the hair and at the latest after 2 days.

Dose per application:
• Adults: up to 1.05 g product or approx. 9 spray hubs per application.
• Children from 0 to 11 years old: 0.5g or approx. 4 spray hubs per application

Product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day:
• Adults and children older than 1 year: 3 times a day
• Children between 0 and 1 year old: 2 times a day

When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.</td></tr>
</table>

Category(ies) of user(s)	General public
Pack sizes and packaging material	**Type**: Bottle with a pump spray head; **Material**: Plastic: HDPE; **Size**: 100 to 250 mL

Table 2. Intended use # 2 – Spray to treat textiles as barrier treatment against human head lice (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	**Scientific name**: *Pediculidae*; **Common name**: Human head louse; **Development stage**: Adults
Field of use	Indoors in well ventilated areas. SPRAY REPULSIF IR200 is a ready to use repellent product to prevent reinfestation with human head lice (*Pediculus humanus capitis*). It is to be applied on bed linen and/or cloth's surface in contact with the top of the body (head, neck and shoulders).
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly onto the fabric (bed linen).
Application rate(s) and frequency	RTU leave-on product. Timing: The bed linen should be treated everyday or after their washing Dose per application: 10 g/m² of fabric
Category(ies) of user(s)	General public
Pack sizes and packaging material	**Type**: Bottle with a pump spray head; **Material**: Plastic: HDPE; **Size**: 100 to 250 mL

Table 3. Intended use # 3 – Spray to treat clothes against mosquitoes (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	**Scientific name** / **Common name** / **Development stage** Aedes aegypti / Aedes spp. / Adults Culex quinquefasciatus / Culex spp. Aedes albopictus / Anopheles spp. Anopheles gambia
Field of use	Indoor use
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly onto the textile.
Application rate(s) and frequency	RTU leave-on product. Timing: - Clothes should be treated every 30 days or after their washing Dose per application: - 6.0 g/m² of fabric
Category(ies) of user(s)	General public
Pack sizes and packaging material	**Type** / **Material** / **Size** Bottle with a pump spray head / Plastic: HDPE / 100 to 250 mL

Table 4. Intended use # 4 – Spray for skin application to repel mosquitoes (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	**Scientific name** / **Common name** / **Development stage** Aedes aegypti / *Aedes spp.* / Adults *Culex quinquefasciatus* / *Culex spp.* *Aedes albopictus* / *Anopheles spp.* *Anopheles gambia*
Field of use	Indoor use Outdoor use
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly on skin.

Application rate(s) and frequency	RTU leave-on product. Timing for temperate conditions: Child >6 years old and adult: 2 applications per day, Child ≥ 6 months old-6 years: 1 application per day. Timing for tropical conditions: Child >11 years old and adult: 2 applications per day, Child ≥ 6 months old-11 years: 1 application per day. Dose per application: - 6 g of product/m² in temperate conditions against A. aegypti and C. quinquefasciatus; - 8 g of product/m² in tropical conditions against A. albopictus and A. gambia.
Category(ies) of user(s)	General public
Pack sizes and packaging material	**Type**: Bottle with a pump spray head **Material**: Plastic: HDPE **Size**: 100 to 250 mL

Table 5. Intended use # 5 – Spray to treat clothes against ticks (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	**Scientific name**: Ixodes ricinus **Common name**: Hard ticks **Development stage**: Nymphs and Adults
Field of use	Indoor use
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly onto the fabric.
Application rate(s) and frequency	RTU leave-on product. Timing: - Clothes should be treated every 7 days or after their washing Dose per application: - 8.5 g/m² of fabric
Category(ies) of user(s)	General public

Pack sizes and packaging material	**Type**	**Material**	**Size**
	Bottle with a pump spray head	Plastic: HDPE	100 to 250 mL

Table 6. Intended use # 6 – Spray for skin application to repel ticks (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)		
Where relevant, an exact description of the authorised use	Repellent		
Target organism (including development stage)	**Scientific name**	**Common name**	**Development stage**
	Ixodes ricinus	Hard ticks	Nymphs and Adults
Field of use	Indoor use Outdoor use		
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly on skin.		
Application rate(s) and frequency	RTU leave-on product. Timing: - Child >6 years old and adult: 2 applications per day, - Child ≥ 6 months old-6 years: 1 application per day. Dose per application: - 6 g of product/m².		
Category(ies) of user(s)	General public		
Pack sizes and packaging material	**Type**	**Material**	**Size**
	Bottle with a pump spray head	Plastic: HDPE	100 to 250 mL

Table 7. Intended use # 7 – Spray to treat fabric against dust mites (general public)

Product Type(s)	PT19 – Repellents and attractants (Pest control)		
Where relevant, an exact description of the authorised use	Repellent		
Target organism (including development stage)	**Scientific name**	**Common name**	**Development stage**
	Dermatophagoides pteronyssinus	Dust mite	Adults
Field of use	indoor use		

Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly onto the fabric (bed linen).
Application rate(s) and frequency	RTU leave-on product. Timing: - The bed linen should be treated everyday or after their washing Dose per application: - 8.5 g/m² of fabric
Category(ies) of user(s)	General public
Pack sizes and packaging material	**Type**: Bottle with a pump spray head; **Material**: Plastic: HDPE; **Size**: 100 to 250 mL

- **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2021 (FR CA)**

Table 3. Use # 1 – Spray to repel human head lice (general public)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Pediculidae Human Head louse (*Pediculus humanus capitis*) Adults
Field of use	Indoor
Application method(s)	Spraying
Application rate(s) and frequency	Adults: up to 1.05 g product per application; Children from 0 to 11 years old: 0.5g per application - Ready-to-use (no dilution needed) - RTU leave-on product Timing: Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used to prevent reinfestation with human head lice (Pediculus humanus capitis) only after a pediculicidal treatment. Reapply after washing the hair and at the latest after 2 days. Dose per application: • Adults: up to 1.05 g product per application. • Children from 0 to 11 years old: 0.5g hubs per application

	When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 4. Use # 2 – Spray to be applied on clothes to repel mosquitoes (temperate conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism (including development stage)	*Aedes spp.* *Culex spp.* Development stage: adults
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles
Application rate(s) and frequency	0.6 mg of product per cm² of fabric Protection time: 8 hours (in temperate conditions and tropicale conditions), even after up to 30 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 3. Use # 3 – Spray to be applied on clothes to repel mosquitoes (tropical conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism (including development stage)	*Aedes spp.* *Anopheles spp.* Development stage: adults
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles

Application rate(s) and frequency	0.6 mg of product per cm² of fabric Protection time: 8 hours (tropical conditions), even after up to 30 days of storage of the treated cloth (before being worn). Reapply after each washing or use of the treated cloth in a closed packaging (such as a plastic bag).
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 4. Use # 4 – Spray for skin application to repel mosquitoes (temperate conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Aedes spp.* *Culex spp.* Development stage: adults
Field of use	Skin application
Application method(s)	Spraying Spray directly on skin
Application rate(s) and frequency	Application rate in temperate conditions: 0,6 mg of product per cm² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 5. Use # 5 – Spray for skin application to repel mosquitoes (tropical conditions)

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Aedes spp.* *Anopheles spp.* Development stage: adults
Field of use	Skin application
Application method(s)	Spraying Spray directly on skin
Application rate(s) and frequency	Application rate in tropical conditions: 0,8 mg of product per cm² of skin Protection time: 3 hours in tropical conditions

Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 6. Use # 6 – Spray to be applied on clothes to repel ticks

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against ticks.
Target organism (including development stage)	Hard ticks *Ixodes ricinus* Development stage: adults and nymphs
Field of use	Application on clothes
Application method(s)	Spraying Spray directly onto the textiles
Application rate(s) and frequency	0.85 mg of product per cm² of fabric Protection time (in temperate conditions) during 6 hours even after 7 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

Table 7. Use # 7 – Spray for skin application to repel ticks

Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Hard ticks *Ixodes ricinus* Development stage: adults and nymphs
Field of use	Skin application
Application method(s)	Spraying Spray for skin application to repel ticks
Application rate(s) and frequency	0,6 mg of product per cm² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

2.2.2 Clarification on product composition and compositions tested

In the studies submitted several test materials were used. Below, the differences to the product Insect Repellent Pump Spray Lice IR3535® 20% are described, whereas the full composition of the test materials is provided in the confidential part of the PAR.

- **Insect Repellent Pump Spray Lice IR3535® 20%**
- **Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex**
- **Insect Repellent Pump Spray IR3535® 20% without Bitrex:** Slightly lower concentration emollient, film forming substance present, and no Bitrex present
- **US Pump Spray Formulation**: In the US EPA formulation, ethanol denatured with Bitrex and tertbutanol (final concentrations 0.0002% and 0.042 %, respectively) is used, whereas in the EU Lice formulation (Insect Repellent Pump Spray Lice IR3535® 20%) a final concentration of 0.0011% Bitrex is present. Other components are similar in both formulations. The pump spray formulation contains a slightly lower concentration emollient and a film forming substance. The water content was adjusted to compensate for the slight differences in composition.
- **Pump Spray IR3535® 19.5%** (2005 particle size test): The test material contained slightly less IR3535®. It also did not contain Bitrex. Only the water content was adjusted to compensate for the slight differences in composition.

2.2.3 Physical, chemical and technical properties

- **FIRST AUTHORISATION – 2017 (BE CA)**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
Physical state at 20 °C and 101.3 kPa	Organoleptic	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	Homogeneous liquid	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Colour at 20 °C and 101.3 kPa	Organoleptic	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	Clear, colourless to slightly yellowish	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Odour at 20 °C and 101.3 kPa	Organoleptic	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	Mild characteristic, slight alcoholic	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Acidity / alkalinity	CIPAC MT 75.3, under GLP regulation	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	100 % v/v: 5.7-5.8 1 % v/v: 5.8-6.7 [At 20°C±1.6°C, using combined glass electrode]	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
Relative density / bulk density	OECD 109, under GLP regulation. EPA OPPTS 830.7300, under GLP regulation.	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	0.951 g/mL [At 20°C±0.1°C, using pycnometer]	63171182, Fieseler, A., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Storage stability test – accelerated storage	CIPAC MT 46.3, under GLP regulation – HPLC method (see 2.2.5) and Organoleptic	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	- No change in colour, odour, or clarity. - No change in packaging appearance. - Mass changes: 154.6g - 162.2g -> 158.4g - 161.9g - Change in A.S.: 19.3% w/w -> 18.8% (= 2.59% change) - Free acid content: <0.5 % w/w before and after storage - pH change: 5.8 -> 5.3 [8 weeks at 40±2°C. Humidity 30-65%. Packaging: HDPE pump spray bottle – 150 mL]	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
Storage stability test – long term storage at ambient temperature	OPPTS 830.6319, under GLP regulation – HPLC method (see 2.2.5) and Organoleptic	READ-ACROSS US Pump Spray Formulation	- No change in colour, odour, or clarity. - No change in packaging appearance. - Mass changes: 135.6g - 136.2g ->
134.9g - 135.7g (= 0.37±0.04% change) - Change in A.S.: 20.1% w/w -> 17.9% (= 10.94% change <u>after 24 months)</u> 20.1% w/w -> 19.1% (= 4.98% change <u>after 18 months)</u> - Free acid content: 0.1% w/w -> 2.1 % w/w - pH change: 5.0 -> 4.4 [2 years at 25±2°C. Humidity 40-68%. Packaging: HDPE pump spray bottle – 100 mL]	31232204, Meinerling, M., 2009. Institut für Biologische Analytik und Consulting IBACON GmbH	
Storage stability test – low temperature stability test for liquids	CIPAC MT 39.3, under GLP regulation – Organoleptic	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	- No change in colour, odour, or clarity. - No precipitation or separated material was observed. [7 days at 0±2°C. Packaging: Centrifuge tube – 100 mL]	63173204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Effects on content of the active substance and technical characteristics of the biocidal product - light	Waived	-	The product is intended to be placed on the market in lightproof plastic flasks with pump stopper and cap, so that effects of light can be excluded.	-	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Waived	-	- Since the product is tightly closed there are no effects due to humidity. - Effects of temperature have been studied during the storage stability tests (see above). The product should not be stored for prolonged times at temperatures >40°C.	-	
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	OPPTS 830.6319, under GLP regulation CIPAC MT 46.3, under GLP regulation	(Refer to the sections on the storage stability tests)	Interaction with primary packaging is monitored during the storage stability tests (see above)	31232204, Meinerling, M., 2009. Institut für Biologische Analytik und Consulting IBACON GmbH 63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH	
Wettability	Waived	-	Not applicable since biocidal product is not a solid preparations to be dispersed in water.	-	
Suspensibility, spontaneity and dispersion stability	Waived	-	Not applicable since biocidal product does not need to be diluted.	-	
Wet sieve analysis and dry sieve test	Waived	-	Not applicable since biocidal product is a ready to use liquid.	-	
Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	Not applicable since biocidal product does not need to be emulsified.	-	
Disintegration time	Waived	-	Not applicable since biocidal product is not a tablet and is not used in a water soluble bag.	-	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
Particle size distribution, content of dust/fines, attrition, friability	Waived	-	Not applicable since biocidal product is not a granule or tablet.	-	
Persistent foaming	Waived	-	Not applicable since biocidal product is a ready for use product.	-	
Flowability/Pourability/Dustability	Waived	-	Not applicable since biocidal product is not granular/a suspension.	-	
Burning rate — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-	
Burning completeness — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-	
Composition of smoke — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-	
Spraying pattern — aerosols	Waived	-	Not applicable since the biocidal product is no aerosol.	-	
Physical compatibility	Particle size distribution [Laser light diffraction, technical compliance to the requirements of 21 CFR Part 11 and the ISO13320:2009]	READ-ACROSS Pump Spray IR3535® 19.5% Insect Repellent Pump Spray	Fraction of particles <5µm: <0.6 %. Range (n=50): 0.28 - 0.68 microns, with a mean of 0.45 % < 5.23 microns. Fraction of particles <50µm: 51.79<x<60.27 % Range (n=50): 47.78 – 54.86 microns, with respective means of 59.95 % and 51.46 %. [Malvern SprayTec Spectrometer, Distance nozzle to beam center: 3cm, Focal length: 200mm, Test time 200ms, Data recording rate: 1000Hz, Optical parameters: 1.34/0/1, Laser wave length: 670nm]	214-001, 2005. Fa. Aero Pump GmbH 2016. Fa. Aero Pump GmbH	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	
		Lice IR3535® 20%	Fraction of particles <10µm: ~1.5 %. Range (n=12): 0.98 – 1.95%, with an average of 1.495 % <10 microns. [Malvern SprayTec Spectrometer, Focal length: 300mm, Test time 400ms, Data recording rate: 2.5kHz, Laser wave length: 632.8nm]		
Chemical compatibility	Waived	-	The biocidal product is not intended to be added or mixed with any other products.	-	
Degree of dissolution and dilution stability	Waived	-	The biocidal product is not intended to be added or mixed with any other products.	-	
Surface tension	OECD Test Guideline 115	Insect Repellent Pump Spray Lice IR3535® 20%	29.447 mN/m [At 20°C ± 0.5°C, DCAT11 tensiometer]	009093 - IR3535_Ref Formulations surgace tension visco_Reg.Aff, Zur Lage, J., 2016. Merck.	
Viscosity	OECD Test Guideline 114	Insect Repellent Pump Spray Lice IR3535® 20%	5.66 mPa s [Neat product at 20°C ± 0.2°C, rotational viscometer] 3.17 mPa s [At 40°C ± 0.2°C, rotational viscometer] Product with Newtonian behaviour	009093 - IR3535_Ref Formulations surface tension visco_Reg.Aff, Zur Lage, J., 2016. Merck. 009093 - IR3535_Ref Formulations Surface tension Viscosity_Reg.Aff, Zur Lage, J., 2016. Merck.	

Conclusion on the physical, chemical and technical properties of the product
The Insect Repellent Pump Spray Lice IR3535® 20% as manufactured is a clear, colourless to slightly yellowish, homogenous liquid with a mild characteristic, slight alcoholic smell. The relative density of the product is 0.951 g/mL at 20 °C. At 20°C and a concentration between 1.0 vol% and 100 vol%, the pH value is between 5.7 and 6.7. The product has a long term stability, with changes in active substance content smaller than 10% for up to and including 18 months, and is stable under cold and accelerated storage conditions. The shelf life of the product is 2 years. Light

influence is avoided by using a lightproof plastic packaging. There are no humidity effects expected in that closed package. The product should not be stored for prolonged times (more than 8 weeks) at temperatures >40°C. Based on read-across with the Pump Spray IR3535 15%, more than 99.4% of particle fraction is greater than or equal to 5 microns. The surface tension is 29.447 mN/m and the viscosity at 20°C is 5.66 mPa.s. At 40°C the viscosity is 3.17 mPa.s. Physical and chemical compatibility with other products are not relevant.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**Comments**

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>Method MT46.3

Method to quantify the AS study # 18-905023-003</td>
<td>Batch # CTG181101/00/04:
20.7%$_{w/w}$ IR3535
100mL HDPE Spray</td>
<td>Batch # CTG181101/00/04:
<table>
<tr><td></td><td>T0</td><td>T8weeks at 40°C in HDPE</td></tr>
<tr><td>Appearance</td><td>Homogeneous colourless limpid liquid with a characteristic odour</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>White opaque HDPE flask</td><td>No weight change

No sign of degradation or leak</td></tr>
<tr><td>AS content</td><td>20.7 %$_{w/w}$</td><td>20.6 %$_{w/w}$</td></tr>
<tr><td>%variation</td><td></td><td>-0.5% compared to T0</td></tr>
<tr><td>Determination of the satisfactory operation of the spray</td><td>No blocking observed</td><td>No blocking observed</td></tr>
<tr><td>Spray volume (mean)</td><td>0.099 mL</td><td>0.093 mL</td></tr>
<tr><td>Spay diameter and pattern at a distance of 30 cm</td><td>10 cm

Circular point cloud</td><td>10 cm

Circular point cloud</td></tr>
<tr><td>Droplet size

[Laser light diffraction]</td><td>Dv(10) = 37.6 µm
Dv(50) = 68.6 µm
Dv (90) = 118 µm</td><td>Dv(10) = 23.12 µm
Dv(50) = 64.45 µm
Dv (90) = 140.3 µm</td></tr>
</table>
<table>
<tr><td></td><td>T0</td><td>T8weeks at 40°C in HDPE</td></tr>
</table>
</td>
<td>Demangel, 2018

Estace (2018a)
Ref : CTG181101/00/04 – 24/07/2018

Estace (2018b)
Ref : CTG181101/00/02 – 24/07/2018

Keravec (2019a)
Ref : CTG181101/00/04 – 24/07/2018

Keravec (2019b)
Ref : CTG181101/00/02 – 24/07/2018</td>
<td>Product is stable after 8weeks at 40°C. Tests are performed with the new sprayer system as the older is not used anymore. Product should not be stored at a temperature above 40°C.</td>
</tr>
</table>

		Batch# CTG181101/00/02: 20.7%$_{w/w}$ IR3535 250mL HDPE spray trigger flask	Appearance	Homogeneous colourless limpid liquid with a characteristic odour	No change		
			Appearance of packaging	White opaque HDPE flask	No weight change No sign of degradation or leak		
			AS content	20.7 %$_{w/w}$	19.9 %$_{w/w}$		
			%variation		-3.9% compared to T0		
			Determination of the satisfactory operation of the spray	No blocking observed	No blocking observed		
			Spray volume	0.396 mL	0.445 mL		
			Spay diameter and pattern at a distance of 30 cm	28 cm Dispersed point cloud	23 cm Dispersed point cloud		
			Droplet size [Laser light diffraction]	Dv(10) = 37.5 µm Dv(50) = 69.3 µm Dv (90) = 120.7 µm	Dv(10) = 32.8 µm Dv(50) = 65.6 µm Dv (90) = 117.1 µm		

Physical compatibility	[Laser light diffraction, technical compliance to the requirements of21 CFR Part 11 and the ISO13320:2009]	Batch # CTG181101/00/04: 20.7%$_{w/w}$ IR3535 100mL HDPE Spray	Determination of the satisfactory operation of the spray: No blocking observed Spray volume (mean): 0.099 mL Spay diameter and pattern at a distance of 30 cm: 10 cm, Circular point cloud Droplet size [Laser light diffraction]: Dv(10) = 37.6 µm; Dv(50) = 68.6 µm; Dv (90) = 118 µm		Acceptable Tests are available with the new sprayer system as the older are not used anymore
		Batch# CTG181101/00/02: 20.7%$_{w/w}$ IR3535 250mL HDPE spray trigger flask	Determination of the satisfactory operation of the spray: No blocking observed Spray volume: 0.396 mL Spay diameter and pattern at a distance of 30 cm: 28 cm, Dispersed point cloud Droplet size [Laser light diffraction]: Dv(10) = 37.5 µm; Dv(50) = 69.3 µm; Dv (90) = 120.7 µm		

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

The SPRAY REPULSIF IR200 – 2019 (major change) as manufactured is a clear, colourless to slightly yellowish, homogenous liquid with a mild characteristic, slight alcoholic smell. The relative density of the product is 0.951 g/mL at 20 °C. At 20°C and a concentration between 1.0 vol% and 100 vol%, the pH value is between 5.7 and 6.7. The product is stable under cold and accelerated (8 weeks at 40°C) storage conditions. As the long term storage study is not yet available and the old study is not acceptable after 24 months storage (loss of active substance >10%), the shelf life of the product is kept at 18 months.
A long term storage study (on actual sprayer system product and with free acid content before and after storage) can be provided in a minor change dossier to claim a new shelf life for the product.

Light influence is avoided by using a lightproof plastic packaging. There are no humidity effects expected in that closed package. The product should not be stored for prolonged times (more than 8 weeks) at temperatures >40°C. The surface tension is 29.447 mN/m and the viscosity at 20°C is 5.66 mPa.s. At 40°C the viscosity is 3.17 mPa.s. Physical and chemical compatibility with other products are not relevant.

The change of spray device (major change 2019) was supported with sufficient data.

- **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2021 (FR CA)**

New data are presented in the context of this minor change to support:

- The increase of the shelf-life from 18 to 24 months.
  - Ambient storage data on two packs (100 mL with 100 µL discharge rate and 250 mL with 400 µL discharge rate) covering all requirements up to 24 months. A partial data set is also available up to 30 months of storage.
- The addition of a new spray pump with a 300 µL/spray discharge rate.
  - The selected 300µl pump differs from the already authorised 100µl pump only by the sprayed volume. This volume depends on the combination of the stroke of the sprayer with the volume contained in the pump body. These elements have no impact on the quality of the spraying. Indeed, spraying characteristics such as the spray pattern and drop size depend only on the nozzle in the push button. This nozzle is identical in both pumps (100 and 300 µl). The quality of spraying will therefore be identical between the 2 pumps.
    Concerning the compatibility of the 300µl pump with the formula, the materials used for each component being the same as for the 100µl version, the physicochemical interactions between the formula and the two pumps will be identical. Finally, as far as the tightness of the pump is concerned, this is given by the internal seal (internal gasket) at the nozzle and through the external gasket at the bottle, in the same crimping conditions on the same bottle, the sealing will be assured of the same way between the 2 pumps of 100 and 300 µl.
  - An accelerated storage stability study is submitted on this new pump to show that its stability is similar to the 100 µL pump.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments

<table>
<tr>
<td>Storage stability test – Long term storage</td>
<td>Gifap Monograph No.17
Method to quantify the AS study # 18-905023-003</td>
<td>Spray Repulsif IR200, 20% w/w IR3535, Batch CTG181101/00/04</td>
<td>Storage at ambient temperature (20°C) in a 100 mL commercial packaging (HDPE) with a spray head of 100 µL discharge rate.
<table>
<tr><td></td><td>T0</td><td>After 24 months</td><td>After 30 months</td></tr>
<tr><td>Appearance</td><td>Homogeneous colourless limpid liquid with a characteristic odour</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>White opaque HDPE flask</td><td>No change
No sign of degradation or leak</td><td>No change
No sign of degradation or leak</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0.9%</td><td>1.3%</td></tr>
<tr><td>AS content</td><td>20.7 %w/w</td><td>20.4 %w/w</td><td>20.8 %w/w</td></tr>
<tr><td>%variation</td><td>/</td><td>-1.4% compared to T0</td><td>+0.5% compared to T0</td></tr>
<tr><td>pH</td><td>/</td><td>5.35</td><td>5.20</td></tr>
<tr><td>Clogging</td><td>No blocking observed</td><td>No blocking observed</td><td>Ongoing</td></tr>
<tr><td>Discharge rate</td><td>0.092ml</td><td>0.098ml</td><td>Ongoing</td></tr>
<tr><td>Spray pattern</td><td>9cm
Circular point cloud</td><td>17cm
Circular point cloud</td><td>Ongoing</td></tr>
<tr><td>Droplet size distribution</td><td>Dv(10) = 37.6 µm
Dv(50) = 68.6 µm
Dv (90) = 118 µm</td><td>Dv(10) = 35.43 µm
Dv(50) = 82.23 µm
Dv (90) = 164.12 µm</td><td>Ongoing</td></tr>
</table>
</td>
<td>B. Demangel, 2021, Report No. 18-905023-002

B. Demangel, 2021, Report No. 19-905023-001 intermediary</td>
<td>Product is stable after 24 and 30 months at ambient temperature.</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Gifap Monograph No.17
Method to quantify the AS study # 18-905023-003</td>
<td>Spray Repulsif IR200, 20% w/w IR3535, Batch CTG181101/00/02</td>
<td>Storage at ambient temperature (20°C) in a 250 mL commercial packaging (HDPE) with a spray head of 400 µL discharge rate.
<table>
<tr><th></th><th>T0</th><th>After 24 months</th><th>After 30 months</th></tr>
<tr><td>Appearance</td><td>Homogeneous colourless limpid liquid with a characteristic odour</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>White opaque HDPE flask</td><td>No change
No sign of degradation or leak</td><td>No change
No sign of degradation or leak</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0.2%</td><td>0.4%</td></tr>
<tr><td>AS content</td><td>20.7 %w/w</td><td>19.8 %w/w</td><td>20.2 %w/w</td></tr>
<tr><td>%variation</td><td>/</td><td>-4.3% compared to T0</td><td>-2.4% compared to T0</td></tr>
<tr><td>pH (19°C)</td><td>/</td><td>5.35</td><td>5.15</td></tr>
<tr><td>Clogging</td><td>No blocking observed*</td><td>No blocking observed</td><td>No blocking observed</td></tr>
<tr><td>Discharge rate</td><td>0.396 mL*</td><td>0.398 ml</td><td>0.400 mL</td></tr>
<tr><td>Spray pattern</td><td>28 cm
Circular point cloud*</td><td>24 cm
Circular point cloud</td><td>24 cm
Circular point cloud</td></tr>
<tr><td>Droplet size distribution</td><td>Dv(10) = 37.5 µm
Dv(50) = 69.3 µm
Dv (90) = 120.7 µm*</td><td>Dv(10) = 42.28 µm
Dv(50) = 79.69 µm
Dv (90) = 145.76 µm</td><td>Dv(10) = 82.92 µm
Dv(50) = 192 µm
Dv (90) =</td></tr>
</table>
</td>
<td>B. Demangel, 2021, Report No. 18-905023-002</td>
<td>Product is stable after 24 months at ambient temperature.</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td></td><td></td><td>326.5 µm</td></tr>
</table>
*: taken from the t0 results of the accelerated storage study performed on the same batch
</td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT46.3</td><td>Spray Repulsif IR200, 20% w/w IR3535, Batch # CTG201228/00/01-A</td><td>Storage at 40°C for 8 weeks in a 100 mL commercial packaging (HDPE) with a spray head of 300 µL discharge rate.
<table>
<tr><td></td><td>T0</td><td>After storage</td></tr>
<tr><td>Appearance</td><td>Homogeneous colourless limpid liquid with a characteristic odour</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>White opaque PE spray</td><td>No change
No sign of degradation or leak</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0.6%</td></tr>
<tr><td>pH Value (19°C)</td><td>6.10</td><td>5.85</td></tr>
<tr><td>Clogging</td><td>No blocking observed</td><td>No blocking observed</td></tr>
<tr><td>Discharge rate</td><td>0.268 mL</td><td>0.265 mL</td></tr>
<tr><td>Spray pattern</td><td>15 cm
Circular point cloud</td><td>15 cm
Circular point cloud</td></tr>
</table>
</td><td>P. Padilla, 2020, Report No. 20-905023-001</td><td>Acceptable.
The product in its 100 mL-300 µL packaging can be concluded to be stable for two years at 40°C.
The stability of this new spray head is identical to the one of the spray head already authorised (100 µL discharge rate).</td></tr>
</table>

Conclusion on the physical, chemical and technical properties of the product – Minor Change application 2021
New storage stability studies have been submitted in the context of a minor change application (2021): - Ambient storage up to 24 months in a 100 mL packaging with a spray head with a discharge rate of 100 µL/spray. - Ambient storage up to 30 months in a 100 mL packaging with a spray head with a discharge rate of 100 µL/spray and in a 250 mL packaging with a spray head with a discharge rate of 400 µL/spray. - Accelerated storage (8 weeks at 40°C) in a 100 mL packaging with a new spray head with a discharge rate of 300 µL/spray.

The results show that the product is stable in all of the test packs. The accelerated storage results on the new spray head show that it is at least as stable as the previously authorised spray head with a 100 µL discharge rate.

In conclusion:

- The addition of a spray device with a 300 µL discharge rate is supported with sufficient data.
- The shelf-life of the product is increased to 24 months.

- **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2022**

New data are presented in the context of this minor change to support:

- The increase of the shelf-life from 24 to 30 months.
  - Complete ambient storage data on 100 mL with 100 µL discharge rate covering all requirements up to 30 months (interim data were provided in the previous minor change).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments

<table>
<tr>
<td>Storage stability test – Long term storage</td>
<td>Gifap Monograph No.17
Method to quantify the AS study # 18-905023-003</td>
<td>Spray Repulsif IR200, 20% w/w IR3535, Batch CTG181101/00/04</td>
<td>Storage at ambient temperature (20°C) in a 100 mL commercial packaging (HDPE) with a spray head of 100 µL discharge rate.
<table>
<tr><td></td><td>T0</td><td>After 24 months</td><td>After 30 months</td></tr>
<tr><td>Appearance</td><td>Homogeneous colourless limpid liquid with a characteristic odour</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>White opaque HDPE flask</td><td>No change
No sign of degradation or leak</td><td>No change
No sign of degradation or leak</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-1%</td><td>-0.9%</td></tr>
<tr><td>AS content</td><td>20.7 %w/w</td><td>20.4 %w/w</td><td>20.8 %w/w-</td></tr>
<tr><td>pH</td><td>/</td><td>5.20</td><td>5.20</td></tr>
<tr><td>Clogging</td><td>No blocking observed</td><td>No blocking observed</td><td>No blocking observed</td></tr>
<tr><td>Discharge rate</td><td>0.092ml</td><td>0.098ml</td><td>0.097ml</td></tr>
<tr><td>Spray pattern</td><td>9cm
Circular point cloud</td><td>17cm
Circular point cloud</td><td>17cm
Circular point cloud</td></tr>
<tr><td>Droplet size distribution</td><td>Dv(10) = 37.6 µm
Dv(50) = 68.6 µm
Dv (90) = 118 µm</td><td>Dv(10) = 35.43 µm
Dv(50) = 82.23 µm
Dv (90) = 164.12 µm</td><td>Dv(10) = 28.55 µm
Dv(50) = 68.05 µm
Dv (90) = 144.72 µm</td></tr>
</table>
</td>
<td>B. Demangel, 2021, Report No. 19-905023-001

B. Demangel, 2021, Report No. 18-905023-002</td>
<td>Product is stable after 30 months at ambient temperature.</td>
</tr>
</table>

Conclusion on the physical, chemical and technical properties of the product – Minor Change application 2022

New storage stability studies have been submitted in the context of a minor change application (2022):

- Ambient storage up to 30 months in a 100 mL packaging with a spray head with a discharge rate of 100 µL/spray.

Previous results and data were deemed enough to support 30 months shelf life for 250 mL packaging with a trigger spray of 450µL/spray (refer to data submitted in MIC 2021). Additionally, an accelerated storage results on the 300 µL/spray head showed that this packaging was at least as stable as the previously authorized spray head with a 100 µL discharge rate. Therefore the shelf life of 30 months can be granted for this spray device with a 300 µL discharge rate.

All these results show that the product is stable in all of the test packs at 30 months.

In conclusion:

- The shelf-life of the product is increased to 30 months.

2.2.4 Physical hazards and respective characteristics

- **FIRST AUTHORISATION – 2017 (BE CA)**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived	-	None of the ingredients of the product is classified as explosive.	-
Flammable gases	Waived	-	Not applicable since biocidal product is a liquid.	-
Flammable aerosols	Waived	-	Not applicable since biocidal product is a liquid.	-
Oxidising gases	Waived	-	Not applicable since biocidal product is a liquid.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Gases under pressure	Waived	-	Not applicable since biocidal product is a liquid.	-
Flammable liquids	EC A.9, under GLP, with elements of ISO 2719 OPPTS 830.6315 ASTM D 7094-04	READ-ACROSS Insect Repellent Pump Spray IR3535® 20% without Bitrex	Flash point: 28.7°C	63161189, Fieseler, A., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH
Flammable solids	Waived	-	Not applicable since biocidal product is a liquid.	-
Self-reactive substances and mixtures	Waived	-	The mixture does not contain any substances known to self-react or with chemical groups present in their molecules that are associated with explosive or self-reactive properties.	-
Pyrophoric liquids	Waived	-	The mixture does not contain any substances known to react with air so the mixture is no pyrophoric liquid.	-
Pyrophoric solids	Waived	-	Not applicable since biocidal product is a liquid.	-
Self-heating substances and mixtures	Waived	-	The mixture is not self-heating since it is a liquid at room temperature. Since the liquid will also not be absorbed onto powder particles thus generating a large surface, no self-heating must be considered.	-
Substances and mixtures which in contact with water emit flammable gases	Waived	-	Not applicable since biocidal product is a ready to use liquid.	-
Oxidising liquids	Waived	-	None of the ingredients of the product is classified as oxidising.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising solids	Waived	-	Not applicable since biocidal product is a liquid.	-
Organic peroxides	Waived	-	Not applicable since biocidal product does not contain any organic peroxide.	-
Corrosive to metals	Waived	-	None of the ingredients in the mixture is classified as corrosive or suspected from a chemical point of view to be able to react with metals and thus, the mixture is also not corrosive to metal.	-
Auto-ignition temperatures of products (liquids and gases)	EC A.15, under GLP	READ-ACROSS Insect Repellent Pump Spray IR3535® 20% without Bitrex	Auto-ignition temperature: 440°C	20110103.01, Dornhagen, J., 2011. Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany
Relative self-ignition temperature for solids	Waived	-	Not applicable since biocidal product is a liquid.	-
Dust explosion hazard	Waived	-	Not applicable since biocidal product is a liquid.	-

Conclusion on the physical hazards and respective characteristics of the product
Based on read-across from the Pump Spray IR3535® 20%, the auto-ignition temperature of the product is 440°C and the flashpoint is 28.7°C. The product contains no ingredients that are classified as explosive, has no self-reacting properties, does not react with air, and is not self-heating since it is a liquid at room temperature. It is not able to react with metals and is not corrosive. The product is not oxidizing nor explosive yet, given the flashpoint results, must be classified as flammable liquid, category 3.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Conclusion on the physical hazards and respective characteristics of the product
No modification of physical hazard conclusions.

- **MINOR CHANGE FOR SPRAY REPULSIF IR200 – 2021 (FR CA)**

Conclusion on the physical hazards and respective characteristics of the product
No modification of physical hazard conclusions.

2.2.5 Methods for detection and identification

- **FIRST AUTHORISATION – 2017 (BE CA)**

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IR3535 – Lice Spray	HPLC-UV (*) SANGO/3030/99 rev. 4 guideline (*) Method previously validated in 3121101, Meinerling, M., 2007. Institut für Biologische Analytik und Consulting IBACON GmbH HPLC-UV (*) SANGO/3030/99 rev. 4 guideline	2 levels (90% and 110%) 5 replicates	Calibration curve between 5 and 1750 mg/L, based on 10 data points, r2 = 0.9999	Comparison of UV-spectra with fortified sample solutions, no difference by more than 1%	90% 99-102 110% 99-100	90% 100 110% 100	90% 1.2 110% 0.5	5% w/w (=250 mg/L) 7mg/L LOD	63172204, Meinerling, M. and Herrmann, S., 2011. Institut für Biologische Analytik und Consulting IBACON GmbH Meinerling, M. and Fieseler, A., 2016 READ-ACROSS from 98322204, Fieseler, A. 2015. Institut für Biologische Analytik und Consulting IBACON GmbH
Free acid – Lice Spray			Calibration curve between 5 and 300 mg/L, based on at least 8 data points, r2 =0.9999		90% 107-114 110% 101-103	90% 111 110% 102	90% 2.5 110% 0.9	0.1% w/w (=5 mg/L) 3mg/L LOD	

Conclusion on the methods for detection and identification of the product
IR3535 and its metabolite IR3535 free acid (hydrolysis product) can both be determined in the Pump Spray Lice product with an HPLC-Diode Array Detector/UV-VIS detector (at 220nm) and a RP18 (250*4 mm) column. The identity of the analyte is confirmed by comparison of the retention times. The standard regression is linear. The method is repeatable. The mean recovery rates at each spiking level are in the range of 100-111%. Repeated injection of the Pump Spray Lice samples resulted in a coefficient of variation which was less than 1.7 %. The limit of quantification (LOQ) is 5% for IR3535 corresponding to 250 mg/L and the limit of detection (LOD) is 7 mg/L for IR3535. The limit of quantification (LOQ) is 0.1% for IR3535 free acid corresponding to 5 mg/L and the limit of detection (LOD) is 3 mg/L for IR3535 free acid. For other analytical methods refer to the CAR of active substance.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Conclusion on the methods for detection and identification of the product
No modification of the conclusion on the methods for detection and identification of the product.

2.2.6 Efficacy against target organisms

2.2.6.1 Function and field of use

- **FIRST AUTHORISATION – 2017 (BE CA)**

Main Group 03: Pest Control

Product Type 19: Repellents and attractants

The product ***Insect Repellent Pump Spray Lice IR3535® 20%*** is presented as a ready-to-use leave-on pump spray to be applied on clean & dried human hair, the nape of the neck and behind the ears; and is intended to be used to repel human head-lice (*Pediculus humanus capitis)* only, after a pediculicidal treatment.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The product SPRAY REPULSIF IR200 (same as INSECT REPELLENT PUMP SPRAY LICE IR3535® 20%), was initially authorized to be used to repel human head-lice (*Pediculus humanus capitis*) only, after a pediculicidal treatment.

The applicant requires a major change application consisting of the addition of uses by application on skin or on bed linen and/or cloth's surface and the addition of target organisms: mosquitoes (*Aedes spp., Culex spp.* and *Anopheles spp.*), hard ticks (*Ixodes Ricinus*) and house dust mites (*Dermatophagoïdes pteronyssinus*).

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

According to the use claimed by the Applicant :

- The product ***Insect Repellent Pump Spray Lice IR3535® 20%*** is intended to be used to repel arthropods (PT19).

- The target organisms to be control are human head-lice (*Pediculus humanus capitis)* only.

- The organisms to be protected are humans.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

According to the new uses claimed by the applicant, in the frame of the major change application, the new target organisms to be control are:

- Mosquitoes (*Aedes aegypti, Culex quinquefasciatus, Aedes albopictus and Anopheles gambiae*) by application on skin and cloth's surface (cotton and polyester) in temperate and tropical conditions.
- Hard ticks (*Ixodes Ricinus*) by application on skin and cloth's surface (cotton and polyester) in temperate conditions.
- Human head lice (*Pediculus humanus capitis*) by application on skin and cloth's surface (cotton and polyester).
- House dust mites (*Dermatophagoïdes pteronyssinus*) by application on bed linen/cloth's surface (cotton).

2.2.6.3 Effects on target organisms, including unacceptable suffering

- **FIRST AUTHORISATION – 2017 (BE CA)**

Important note from the eCA :

Requirements and pass criteria for repellents used against lice are not currently mentioned in the TNsG on Product Evaluation-PT18&19.

Lice are irritating, not highly dangerous but they might spread diseases. Lice are most common in children in a school or day care setting and may be considered as a public health issue. So, BE eCA is of the opinion that a repellent against lice might be considered to be sufficiently "effective" if more than 90% repellence can be achieved in lab conditions and more than 80% repellence in field conditions*.

* Please note that other MSs are rather in favour of an efficacy criteria of 90 % for field test (same efficacy criteria than ticks for field test). This issue about pass criteria must be discussed & confirmed by the WG and then applied for all other similar products.
However, since the claim should read "limits the infestation with head lice" and not "prevents... ", we're of the opinion that a 80% pass criteria could be acceptable and sufficient.

The applicant submitted 2 following field studies:

1) *A randomised comparative bio-clinical in vivo trial to demonstrate the efficacy of a repellent lotion (20% w/w IR3535 in an ethanol excipient a 95%) versus a negative control formulation and a reference product (20% w/w DEET) in order to evaluate its efficacy to prevent re-infestation of adult lice on children living in a very infested environment, after treatment with an anti-lice shampoo.*

   The duration of efficacy of the product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535 - composition reported in the test report & validated) was tested under field conditions (Doc N° 336-1905/1993) against head-lice *Pediculus humanus capitis* by 60 volunteers.

   Study centre :

   A school in Madagascar where the prevalence of the pediculosis is very high.

   Duration of the study : 7 days

   Methodology :

   After treatment with a pediculicidal shampoo, the 60 highly lice infected (26 adult lice per subject) volunteers are separated into 3 groups : one group treated with 0.5 mL of the lotion containing 20% w/w IR3535; one group treated with a spray containing 20% w/w DEET (reference product) and one group untreated.

   The subjects in the tested groups were sent to the investigating doctors who moistened the hair with repellent lotion, making sure to include behind the ears and the nape of the neck, lifting up the hair in the case of long or mid-length hair.

   The repellent was applied a second time four days later.

   At Day 7, the children were then combed out with a fine toothcomb to note the attendance/absence of alive adult lice.

   Results :

	Infestation Day 0	Infestation Day 7
20% w/w IR3535 Lotion	520 (26 adult lice / subject)	3 => > 97% less adult lice
20% w/w DEET spray	531 (27 adult lice / subject)	8 => > 93% less adult lice
Control – untreated	493 (25 adult lice / subject)	116

On D7, the study showed that the group treated with a repellent spray (20% w/w IR3535 or 20% w/w DEET) has 90% less more adult lice than the untreated group.

Conclusion : Reliability 2 – Old study

Based on these efficacy data, the product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535), used at a rate of 0.5 mL after treatment with an anti-lice shampoo and applied every 4 days, does limit (> 90 % repellency) adult lice re-infestation up to 7 days.

2) *A randomised comparative bio-clinical in vivo trial to demonstrate the efficacy of a repellent spray (20% w/w IR3535 in an ethanol excipient at 95%) versus a negative control formulation in order to evaluate its efficacy to prevent re-infestation of lice on children living in a very infested environment, after treatment with a pediculicidal lotion.*

The duration of efficacy of the product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535 - composition reported in the test report & validated) was tested under field conditions (Doc N° 336-1920/2009) against head-lice *Pediculus humanus* capitis by 80 volunteers.

Study centre :

A school in Brazil where the prevalence of the pediculosis is very high.

Duration of the study : 9 days

Methodology :

After treatment with a pediculicidal lotion (containing oxyphthirine – 8h contact time) and a washing with an ordinary shampoo, the 80 highly lice infected (10 adult lice per subject) volunteers are separated into 2 groups : one group treated with the lotion containing 20% w/w IR3535 (Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex – at a rate of 0.5 mL per treatment) and the other group with the negative control formulation (same co-formulants but IR3535 replaced by water). The subjects in the tested groups were sent to the investigating doctors who applied the product i.e. on hair closed to the scalp and specially behind the ears and the nape of the neck, then sprayed on the totality of hair like a lacquer and lifting up the hair in the case of long or mid-length hair. The repellent spray or the negative control formulation was applied every 2 days (on D1; 3; 5 and 7 - 4 times treatment). The children were then combed out with a fine toothcomb to note the attendance/absence of alive adult and/or immature lice.

Results :

	Infestation Day 0	Infestation Day 5	Infestation Day 9
20% w/w IR3535 Lotion	7.9 [a]	0.27 [a]	0.42 [a*]
Control – untreated	10.23[a]	0.52 [a]	1.72 [a*]

[a] total infestation (mean lice per subject)

[*] significant difference (t-test P = 0.0447)

On D5, the difference between both groups was not significant.

In contrast, on D9, the study showed that the group treated with the negative control formulation has 4 times more lice than the group treated with the Insect Repellent Pump Spray Lice IR3535® 20% i.e. 80%* repellency.

* Please note that the 80% value has been determined taking into account some practical deviations.

Justification : Some children were not present for treatment on day 5 (Saturday, school was closed). They have been included into the results as they received a treatment on day7. Further, the number of alive lice differ even more between the treatment groups indicative of repellence > 80% on day 9. Further evaluation shows that the number of children without lice in the treatment group is higher and the number of lice on the remaining affected children is reduced too.

Conclusion : Reliability 1

Based on these efficacy data, the product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535), used at a rate of 0.5 mL per treatment after a pediculicidal treatment and applied every 2 days, does limit adult lice re-infestation (80 % up to 9 days).

2.2.6.4 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.

2.2.6.5 Efficacy data

- **FIRST AUTHORISATION – 2017 (BE CA)**

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**
PT19 Repellent	- Anti-lice repellent pump spray to prevent lice re-infection – RTU leave-on product - After the use of a pediculicidal shampoo - RTU pump spray - Applied on human scalp and hair - For consumers	IR3535® 20% alcoholic solution	HEAD LICE *Pediculus humanus capitis*	Comparative bio-clinical *in vivo* trial	- with 60 volunteers - 0.5 mL /application - Every 4 days application, like a lacquer on dried hair/scalp - Up to 7 days	> 90% less adult lice than the untreated group	Doc N° 336-1905/1993 Reliability 2 (old study)
PT19 Repellent	- Anti-lice repellent pump spray to prevent lice re-infection – RTU leave-on product - After the use of a pediculicidal lotion - RTU pump spray - Applied on human scalp and hair - For consumers	Insect Repellent Pump Spray Lice IR3535® 20% without Bitrex	HEAD LICE *Pediculus humanus capitis*	Comparative bio-clinical *in vivo* trial	- with 80 volunteers - 0.5 mL /application - Every 2 days application, like a lacquer on dried hair/scalp - Up to 9 days	> 80% less adult lice than the untreated group	Doc N° 336-1920/2009 Reliability 1

Conclusion on the efficacy of the product
The RTU leave-on product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535), used after a pediculicidal treatment and applied every 2 days at a rate of 0.5 mL, does limit adult head lice (*Pediculus humanus capitis*) re-infestation only.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

To support the efficacy of the product SPRAY REPULSIF IR200 by application on skin or on bed linen and/or cloth's surface, the applicant has submitted the following studies:

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	Skin application	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	*Aedes aegypti* *Culex quinquefasciatus* 200 mosquitoes +/- 10 per cage (females between 5 and 7 days old) density: 1 mosquito per 320 cm^3	Based on WHO/HTM/NTD/WHOPES/2009.4 Guideline for efficacy testing of mosquito repellents for human skin	Arm in cage with 10 human volunteers (five men and five women) Application rate: 6 $g.m^{-2}$ The control forearm was inserted into the cage for 30 seconds and after validation of this control (10 landings/bites), the treated forearm was inserted into the cage 5 minutes (exposure time). The same procedure was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product. Landings and bites were counted during each exposure time. Temperate conditions: 25°C +/- 2°C; 70% RH +/- 5%	After application of the product of skin, complete protection time (CPT) was: - 4 hours for *A. aegypti* and *C. quinquefasciatus*	Serrano, 2018 RI=1 Report 2302-IR353520%-mosq-AIC/0118R
Repellent	Skin application	SPRAY IR3535 20% ANTI-POUX	Aedes albopictus	Based on WHO/HTM/NT	Arm in cage with 10 human volunteers (five men and five women)	After application of the product of skin, complete	Serrano, 2018

		Batch No 20180118L1	Anopheles gambiae 200 mosquitoes +/- 10 per cage (females between 5 and 7 days old) density: 1 mosquito per 320 cm3	D/WHOPES/2009.4 Guideline for efficacy testing of mosquito repellents for human skin	Application rate: 8 g.m-2 The control forearm was inserted into the cage for 30 seconds and after validation of this control (10 landings/bites), the treated forearm was inserted into the cage 5 minutes (exposure time). The same procedure was repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product. Landings and bites were counted during each exposure time. Tropical conditions : 32°C +/- 2°C; 80% RH +/- 5%	protection time (CPT) was: - 3h against A. Albopictus - 4h against A. Gambiae Based on the less sensitive species, the complete protection time of the product is 3 hours when the product is applied on skin under tropical conditions.	RI=1 Report 2302-IR353520%-mosq2-AIC/0118R
Repellent	Application on fabric (clothes)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Aedes albopictus Aedes aegypti Culex quinquefasciatus Anopheles gambiae 200 mosquitoes +/- 10 per cage (females between 5 and 7 days old) density: 1 mosquito per 320 cm3	Derivated from WHO/HTM/NTD/WHOPES/2009.4	Arm in cage with 10 human volunteers (five men and five women) Application rates: 8.5 g.m-2 and 10 g.m-2 Application on two types of fabric: cotton (density: 75 g/m2) and polyester (density: 130g/m2). Before the test, the subject's forearms were washed thoroughly with a fragrance-free soap. Each hand was covered with a vinyl glove. For each volunteer, one of the forearm, covered by a fabric not treated with the test product, was used as a control to	For both application rate and all species: 100% of protection (no bite) 30 days after the product application. Nevertheless this study has not been used to derive a CPT against mosquitoes when the product is applied on fabric as only one observation has been carried out.	Serrano, 2018 RI=3 (supportive data) Report 2302-mosq/0118

					demonstrate the attractiveness of arthropods to the volunteer's skin. The control forearm was inserted into the cage for 30 seconds and after validation of this control (10 landings or 5 bites), the treated forearm was inserted into the cage 5 minutes (exposure time), 30 days after the product application (flat storage at 32 ° C +/- 2 ° C and 70% relative humidity) Landings and bites were counted during exposure time. Temperate conditions (i.e. 27°C +/- 2°C; 60% +/- 5% RH), except for A. gambiae (Tropical condition: 32°C +/- 2°C, 80% +/- 5% RH).		
Repellent	Application on fabric (clothes)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Aedes albopictus Aedes aegypti Culex quinquefasciatus Anopheles gambiae 200 mosquitoes +/- 10 per cage (females between 5 and 7 days old)	Derivated from WHO/HTM/NTD/WHOPES/2009.4	Arm in cage with 10 human volunteers (five men and five women) Application rates: 6.0 g.m-² and 8.5 g.m-2 Application on two types of fabric: cotton (fabric density: 75 and 130 g.m-2) and polyester (fabric density: 100 and 150 g.m-2). Before the test, the subject's forearms were washed thoroughly with a fragrance-free soap. Each hand was covered with a vinyl glove.	For both application rate, all fabrics, and all species: 8 hours of complete protection time, after 0, 15, and 30 days of fabric storage post-treatment.	Serrano, 2019 RI=1 Report 2437-mosq/0319

			density: 1 mosquito per 320 cm3		For each volunteer, one of the forearm, covered by a fabric not treated with the test product, was used as a control to demonstrate the attractiveness of arthropods to the volunteer's skin. The control forearm was inserted into the cage for 30 secondes and after validation of this control (5 landings and 2 bites), the treated forearm was inserted into the cage 5 minutes (exposure time). The same procedure was repeated every hour until 8 hours or inefficacy of the product (after 0, 15, and 30 days after application on fabric). Landings and bites were counted during each exposure time. Temperate conditions (i.e. 27°C+/- 2°C; 60% RH +/- 5%), except for A. albopictus and A. gambiae (tropical conditions: 32°C +/- 2°C; 80% RH +/- 5%)		
Repellent	Application on fabric (clothes)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Ixodes ricinus 5 female adults per replicates 5 nymphs per replicates 10 replicates per development stage	Derivated from EPA Guidance OPPTS 810.3700 (2010) Temperature: 25°C ± 2°C,	Laboratory choice test with 10 mice (Mus musculus) per condition. Application rate: 6 g.m-2 Application on two types of fabric: cotton (density: 175 g/m2) and polyester (density: 125 g/m2).	At 6 g.m-2, 100 % of repellency 24h after the product application on both type of fabric Nevertheless this study has not been used to derive a CPT against ticks	Serrano, 2018 RI=3 (supportive data) Report 2302-IR353520%-ticks/0118R

				Relative humidity: 65% ± 5%	The mice are maintained inside a net cage with their head and eyes protected from the bites. The fabric sleeves (24h after application of the product) are tightly twisted around the body of the mice. Ticks placed on an untreated zone 3 cm away from the treated mouse. Records of the number of ticks crossing the separating line between the untreated area and the treated part during 5 minutes (exposure time). A tick that walked these 3 cm and went on the mouse into the treated area or that crawls into the treated area but immediately turns back or falls off was reported as "repelled".	when the product is applied on fabric as only one observation has been carried out.	
Repellent	Application on fabric (clothes)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Ixodes ricinus 10 female adults per replicates 10 nymphs per replicates 10 replicates per development stage	Derivated from OPPTS 810.3700 (2010) Temperature: 27°C ± 2°C, Relative humidity: 60% ± 5%	Laboratory choice test with 10 mice (Mus musculus) per condition. Application on two types of fabric: cotton (fabric density: 75 and 130 g.m-2) and polyester (fabric density: 100 and 150 g.m-2). Application rate: 8.5 g.m-2 The mice are maintained inside a net cage with their head and eyes protected from the bites. The fabric sleeves (0, 3 and 7 days after application of the	For all fabrics after 0, 3, and 7 days of fabric storage post-treatment, the test item has proven a protection over a period of 6.0 hours against the adults and the nymphs of the tick Ixodes ricinus.	Serrano, 2019 RI=2 Report 2437-tick/0319

					product) are tightly twisted around the body of the mice. Ticks are placed on an untreated zone 3 cm away from the treated mouse. Fresh ticks were exposed to the treated area at regular intervals for the duration of the test (or until inefficacy) and the number of ticks crossing the separating line between the untreated area and the treated area during 5 minutes (exposure time) have been recorded. Some human volunteers keep the sleeves on their forearms during the trial (between exposures) in order to reproduce the reality of use along a day of wearing a cloth. A tick that walked these 3 cm and went on the mouse into the treated area or that crawls into the treated area but immediately turns back or falls off was reported as "repelled".		
Repellent	Application on fabric (clothes)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Ixodes ricinus 5 female adults per replicates 5 nymphs per replicates 10 replicates per development stage	Derivated from EPA Guidance OPPTS 810.3700 (2010) Temperature: 25°C ± 2°C, Relative humidity: 65% ± 5%	Laboratory choice test with 10 mice (Mus musculus) per condition. Application rate: - 8.5 g.m-2 (after 10 and 14 days of storage) - 10 g.m-2 (after 14 and 30 days of storage)	This study has not been used to derive a CPT against ticks when the product is applied on fabric as only one observation has been carried out.	Serrano, 2018 RI=3 (supportive data) Report 2302-tick/0118

					Application on two types of fabric: cotton (density: 75 g/m2) and polyester (density: 130 g/m2). The mice are maintained inside a net cage with their head and eyes protected from the bites. The fabric sleeves are tightly twisted around the body of the mice. Ticks placed on an untreated zone 3 cm away from the treated mouse. Records of the number of ticks crossing the separating line between the untreated area and the treated part during 5 minutes (exposure time). A tick that walked these 3 cm and went on the mouse into the treated area or that crawls into the treated area but immediately turns back or falls off was reported as "repelled".		
Repellent	Skin application	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	Ixodes ricinus 5 female adults per replicates 5 nymphs per replicates 10 replicates per development stage	Derivated from EPA Guideline OPPTS 810.3700 (2010) Temperature: 25°C ± 2°C, Relative humidity: 65% ± 5%	Laboratory choice tests with 10 mice (Mus musculus) per condition. Application rate: 6 g.m-2 The mice are maintained inside a net cage with their head and eyes protected from the bites. Ticks placed on an untreated zone 3 cm away from the treated mouse (fur).	After application of the product of skin, complete protection time was 4.5 hours against adults and 4.0 hours against nymphs. Based on the less sensitive development stage,	Serrano, 2018 RI=2 Report 2302-ticks/0118R

					Fresh ticks were exposed to the treated area at regular intervals for the duration of the test (or until inefficacy) and the number of ticks crossing the separating line between the untreated area and the treated mouse (fur) during 5 minutes (exposure time) have been recorded. A tick that walked these 3 cm and went on the mouse into the treated area or that crawls into the treated area but immediately turns back or falls off was reported as "repelled".	the complete protection duration of the product is 4 hours when the product is applied on skin.	
Repellent	Application on fabric (bed linen)	SPRAY IR3535 20% ANTI-POUX Batch No 20180118L1	House Dust mites Dermatophagoïdes pteronyssinus 1000 dust mites +/- 10 % per replicate	No guideline available for replellency test against dust mites (application on fabric), in-house method according to the principle of choice test described in the ECHA Guidance on the Biocidal Products Regulation Vol.II, part B+C (2018)	Laboratory choice test The testing apparatus was an arena of 0.5 m² (1 m long x 0.5 m wide) separated in 2 equal areas of 0.25 m², covered by a cotton, treated or not with the product. The treated side contains a source food. 1000 mites were released in the centre of the untreated half and all was left in incubation during 24 hours. Application rate: 8.5 g.m-2 4 replicates Records of the number of mites on the treated half and on the untreated half at 24 hours post-treatment.	Trials without any treatment demonstrate the palatability of the source food. At 8.5 g.m-2, 90.6% of repellency 24 hours after the product application on cotton fabric.	Serrano, 2018 RI=1 Report 2302-IR353520%-dustmites/0118
Repellent	Application on fabric (bed linen)	SPRAY IR3535 20% ANTI-POUX	Wild human head lice	In-house method	Laboratory choice test	The number of lice observed in the untreated textile	Toubaté, 2018

		Batch No 20180118L1	Pediculus humanus capitis	No guideline available for replellency test against head lice.	Application on two types of fabric: cotton and polyester. Application rate: 10 g.m-2 Evaluation of the repulsive efficacy of the product at different times (4h, 8h, 24h) after application of the product on the textile materials (disk with a diameter of 1.8 cm) placed in the middle of a target. At each time, the repulsive activity was measured 15 minutes after placing 11 lice around the treated tissue sample or not. Each test was repeated 5 times. Effectiveness criteria (percentage of repellent effect) as follows: - The percentage of lice that are at a distance of more than 6 cm from the target; - The percentage of lice that are at a distance of more than 2 cm from the target.	materials is too low (between 0 and 1 depending on the replicate) to be compared to the number of lice observed in the treated textile materials (0). Moreover, it is not possible to derive a CPT with the method used as only one observation has been carried out. Then this study has not been accepted to support the efficacy by application on fabric against lice.	Toubaté, 2019 (additional data) RI=4

- Regarding the efficacy claims by skin application:
  - The product is efficient in arm-in-cage tests at the application rate of 6 g product/m² on skin application against *Aedes aegypti* and *Culex quinquefasciatus* with a complete protection time of 4 hours under temperate conditions.

  - The product is efficient in arm-in-cage test at the application rate of 8 g product/m² on skin application against *Aedes albopictus* and *Anopheles gambiae* with a complete protection time of 3 hours (based on the less sensitive species) under tropical conditions.

  - The product is efficient at the application rate of 6 g product/m² against *Ixodes ricinus* (adult and nymphs) with a complete protection time of 4 hours under temperate conditions. Please note that laboratory choice tests have been carried out on mice instead of human volunteers as proposed in the ECHA Guidance on the Biocidal Products Regulation - Volume II Efficacy (part B/C) 2018 (paragraph 5.6.7.2.2.).

- Regarding the efficacy claims by clothes (cotton and polyester) application:
  - The product is efficient at the minimum application rate of 6 g product/m² against *Culex quinquefasciatus* and *Aedes aegypti* by clothes application in temperate conditions during 8 hours and up to 30 days after storage in a closed packaging (such as a plastic bag).

  - The product is efficient at the minimum application rate of 6 g product/m² against *Anopheles gambiae* and *Aedes albopictus* by clothes application in tropical conditions during 8 hours and up to 30 days after storage in a closed packaging (such as a plastic bag).

  - The product is efficient at the application rate of 8.5 g product/m² against *Ixodes ricinus* (adults and nymphs) by clothes application in temperate conditions during 6 hours and up to 7 days after storage in a closed packaging (such as a plastic bag). Please note that laboratory choice tests have been carried out on mice instead of human volunteers as proposed in the ECHA Guidance on the Biocidal Products Regulation - Volume II Efficacy (part B/C) 2018 (paragraph 5.6.7.2.2.).

- Regarding the efficacy claim against House Dust mites (*Dermatophagoïdes pteronyssinus*):
  - The product is efficient at the application rate of 8.5 g product/m² by application on bed linen (cotton) during 24 hours.

- Regarding the efficacy claims against human head lice (*Pediculus humanus capitis*) by application on bed linen and/or cloth's surface in contact with the top of the body:
  - FR CA consider that the test design in not relevant to demonstrate the efficacy of the product and to derive a CPT. Please note that additional data have been provided by the applicant (Toubaté, 2019) regarding the distribution of lice on the untreated textile materials tested depending on their location in the test. Nevertheless, even with these additional data, this study has not been accepted to support the efficacy by application on fabric against lice.
    Then, efficacy against human head lice (*Pediculus humanus capitis)* by application on bed linen and/or cloth's surface is not validated.

Conclusion on the efficacy of the product

French competent authorities (FR CA) considers that the elements presented, in the frame of the assessment of the major change application, are sufficient to demonstrate the efficacy of the product SPRAY REPULSIF IR200:

- against mosquitoes (*Culex* spp. and *Aedes* spp.) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,
- against mosquitoes (*Anopheles* spp. and *Aedes* spp.) with a protection time of 3 hours when applied on skin at the application rate of 8 g product/m² under tropical conditions,
- against ticks (*Ixodes ricinus*) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,
- against House Dust mites (*Dermatophagoïdes pteronyssinus*) up to 24 hours when applied on bed linen (cotton) at the application rate of 8.5 g product/m²,
- against mosquitoes (*Culex* spp. and *Aedes* spp.) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under temperate conditions during a protection time of 8 hours after application and up to 30 days after storage in a closed packaging (such as a plastic bag),
- against mosquitoes (*Anopheles* spp. and *Aedes* spp.) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under tropical conditions during a protection time of 8 hours after application and up to 30 days after storage in a closed packaging (such as a plastic bag),
- against ticks (*Ixodes ricinus*) when applied on textile (cotton and polyester) at the application rate of 8.5 g product/m² under temperate conditions during a protection time of 6 hours after application and up to 7 days after storage in a closed packaging (such as a plastic bag).

Nevertheless, FR CA considers that the elements presented in the dossier are not sufficient to demonstrate the efficacy of the product SPRAY REPULSIF IR200 against human head lice (*Pediculus humanus capitis*) when applied on bed linen (cotton) and/or cloth's surface (cotton and polyester) at the application rate of 10 g product/m² under temperate conditions. Indeed the efficacy tests provided present methodological biases (random behaviour of lice in controls, not attracted by the textile) and the test design in not relevant to derive a CPT.

2.2.6.6 Occurrence of resistance and resistance management

Only very limited occurrence of resistance towards IR3535 has been reported so far.

A recent study[6] showed reduced sensitivity to IR3535 (12-fold) in a pyrethroid resistant Puerto Rico strain of *Aedes aegypti* compared to a non pyrethroid resistant strain (Orlando). This broad cross-resistance may suggest that the repellency resistance could be due in part to a fitness cost, expressed as altered physiological responses in olfactory pathways related to the *kdr* mutation in the sodium channel.

Considering the importance of this active substance in vector control, the authorisation holder has to implement a monitoring of scientific literature toward the active substance IR3535. Results of this assessment must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.

2.2.6.7 Known limitations

- **FIRST AUTHORISATION – 2017 (BE CA)**

6 Yiang L, at al (2019): Reduced effectiveness of repellents in a pyrethroid-resistant strain of *Aedes aegypti* (Diptera: culicidae) and its correlation with olfactory sensitivity, Pakistan, Pest Manag Sci (2019) doi: 10.1002/ps.5562.

- Only apply after use of a pediculicidal treatment

- The application must be repeated after washing the hair. The biocidal product should only be applied by adults to children under 11 years (see next comment).

- For continued protection: Reapply at the latest after 2 days on cleaned and dry or towel dried hair. Reapply earlier, if the hair was in contact with water (like after rain or swimming) until there is no longer a risk of infestation.

2.2.6.8 Evaluation of the label claims

- **FIRST AUTHORISATION – 2017 (BE CA)**

- As the application rate is not mentioned on the label, eCA have suggested to the Applicant to mention on the label "make sure that scalp & hair is sufficiently moistened".

- As the application time is not mentioned on the label, eCA have suggested to the Applicant to mention on the label that the product is a leave-on product and that the "protection time can be lowered by wash off".

- eCA is in favour to use the term "limit" instead of "prevent" to reflect the fact that the product doesn't exhibit 100% repellence !

According to the label, the product Insect ***Insect Repellent Pump Spray Lice IR3535® 20%*** is intended to be used in Europe in case of a known lice infestation (after having used a pediculicidal treatment) in order to prevent infestation or re-infestation of head lice.

Based on the efficacy tests submitted and validated, this claim is fully supported. Thus, the RTU leave-on product ***Insect Repellent Pump Spray Lice IR3535® 20%*** (hydroalcoholic solution, 20% IR3535), used after a pediculicidal treatment and applied every 2 days at a rate of 0.5 mL per treatment, does limit adult lice (*Pediculus humanus capitis*) re-infestation only and can be granted.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

French competent authorities (FR CA) assessed that the product SPRAY REPULSIF IR200 has shown a sufficient efficacy:

- against mosquitoes (genus *Culex spp*. and *Aedes spp*.) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,
- against mosquitoes (genus *Anopheles spp*. and *Aedes spp.*) with a protection time of 3 hours when applied on skin at the application rate of 8 g product/m² under tropical conditions,
- against ticks (*Ixodes ricinus*) with a protection time of 4 hours when applied on skin at the application rate of 6 g product/m² under temperate conditions,
- against House Dust mites (*Dermatophagoïdes pteronyssinus*) up to 24 hours when applied on bed linen (cotton) at the application rate of 8.5 g product/m²,
- against mosquitoes (genus *Culex spp.* and *Aedes spp.*) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under temperate conditions during a protection time of 8 hours after application and up to 30 days

after storage,
- against mosquitoes (genus *Anopheles spp.* and *Aedes spp*.) when applied on textile (cotton and polyester) at the application rate of 6 g product/m² under tropical conditions during a protection time of 8 hours after application and up to 30 days after storage,
- against ticks (*Ixodes ricinus*) when applied on textile (cotton and polyester) at the application rate of 8.5 g product/m² under temperate conditions during a protection time of 6 hours after application and up to 7 days after storage.

Please note that for uses against mosquitoes, only the efficacy against the species tested and validated under temperate conditions have been authorised under temperate conditions and only the efficacy against the species tested and validated under tropical conditions have been authorised under tropical conditions.

According to the proposal of the applicant, for the uses by clothes application an instruction of use has been added in the SPC saying that "In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).".

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

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

The product ***Repellent Pump Spray Lice IR3535 20***% is intended to be used after a pediculicidal treatment.

2.2.7 Risk assessment for human health

2.2.7.1 Assessment of effects on Human Health

- **FIRST AUTHORISATION – 2017 (BE CA)**

Acute dermal toxicity, skin and eye irritation and sensitising properties were assessed using formula EUS26-15 Insect Repellent Spray. The test substance can be regarded as representative for the product under evaluation. The main difference between the 2 formulas is the presence of an emollient at a slightly higher concentration in the product under evaluation than in EUS26-15; this substance carries no classification. The slightly higher concentration of Bitrex in the product under evaluation is not expected to influence the properties of the biocidal product. Thirdly, we note the presence (EUS26-15) / absence (product under evaluation) of a small amount of denaturant and of a film forming component. The harmonized classification of the denaturant indicates that it will not affect the results of the properties tested. The film forming component is an eye irritant; other properties of the tested mixture will not be affected. For details, see section 2.2.2 and confidential part of the PAR.

(I) Skin corrosion and irritation

- **FIRST AUTHORISATION – 2017 (BE CA)**

New data for this section are due to differences in product composition.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OPPTS 870.2500 OECD 404 EU 92/69 Annex V, B4 GLP=yes Rel=1	Albino rabbit New Zealand White 2♂, 1♀ 1 test group, 3 animals	EUS26-15 Insect Repellent Spray No vehicle 0.5 ml / 2.5 cm x 2.5 cm 4h	Erythema: 24h: 1.0 48h: 0.6 72h: 1.0 Edema: 24h: 1.0 48h: 0.6 72h: 0.3 Very slight erythema and edema. Max score erythema 1, earliest onset 0.5-1h; max score edema 1, earliest onset 0.5-1h. Very slight erythema persisted for 2 animals through study termination. No deaths, no remarkable bw changes	Tested on similar formulation; US Pump Spray Formulation	[redacted]

Individual and mean dermal scores for erythema and edema (Hurley, J.M., 2006 (a))

Animal	Erythema									Edema						
	Sex	Site	0.5 – 1 h	24 h	48 h	72 h	4 d	7 d	14 d	0.5 – 1 h	24 h	48 h	72 h	4 d	7 d	14 d
45169	M	B	1	1	1	1	1	1	1	1	1	1	0	0	0	0
45171	M	D	1	1	0	1	1	1	0	0	1	0	0	0	0	0
45186	F	B	1	1	1	1	1	1	1	0	1	1	1	1	1	0
Means 24-72 hours (individual animals)																
45169	1									0.67						
45171	0.67									0.33						
45186	1									1						
Mean 24-72 hours (all animals)																
	0.89									0.67						

Skin corrosion/irritation was assessed on EUS26-15 Insect Repellent Spray, a formulation similar to Insect Repellent Pump Spray Lice IR3535® 20%.

There were no deaths or remarkable body weight changes noted during the study. Dermal findings for the 4-hour exposure sites consisted of very slight erythema and edema (grade 1). Very slight erythema persisted for two animals through study termination. Based on the evaluation according to EU criteria, the mean scores at 24-72 hours for erythema and edema were calculated to be 0.89 and 0.67, respectively.

The mean scores determined for erythema (0.89) and edema (0.67) do not require a classification according to the EU and GHS classification and labelling system.

Although erythema grade 1 (very slight erythema, barely perceptible, area of edges not well defined) persisted in two out of three animals until the end of the 14-day post-observation period, a classification as a potential skin irritant is not required. According to EU Directive 2001/59/EC or Regulation (EC) No. 1272/2008 (CLP), a classification as a skin irritant should be considered when hyperplasia, hyperkeratosis, scaling, discoloration, fissures, scabs or alopecia persist in two or more animals at the end of the observation period which has not been observed in the skin irritation study with EUS26-15 Insect Repellent Spray.

Since EUS26-15 Insect Repellent Spray and Insect Repellent Pump Spray Lice IR3535® 20 % are nearly identical in composition, the results obtained in the test described here are considered relevant for Insect Repellent Pump Spray Lice IR3535® 20 %.

No *in vitro* or human data are available for skin corrosion/irritation.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Biocidal product not classified for skin corrosion/irritation according to (EU) nr. 1272/2008
Justification for the value/conclusion	Test performed on similar formulation. Mean scores for erythema and edema do not trigger a classification. Severity of skin reactions that persisted to the end of the observation period was limited (erythema grade 1).
Classification of the product according to CLP and DSD	none

(II) Eye Irritation

- **FIRST AUTHORISATION – 2017 (BE CA)**

New data for this section are due to differences in product composition.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OPPTS 870.2400 OECD 405 EU 92/69 Annex V, B5 GLP=yes Rel=1	Albino rabbit New Zealand White 2♂, 1♀ 1 test group, 3 animals	EUS26-15 Insect Repellent Spray No vehicle 0.1ml 1 single unwashed exposure	Cornea: 24h: 2.0 48h: 1.3 72h: 1.0 Iris: 24h: 0.0 48h: 0.0 72h: 0.0 Conjunctiva; redness: 24h: 3.0 48h: 3.0 72h: 2.3 Conjunctiva; chemosis: 24h: 2.3 48h: 2.3 72h: 2.0 Reversibility: Yes Earliest onset for all symptoms: 1h Max scores: cornea 2, conjunctiva, redness 3, conjunctiva, chemosis 4 Reversible at d14 2 out of 3 animals: average corneal opacity ≥1, average conjunctival redness ≥2	Tested on similar formulation; US Pump Spray Formulation	[redacted]

Individual Total Scores and for Ocular Irritation (Hurley, J.M., 2006 (b))

Rabbit No/sex	No. 45158/male				No. 45170/male				No. 45182/female			
Time after treatment [hours]	1	24	48	72	1	24	48	72	1	24	48	72
Cornea												
Opacity	1	2	1	0	2	2	2	2	1	2	1	1
Area involved	1	2	2	0	1	4	4	3	1	2	1	1
Iris	0	0	0	0	0	0	0	0	0	0	0	0
Conjunctivae												
Redness	3	3	3	2	3	3	3	3	3	3	3	2
Chemosis	4	2	3	3	3	2	2	1	4	3	2	2
Discharge	3	2	2	0	3	3	2	1	3	2	2	1
Mean of 24-72-hour Readings: individual animals	Opacity: 1 Iris: 0 Redness: 2.7 Chemosis: 2.7				Opacity: 2 Iris: 0 Redness: 3 Chemosis: 1.7				Opacity: 1.33 Iris: 0 Redness: 2.7 Chemosis: 2.3			
Mean of 24-72-hour Readings: all animals	Opacity: 1.44 Iris: 0 Redness: 2.8 Chemosis: 2.2											
Classification	Irritant (EU: Xi, R36; GHS: Eye Irrit. 2, H319)											

Eye irritation was assessed on EUS26-15 Insect Repellent Spray, a formulation similar to Insect Repellent Pump Spray Lice IR3535® 20%.

There were no deaths or remarkable body weight changes noted during the study. Positive corneal and conjunctival irritations were noted for all animals. Corneal irritation subsided by study day 10 and conjunctival irritation subsided by study day 14. The left (control) eyes were free of evidence of ocular irritation and other findings for the duration of the study. According to EU and CLP criteria, the mean scores for corneal reactions, iritis, conjunctival redness and chemosis were 1.44, 0, 2.8 and 2.2, respectively, resulting in a classification as a potential eye irritant (EU criteria: Xi, R36; GHS criteria: Eye Irrit. 2, H319).

Based on the results obtained in the eye irritation study with EUS26-15 Insect Repellent Spray in rabbits, the biocidal product is a potential eye irritant and needs to be classified with respect to eye irritancy (EU criteria: Xi, R36; GHS criteria: Eye Irrit. 2, H319).

Since EUS26-15 Insect Repellent Spray and Insect Repellent Pump Spray Lice IR3535® 20 % are nearly identical in composition, the results obtained in the test described here are considered relevant for Insect Repellent Pump Spray Lice IR3535® 20 %.

No *in vitro* or human data are available for eye corrosion/irritation.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	the biocidal product has to be classified as a potential eye irritant according to (EU) nr. 1272/2008 (Eye Irrit. 2, H319)
Justification for the value/conclusion	Test performed on similar formulation. Average score was ≥ 1 for corneal opacity and ≥ 2 for conjunctival redness and chemosis in 2 out of 3 animals

Classification of the product according to CLP and DSD	Eye damage/irritation cat 2, H319

(III) Respiratory tract irritation

- **FIRST AUTHORISATION – 2017 (BE CA)**

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to respiratory tract irritation. Insect Repellent Pump Spray Lice IR3535® 20 % does not pose a respiratory tract irritation hazard.
Classification of the product according to CLP and DSD	There is no indication that a classification with respect to respiratory tract irritation is necessary for Insect Repellent Pump Spray Lice IR3535® 20 %.

(IV) Skin sensitization

- **FIRST AUTHORISATION – 2017 (BE CA)**

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 406 OPPTS 870.2600 EU 92/69 Anex V, B6	Guinea pig Hartley [Crl: HA] 10 ♂ and 10 ♀/ test group 5 ♂ and 5 ♀/ naïve control group	EUS26-15 Insect Repellent Spray No vehicle Undiluted 0.3 ml/site 6h exposure Epicutaneous, occlusive	No positive dermal reactions in the test or the naive control groups No deaths, no test article related clinical findings, no remarkable bw changes	Tested on similar formulation; US Pump Spray Formulation	[redacted]

Dermal Observations and Severity Indices (Hurley, J.M., 2006 (c))

Dermal Scores													
Group	**Material**	**24 hour**					**48 hour**					**Severity Index**		**Incidence Index**
		0	+/-	1	2	3	0	+/-	1	2	3	24 h	48 h	
Test		17	3	0	0	0	16	4	0	0	0	0.1	0.1	0 %
Naive Control-I		10	0	0	0	0	9	1	0	0	0	0.0	0.1	NA

TA = Test Article
NA = Not Applicable

Skin sensitization was assessed on EUS26-15 Insect Repellent Spray, a formulation similar to Insect Repellent Pump Spray Lice IR3535® 20%.

The skin sensitisation potential of EUS26-15 Insect Repellent Spray was evaluated using the modified Buehler test method.

Animal welfare benefits and scientific advantages make the LLNA the preferred test for sensitization. However, existing data of good quality derived from a Buehler test should be acceptable as they preclude the need for further in vivo testing. As none of the cosmetic ingredients in the formulation have a sensitizing potential and as the active substance is not considered as sensitizing (Buehler test and Photoallergenicity maximisation test), the Buehler test was regarded as acceptable.

There were no deaths, nor were there any test article-related clinical findings or remarkable body weight changes during the study period. Following challenge dosing with EUS26-15 Insect Repellent Spray, there were no positive dermal reactions (score ≥ 1) in the test or

the naive control groups. The Incidence Index for the test group with a score ≥ 1 was 0 % (0/20) following challenge dosing.

In the positive control experiments which were performed as a separate study, the positive control substance HCA was a sensitizer when administered as both a 10 % concentration in 70/30 (v/v) in acetone/PEG 400 and a 20 % concentration in 70/30 (v/v) in acetone/PEG 400 under the conditions of the study. The mean incidence indices for the positive controls were 20 % and 60 % at a concentration of 10 % and 20 %, respectively. This confirms the reliability of the test system as indicated by the dose-response relationship.

EUS26-15 Insect Repellent induced no skin sensitisation reactions in albino guinea pigs when using the modified Buehler test method. A classification with respect to skin sensitisation is not required.

Since EUS26-15 Insect Repellent and Insect Repellent Pump Spray Lice IR3535® 20 % are nearly identical in composition, the results obtained in the test described here are considered relevant for Insect Repellent Pump Spray Lice IR3535® 20 %.

No in vitro or human data are available for skin sensitisation.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Biocidal product not classified for skin sensitisation according to (EU) nr. 1272/2008
Justification for the value/conclusion	Test performed on similar formulation. Following challenge dosing with EUS26-15 Insect Repellent Spray, there were no positive dermal reactions (score ≥ 1) in the test or the naive control groups. The Incidence Index for the test group with a score ≥ 1 was 0 % (0/20) following challenge dosing.
Classification of the product according to CLP and DSD	None

(V) Respiratory sensitization (ADS)

- **FIRST AUTHORISATION – 2017 (BE CA)**

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	
Justification for the value/conclusion	None of the ingredients of the product is known to be sensitizing to the respiratory tract. Moreover, from tests in guinea pigs a similar formulation was proven not to exert any skin sensitizing properties. In addition, the active ingredient IR3535 did not show a sensitizing or photosensitizing potential from tests in guinea pigs. Finally, IR3535 products are on the market for more than 40 years and there are no indications for any sensitizing potential neither to the skin nor to the respiratory tract. Based on all this data it is thus concluded that the product is not sensitizing to the respiratory tract.
Classification of the product according to CLP and DSD	None

(VI) Acute toxicity

- **FIRST AUTHORISATION – 2017 (BE CA)**

a. <u>Acute toxicity by oral route</u>

Value used in the Risk Assessment – Acute oral toxicity	
Value	Biocidal product not classified for acute oral toxicity according to (EU) nr. 1272/2008
Justification for the selected value	Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to acute oral toxicity. Thus, Insect Repellent Pump Spray Lice IR3535® 20 % has no potential for an acute oral toxicity hazard and no classification with respect to acute oral toxicity is required. No human data are available for acute oral toxicity.
Classification of the product according to CLP and DSD	None

Data waiving	
Information requirement	Acute oral toxicity: Study scientifically unjustified
Justification	Since the acute oral toxicity of Insect Repellent Pump Spray Lice IR3535® 20 % can be assessed on the basis of the properties of the ingredients, the performance of an acute oral toxicity study with the biocidal product is scientifically not justified. See IUCLID data point 8.5.1 Endpoint study record: Acute toxicity: oral.001.

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

b. Acute toxicity by inhalation

No human data are available for acute inhalation toxicity.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Biocidal product not classified for acute toxicity (inhalation) according to (EU) nr. 1272/2008
Justification for the selected value	None of the components of the biocide are classified for acute inhalation toxicity according to (EU) nr. 1272/2008.
Classification of the product according to CLP and DSD	none

Data waiving	
Information requirement	Acute inhalation toxicity: Study scientifically unjustified
Justification	Since the acute inhalation toxicity of Insect Repellent Pump Spray Lice IR3535® 20 % can be assessed on the basis of the properties of the ingredients, the performance of an acute inhalation toxicity study with the biocidal product is scientifically not justified. See IUCLID data point 8.5.2 Endpoint study record: Acute toxicity: inhalation.001. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

c. Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402 EU 92/69 Annex V, B.3 EPA OPPTS 870.1200 GLP=yes Rel=1	Rat Crl:CD(SD) 5♀, 5♂/dose	EUS26-15 Undiluted 5000 mg/kg bw 10% of body area Semiocclusive	See below	>5000 mg/kg bw	Tested on similar formulation; US Pump Spray Formulation	[redacted]

Acute dermal toxicity was assessed on EUS26-15 Insect Repellent Spray, a formulation similar to Insect Repellent Pump Spray Lice IR3535® 20%.

There were no deaths, remarkable body weight changes or macroscopic findings at the scheduled necropsy. Clinical findings noted persisted until day 1 post-dosing and included abnormal excretion, and various discoloured areas due to discharges/excretions which were observed. Dermal findings noted during the study consisted of very slight erythema (grade 1) and pinpoint scabbing at the dose sites. Very slight erythema (grade 1) persisted until study termination on day 14.

Based on the results of this study, the LD_{50} of EUS26-15 Insect Repellent Spray was greater than 5000 mg/kg bw when administered once for 24 hours to the clipped, unabraded skin of male and female albino rats. A classification of the biocidal product with respect to acute dermal toxicity is not required.

Since EUS26-15 Insect Repellent Spray and Insect Repellent Pump Spray Lice IR3535® 20 % are nearly identical in composition, the results obtained in the test described here are considered relevant for Insect Repellent Pump Spray Lice IR3535® 20 %.

No human data are available for acute dermal toxicity.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Biocidal product not classified for acute dermal toxicity according to (EU) nr. 1272/2008
Justification for the selected value	Test performed on similar formulation. In an acute dermal toxicity study, the LD_{50} of EUS26-15 Insect Repellent Spray was greater than 5000 mg/kg bw.
Classification of the product according to CLP and DSD	None

(VII)Information on dermal absorption

- **FIRST AUTHORISATION – 2017 (BE CA)**

In a dermal toxicokinetics/metabolism study with 5 male and 5 female human volunteers, the dermal absorption of the active substance IR3535® from a pump spray containing 20% IR3535® has been determined in parallel (Dekant, 2010). In this study, approx. 3 grams of the formulation were applied once to hands, arms, legs, feet, face and neck of each volunteer (ca. 64% of total body area). The total amount of IR3535® and its metabolite IR3535®-free acid excreted with the urine over a period of 48 hours presented 13.3% of the dermal dose of IR3535® applied. Since IR3535® is rapidly and extensively metabolized and as IR3535®-free acid has a low molecular weight and high water solubility, it is expected that urinary excretion of IR3535®-free acid and IR3535® represents the total extent of absorption of IR3535® in humans and a distribution to organs and tissues is considered to be negligible. The results of this study have been summarized in in the active substance dossier and were assessed for the approval of IR3535®.

The assessment of this study resulted in an overall dermal penetration of 14% IR3535®.

Since the composition of Insect Repellent Pump Spray Lice IR3535® 20 % is nearly identical to the product tested in the dermal toxicokinetics/metabolism study, a separate skin absorption study with the biocidal product can be waived. Instead, the skin absorption of 14% for IR3535® can be applied to Insect Repellent Pump Spray Lice IR3535® 20%. A

dermal penetration of 14% will be used in the human exposure assessments for the intended use of the biocidal product.

See IUCLID datapoint 8.6 Dermal absorption Endpoint study record: Dermal absorption.001.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Insect Repellent Pump Spray Lice IR3535® 20%		
Value(s)*	14%		
Justification for the selected value(s)	Read-across from human volunteer study on a water/ethanol-based 20 % IR3535® formulation (Dekant, 2010)		

Data waiving	
Information requirement	Skin absorption study
Justification	Read-across from human volunteer study on a water/ethanol-based 20 % IR3535® formulation

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The major change has no impact on the dermal absorption and the classification.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The major change has no impact on the determination of SOC.

(IX) Available toxicological data relating to a mixture

- **FIRST AUTHORISATION – 2017 (BE CA)**

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

(X) Other

Not applicable.

2.2.7.2 Exposure assessment

- **FIRST AUTHORISATION – 2017 (BE CA)**

The active substance contained in the product Insect Repellent Pump Spray Lice 20 % is the same as evaluated in the CAR for IR3535® and therefore no new data/information on the active substance is required.

The product Insect Repellent Pump Spray Lice IR3535® 20 % is a clear solution containing IR3535® at a concentration of 20 %. It does not contain substances of toxicological concern apart IR3535®.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Dermal	yes	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	Yes	n.a.

For primary exposure, the most relevant route of exposure is the dermal route. During the application phase, inhalation exposure is possible resulting from respiring aerosols after spraying. It was considered that the respirable particles will be absorbed via the lower airways and that the non-respirable particles will precipitate in the upper airways and be taken in orally. Direct oral exposure is not considered to be relevant because of the repellent taste (bad palatability) of the active substance and because the biocidal product is not intended to be applied by children younger than 11 years.

For secondary exposure, dermal exposure is possible for adults treating or handling children. However this scenario is fully covered by primary adult dermal exposure. Hand to mouth transfer is also possible for adults and children; nonetheless, the biocidal product is not intended to be applied on children's hands which reduces potential oral uptake of the dermally applied active substance. For inhalative exposure, the inhalation of volatilized residues after application is also relevant.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The product is intended to be use:

- against head lice on skin or on clothes/bed linen,

- against mosquitos and ticks on skin or on clothes,

- against dust mites on bed linen.

Exposure can occur during application and post-application.

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	[redacted]
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	
Dermal	n.a	n.a.	Yes	n.a.	n.a.	Yes	
Oral	n.a.	n.a.	n.a	n.a.	n.a.	Yes	

Primary exposure:

For application on skin, dermal and inhalation exposure occur. It is considered that the exposure of the person spraying the product is covered by the exposure after application on the skin. According to consumer spraying model 2 for trigger spray, the user will be exposed to 10.5 mg of product /m3 during few minutes whereas he will be exposed to several grams (6 g) of product on skin with a dermal absorption of 14%. Therefore, the inhalation is assumed to be negligible. Therefore, the primary exposure is limited to the dermal route.

For application on fabrics, dermal and inhalation when spraying are taken into account.

Secondary exposure:

For skin application, despite the fact that the product contains a bittering agent, oral exposure is taken into account for infants and toddlers (hand-to-mouth behavior) and children and adults which can be incidentally exposed orally to the biocidal product.

Dermal exposure from dried residues is considered when wearing treated clothes and sleeping in treated linen.
Inhalation of volatilised residues after application is considered when spraying to textiles and bed linen.

Major change for SPRAY REPULSIF IR200 – 2019

A dietary exposure and risk assessment is also proposed by FR.

(I) General information

- **FIRST AUTHORISATION – 2017 (BE CA)**

General default values for exposure assessment

Default value considering age groups[1]			
Age groups	**Body weight (kg)**	**Respiration rate [m^3/air/hour]**	**Head surface area (cm^2)**
ADULT irrespective of gender (based on female 30 to <40 years old)	60	1.25	1110 cm^2
CHILD irrespective of gender (based on female 6 to <11 years old)	23.9	1.32	529 cm^2
TODDLER irrespective of gender (based on female 1 to <2 years old)	10	1.26	403.2 cm^2
INFANT irrespective of gender (based on female 6 to <12 months old)	8	0.84	344.4 cm^2

[1] Biocide Human Health Exposure Methodology, Oct 2015

Treated surface, applied amount of biocidal product and number of application per day:

Treated surface:

In a worst case assessment, the total area of the head has been considered to be treated since there is no harmonized default values for the area of hair for adults, children, toddlers and infants.

Amount of biocidal product:

The product amounts used in the exposure assessment are based on an efficacy study (Militão de Sousa, F. and Lang-Combescot, C., 2009) performed with Insect Repellent Pump Spray Lice IR3535® 20% on 80 subjects aged between 6 and 11 years. In this study, an amount of 0.5 g product/application has been calculated to be the 90th percentile based on real application rates.

According to the Biocide Human Health Exposure Methodology (Oct 2015), the head surface of children at the age of 6 to 11 years is equivalent to 529 cm^2. For children, an area of 529 cm^2 and an amount of 0.5 g product per application have been used in the Tier I human health risk assessment for Insect Repellent Pump Spray Lice IR3535® 20%.

Considering the information provided by the applicant on the device (0,115 mL/pump, supposing a density = 1) and considering that approximatively 4 pumps are needed to cover the child head (one pump on the neck, one pump behind each ear and one pump on the top of the head), the dose will be the same for toddler and infant. For adult, this dose can be higher (since the head will be larger):

- Adults: 0.5 g x 1110 / 529 = 1.05 g (up to 9 pumps/application)

Number of application per day:

The applicant proposes : "*Insect Repellent Pump Spray Lice IR3535® 20 % is used as an insect repellent and is applied evenly over hair. For a single application of Insect Repellent Pump Spray Lice IR3535® 20%, 0.5 g product per application which is equivalent to 100 mg a.s. / application) is sufficient to treat the hair after having used a pediculicide. The product can be applied 3 times per day. The application must be repeated after washing the hair*".

Summary : Amount of product used per application for the different age groups, treated surface and number of application per day		
Age groups	**Amount of product used per application (g)**	**number of applications per day**
ADULT irrespective of gender (based on female 30 to <40 years old)	1.05	3
CHILD irrespective of gender (based on female 6 to <11 years old)	0.5	3
TODDLER irrespective of gender (based on female 1 to <2 years old)	0.5	3
INFANT irrespective of gender (based on female 6 to <12 months old)	0.5	3

Dermal, inhalatory and oral absorption:

- Inhalatory absorption : 100 %
- Dermal absorption : 14 %
- Oral absorption : 100 %

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The general default values are presented in each scenario:

Treated surfaces:

- Application to the skin: approximately 55% of the total body surface is considered according to the Recommendation no. 11, 2018[7] which represents the uncovered body surface area.
- Application to clothes: surface area of the treated clothes corresponds to long trouser and tee-shirt if only clothes application is considered and the total body surface area

[7] Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure: Proposal for harmonising the assessment of human exposure to repellents (PT19), 2018.

and removing approximately 55% body surface according to the Recommendation no. 11, 2018 if the use is combined to skin application.

- Application to bed linen: as a worst-case, whole body surface is considered.

Amount of biocidal product and number of application per day:

Targets	Fabrics	Human skin
Head lices	**Intended use # 2 -** *directly onto the fabric* BP: 1 mg/cm² / AS: 0.20 mg/cm² It is to be applied on bed linen and/or cloth's surface in contact with the top of the body (head, neck and shoulders).	**Intended use # 1 -** *directly onto the head* Adults: up to 1.05 g product or approx. 9 spray hubs/application Children (0 to 11 years old): 0.5g or approx. 4 spray hubs/application ➔ **Use is already authorized.**
Mosquitoes	**Intended use # 3** - *directly onto the textile* BP: 0.6 mg/cm² / AS: 0.12 mg/cm²	**Intended use # 4 -** *directly on skin* <u>*Temperate conditions*</u> BP: 0.6 mg/cm² / AS: 0.12 mg/cm² Child >6 years old and adult: 2 applications/day, Child ≥6 months old-6 years: 1 application/day. <u>*Tropical conditions*</u> BP: 0.8 mg/cm² / AS: 0.16 mg/cm² Child >11 years old and adult: 2 applications/day, Child ≥6 months old-11 years: 1 application/day.
Ticks	**Intended use # 5**- *directly onto the textile* BP: 0.85 mg/cm² / AS: 0.17 mg/cm²	**Intended use # 6 -** *directly on skin* **.** BP: 0.6 mg/cm² / AS: 0.12 mg/cm² Child >6 years old and adult: 2 applications/day, Child ≥6 months old-6 years: 1 application/day.
Dust mites	**Intended use # 7 -** *onto the fabric (bed linen).* BP: 0.85 mg/cm² / AS: 0.17 mg/cm² It is to be applied on bed linen. The bed linen should be treated everyday or after their washing.	
BP: Biocidal Product / AS: Active substance		

(II) List of scenarios

- **FIRST AUTHORISATION – 2017 (BE CA)**

Insect Repellent Pump Spray IR3535® Lice 20 % is used by the general public. The primary route of exposure is dermal.

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of primary exposure, because of the repellent taste (bad palatability) of the active substance, thus, preventing repeated mouthing of IR3535® by children and infants. Furthermore, the biocidal product is not intended to be applied by children younger than 11 years which makes an oral uptake of the applied active substance inconsiderable.

A potential inhalation exposure is only possible during the application phase via spraying. After application, no inhalation exposure risk is anticipated due to the low vapour pressure of IR3535®. Moreover, it has to be taken into account that the exposure time to the spray is extremely short and that it is not recommended to spray the biocidal product onto the face.

Dermal secondary exposure is possible for adults treating or handling children. However, this scenario is fully covered by primary adult dermal exposure. A parent applying (spraying) the product on children and herself/himself has been taken into account for inhalative secondary exposure.

Hand to mouth transfer has been developed consistently with the DEET dossier. It was proposed to use a reverse scenario to estimate this exposure.

Inhalation of volatilized residues after application is relevant based on the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance. The exposure to volatilised residues indoors was calculated using ConsExpo model.

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application phase	Primary exposure: Dermal exposure assessment for adults, children, toddlers and infants.	Non-professionals
2.	Application phase	Primary exposure: Inhalation exposure assessment for adults, children, toddlers and infants.	Non-professionals
3.	Post-application phase	Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure)	Non-professionals
4.	Post-application phase	Parent treating two children and himself/herself (spraying) (combined inhalative and oral exposure)	Non-professionals
5.	Post-application phase	Inhalation of volatilised residues after application (inhalative exposure)	Non-professionals
6.	Exposure during production	Mixing and Loading model – worst case for the production, formulation and disposal of the biocidal product	Professionals

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Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Skin application (dermal exposure)	Primary exposure: Dermal exposure assessment for adults, children, toddlers and infants when spraying to the skin, against mosquitoes in temperate conditions (scenario 1a) and tropical conditions (scenario 1b). The application on skin against ticks is covered by the application on skin against mosquitoes in temperate conditions The application on skin against head lice has ever been assessed by BE. However, in order to harmonise the different class of population with the other uses, the exposure was reviewed (scenario 1c) Inhalation exposure is covered by dermal exposure.	General public (adults, children, toddlers and infants)
2.	Application of products on fabric (inhalation and dermal exposure)	Primary exposure: inhalation and dermal exposures will occur when spraying fabrics (bed linen or clothes).	General public (adults)
3.	Post-application phase - Hand-to-mouth transfer after skin application	Secondary exposure: Hand-to-mouth transfer for adults, children, toddlers and infants.	General public (adults, children, toddlers and infants)
5.	Post-application phase – Inhalation of volatilised residues	Secondary exposure: Inhalation of volatilised residues after application on fabrics.	General public (adults, children, toddlers and infants)
6.	Post-application phase - dermal exposure to treated clothes	Secondary exposure: Contact with treated clothes against ticks at 0.85 mg/cm² (scenario 6a/6c) and against mosquitoes at 0.60 mg/cm² (scenario 6b/6d) against head lice at 1 mg/cm2 (scenario 6e)	General public (adults, children, toddlers and infants)
7.	Post-application phase - dermal exposure to treated bed linen	Secondary exposure: In the post-application phase, adults, children and toddlers will be exposed during sleeping in a treated bed Against head lice (scenario 7a) Against dust mites (scenario 7b)	General public (adults, children, toddlers and infants)

(III) Industrial exposure

- **FIRST AUTHORISATION – 2017 (BE CA)**

There is no concern about industrial exposure because of the intend of use apart for the production/formulation and disposal of the biocidal product. This exposure is addressed under a point below (scenario 6).

(IV) Professional exposure

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not relevant since the product Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used by general public.

(V) Non-professional exposure

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 1: Primary exposure: Dermal exposure assessment for adults, children, toddlers and infants.

Description of Scenario 1		
This scenario is based on the one available in the CAR of IR3535®. It has been adapted with the document : Biocide Human Health Exposure Methodology (Oct 2015).		
Dermal exposure: Number of application/day x amount b.p./application x percent of a.s. in b.p. **Systemic exposure:** Dermal exposure x percent of dermal absorption **Dermal systemic exposure:** Systemic exposure / body weight		
	Parameters	**Value**
For All categories	Dermal absorption[1]	14%
	% of active substance in biocidal product[1]	20%
Tier 1- Adult	Number of application / day[1]	3
	Body weight[1]	60 kg
	Amount of biocidal product/ application[1]	1.05 g
Tier 1- Child	Number of application / day[1]	3
	Body weight[1]	23.9 kg
	Amount of biocidal product/ application[1]	0.5 g
Tier 1- Toddler	Number of application / day[1]	3
	Body weight[1]	10 kg
	Amount of biocidal product/ application[1]	0.5 g
Tier 1- Infant	Number of application / day[1]	3
	Body weight[1]	8 kg
	Amount of biocidal product/ application[1]	0.5 g
Tier 2 - Infant	Number of application / day[1]	2
	Body weight[1]	8 kg
	Amount of biocidal product/ application[1]	0.5 g

[1] General information, see justification above

Calculations for scenario 1

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake**
Scenario 1 – ADULT 3 appl/d	Tier 1 / no PPE	1.47 mg/kg bw/day
Scenario 1 – CHILD 3 appl/d	Tier 1 / no PPE	1.76 mg/kg bw/day
Scenario 1 – TODDLER 3 appl/d	Tier 1 / no PPE	4.2 mg/kg bw/day
Scenario 1 – INFANT 3 appl/d	Tier 1 / no PPE	5.25 mg/kg bw/day
Scenario 1 – INFANT 2 appl/d	Tier 2 / no PPE	3.5 mg/kg bw/day

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In order to harmonise classes of population, exposure assessment has been updated for spraying to the head against lice with the following parameters:

*Scenario [1c] - Primary exposure – **application to the head**: Dermal exposure assessment for adults, children, toddlers and infants*

Description of Scenario 1c			
Adults, children, toddlers and infants can be exposed directly when spraying the product to the head.			
	Parameters	**Value**	**References**
Tier 1	Dermal absorption	14%	CAR IR3535
	% of active substance in biocidal product	20%	Applicant's data
	Application rate for adult (g product)	**1.05**	Applicant's data
	Number of applications claimed for adult	**3**	Applicant's data
	Application rate for children from 0 to 11 years old (g product)	**0.5**	Applicant's data
	Number of applications claimed for children older than 1 year	**3**	Applicant's data
	Number of applications claimed for children between 0 and 1 year old	**2**	Applicant's data
	Body weight (kg)		Recommendation no. 14, 2017[8]
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	

Calculations for Scenario [1c]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1	1.47
Child (6 to <12 years old)	Tier 1	1.75
Child (2 to <6 years old)	Tier 1	2.69
Toddler (1 to <2 years old)	Tier 1	4.2
Infant (<1 year old)	Tier 1	3.5

*Scenario [1a]: Primary exposure – **application to the skin against mosquitoes/ticks**: Dermal exposure assessment for adults, children, toddlers and infants – **temperate conditions***

[8] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products, 2017.

Description of Scenario 1a

Adults, children, toddlers and infants can be exposed directly when spraying the product to the skin. It is considered that the exposure of the adult spraying the biocidal product is covered by the exposure to the biocidal product he/she applies on his/her skin.
The exposure by dermal route to the biocidal product can be calculated according to the following equation:

$$ID = \frac{ARp \times CIR3535 \times BS \times DA \times N}{100 \times 100 \times BW}$$

where:
ID Internal dose (mg/kg bw/day)
ARp Average dose of product applied on skin (mg/cm²)
CIR3535 Average concentration of substance in product (%)
BS Body surface exposed to the product (cm²)
DA Dermal absorption (%)
N Number of product application per day (/day)
BW Body weight (kg)

The product is not intended to be applied on the total body surface but on the following body segments corresponding to uncovered parts. According to Recommendation no. 11, 20189, the uncovered body surface area is approximately equal to 55% of the total body surface (head, neck, hands, lower arms, lower legs, feet and 70% of upper arms and thighs), assuming that during the whole season (mid-term exposure within a year) a short-sleeved shirt (i.e. T-shirt) and shorts are worn).

	Parameters	Value	References
Tier 1	Dermal absorption	14%	CAR IR3535
	% of active substance in biocidal product	20%	Applicant's data
	Application rate (g product/m²)	6	Applicant's data
	Number of application/day claimed by applicant		Applicant's data
	Child >6 years old and adult	2	
	Child ≥ 6 months old - 6 years old	1	
	Body weight (kg)		Recommendation no. 14, 201710
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	
	Body surface exposed (cm²)		Recommendation no. 11, 2018 Recommendation no. 14, 2017 Body surface considering exposure to head, neck, hands (palms and backs), arms (lower arms and 70% of upper arms), lower legs, 70% of thighs and feet.
	Adult	9588.2	
	Child (6 to <12 years old)	5096.3	
	Child (2 to <6 years old)	3779.0	
	Toddler (1 to <2 years old)	2676.5	
	Infant (<1 year old)	2286.2	

Calculations for Scenario [1a]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1 (2 applications)	5.37
Adult	Tier 1 (1 application)	2.68
Child (6 to <12 years old)	Tier 1 (2 applications)	7.16
Child (6 to <12 years old)	Tier 1 (1 application)	3.58
Child (2 to <6 years old)	Tier 1 (1 application)	4.07
Toddler (1 to <2 years old)	Tier 1 (1 application)	4.50
Infant (<1 year old)	Tier 1 (1 application)	4.80

*Scenario [1b]: Primary exposure – **application to the skin**: Dermal exposure assessment*

9 Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure: Proposal for harmonising the assessment of human exposure to repellents (PT19), 2018.

10 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products, 2017.

*for adults, children, toddlers and infants – **tropical conditions***

Description of Scenario 1b			
Same parameters are used from Scenario 1a for the intended uses against mosquitoes (intended use #4 - tropical conditions) with an application rate of 8 g product/m².			
	Parameters	Value	References
Tier 1	Dermal absorption	14%	CAR IR3535
	% of active substance in biocidal product	20%	Applicant's data
	Application rate (g product/m²)	8	Applicant's data
	Number of application/day		Applicant's data
	Child >11 years old and adult	2	
	Child ≥ 6 months old - 11 years old	1	
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	
Tier 1	Body surface exposed (cm²)		Recommendation no. 11, 2018 Recommendation no. 14, 2017 Body surface considering exposure to head, neck, hands (palms and backs), arms (lower arms and 70% of upper arms), lower legs, 70% of thighs and feet.
	Adult	9588.2	
	Child (6 to <12 years old)	5096.3	
	Child (2 to <6 years old)	3779.0	
	Toddler (1 to <2 years old)	2676.5	
	Infant (<1 year old)	2286.2	

Calculations for Scenario [1b]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/ kg bw/d)
Adult	Tier 1 (2 applications)	7.16
Adult	Tier 1 (1 application)	3.58
Child (6 to <12 years old)	Tier 1 (1 application)	4.78
Child (2 to <6 years old)	Tier 1 (1 application)	5.43
Toddler (1 to <2 years old)	Tier 1 (1 application)	6.00
Infant (<1 year old)	Tier 1 (1 application)	6.40

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 2: Primary exposure: Inhalation exposure assessment for adults, children, toddlers and infants

Description of Scenario 2

This scenario is based on the one available in the CAR of IR3535®. It has been adapted with the documents : Biocide Human Health Exposure Methodology (Oct 2015) and Guidance on the biocidal products Regulation (volume III Human Health – Part B Risk Assessment, Oct 2015).

Model used: "Consumer spraying and dusting model 2 - Hand-held trigger spray" from Biocide Human Health Exposure Methodology, p. 220

Inhaled product =
Inhalation rate x number of application/day x spray duration (min.) / 60 min. x indicative value for inhalation
Inhaled active substance =
inhaled product x percent of a.s. in the b.p.

Particle size distribution will determine the respirable fraction of the product released. Regarding the cut-off value for respirable droplet size, different sources are available. The BPR guidance VIII part B states that particles below 15 µm may reach the alveolar region of the respiratory tract. According to the Biocides Human Health Exposure Methodology, particles larger than 20 µm are all non-respirable and particles smaller than 5 µm are respirable for about 35%. The draft Proposal for harmonising the assessment of human exposure to repellents (PT19) states that in general, the cut-off for the respirable fraction is 10 µm, and refers to ConsExpo 4.1 for the assessment of inhalation exposure. In ConsExpo 4.1, the default cut-off for the respirable fraction has been set at 15 µm. For the present assessment, a cut-off value of 15 µm for the respirable fraction has been chosen.

The enterprise provided a study for the distribution of particles and their size. 11.21%(V) of the released biocidal product has a diameter below 15.81 µm. (V). The rest is regarded as non-respirable and is assumed to be taken in orally.

Inhalation systemic exposure:
11.21 % x inhaled a.s. x inhalation absorption / body weight
Oral systemic exposure:
88.79 % x inhaled a.s. x oral absorption / body weight

	Parameters	**Value**
For All categories	Inhalation absorption[1]	100%
	Oral absorption[1]	100%
	% of active substance in biocidal product[1]	20%
	Indicative value for inhalation[2]	10.5 mg/m^3
	Spray duration[3]	4 minutes
Tier 1- Adult	Number of application / day[1]	3
	Body weight[1]	60 kg
	Respiration rate [m^3/air/hour] [1]	1.25 m³/h
	Body weight[1]	60 kg
	Respiration rate [m^3/air/hour] [1]	1.25 m³/h
Tier 1- Child	Number of application / day[1]	3
	Body weight[1]	23.9 kg
	Respiration rate [m^3/air/hour] [1]	1.32 m³/h
Tier 1- Toddler	Number of application / day[1]	3
	Body weight[1]	10 kg

	Respiration rate [m^3/air/hour] [1]	1.26 m^3/h
Tier 1- Infant	Number of application / day[1]	3
	Body weight[1]	8 kg
	Respiration rate [m^3/air/hour] [1]	0.84 m^3/h
Tier 2- Infant	Number of application / day[1]	2

[1] General information, see justification above

[2] Model used: "Consumer spraying and dusting model 2 - Hand-held trigger spray" Biocide Human Health Exposure Methodology, p. 220

[3] CAR of IR3535® (expert judgement)

Calculations for scenario 2

Summary table: estimated exposure for Inhalation Primary exposure			
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated oral uptake**
Scenario 2 – ADULT 3 appl/d	Tier 1 / no PPE	0.000981 mg/kg bw	0.00777 mg/kg bw
Scenario 2 – CHILD 3 appl/d	Tier 1 / no PPE	0.0026 mg/kg bw	0.021 mg/kg bw
Scenario 2 – TODDLER 3 appl/d	Tier 1 / no PPE	0.00593 mg/kg bw	0.0470 mg/kg bw
Scenario 2 – INFANT 3 appl/d	Tier 1 / no PPE	0.00494 mg/kg bw	0.0392 mg/kg bw
Scenario 2 – INFANT 2 appl/d	Tier 2 / no PPE	0.0033 mg/kg bw	0.026 mg/kg bw

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*Scenario [2] - Primary exposure – **application to the bed linen/clothes –** inhalation and dermal exposure*

Description of Scenario 2			
For application to the bed linen and/or clothes, exposure assessment has been assessed. According to BHEEM (p.220), the model Consumer spraying and dusting model 2 from TNsG part 2 (p 197) can be used for inhalation and dermal exposure. The values for trigger spray are used.			
	Parameters	Value	References
Tier 1	Inhalation absorption	100%	Default
	Dermal absorption	14%	CAR IR3535
	% of active substance in biocidal product	20%	Applicant's data
	Duration (min)	10	
	Indicative inhalation value for hand-held trigger spray (mg/m3)	10.5	Consumer spraying and dusting model 2
	Indicative dermal value for hand-held trigger spray (mg/min) – hand/forearm	36.1	
	Indicative dermal value for hand-held trigger spray (mg/min) – legs/feet/face	9.7	
	Inhalation rate (m3/h)	1.25	
	Body weight (kg)	60	

Calculations for Scenario [2]

Summary table: estimated exposure for Dermal Primary exposure				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/ kg bw/d)**	**Estimated dermal uptake (mg/ kg bw/d)**	**Total uptake (mg/ kg bw/d)**
Adult	Tier 1	7.29E-03	2.14E-01	2.21E-01

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 3: Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure)

Description of Scenario 3
This scenario is based on the one available in the CAR of IR3535®. It has been updated with the document : Biocide Human Health Exposure Methodology (Oct 2015).
Hand to mouth transfer might be possible for small children. However this scenario is not considered to be a significant route of exposure because of bad palatability (bitterness) preventing repeated mouthing by small children and you may not apply to children's hand. At TM IV 2010, it was agreed to develop the scenario "hand-mouth transfer" consistently with the DEET dossier evaluated by SE and to be discussed with HEEG and TM agreed not to sum up the two routes (oral and dermal) in small children. Reverse reference scenario is included to show how much IR3535® anyone can be exposed to, after oral exposure without exceeding reference dose (AEL for IR3535® is 5 mg/kg bw/d). **External dermal amount of a.s. per application**: Amount of b.p./application x percent of a.s. in b.p. / body weight **Oral systemic exposure via hand-mouth transfer is:** External dermal amount of a.s. per application x Factor for oral intake by hand-mouth transfer x oral absorption **Number of time of application b.p. before exceeding the AEL via hand-mouth transfer :** AEL / Oral systemic exposure via hand-mouth transfer

	Parameters	**Value**
For All categories	Oral absorption[1]	100%
	% of active substance in biocidal product[1]	20%
Tier 1- Adult	Factor for oral intake by hand-mouth transfer[2]	40 %
	Body weight[1]	60 kg
	Amount of biocidal product/ application[1]	1.05 g
Tier 1- Child	Factor for oral intake by hand-mouth transfer[2]	40 %
	Body weight[1]	23.9 kg
	Amount of biocidal product/ application[1]	0.5 g
Tier 1- Toddler	Factor for oral intake by hand-mouth transfer[2]	29 %
	Body weight[1]	10 kg
	Amount of biocidal product/ application[1]	0.5 g
Tier 1- Infant	Factor for oral intake by hand-mouth transfer[2]	29 %
	Body weight[1]	8 kg
	Amount of biocidal product/ application[1]	0.5 g

[1] General information, see justification above

[2] For repellent which could be applied on the uncovered parts of the body, 4% for adults and 8 % for children are used (factor of the surface area of the fingers/hands reported to the treated body surface). These factors cannot be used here since the product is applied only on head. The factor was calculated between the head and the palms of the hands (possible area for transfer of product, the transfer is considered to be 100%). For adults and children, this factor can be approximated by 40% and for toddlers and infants, it will be 29%.

Calculations for scenario 3

Summary table: estimated exposure for Hand-mouth transfer reverse reference scenario (oral exposure)		
Exposure scenario	**Tier/PPE**	**Calculated exposure to IR3535®**
Scenario 3 – ADULT	Tier 1 / no PPE	Adult up to 3.57 applications
Scenario 3 – CHILD	Tier 1 / no PPE	Child up to 2.99 applications
Scenario 3 – TODDLER	Tier 1 / no PPE	Toddler up to 1.72 applications
Scenario 3 – INFANT	Tier 1 / no PPE	Infant up to 1.38 applications

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Scenario [3]: Post-application phase - Hand-to-mouth transfer

Description of Scenario 3			
After application on the skin, a person can be exposed orally to the biocidal product via hand-to-mouth behaviour. Even if the product contains a bittering agent, a reverse scenario calculation was included, with the application rate of 0.8 mg/cm².			
	Parameters	Value	References
Tier 1	Oral absorption	100%	Default value
	% of active substance in biocidal product	20%	Applicant's data
	Application rate (mg/cm²)	0.8	Applicant's data
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	
	Hand surface area (one hand) (cm²)		Recommendation no. 14, 2017
	Adult	410	
	Child (6 to <12 years old)	213.9	
	Child (2 to <6 years old)	165.9	
	Toddler (1 to <2 years old)	115.2	
	Infant (<1 year old)	98.4	

Calculations for Scenario [3]

Summary table: estimated exposure for Dermal Primary exposure			
Exposure scenario	**Maximum external quantity IR3535 (mg)**	**Skin surface area to put in the mouth to reach the AEL short-term (cm²)**	**% hand surface area to put in the mouth to reach the AEL short-term**
Adult (1 application)	300.0	1875	457.3%
Child (6 to <12 years old) (1 application)	119.5	746	349.2%
Child (2 to <6 years old) (1 application)	78.0	487	294.7%
Toddler (1 to <2 years old) (1 application)	50.0	312	271.3%
Infant (<1 year old) (1 application)	40.0	250	254.1%

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 4: Parent treating two children and himself/herself (spraying) (combined dermal and inhalative exposure)

Description of Scenario 4		
Worst case: a parent applying (spraying) the product on two children and herself/himself **Model used:** it's the same model than the one used to do the scenario 2. Remark: the secondary dermal exposure was not assessed. It is covered by the primary dermal use exposure of the adult. The product would probably be rubbing on the child scalp and the layer on hands will not exceed the amount the adult will put on himself. So, BE has decided to follow the CAR which supposes that the dermal secondary exposure will be covered by the primary dermal exposure. Only inhalation exposure is relevant in this case.		
	Parameters	**Value**
Tier 1- Adult	Inhalation absorption[1]	100%
	Oral absorption[1]	100%
	% of active substance in biocidal product[1]	20%
	Indicative value for inhalation	10.5 mg/m^3
	Body weight[1]	60 kg
	Respiration rate [m^3/air/hour][1]	1.25 m^3/h
	Spray duration[3]	4 minutes
Tier 1- Adult	Number of application / day[1]	9 (3 appl/d for Adult himself and 3 appl/d for each of the 2 children)

[1] General information, see justification above

[2] Model used: "Consumer spraying and dusting model 2 - Hand-held trigger spray" Biocide Human Health Exposure Methodology, p. 220

[3] CAR of IR3535® (expert judgement)

Calculations for scenario 4

Summary table: estimated exposure for treating two children and himself/herself				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4 – ADULT	Tier 1 / no PPE	0.00294 mg/kg bw	0.0233 mg/kg bw	0.0262 mg/kg bw

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

This scenario was not retained for major change application.

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 5: Inhalation of volatilised residues after application (inhalative exposure)

Description of Scenario 5
This scenario is not based on the one available in the CAR of IR3535® because it's has been demonstrated that the SVC could exceed 1% in a number of cases. Considering HEEG opinion 13 (Assessment of Inhalation Exposure of Volatilized Biocide Active Substance), the inhalation of volatilised residues after application has to be taken into account. The scenario is based on ConsExpo : inhalation of vapour, instantaneous release as a worst case and based on the document: Biocide Human Health Exposure Methodology (Oct 2015).
Inhalation of volatilized residues after application is relevant considering the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance. $$\frac{0.328 \times\ 215.29 \times 0.15}{5} = 2.12$$ The result of this equation is superior to 1 which means that the inhalation exposure couldn't be considered as negligible. So this scenario was assessed using ConsExpo – exposure to vapour – instantaneous release. **General inputs to the model :** Exposure duration: 24 hours (all day) Product amount: calculated dependant of the amount applied per day and per age categories Weight fraction compound: 20% (biocidal product information) Room volume: 20m^3 (default value of ConsExpo) Ventilation rate: 0.6 /h (default value of ConsExpo) Vapour pressure: 0.15 Pa (at 20 °C) = 1.5 x 10^{-3} mbar (active substance information) Molecular weight: 215.29 g/mol (active substance information) Temperature : 25°c (ambient temperature)

	Parameters	**Value**
Tier 1- Adult	Product amount[1]	3 x 1,05 = 3.15g
	Body weight[1]	60 kg
	Respiration rate [m^3/air/hour] [1]	1.25 m³/h
Tier 1- Child	Product amount[1]	3 x 0.5 = 1.5g
	Body weight[1]	23.9 kg
	Respiration rate [m^3/air/hour] [1]	1.32 m³/h
Tier 1- Toddler	Product amount[1]	3 x 0.5 = 1.5g
	Body weight[1]	10 kg
	Respiration rate [m^3/air/hour] [1]	1.26 m³/h
Tier 1- Infant	Product amount[1]	3 x 0.5 = 1.5g
	Body weight[1]	8 kg
	Respiration rate [m^3/air/hour] [1]	0.84 m³/h

[1] General information, see justification above

Calculations for scenario 5

Summary table: estimated exposure for inhalation of volatilised residues after application (inhalative exposure)		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake of volatilised residues after application**
Scenario 5 – ADULT	Tier 1 / no PPE	1.1 mg/kg bw/day
Scenario 5 – CHILD	Tier 1 / no PPE	1.4 mg/kg bw/day
Scenario 5 – TODDLER	Tier 1 / no PPE	3.1 mg/kg bw/day
Scenario 5 – INFANT	Tier 1 / no PPE	2.6 mg/kg bw/day

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Scenario [5] - Post-application phase – inhalation of volatilised residues after application

Description of Scenario 5			
In the post-application phase, inhalation exposure of volatile residues is assessed for adults, children, toddlers and infants. According to the CAR of IR3535, it was assumed that the airborne concentration of IR3535® will not exceed 1 % of the saturated vapour concentration (SVC). Residential time is considered to be 24 hours. The assessment is done according to the HEEG opinion 13 "Assessment of inhalation exposure of volatilised biocides active substance".			
	Parameters	Value	References
Tier 1	Inhalation absorption	100%	Default
	% of active substance in biocidal product	20%	Applicant's data
	Vapour pressure IR3535 (Pa)		CAR IR3535
	Molecular weight IR3535 (g/mol)		CAR IR3535
	Saturated vapour concentration (SVC) (mg/m3)	3.45*10-3	HEEG opinion 13, 2011
	Inhalation rate (m3/24h)		Recommendation no. 14, 2017
	Adult	16	
	Child (6 to <12 years old)	12	
	Child (2 to <6 years old)	10.1	
	Toddler (1 to <2 years old)	8	
	Infant (<1 year old)	5.4	
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	

Calculations for Scenario [5]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**
Adult	Tier 1	3.53E-02
Child (6 to <12 years old)	Tier 1	6.66E-02
Child (2 to <6 years old)	Tier 1	8.58E-02
Toddler (1 to <2 years old)	Tier 1	1.06E-01
Infant (<1 year old)	Tier 1	8.95E-02

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Treated linen and treated clothes have been considered for the major change.

*Scenario [6]: Secondary exposure – application to the **treated clothes**: dermal exposure assessment for adults, children, toddlers and infants*

Description of Scenario 6

The ready to use product is a pump spray which is sprayed directly onto the textile.
Adults, children, toddlers and infants could be exposed when wearing treated clothes.

For mosquitos and ticks, in order to determine the exposure, as a worst case situation, it is considered that the person wears long clothes and that the treated surface is the total body surface area and removing surface of the head, hands and neck (treated socks are considered as a worst-case assumption).

The assumption was made according to the following uses:
intended use #5 (ticks, 8.5 g/m² of fabric) (scenario 6a),
intended use #3 (mosquitos, 6 g/m² of fabric) (scenario 6b).

Moreover, if the application on clothes is combined to the application on skin, the harmonised surfaces for covered areas proposed in the Recommendation no. 11, 2018 (short-sleeved shirt (i.e. T-shirt) and shorts) are used.

The assumption was made according to the following uses:
intended use #5 (ticks, 8.5 g/m² of fabric) (scenario 6c),
intended use #3 (mosquitos, 6 g/m² of fabric) (scenario 6d).

For head lice, it is considered that cloths in contact with the top of the body is treated. Therefore, the treated surface corresponds to arms (upper and lower), 12/head to take in consideration the hood and trunk.
The assumption was made according to the following uses:
intended use #2 (10 g/m² of fabric) (scenario 6e),

According to Recommendation no.811, "a protection factor of 50% can be assumed for one layer of clothing against dry contamination or light liquid contamination'.

	Parameters	Value	References
Tier 1	Application rate (g product/m² fabric)	8.5 and 6	Applicant's data
	% of active substance in biocidal product	20%	Applicant's data
	Reduction in exposure (long sleeve shirt and long pants)	50%	Recommendation no. 8, 2015
	Dermal absorption (%)	14%	CAR IR3535
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	

	Treated textile surface (cm²) **LONG TROUSERS + LONG SHIRT = total BS - (head + hands + neck) (cm²)**		Recommendation no. 14, 2017
	Adult	9130	
	Child (6 to <12 years old)	5060	
	Child (2 to <6 years old)	3740	
	Toddler (1 to <2 years old)	2640	
	Infant (<1 year old)	2255	
	Treated textile surface (cm²) **T shirt + short = total BS - (uncovered surface proposed in recommendation 11 of Adhoc) (cm²)**		Recommendation no. 14, 2017
	Adult	7072	
	Child (6 to <12 years old)	4104	
	Child (2 to <6 years old)	3021	
	Toddler (1 to <2 years old)	2124	
	Infant (<1 year old)	1814	
	Treated textile surface (cm²) arms (upper and lower), ½ head to take in consideration the hood and trunk		Recommendation no. 14, 2017
	Adult	8765	
	Child (6 to <12 years old)	5160	
	Child (2 to <6 years old)	3981	
	Toddler (1 to <2 years old)	2861	
	Infant (<1 year old)	2444	

[11] Recommendation no. 8 of the BPC Ad hoc Working Group on Human Exposure Consumer use of biocidal product and protection from typical clothing, 2015.

Calculations for Scenario [6a] - ticks, 8.5 g/m² of fabric

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult	Tier 1	2.86
Child (6 to <12 years old)	Tier 1	3.98
Child (2 to <6 years old)	Tier 1	4.35
Toddler (1 to <2 years old)	Tier 1	4.74
Infant (<1 year old)	Tier 1	5.06

Calculations for Scenario [6b] - mosquitos, 6 g/m² of fabric

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult	Tier 1	2.02
Child (6 to <12 years old)	Tier 1	2.81
Child (2 to <6 years old)	Tier 1	3.07
Toddler (1 to <2 years old)	Tier 1	3.35
Infant (<1 year old)	Tier 1	3.57

Calculations for Scenario [6c] - ticks, 8.5 g/m² of fabric combined to skin application

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult	Tier 1	2.78
Child (6 to <12 years old)	Tier 1	2.04
Child (2 to <6 years old)	Tier 1	2.30
Toddler (1 to <2 years old)	Tier 1	2.53
Infant (<1 year old)	Tier 1	2.70

Calculations for Scenario [6d] - mosquitos, 6 g/m² of fabric

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult	Tier 1	1.96
Child (6 to <12 years old)	Tier 1	2.88
Child (2 to <6 years old)	Tier 1	1.63
Toddler (1 to <2 years old)	Tier 1	1.78
Infant (<1 year old)	Tier 1	1.90

Calculations for Scenario [6e] – Head lice, 10 g/m² of fabric

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult	Tier 1	2.0
Child (6 to <12 years old)	Tier 1	3.0
Child (2 to <6 years old)	Tier 1	3.6
Toddler (1 to <2 years old)	Tier 1	4.0
Infant (<1 year old)	Tier 1	4.3

*Scenario [7]: Secondary exposure – application to the **treated linen**: dermal exposure assessment for adults, children, toddlers and infants*

Description of Scenario 7

Adults, children, toddlers and infants will be exposed during sleeping in a treated bed. According to the intended uses by the applicant, the intended use #2 (anti-lice, 10 g/m² of fabric) and #7 (anti-dust mites, 8.5 g/m² of fabric), the biocidal product is applied to bed linen (fitted sheets, sheets, pillowcases). The aim of this treatment is to prevent or removed the presence of the targets.

For anti-lice, the dose of 10 g/m² is used and it is considered that the top of body is exposed: head, trunk, arm and hands. (scenario 7a)

For anti-dust mites, the dose of 10 g/m² is used as a worst-case for application to the treated linen, considering the whole body surface in contact with treated bed sheet.
In order to determine the exposure, as a worst case it is considered that general public sleep naked and all the surface body can be exposed. (scenario 7b)

The surfaces body used are determined according to the Ad hoc recommendation 14.
From this surface a fraction of active substance is dislodgeable. For dried surface, the value of 30 % proposed in BHHEM for cotton dried surface is used.

	Parameters	Value	References
Tier 1	Application rate (g product/m² fabric)	10	Applicant's data
	% of active substance in biocidal product	20%	Applicant's data
	Dose required of IR3535 (mg/m²)	2.0E+03	
	Dislodgeable fraction from sheets to skin	30%	30% for dried surface (TNsG)
	Dermal absorption (%)	14%	CAR IR3535
	Total body area in contact with bed for anti head lice treatment (cm²)		
	Adult	10140	
	Child (6 to <12 years old)	5854	
	Child (2 to <6 years old)	4574	
	Toddler (1 to <2 years old)	3293	
	Infant (<1 year old)	2813	
	Total body area in contact with bed for anti dust treatment (cm²)		Recommendation no. 14, 2017
	Adult	16600	
	Child (6 to <12 years old)	9200	
	Child (2 to <6 years old)	6800	
	Toddler (1 to <2 years old)	4800	
	Infant (<1 year old)	4100	
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	

	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	

Calculations for Scenario [7a] – head lice

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult	Tier 1	1.42
Child (6 to <12 years old)	Tier 1	2.06
Child (2 to <6 years old)	Tier 1	2.46
Toddler (1 to <2 years old)	Tier 1	2.77
Infant (<1 year old)	Tier 1	2.95

Calculations for Scenario [7b] – dust mites

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult	Tier 1	2.32
Child (6 to <12 years old)	Tier 1	3.23
Child (2 to <6 years old)	Tier 1	3.66
Toddler (1 to <2 years old)	Tier 1	4.03
Infant (<1 year old)	Tier 1	4.31

- **FIRST AUTHORISATION – 2017 (BE CA)**

Combined scenarios : Total primary exposure : combination of scenario 1 and 2

Summary table: estimated exposure for combined scenarios 1+2					
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw]**	**Estimated oral uptake [mg/kg bw]**	**Estimated total acute uptake for primary use [mg/kg bw]**
Scenarios 1+2 – ADULT 3 appl/d	Tier 1 / no PPE	1.47	0.000981	0.00777	1.48
Scenarios 1+2 – CHILD 3 appl/d	Tier 1 / no PPE	1.76	0.0026	0.021	1.78
Scenarios 1+2 – TODDLER 3 appl/d	Tier 1 / no PPE	4.2	0.00593	0.0470	4.26
Scenarios 1+2 – INFANT 3 appl/d	Tier 1 / no PPE	5.25	0.00494	0.0392	5.29
Scenarios 1+2 – INFANT 2 appl/d	Tier 2 / no PPE	3.5	0.0033	0.026	3.53

The exposure of inhalation of volatilized residues after application and the combined inhalative and oral exposure of a parent treating two children are negligible compared to primary (dermal) exposure.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Combined scenarios:

Different combined scenario are considered:

- **For application against head lice:**
  - **Skin application on head + exposure linked to application on clothes + exposure during application on clothes**
  - **Skin application on head + exposure linked to application on bed linen + exposure to volatilised residues + exposure during application on fabrics**
- **For application against mosquitoes**
  - **Skin application (tropical zone) + exposure linked to application on clothes+ exposure during application on clothes**
  - **Skin application (temperate zone) + exposure linked to application on clothes+ exposure during application on clothes**
- **For application against ticks**
  - **Skin application + exposure linked to application on clothes+ exposure during application on clothes**
- **For application against dust mites**
  - **Exposure linked to application on bed linen + exposure to volatilised residues + exposure during application on fabrics**

- **<u>For application against head lice:</u>**
  - **Skin application on head + exposure linked to application on clothes + exposure during application on clothes**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult	Tier 1	3.74
Child (6 to <12 years old)	Tier 1	4.78
Child (2 to <6 years old)	Tier 1	6.27
Toddler (1 to <2 years old)	Tier 1	8.21
Infant (<1 year old)	Tier 1	7.78

- **Skin application on head + exposure linked to application on bed linen + exposure to volatilised residues + exposure during application on fabrics**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult	Tier 1	3.15
Child (6 to <12 years old)	Tier 1	3.88
Child (2 to <6 years old)	Tier 1	5.24
Toddler (1 to <2 years old)	Tier 1	7.07
Infant (<1 year old)	Tier 1	6.54

- **For application against mosquitoes**

- **Skin application (tropical zone) + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult (one application)	Tier 1	4.78
Child (6 to <12 years old)	Tier 1	6.22
Child (2 to <6 years old)	Tier 1	7.05
Toddler (1 to <2 years old)	Tier 1	7.78
Infant (<1 year old)	Tier 1	8.31

- **Skin application (temperate zone) + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/kg bw/d)**
Adult (one application)	Tier 1	3.89
Child (6 to <12 years old)	Tier 1	5.02
Child (2 to <6 years old)	Tier 1	5.70
Toddler (1 to <2 years old)	Tier 1	6.28
Infant (<1 year old)	Tier 1	6.71

- **For application against ticks**
  - **Skin application + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult (one application)	Tier 1	4.30
Child (6 to <12 years old)	Tier 1	5.63
Child (2 to <6 years old)	Tier 1	6.37
Toddler (1 to <2 years old)	Tier 1	7.02
Infant (<1 year old)	Tier 1	7.50

- **For application against dust mites**

  - **Exposure linked to application on bed linen + exposure to volatilised residues + exposure during application on fabrics**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult	Tier 1	2.58
Child (6 to <12 years old)	Tier 1	3.30
Child (2 to <6 years old)	Tier 1	3.75
Toddler (1 to <2 years old)	Tier 1	4.14
Infant (<1 year old)	Tier 1	4.39

(VI) Exposure of the general public

- **FIRST AUTHORISATION – 2017 (BE CA)**

Exposure of the general public is covered by the secondary exposure of non-professional.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

For clarity, exposure of infants, toddlers and children have been added in the section (V) Non-professional exposure.

(VII)Monitoring data

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not applicable.

(VIII) Dietary exposure

- **FIRST AUTHORISATION – 2017 (BE CA)**

Considering the scenario 3 (hand to mouth transfer), considering that the amount in scenario 3 will be superior to the amount on the fingers of the hands (possible contact surface for transfer of residue to food) and finally considering that the biocidal product is not used for and/or during food production, or in rooms where food is produced processed or stored, the dietary risk would be covered by the scenario 3.

However, Belgium is of advice that the restriction measures (Wash hands thoroughly after handling) must stay to avoid any misuse of the product.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

A dietary exposure proposed by FR is presented below.

As regards to the intended use of the product SPRAY REPULSIF IR200 on human skin a contamination of food cannot be excluded. As a consequence, a dietary risk assessment is proposed in framework of this dossier.

Residue definitions

IR3535 is the only active substance considered for the biocidal products of SPRAY REPULSIF IR200. The parent compound, IR3535 (ethyl butylacetylaminopropionate) is the only compound considered relevant regarding the dietary exposure.

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
Use # 4 – Spray for skin application to repel mosquitoes **Use # 6 – Spray for skin application to repel ticks**			
DRA 1.	General public	Contamination of food with contact with palm of treated hands	All kind of food

[1] e.g. animal husbandry, food industry, professional use, residential use.

[2] e.g. chicken, milk, beer

Information of non-biocidal use of the active substance

IR3535 is not known to be used in other areas.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Regarding the intended use of the products of SPRAY REPULSIF IR200, no livestock exposure to IR3535 is expected.

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

Scenario DRA 1

An exposure estimation scenario for PT19 with skin application is presented below. It is a model proposed by FR and its development is still under discussions in framework of ART Food.

Scenario DRA 1 has been performed for toddler, child and adult considering reference values mentioned in HEADhoc recommendation No. 14.

The scenario is not considered relevant for infant (<1 year), as the diet of infant consists mainly of milk and puree food, the contamination from hand to food is very limited.	toddler 1-2 years	Child 2-6 years	Child 6-12 years	Adult
body weight (kg)	10	15.6	23.9	60
hands (palms and back of both hands) (cm^2)	230.4	330.9	427.8	820

These biocidal products are intended for children ≤6 years with 1 application per day, and for children > 6 years and adults until 2 applications per day.

To estimate dietary exposure, the following assumptions and reference values were used:

Ratio surface factor of the palm compared to whole hand	0.5
transfer factor (hand to food) in %	100%
transfer factor (food to mouth) in %	100%
Cumulative exposure considering daily application number	1-2
handwash after use (i.e rinsing factor)[12]	3 (considering that a recommendation to wash hands is proposed)
exposure for children ≤6 years	not relevant (considering the risk mitigation measure: *Do not apply the product on the hands of child 6 years old)*

Indirect exposure via food:

Product application rate (mg product/cm^2) (effective)	0.8 (dose max covered lower dose of 0.6)			
Concentration (a.s in % w/w in the product)	20			
Applied active substance (mg a.s/cm^2) (effective)	0.16			
age	toddler (1-2 years)	child (2-6 years)	child (6-12 years)	adult
hands (palms and back of both hands) (cm^2)	230.4	330.9	427.8	820
Intended number of application (evaluated)	1	1	2	2
Ratio surface factor of the palm compared to whole hand	0.5	0.5	0.5	0.5
Hand exposure per application (a.s in mg)	**18**	**26**	**68**	**131**
transfer factor (hand to food) in %	100	100	100	100

12 Dilution factor from ConsExpo 4.0, Consumer Exposure and Uptake Models. Program Manuel. Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 320104004. & RIVM report 320104001/2006 : Cosmetics Fact Sheet To assess the risks for the consumer (Updated version for ConsExpo 4) H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen [p34 : "Weight fraction dilution Wf / 3" " Estimate dilution factor 3 (wetting hands)]

transfer factor (food to mouth) in %	100	100	100	100
ingested a.s in mg and per application	18	26	34	66
total ingested a.s in mg	18	26	68	131
Body weight in kg	10	15.6	23.9	60
Exposure per application in mg a.s/kg b.w./day	1.8	1.7	1.4	1.1
Total exposure in mg a.s/kg b.w./day	1.8	1.7	2.9	2.2
Proposed restriction : handwash after use (i.e rinsing factor) Do not apply on the hands of child 6 years old	n.r.	n.r.	3	3
Exposure per application in mg a.s/kg b.w./day including precautionary proposal	n.r.	n.r.	0.48	0.36
Total exposure in mg a.s/kg b.w./day including precautionary proposal	**n.r.**	**n.r.**	**1**	**0.73**

in bold : results related to intended uses considering measures proposed by the applicant

Conclusion

As regards the intended use of the product SPRAY REPULSIF IR200 on human skin, an estimation of indirect exposure via food for toddlers, children and adults was performed. These estimations are considered to be worst case using the assumption that all the active substance from the palm hands will be ingested. The calculated exposures via food range from 1.8 to 2.9 mg/kg bw/d for children and up to 2.2 mg/kg bw/d for adults.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

In modern formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). The workers (trained professionals) usually wear personal protective equipment (e.g. gloves). Thus the exposure can occur during the mixing and loading and have been calculated as a worst case.

Scenario 6 : Mixing and Loading model – worst case for the production, formulation and disposal of the biocidal product

Description of Scenario 6
For a worst case situation, it was estimated that the more sustainable model for industrial exposure production, formulation and disposal is : RISKOFDERM Dermal model (loading liquid, automated or semi-automated) from HEEG opinion 1 (2008). **Dermal exposure via clothing:** default potential exposure rates on clothing x Purity of the active substance x Duration of task x Number of events per day (x (1-Factor of protection for clothing)) **Dermal exposure via hands:** default potential exposure rates on hands x Purity of the active substance x Duration of task x Number of events per day (x (1-Factor of protection for gloves)) **Dermal systemic exposure:** (Dermal exposure via clothing + Dermal exposure via hands) x percent of dermal absorption / body weight **Inhalation exposure:** Inhalation is no relevant for this model and is not taken into account **Systemic exposure**: Dermal systemic exposure + 0 (inhalation exposure n.r.)

	Parameters[1]	**Value**
Tier 1	Purity of the active substance[1]	99%
	Dermal absorption[1]	50%
	default potential exposure rates on clothing[2]	101 mg/min
	default potential exposure rates on hand[2]	2.02 mg/ min
	default potential exposure rates for inhalation[2]	n.r. mg/m³ (and the substance has a low vapour pressure)
	Bodyweight[3]	60 kg
	Number of events per day	1/day
	Duration of task	10 min
Tier 2	Factor of protection for Uncoated cotton coverall[3]	75%
Tier 3	Factor of protection for gloves[3]	90%

[1] CAR (doc IIA)

General information, see justification above
[2] RISKOFDERM Dermal model: loading liquid, automated or semi-automated (HEEG opinion 1, 2008)
[3] Biocide Human Health Exposure Methodology (Oct 2015)

Calculations for Scenario 6

Summary table: systemic exposure associated with production, formulation, and disposal					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake**	**Estimated total uptake [mg/kg bw/d]**
Scenario 6	Tier 1/ no PPE	n.r.	8.5	n.r.	8.5
Scenario 6	Tier 2/ Uncoated cotton coverall	n.r.	2.25	n.r.	2.25
Scenario 6	Tier 3/ Uncoated cotton coverall and gloves	n.r.	2.1	n.r.	2.1

(X) Aggregated exposure

Not applicable

(XI) Summary of exposure assessment

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
1.	Non-professionals, adult	Tier 1, no PPE, dermal, 3 applications/day	1.47 mg/kg bw/day
	Non-professionals, child	Tier 1, no PPE, dermal, 3 applications/day	1.76 mg/kg bw/day
	Non-professionals, toddler	Tier 1, no PPE, dermal, 3 applications/day	4.2 mg/kg bw/day
	Non-professionals, infant	Tier 1, no PPE, dermal, 3 applications/day	5.25 mg/kg bw/day
	Non-professionals, infant	Tier 2, no PPE, dermal, 2 applications/day	3.5 mg/kg bw/day
2.	Non-professionals, adult	Tier 1, no PPE, inhal+oral, 3 applications/day	0.00875 mg/kg bw
	Non-professionals, child	Tier 1, no PPE, inhal+oral, 3 applications/day	0.0232 mg/kg bw
	Non-professionals, toddler	Tier 1, no PPE, inhal+oral, 3 applications/day	0.0529 mg/kg bw
	Non-professionals, infant	Tier 1, no PPE, inhal+oral, 3 applications/day	0.0441 mg/kg bw
	Non-professionals, infant	Tier 2, no PPE, inhal+oral, 2 applications/day	0.0294 mg/kg bw
3.	Non-professionals, adult	Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral	up to 3.57 applications
	Non-professionals, child	Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral	up to 2.99 applications
	Non-professionals, toddler	Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral	up to 1.72 applications
	Non-professionals, infant	Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral	up to 1.38 applications
4.	Non-professionals, adult	Tier 1, no PPE, inhal+oral, 9 appl/d	0.0262 mg/kg bw
5.	Non-professionals, adult	Tier 1 / no PPE	1.1 mg/kg bw/day
	Non-professionals, child	Tier 1 / no PPE	1.4 mg/kg bw/day
	Non-professionals, toddler	Tier 1 / no PPE	3.1 mg/kg bw/day
	Non-professionals, infant	Tier 1 / no PPE	2.6 mg/kg bw/day
6.	Professionals	Tier 1 / no PPE	8.5 mg/kg bw/d
	Professionals	Tier 2/ Uncoated cotton coverall	2.25 mg/kg bw/d
	Professionals	Tier 3/ Uncoated cotton coverall and gloves	2.1 mg/kg bw/d

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Scenario number	Exposed group	Tier (number of applications)	Estimated total uptake (mg/kg bw/day)
1a: skin (mosquitoes, ticks)	Adult	Tier 1 (2 applications)	5.37
1a: skin (mosquitoes, ticks)	Adult	Tier 1 (1 application)	2.68
1a: skin (mosquitoes, ticks)	Child (6 to <12 years old)	Tier 1 (2 applications)	7.16
1a: skin (mosquitoes, ticks)	Child (6 to <12 years old)	Tier 1 (1 application)	3.58
1a: skin (mosquitoes, ticks)	Child (2 to <6 years old)	Tier 1 (1 application)	4.07
1a: skin (mosquitoes, ticks)	Toddler (1 to <2 years old)	Tier 1 (1 application)	4.50
1a: skin (mosquitoes, ticks)	Infant (<1 year old)	Tier 1 (1 application)	4.80
1b: skin (mosquitoes)	Adult	Tier 1 (2 applications)	7.16
1b: skin (mosquitoes)	Adult	Tier 1 (1 application)	3.58
1b: skin (mosquitoes)	Child (6 to <12 years old)	Tier 1 (1 application)	4.78
1b: skin (mosquitoes)	Child (2 to <6 years old)	Tier 1 (1 application)	5.43
1b: skin (mosquitoes)	Toddler (1 to <2 years old)	Tier 1 (1 application)	6.00
1b: skin (mosquitoes)	Infant (<1 year old)	Tier 1 (1 application)	6.40
1c: head (lice)	Adult	Tier 1 (3 applications)	1.47
1c: head (lice)	Child (6 to <12 years old)	Tier 1 (3 applications)	1.75
1c: head (lice)	Child (2 to <6 years old)	Tier 1 (3 applications)	2.69
1c: head (lice)	Toddler (1 to <2 years old)	Tier 1 (3 applications)	4.2
1c: head (lice)	Infant (<1 year old)	Tier 1 (3 applications)	3.5
2: application (bed linen)	Adult	Tier 1 (1 application)	2.21E-01
5: inhalation (volatilised residues)	Adult	Tier 1 (1 application)	3.53E-02
5: inhalation (volatilised residues)	Child (6 to <12 years old)	Tier 1 (1 application)	6.66E-02
5: inhalation (volatilised residues)	Child (2 to <6 years old)	Tier 1 (1 application)	8.58E-02
5: inhalation (volatilised residues)	Toddler (1 to <2 years old)	Tier 1 (1 application)	1.06E-01
5: inhalation (volatilised residues)	Infant (<1 year old)	Tier 1 (1 application)	8.95E-02
6a: treated clothes (ticks)	Adult	Tier 1	2.86
6a: treated clothes (ticks)	Child (6 to <12 years old)	Tier 1	3.98
6a: treated clothes (ticks)	Child (2 to <6 years old)	Tier 1	4.35
6a: treated clothes (ticks)	Toddler (1 to <2 years old)	Tier 1	4.74
6a: treated clothes (ticks)	Infant (<1 year old)	Tier 1	5.06
6b: treated clothes (mosquitoes)	Adult	Tier 1	2.02
6b: treated clothes (mosquitoes)	Child (6 to <12 years old)	Tier 1	2.81
6b: treated clothes (mosquitoes)	Child (2 to <6 years old)	Tier 1	3.07
6b: treated clothes (mosquitoes)	Toddler (1 to <2 years old)	Tier 1	3.35
6b: treated clothes (mosquitoes)	Infant (<1 year old)	Tier 1	3.57
6c: treated clothes combined (ticks)	Adult	Tier 1	2.78

6c: treated clothes combined (ticks)	Child (6 to <12 years old)	Tier 1	2.04
6c: treated clothes combined (ticks)	Child (2 to <6 years old)	Tier 1	2.30
6c: treated clothes combined (ticks)	Toddler (1 to <2 years old)	Tier 1	2.53
6c: treated clothes combined (ticks)	Infant (<1 year old)	Tier 1	2.70
6d: treated clothes combined (mosquitoes)	Adult	Tier 1	1.96
6d: treated clothes combined (mosquitoes)	Child (6 to <12 years old)	Tier 1	2.88
6d: treated clothes combined (mosquitoes)	Child (2 to <6 years old)	Tier 1	1.63
6d: treated clothes combined (mosquitoes)	Toddler (1 to <2 years old)	Tier 1	1.78
6d: treated clothes combined (mosquitoes)	Infant (<1 year old)	Tier 1	1.90
6e: treated clothes (head lice)	Adult	Tier 1	2.0
6e: treated clothes (head lice)	Child (6 to <12 years old)	Tier 1	3.0
6e: treated clothes (head lice)	Child (2 to <6 years old)	Tier 1	3.6
6e: treated clothes (head lice)	Toddler (1 to <2 years old)	Tier 1	4.0
6e: treated clothes (head lice)	Infant (<1 year old)	Tier 1	4.3
7a: treated bed linen (head lice)	Adult	Tier 1	1.42
7a: treated bed linen (head lice)	Child (6 to <12 years old)	Tier 1	2.06
7a: treated bed linen (head lice)	Child (2 to <6 years old)	Tier 1	2.46
7a: treated bed linen (head lice)	Toddler (1 to <2 years old)	Tier 1	2.77
7a: treated bed linen (head lice)	Infant (<1 year old)	Tier 1	2.95
7b: treated bed linen (dust mites)	Adult	Tier 1	2.32
7b: treated bed linen (dust mites)	Child (6 to <12 years old)	Tier 1	3.23
7b: treated bed linen (dust mites)	Child (2 to <6 years old)	Tier 1	3.66
7b: treated bed linen (dust mites)	Toddler (1 to <2 years old)	Tier 1	4.03
7b: treated bed linen (dust mites)	Infant (<1 year old)	Tier 1	4.31

2.2.7.3 Risk characterisation for human health

- **FIRST AUTHORISATION – 2017 (BE CA)**

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study	500 (1500) mg/kg bw/d	100	100%	5 mg/kg bw/d

		300 (600) mg/kg bw/d			
AELmedium-term	Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study	500 (1500) mg/kg bw/d 300 (600) mg/kg bw/d	100	100%	5 mg/kg bw/d
AELlong-term	Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study	500 (1500) mg/kg bw/d 300 (600) mg/kg bw/d	100	100%	5 mg/kg bw/d (not applicable here,no long-term use of the BP)
ARfD	n.a.	n.a.			not applicable, no residues in food or feed occur
ADI	n.a.	n.a.			not applicable, no residues in food or feed occur

[1] reason for assessment factor: factor 10 for both intra-species and interspecies differences. No extrapolation factor for duration is needed, as the overall NOAEL is derived from a repeated 28d-oral toxicity study and a teratogenicity study.

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No change is necessary.

(I) Risk for industrial users

- **FIRST AUTHORISATION – 2017 (BE CA)**

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 6, mixing & loading, professional	1	500 mg/kg bw/d	5 mg/kg bw/d	8,5 mg/kg bw/d	170%	no
Scenario 6, mixing & loading, professional	2	500 mg/kg bw/d	5 mg/kg bw/d	2,25 mg/kg bw/d	45%	yes
Scenario 6, mixing & loading, professional	3	500 mg/kg bw/d	5 mg/kg bw/d	2,1 mg/kg bw/d	42%	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
n.a.						

Local effects

The biocidal product is classified as eye damage/irritation cat 2, H319. However, appropriate risk mitigation measures are assumed to be taken by professionals during production, formulation and disposal. Consequently, there is no need to consider local effects separately.

Conclusion

There is no concern for professionals working with Insect Repellent Pump Spray Lice IR3535® 20% during production, formulation and disposal when using appropriate PPE (minimum PPE required: uncoated cotton coverall).

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Assessement for industrials is not retained for the major change.

(II) Risk for professional users

- **FIRST AUTHORISATION – 2017 (BE CA)**

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
n.a.						

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
n.a.						

Local effects

n.a.

Conclusion

n.a.

(III) Risk for non-professional users

- **FIRST AUTHORISATION – 2017 (BE CA)**

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL [mg/kg bw/d]	AEL [mg/kg bw/d]	Estimated Uptake	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1, dermal, adult	1	500	5	1.47 mg/kg bw/day	29.4	yes
Scenario 1, dermal, child	1	500	5	1.76 mg/kg bw/day	35.2	yes

Scenario 1, dermal, toddler	1	500	5	4.2 mg/kg bw/day	84	yes
Scenario 1, dermal, infant	1	500	5	5.25 mg/kg bw/day	105	no
Scenario 1, dermal, infant	2	500	5	3.5 mg/kg bw/day	70	yes
Scenario 2, inhal+oral, adult	1	500	5	0.00875 mg/kg bw	0.2	yes
Scenario 2, inhal+oral, child	1	500	5	0.0232 mg/kg bw	0.5	yes
Scenario 2, inhal+oral, toddler	1	500	5	0.0529 mg/kg bw	1.1	yes
Scenario 2, inhal+oral, infant	1	500	5	0.0441 mg/kg bw	0.9	yes
Scenario 2, inhal+oral, infant	2	500	5	0.0294 mg/kg bw	0.6	yes
Scenario 3, hand-mouth transfer, adult	1	500	5	up to 3.57 applications	n.a.	Reverse reference scenario
Scenario 3, hand-mouth transfer, child	1	500	5	up to 2.99 applications	n.a.	Reverse reference scenario
Scenario 3, hand-mouth transfer, toddler	1	500	5	up to 1.72 applications	n.a.	Reverse reference scenario
Scenario 3, hand-mouth transfer, infant	1	500	5	up to 1.38 applications	n.a.	Reverse reference scenario
Scenario 4, inhal+oral, adult	1	500	5	0.0262 mg/kg bw	0.5	yes
Scenario 5, inhal, adult	1	500	5	1.1 mg/kg bw/day	22	yes
Scenario 5, inhal, child	1	500	5	1.4 mg/kg bw/day	28	yes
Scenario 5, inhal, toddler	1	500	5	3.1 mg/kg bw/day	66	yes
Scenario 5, inhal, infant	1	500	5	2.6 mg/kg bw/day	54	yes

Combined scenarios

Scenarios combined	**Tier**	**Systemic NOAEL [mg/kg bw/d]**	**AEL [mg/kg bw/d]**	**Estimated uptake [mg/kg bw]**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenarios 1+2 – ADULT 3 appl/d	Tier 1 / no PPE	500	5	1.48 mg/kg bw	29.6	yes
Scenarios 1+2 – CHILD 3 appl/d	Tier 1 / no PPE	500	5	1.78 mg/kg bw	35.6	yes
Scenarios 1+2 – TODDLER 3 appl/d	Tier 1 / no PPE	500	5	4.26 mg/kg bw	85.1	yes
Scenarios 1+2 – INFANT 3 appl/d	Tier 1 / no PPE	500	5	5.29 mg/kg bw	105.6	no
Scenarios 1+2 – INFANT 2 appl/d	Tier 2 / no PPE	500	5	3.53 mg/kg bw	70.6	yes

Local effects

The biocidal product is classified as eye damage/irritation cat 2, H319. However, appropriate risk mitigation measures will be imposed and taken up on the label: When the biocidal product is applied to children under 11 years old, the product should be applied by an adult. Do not spray into the face or apply to eye area. Use in well-ventilated areas.' Consequently, there is no need to consider local effects separately.

Conclusion

There is no concern for adults, children and toddlers using Insect Repellent Pump Spray Lice IR3535® 20% three times a day, and for applying the product to infants twice a day. Neither primary nor secondary exposure to the biocidal product leads to unacceptable risks. The main route of exposure is dermal. Proper use, i.e. use in compliance with correct and complete conditions on the label, of Insect Repellent Pump Spray Lice IR3535® 20% is considered safe for adults and children.

The following RMM are required:

- When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.
- Do not spray into the face or apply to eye area.
- Protect children's eyes and protect the child against inhalation during spraying.
- Do not apply over cuts, wounds or irritated skin.
- Only for external use.
- Use in well-ventilated areas.
- Synthetic materials should be protected during spraying.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed	Acceptable (yes/no)
Scenario 1a: application to the skin - temperate conditions and ticks						
Adult	1	5	5.37	**107%**	**2**	**No**
Adult	1	5	2.68	53.7%	1	Yes
Child (6 to <12 years old)	1	5	7.16	**143%**	**2**	**No**
Child (6 to <12 years old)	1	5	3.58	71.6%	1	Yes
Child (2 to <6 years old)	1	5	4.07	81.4%	1	Yes
Toddler (1 to <2 years old)	1	5	4.50	89.9%	1	Yes
Infant (<1 year old)	1	5	4.80	96.0%	1	Yes
Scenario 1b: application to the skin - tropical conditions						
Adult	1	5	7.16	**143%**	**2**	**No**
Adult	1	5	3.58	71.6%	1	Yes
Child (6 to <12 years old)	1	5	4.78	95.5%	1	Yes
Child (2 to <6 years old)	1	5	5.43	**109%**	1	**No**
Toddler (1 to <2 years old)	1	5	6.00	**120%**	1	**No**
Infant (<1 year old)	1	5	6.40	**128%**	1	**No**
Scenario 1c: application to the head - lice						
Adult	1	5	1.47	29.4%	3	Yes
Child (6 to <12 years old)	1	5	1.75	35.1%	3	Yes
Child (2 to <6 years old)	1	5	2.69	53.8%	3	Yes
Toddler (1 to <2 years old)	1	5	4.2	84.0%	3	Yes
Infant (<1 year old)	1	5	3.5	70%	3	Yes
Scenario 2: application to the bed linen/clothes – inhalation exposure						
Adult	1	5	0.22	4.4%	1	Yes

Task/ Scenario	Tier	AEL mg/kg bw/d	Skin surface area to put in the mouth to reach the AEL short-term (cm2)	% hand surface area to put in the mouth to reach the AEL	Number of applications claimed	Acceptable (yes/no)
Scenario 3: Hand-to-mouth transfer (reverse scenario)						
Adult	1	5	937.5	229%	2	Yes
Adult	1	5	1875.0	457%	1	Yes
Child (6 to <12 years old)	1	5	746.9	349%	1	Yes
Child (2 to <6 years old)	1	5	487.5	295%	1	Yes
Toddler (1 to <2 years old)	1	5	312.5	271%	1	Yes
Infant (<1 year old)	1	5	250	254%	1	Yes

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed	Acceptable (yes/no)
Scenario 5: inhalation of volatilised residues						
Adult	1	5	3.53E-02	0.7%	1	Yes
Child (6 to <12 years old)	1	5	6.66E-02	1.3%	1	Yes

Child (2 to <6 years old)	1	5	8.58E-02	1.7%	1	Yes
Toddler (1 to <2 years old)	1	5	1.06E-01	2.1%	1	Yes
Infant (<1 year old)	1	5	8.95E-02	1.8%	1	Yes
Scenario 6a: treated clothes - ticks						
Adult	1	5	2.86	57.3%	1	Yes
Child (6 to <12 years old)	1	5	3.98	79.6%	1	Yes
Child (2 to <6 years old)	1	5	4.35	87.0%	1	Yes
Toddler (1 to <2 years old)	1	5	4.74	94.8%	1	Yes
Infant (<1 year old)	1	5	5.06	101%	1	No
Scenario 6b: treated clothes - mosquitoes						
Adult	1	5	2.02	40.4%	1	Yes
Child (6 to <12 years old)	1	5	2.81	56.2%	1	Yes
Child (2 to <6 years old)	1	5	3.07	61.4%	1	Yes
Toddler (1 to <2 years old)	1	5	3.35	66.9%	1	Yes
Infant (<1 year old)	1	5	3.57	71.5%	1	Yes
Scenario 6c: treated clothes combined with skin application- ticks						
Adult	1	5	2.04	40.8%	1	nr
Child (6 to <12 years old)	1	5	2.84	56.8%	1	nr
Child (2 to <6 years old)	1	5	3.22	64.3%	1	nr
Toddler (1 to <2 years old)	1	5	3.54	70.8%	1	nr
Infant (<1 year old)	1	5	3.78	75.6%	1	nr
Scenario 6d: treated clothes combined with skin application - mosquitoes						
Adult	1	5	1.44	28.8%	1	nr
Child (6 to <12 years old)	1	5	2.00	40.1%	1	nr
Child (2 to <6 years old)	1	5	2.27	45.4%	1	nr
Toddler (1 to <2 years old)	1	5	2.50	50.0%	1	nr
Infant (<1 year old)	1	5	2.67	53.4%	1	nr
Scenario 6e: treated clothes – head lice						
Adult	1	5	2.0	40.9%	1	Yes
Child (6 to <12 years old)	1	5	3.0	60.5%	1	Yes
Child (2 to <6 years old)	1	5	3.6	71.5%	1	Yes
Toddler (1 to <2 years old)	1	5	4.0	80.1%	1	Yes
Infant (<1 year old)	1	5	4.3	85.5%	1	Yes
Scenario 7a : treated bed linen – head lice						
Adult	1	5	1.42	28.4%	1	Yes
Child (6 to <12 years old)	1	5	2.06	41.1%	1	Yes
Child (2 to <6 years old)	1	5	2.46	49.3%	1	Yes
Toddler (1 to <2 years old)	1	5	2.77	55.3%	1	Yes
Infant (<1 year old)	1	5	2.95	59.1%	1	Yes
Scenario 7b : treated bed linen – dust mites						
Adult	1	5	2.32	46.5%	1	Yes
Child (6 to <12 years old)	1	5	3.23	64.7%	1	Yes
Child (2 to <6 years old)	1	5	3.66	73.2%	1	Yes
Toddler (1 to <2 years old)	1	5	4.03	80.6%	1	Yes
Infant (<1 year old)	1	5	4.31	86.1%	1	Yes

Combined scenarios

Combined scenarios head lice: treated skin [1c], during application on clothes [2] for adult only, and by treated clothes [6e]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult	1	5	3.74	74.7%	3	Yes
Child (6 to <12 years old)	1	5	4.78	95.6%	3	Yes
Child (2 to <6 years old)	1	5	6.27	**125%**	3	**No**
Toddler (1 to <2 years old)	1	5	8.21	**164%**	3	**No**
Infant (<1 year old)	1	5	7.78	**156%**	3	**No**

Combined scenarios head lice: treated skin [1c], during application on bed linen [2] for adult only, and by treated bed linen [7a]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult	1	5	3.15	62.9%	3	Yes
Child (6 to <12 years old)	1	5	3.88	77.6%	3	Yes
Child (2 to <6 years old)	1	5	5.24	**105%**	3	**No**
Toddler (1 to <2 years old)	1	5	7.07	**141%**	3	**No**
Infant (<1 year old)	1	5	6.54	**131%**	3	**No**

Combined scenarios mosquitos (tropical zone): treated skin [1b], during application on clothes [2] for adult only, and by treated clothes [6d]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (1 application)	1	5	4.78	95.6%	1	Yes
Child (6 to <12 years old)	1	5	6.22	**124%**	1	**No**
Child (2 to <6 years old)	1	5	7.05	**141%**	1	**No**
Toddler (1 to <2 years old)	1	5	7.78	**156%**	1	**No**
Infant (<1 year old)	1	5	8.31	**166%**	1	**No**

Combined scenarios mosquitos (temperate zone): treated skin [1a], during application on clothes [2] for adult only, and by treated clothes [6d]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (1 application)	1	5	3.89	77.7%	1	Yes
Child (6 to <12 years old)	1	5	5.02	**100%**	1	**No**
Child (2 to <6 years old)	1	5	5.70	**114%**	1	**No**
Toddler (1 to <2 years old)	1	5	6.28	**126%**	1	**No**

Infant (<1 year old)	1	5	6.71	**134%**	1	**No**

Combined scenarios ticks: treated skin [1a], during application on clothes [2] for adult only, and by treated clothes [6c]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (1 application)	1	5	4.30	5	85.9%	Yes
Child (6 to <12 years old)	1	5	5.63	5	**113%**	**No**
Child (2 to <6 years old)	1	5	6.37	5	**127%**	**No**
Toddler (1 to <2 years old)	1	5	7.02	5	**140%**	**No**
Infant (<1 year old)	1	5	7.50	5	**150%**	**No**

Combined scenarios dust mites: during application on bed linen [2] for adult only, inhalation to volatilised residues [5] and by treated bed linen [7b]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (1 application)	1	5	2.58	5	51.6%	Yes
Child (6 to <12 years old)	2	5	3.30	5	66.0%	Yes
Child (2 to <6 years old)	2	5	3.75	5	74.9%	Yes
Toddler (1 to <2 years old)	2	5	4.14	5	82.8%	Yes
Infant (<1 year old)	2	5	4.39	5	87.9%	Yes

Conclusion
The conclusions on human health are the following:

Intended use #1 (Spray to repel human head lice): the use is already authorized.
The risk is acceptable for adult and children.

Intended use #2(Spray to treat textiles as barrier treatment against human head lice)
The risk is acceptable for adult and children.

Intended use #3 (Spray to treat clothes against mosquitoes)
The risk is acceptable for adult and children.

Intended use #4 (Spray for skin application to repel mosquitoes)
- Temperate condition:

The risk is acceptable for adult and children considering only one application per day.
The 2 applications claimed by applicant for adult and children of 6 years and more lead to unacceptable risk.

- Tropical condition:

The risk is acceptable for adult and children of 12 years and more considering only one application per day.
The 2 applications claimed by applicant lead to unacceptable risk.

For children between 6 and 12 years, the risk is acceptable.
For children younger than 1 year to6 years, the risk is unacceptable.

Intended use #5 (Spray to treat clothes against ticks)
The risk is acceptable for adult and children of 1 year and more.
The risk is unacceptable for children younger than 1 year.

Intended use #6 (Spray for skin application to repel ticks)
The risk is acceptable for adult and children considering only one application per day.
The 2 applications claimed by applicant for adult and children of 6 years and more lead to unacceptable risk.

Intended use #7 (Spray to treat fabric against dust mites):
The risk is acceptable for adult and children.

Risk linked to combined uses are also assessed:

Intended use #1 (Spray to repel human head lice) and #2 (Spray to treat textiles as barrier treatment against human head lice):
For combined treatment, the risk is acceptable for adults and children of 6 years and more.
The risk is unacceptable for children younger than 6 years.
Therefore, the following RMM is proposed for treatment against head lice: For children younger than 6 years, do not apply the product simultaneously on the head and on clothes/bed linen.

Intended use #4 (Spray for skin application to repel mosquitoes) tropical conditions and Intended use #3 (Spray to treat clothes against mosquitoes)
For combined treatment, the risk is acceptable for adults and children more than 12 years but inacceptable for children under 12 years.
Therefore, the following RMM is proposed: for treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes. Moreover, the following RMM is proposed: For adult and children more than 12 years, do not apply the product on skin under clothes.

Intended use #4 (Spray for skin application to repel mosquitoes) temperate conditions and Intended use #3 (Spray to treat clothes against mosquitoes)
For combined treatment, the risk is acceptable for adults and children of 12 years and more but inacceptable for children under 12 years.
Therefore, the following RMM is proposed: for treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes. Moreover, the following RMM is proposed: For adult and children more than 12 years, do not apply the product on skin under clothes.

Intended use #6 (Spray for skin application to repel ticks) and Intended use #5 (Spray to treat clothes against ticks)
For combined treatment, the risk is acceptable for adults and children of 12 years and more but inacceptable for children under 6 years. Therefore, the following RMM is proposed: for treatment against ticks do not apply the product simultaneously on the skin of children under 6 years and on their clothes. Moreover, the following RMM is proposed: For adult and children more than 6 years, do not apply the product on skin under clothes.

Authorisation based on article 19 (5) in France:

Given the risk of vector-borne diseases transmission in France, FR CA considers that Spray Repulsif IR200 could be authorized for application on humans, with appropriate risk mitigation measures that limit human exposure based on article 19(5). The following RMMs are considered as applicable in France:

- For adult: "apply on the *face, neck, hands, ¾ arms, ½ legs"*
- For children: "*do not apply the product on hands of child" and* "apply on the *face, neck, ¾ arms and ½ legs"*

The estimation of exposure is performed considering that wearing a T-shirt and short leads to an exposure of head, hand, ¾ arm and ½ legs (approximately 38 % of body surface for an adult).

The scenario and parameters are similar to the scenario assessed above except exposed area. Indeed, the *primary exposure* is limited to the body surface: head, hand, ¾ arms and ½ legs for Tier 1. For Tier 2, the body surface considered is limited to head, ¾ arms and ½ legs because of the following RMM is proposed: *Do not apply the product on the hands of child*.

Description of Scenario [1a]			
	Parameters	**Value**	**Reference**
National approach Tier 1	Dermal absorption	14%	CAR IR3535
	% of active substance in biocidal product	20%	Applicant's data
	Application rate (g product/m²)	**6 [1a] and 8 [1b]**	Applicant's data
	Number of application/day		Applicant's data
	Child >6 years old and adult	**2**	
	Child ≥ 6 months old - 6 years old	**1**	
	Body surface exposed (cm²)		Recommendation no. 14, 2017 **Total body surface** (head, hands, ¾ arm and ½ legs).
	Adult	6297.5	
	Child (6 to <12 years old)	3282.1	
	Child (2 to <6 years old)	2462.2	
	Toddler (1 to <2 years old)	1754.4	
	Infant (<1 year old)	1498.6	
Tier 2	**Body surface exposed (cm²)**		Recommendation no. 14, 2017 **Total body surface** (head, ¾ arm and ½ legs).
	Child (6 to <12 years old)	2854.3	
	Child (2 to <6 years old)	2131.3	
	Toddler (1 to <2 years old)	1524.0	
	Infant (<1 year old)	1301.8	

Calculations for Scenario [1a]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1 (2 applications)	3.53
Adult	Tier 1 (1 application)	1.76
Child (6 to <12 years old)	Tier 1 (2 applications)	4.61
Child (6 to <12 years old)	Tier 1 (1 application)	2.31
Child (2 to <6 years old)	Tier 1 (1 application)	2.65
Toddler (1 to <2 years old)	Tier 1 (1 application)	2.95
Infant (<1 year old)	Tier 1 (1 application)	3.15
Child (6 to <12 years old)	Tier 2 (2 applications)	4.01
Child (6 to <12 years old)	Tier 2 (1 application)	2.01
Child (2 to <6 years old)	Tier 2 (1 application)	2.30
Toddler (1 to <2 years old)	Tier 2 (1 application)	2.56
Infant (<1 year old)	Tier 2 (1 application)	2.73

Same general parameters than Scenario 1a are used for the intended uses against mosquitoes (intended use #4 - tropical conditions) with an application rate of 8 g product/m².

Calculations for Scenario [1b]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1 (2 applications)	4.70
Adult	Tier 1 (1 application)	2.35
Child (6 to <12 years old)	Tier 1 (1 application)	3.08
Child (2 to <6 years old)	Tier 1 (1 application)	3.54
Toddler (1 to <2 years old)	Tier 1 (1 application)	3.93
Infant (<1 year old)	Tier 1 (1 application)	4.20
Child (6 to <12 years old)	Tier 2 (1 application)	2.68
Child (2 to <6 years old)	Tier 2 (1 application)	3.06
Toddler (1 to <2 years old)	Tier 2 (1 application)	3.41
Infant (<1 year old)	Tier 2 (1 application)	3.64

Risk for non-professional users

Task/ Scenario	**Tier**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Number of applications claimed**	**Acceptable (yes/no)**
Scenario 1a: application to the skin - temperate conditions						

Adult	1	5	3.53	71%	2	Yes
Adult	1	5	1.76	35%	1	Yes
Child (6 to <12 years old)	1	5	4.61	92%	2	Yes
Child (6 to <12 years old)	1	5	2.31	46%	1	Yes
Child (2 to <6 years old)	1	5	2.65	53%	1	Yes
Toddler (1 to <2 years old)	1	5	2.95	59%	1	Yes
Infant (<1 year old)	1	5	3.15	63%	1	Yes
Child (6 to <12 years old)	2	5	4.01	80%	2	Yes
Child (6 to <12 years old)	1	5	2.01	40%	1	Yes
Child (2 to <6 years old)	1	5	2.30	46%	1	Yes
Toddler (1 to <2 years old)	1	5	2.56	51%	1	Yes
Infant (<1 year old)	1	5	2.73	55%	1	Yes
Scenario 1b: application to the skin - tropical conditions						

Adult	1	5	4.70	94%	2	Yes
Adult	1	5	2.35	47%	1	Yes
Child (6 to <12 years old)	1	5	3.08	62%	1	Yes
Child (2 to <6 years old)	1	5	3.54	71%	1	Yes
Toddler (1 to <2 years old)	1	5	3.93	79%	1	Yes
Infant (<1 year old)	1	5	4.20	84%	1	Yes
Child (6 to <12 years old)	1	5	2.68	54%	1	Yes
Child (2 to <6 years old)	1	5	3.06	61%	1	Yes
Toddler (1 to <2 years old)	1	5	3.41	68%	1	Yes
Infant (<1 year old)	1	5	3.64	73%	1	Yes

The risk is acceptable for adult and children.

If the application on clothes is combined to the application on skin, the surfaces for covered areas proposed above are used.

The assumption was made according to the following uses:
- intended use #5 (ticks, 8.5 g/m² of fabric) (scenario 6c),
- intended use #3 (mosquitos, 6 g/m² of fabric) (scenario 6d)

Description of Scenario 6			
The ready to use product is a pump spray which is sprayed directly onto the textile. Adults, children, toddlers and infants could be exposed when wearing treated clothes. According to Recommendation no.8[13], "a protection factor of 50% can be assumed for one layer of clothing against dry contamination or light liquid contamination'.			
	Parameters	**Value**	**References**
Tier 1	Application rate (g product/m² fabric)	**8.5 and 6**	Applicant's data
	% of active substance in biocidal product	20%	Applicant's data
	Reduction in exposure (long sleeve shirt and long pants)	50%	Recommendation no. 8, 2015
	Dermal absorption (%)	14%	CAR IR3535
	Body weight (kg)		Recommendation no. 14, 2017
	Adult	60	
	Child (6 to <12 years old)	23.9	
	Child (2 to <6 years old)	15.6	
	Toddler (1 to <2 years old)	10	
	Infant (<1 year old)	8	
	Treated textile surface (cm²) T shirt + short = total BS - (uncovered surface proposed in FR) (cm²)		Recommendation no. 14, 2017
	Adult	7072	
	Child (6 to <12 years old)	4104	
	Child (2 to <6 years old)	3021	
	Toddler (1 to <2 years old)	2124	
	Infant (<1 year old)	1814	

Calculations for Scenario [6c]

[13] Recommendation no. 8 of the BPC Ad hoc Working Group on Human Exposure Consumer use of biocidal product and protection from typical clothing, 2015.

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1 (1 application)	2.04
Child (6 to <12 years old)	Tier 1 (1 application)	2.95
Child (2 to <6 years old)	Tier 1 (1 application)	3.31
Toddler (1 to <2 years old)	Tier 1 (1 application)	3.62
Infant (<1 year old)	Tier 1 (1 application)	3.87

Calculations for Scenario [6d]

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake (mg/ kg bw/d)**
Adult	Tier 1 (1 application)	1.44
Child (6 to <12 years old)	Tier 1 (1 application)	2.08
Child (2 to <6 years old)	Tier 1 (1 application)	2.34
Toddler (1 to <2 years old)	Tier 1 (1 application)	2.56
Infant (<1 year old)	Tier 1 (1 application)	2.73

The following combined scenario are assessed:

- **For application against mosquitoes**
    - **Skin application (tropical zone) + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult (2 applications)	Tier 1	6.37
Adult (1 application)	Tier 1	4.01
Child (6 to <12 years old)	Tier 2	4.76
Child (2 to <6 years old)	Tier 2	5.40
Toddler (1 to <2 years old)	Tier 2	5.97
Infant (<1 year old)	Tier 2	6.38

    - **Skin application (temperate zone) + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult (2 applications)	Tier 1	4.97
Adult (1 application)	Tier 1	3.43
Child (6 to <12 years old) (2 applications)	Tier 2	6.09
Child (6 to <12 years old) (1 application)	Tier 2	4.09
Child (2 to <6 years old)	Tier 2	4.63
Toddler (1 to <2 years old)	Tier 2	5.12
Infant (<1 year old)	Tier 2	5.47

- **For application against ticks**
  - **Skin application + exposure linked to application on clothes+ exposure during application on clothes**

Exposure scenario	Tier/PPE	Estimated dermal uptake (mg/kg bw/d)
Adult (2 applications)	Tier 1	5.57
Adult (1 application)	Tier 1	4.03
Child (6 to <12 years old) (2 applications)	Tier 2	6.96
Child (6 to <12 years old) (1 application)	Tier 2	4.95
Child (2 to <6 years old)	Tier 2	5.60
Toddler (1 to <2 years old)	Tier 2	6.18
Infant (<1 year old)	Tier 2	6.60

Combined scenarios mosquitos (tropical zone): treated skin [1b], during application on clothes [2] for adult only, and by treated clothes [6d]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (2 applications)	1	5	6.37	**127%**	2	**No**
Adult (1 application)	1	5	4.01	80%	1	Yes
Child (6 to <12 years old)	2	5	4.76	95%	1	Yes
Child (2 to <6 years old)	2	5	5.40	**108%**	1	**No**
Toddler (1 to <2 years old)	2	5	5.97	**119%**	1	**No**
Infant (<1 year old)	2	5	6.38	**128%**	1	**No**

Combined scenarios mosquitos (temperate zone): treated skin [1a], during application on clothes [2] for adult only, and by treated clothes [6d]:

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (2 applications)	1	5	4.97	99%	2	Yes
Adult (1 application)	1	5	3.43	69%	1	Yes
Child (6 to <12 years old) (2 applications)	2	5	6.09	**122%**	2	**No**
Child (6 to <12 years old) (1 application)	2	5	4.09	82%	1	Yes
Child (2 to <6 years old)	2	5	4.63	93%	1	Yes
Toddler (1 to <2 years old)	2	5	5.12	**102%**	1	**No**
Infant (<1 year old)	2	5	5.47	**109%**	1	**No**

Combined scenarios ticks: treated skin [1a], during application on clothes [2] for adult only, and by treated clothes [6c]

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Number of applications claimed *(on skin)*	Acceptable (yes/no)
Adult (2 applications)	1	5	5.57	**111%**	2	**No**
Adult (1 application)	1	5	4.03	81%	1	Yes
Child (6 to <12 years old) (2 applications)	2	5	6.96	**139%**	2	**No**
Child (6 to <12 years old) (1 application)	2	5	4.95	99%	1	Yes
Child (2 to <6 years old)	2	5	5.60	**112%**	1	**No**
Toddler (1 to <2 years old)	2	5	6.18	**124%**	1	**No**
Infant (<1 year old)	2	5	6.60	**132%**	1	**No**

Conclusion

Intended use #4 (Spray for skin application to repel mosquitoes)

- Temperate condition:

The risk is acceptable considering two applications per day for adult and children of 6 years and more and one application per day for children younger than 6 years.

- Tropical condition:

The risk is acceptable for adult and children of 12 years and more considering two applications per day and for children under 12 years considering one application per day.

Intended use #6 (Spray for skin application to repel ticks)

The risk is acceptable considering two applications per day for adult and children of 6 years and more and one application per day for children younger than 6 years.

Risk linked to combined uses are also assessed:

Intended use #4 (Spray for skin application to repel mosquitoes) tropical conditions and Intended use #3 (Spray to treat clothes against mosquitoes)

For combined treatment, the risk is acceptable for adults and children of 6 years and more considering only one application per day on skin.

The risk is unacceptable for children younger than 6 years.

Therefore, the following RMM is proposed: for treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes for children younger than 6 years. For adult and children of 6 years and more, do not apply the product on skin under clothes.

Intended use #4 (Spray for skin application to repel mosquitoes) temperate conditions and Intended use #3 (Spray to treat clothes against mosquitoes)

For combined treatment, the risk is acceptable for adults and children more than 6 years considering 2 applications per day on skin.

The risk for children between 6 and 12 years is acceptable considering only 1 application per day on skin.

The risk for children between 2 and 6 years is acceptable.

The risk for children younger than 2 years is unacceptable.

Therefore, the following RMM is proposed: for treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes. Moreover, the following RMM is proposed: For adult and children of 2 years and more, do not apply the product on skin under clothes.

Intended use #6 (Spray for skin application to repel ticks) and Intended use #5 (Spray to treat clothes against ticks)

The risk is not acceptable for children younger than one year.

For combined treatment, the risk for adult and children between 6 and 12 years is acceptable considering only 1 application per day on skin. The risk for children younger than 6 years is unacceptable.

Therefore, the following RMM is proposed: for treatment against ticks, do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes. Moreover, the following RMM is proposed: For adult and children of 6 years and more, do not apply the product on skin under clothes.

(IV) Risk for the general public

- **FIRST AUTHORISATION – 2017 (BE CA)**

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
n.a.						

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
n.a.						

Local effects

n.a.

Conclusion

n.a.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

For better clarity for the major change, exposure of infants, toddlers and children have been added in the section (V) Non-professional exposure.

(V) Risk for consumers via residues in food

Not applicable

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

A dietary risk assessment proposed by FR is presented below.

As regards the intended use of the product SPRAY REPULSIF IR200 on skin and the ARfD (based on AEL) proposed for IR3535, the following dietary risk assessments were performed:

Scenario DRA 1 :

Use # 4 – Spray for skin application to repel mosquitoes

Use # 6 – Spray for skin application to repel ticks

age	toddler (1-2 years)	child (2-6 years)	child (6-12 years)	adult
Exposure per application in mg a.s/kg b.w./day	n.r. (1,8)	n.r. (1,7)	0.48 (1,4)	0.36 (1,1)
Total exposure in mg a.s/kg b.w./day	**n.r.** (1,8)	**n.r.** (1,7)	**1** (2,9)	**0.73** (2,2)
ARfD (mg a.s/kg b.w./day)	5	5	5	5

% of ARfD (per application)	n.r. (37%)	n.r. (34%)	10% (29%)	7% (22%)
% of ARfD (in total)	**n.r.** (37%)	**n.r.** (34%)	**19%** (57%)	**15%** (44%)

in bold : results related to intended uses and considering measures proposed by the applicant

in parenthesis: estimations realised in framework of the assessment and without considering measures proposed by the applicant

Conclusion

As regards the intended uses of the product SPRAY REPULSIF IR200 on human skin no dietary risk for adults and child is expected..

The following label recommendations are proposed:

- *Wash hands thoroughly after handling*
- *Do not apply the product on the hands of children*

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

Not applicable

2.2.8 Risk assessment for animal health

The product should not be used on animals. So when the product is used correctly, no risk is expected for animal health.

2.2.9 Risk assessment for the environment

- **FIRST AUTHORISATION – 2017 (BE CA)**

For the product Insect Repellent Pump Spray Lice IR3535® 20 % no new studies or additional information for the environment have been provided. The active substance contained in this product is the same as evaluated in the CAR for IR3535 and therefore no new data/information on the active substance is required.

2.2.9.1 Effects assessment on the environment

- **FIRST AUTHORISATION – 2017 (BE CA)**

All data used for the effect assessment of Insect Repellent Pump Spray Lice IR3535® 20% is based on the available information on the active substance IR3535, such as it is presented in its respective CAR.

No new data relevant for the environmental evaluation, nor on the product, nor on the active substance, have been submitted. Apart from the active substance, the product does not contain any formulants that are of ecotoxicological concern.

An overview of the environmental fate and behaviour for the active substance, taken from the EU CAR, is presented in the first two titles below.

Environmental fate and behavior of the active substance

- **FIRST AUTHORISATION – 2017 (BE CA)**

IR3535® is used in insect repellents (PT19) that are applied on uncovered human skin. Products containing IR3535® will be used indoors and outdoors. However the main emission pathway to the environment is assumed to be indirect due to bathing and showering of treated people. Based on the physico-chemical properties it is expected that the emissions primarily will affect the aquatic compartment.

IR3535® is not ready biodegradable according to two screening tests, but in a Sewage Treatment Plant (STP) simulation test 99 % elimination was measured. 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.

No photolysis was observed in water and hydrolysis only occurred slowly under alkaline conditions (DT_{50} = 176.5 h at 25 °C and pH 9 or 866.13 h at 12 °C). Under acidic and neutral conditions IR3535® is hydrolytically stable.

The vapour pressure of IR3535® is low (0.15 Pa at 20 °C) which results in low exposure to the atmosphere. The half-life of IR3535® in air was calculated to be about 0.5482 days or 13.16 hours due to reaction with OH-radicals (24-hr day). Thus, accumulation of IR3535® in air and long range transport is unlikely.

IR3535® is a liquid at room temperature and the solubility in water is 70 g/L (at 20 °C). The log P_{ow} is 1.7 (at 23-24 °C) indicating that IR3535® has a low potential for bioaccumulation.

Based on the adsorption/desorption test a mean (arithmetic) K_{oc} form 475.25 L/kg was registered.

Effect assessment of the active substance

- **FIRST AUTHORISATION – 2017 (BE CA)**

No toxic effects where observed during the acute toxicity studies on fish (*Brachydanio rerio*), *Daphnia magna* and algae (*Desmodesmus subspicatus*) (LC_{50} >100 mg/L). Therefore IR3535® is considered as not toxic for the aquatic environment.

The effect on aerobic biological sewage treatment processes was assessed by determining inhibition of respiration of the micro-organisms present in activated sludge following 3 hours contact. No inhibitory effect on aquatic microbial activity was registered for IR3535® (EC_{50} > 1000 mg/L).

Long term aquatic tests were not required because no acute toxicity was observed for the aquatic environment and the substance is primarily emitted to the STP before reaching the aquatic environment. Besides the Sewage Treatment Plant (STP) simulation test showed an elimination of 99 % in the STP.

No marine species were tested based on the presence of studies performed on freshwater species, all suggesting low toxicity and because no major emissions to the marine environment are expected.

In the absence of any long-term toxicity endpoints and marine data, the TGD on Risk Assessment prescribes an assessment factor of 1000 for the freshwater environment and 10000 for the marine environment.

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

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

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

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

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

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

The product does not contain any substance at such a concentration that it has an effect on the environmental classification of the product. No additional information on the biocidal product is required.

Conclusion on the environmental classification and labelling of the product
Insect Repellent Pump Spray Lice IR3535® 20% does not require any environmental classification or labelling.

(II) Further Ecotoxicological studies

- **FIRST AUTHORISATION – 2017 (BE CA)**

The assessment of the active substance in the CAR showed that there is no concern for the aquatic and terrestrial environment and thus no further ecotoxicological studies are required according to the CAR.

For this particular product, there is no direct exposure to the environment and the product does not contain formulants other than the active substance that could be of ecotoxicological concern, thus the data on the active substance are sufficient for the evaluation of the ecotoxicological effects of the biocidal product.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

No further data is available.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

The product is not in the form of bait or granules, so nonesuch data is required.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

The product is not in the form of bait or granules, so nonesuch data is required.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not relevant.

(VII)Foreseeable routes of entry into the environment on the basis of the use envisaged

- **FIRST AUTHORISATION – 2017 (BE CA)**

The foreseeable routes of entry into the environment have been described in the CAR for the active substance and are also valid for this product.

Direct release to soil is not considered relevant, whereas direct release to surface water (swimming lake scenario) is considered relevant, but was not yet assessed in the CAR due to the lack of an endorsed scenario.

Secondary release via wastewater and STP through showering and bathing is also a relevant route of emission.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

No new data was submitted or is required. Information on the active substance suffices for the environmental risk assessment of the product. Moreover, the product does not contain any other substances relevant for the environment apart from the active substance.

(IX) Leaching behaviour (ADS)

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not relevant.

(X) Testing for distribution and dissipation in soil (ADS)

- **FIRST AUTHORISATION – 2017 (BE CA)**

Since there is no direct release to soil and the soil compartment is not envisioned as a compartment of interest in the evaluation of this product, nonesuch additional data is submitted or required.

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

- **FIRST AUTHORISATION – 2017 (BE CA)**

No new data was submitted or is required.

(XII) Testing for distribution and dissipation in air (ADS)

- **FIRST AUTHORISATION – 2017 (BE CA)**

No new data was submitted or is required.

(XIII) 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)

- **FIRST AUTHORISATION – 2017 (BE CA)**

No new data was submitted or is required.

(XIV) 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)

- **FIRST AUTHORISATION – 2017 (BE CA)**

No new data was submitted or is required.

2.2.9.2 Exposure assessment

- **FIRST AUTHORISATION – 2017 (BE CA)**

The intended use of Insect Repellent Pump Spray Lice IR3535® 20% is not exactly described in the ESD for PT19. In this ESD, scenarios are proposed for repellents that are applied to human skin, while the product being assessed in this PAR is mainly to be applied to the hair.

However, the use is sufficiently similar that the ESD for PT19 will be applied for the risk assessment, considering an application to the head.

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

The Major change for SPRAY REPULSIF IR200 has conducted to a new exposure assessment covering the new intended uses (clothes treatment against mosquitoes/ticks, skin application to repel mosquitoes/ticks, fabric treatment against dust mites/head lice) considering the up to date guidances. All these uses are covered by the scenarios proposed in the table below.

(I) General information

- **FIRST AUTHORISATION – 2017 (BE CA)**

Assessed PT	PT 19
Assessed scenarios	Scenario 1: Removal via showering and bathing of humans (ESD PT19, May 2015, §3.1.4.1) Scenario 2: Release to surface water bodies via swimming (ESD PT19, May 2015, §3.1.4.2)
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015 (ECHA-15-B-10-EN)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on TGD 2003
Groundwater simulation	Not applicable
Confidential Annexes	None
Life cycle steps assessed	Scenario 1: Showering & bathing • Production: No • Formulation: No • Use: Yes • Service life: No Scenario 2: Swimming • Production: No • Formulation: No • Use: Yes • Service life: No
Remarks	

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Assessed PT	PT 19
Assessed scenarios	Scenario 1b (covering the previous Scenario 1): Repellent treatment against mosquitoes or ticks applied on skin – STP release scenario [ESD-PT19 – Section 3.1.4]. **→ Use #1, 4, 6** Scenario 2b (covering the previous Scenario 2): Repellent treatment against mosquitoes or ticks applied on skin – Swimming scenario [ESD-PT19 – Section 3.1.4]. **→ Use #1, 4, 6** Scenario 3: Repellent treatment against mosquitoes or ticks applied on clothes – STP release scenario [ESD-PT19 – Section 3.1.4]. **→ Use #3, 5** Scenario 4: Repellent treatment against head lice or dust mits applied on fabric – environment treatment scenario [ESD-PT19 – Section 3.3.4]. **→ Use #2, 7**
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015 (ECHA-15-B-10-EN) Technical Agreement for Biocides (TAB), August 2018.
Approach	Scenario 1b: Average consumption Scenario 2b: Average consumption Scenario 3: Average consumption Scenario 4: Average consumption
Distribution in the environment	Calculated based on TGD 2003
Groundwater simulation	Not applicable
Confidential Annexes	None
Life cycle steps assessed	Scenarios 1b (Showering & bathing), 2b (Swimming), 3 (Clothes), 4 (Fabrics): • Production: No • Formulation No • Use: Yes • Service life: No
Remarks	Evaluation done taking into account WGV2018 agreement on treated skin surface: TAB ENV v2.0 entry **ENV 172** - Refinement of risk assessment PT19: reduction of treated skin surface area and taking into account dermal adsorption.

	The WG agreed to apply the new value of the HEAdoc recommendation of January 2018 for the treated skin area, i.e. 55% of 16600 cm^2 (= 9130 cm^2), since this could be considered as a mean value taking into account the different skin areas for women, men and children.

(II) Emission estimation

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 1: Removal via showering and bathing

Consumption based scenario

For estimating the emission for products applied on human skin following showering or bathing one could either use a tonnage based scenario or a consumption based scenario.

Tonnage based approaches are mostly only appropriate for assessing an active substance for approval and not so much for the authorisation of biocidal products. Therefore only the consumption based approach is assessed here.

However, the tonnage based approach was calculated in the IR3535 CAR and can be consulted in the confidential annex of said CAR. Anyway when considering the break-even tonnage, the consumption based scenario is deemed to be the most appropriate scenario.

Amount of product per application ($Qform_{appl}$)

The most important input parameter for the consumption based scenario is the amount of product that will be used per application ($Qform_{appl}$).

As a default value in the ESD **0.6 mg product/cm² skin** is proposed.

According to the applicant's use instructions **0.5 g product per application** is recommended. This value needs to be converted to the correct unit for $Qform_{appl}$, using a body surface area to which the product is applied. According to the use instructions, the product should be applied to the hair, the nape of the neck and behind the ears. Since no such value for the surface area is available in the ESD, the surface area for the head (1110 cm²)will be used instead. $Qform_{appl}$ then becomes:

$$Qform_{appl}(applicant) = \frac{500mg}{1110cm^2} = 0.450mg/cm^2$$

Additionally, in the ESD it is noted that the value for $Qform_{appl}$ must coincide with the efficacy of the product and must be adapted accordingly.
The efficacy expert concluded for this product, that when used after a pediculicidal treatment and applied every 2 days at a rate of **0.5 mL**, the product does limit adult head lice re-infestation. This is similar to the applicant's proposed use-instructions.

For a worst case risk assessment, it is decided that the default value will be applied to calculate possible release to the environment.

$Qform_{appl}$ = 0.6 mg product/cm² skin

Number of applications per day (N_{appl})

Another important parameter is the number of applications per day (N_{appl}), which the ESD also links to the efficacy of the product.

According to the submitted efficacy tests, it can be concluded that one application every two days does limit adult lice re-infestation.

Based on this, and considering the type of use envisaged for this product, it is decided that calculations will be made using 1 application per day.

N_{appl} = 1 d^{-1}

Treated area of human skin ($AREA_{skin}$)

The product should be applied to hair and not so much to skin. However, due to lack of a better value, the skin area for a head will be applied.

$AREA_{skin}$ = 1110 cm²

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Release of repellents used on human skin based on the average consumption				
Number of inhabitants feeding one STP	Nlocal	10 000	cap	D
Active substance in product	(B) Cformweight	200	g/kg	(20 %)
Consumption per application	(D2) Qformappl	0.6	mg/cm²	(see above)
Number of applications per day	Nappl	1	d-1	(see above)
Treated area of human skin	$AREA_{skin}$	1110	cm²	(see above)
Fraction realeased to air	Fair	0	[-]	D
Fraction dermally absorbed	Fskin	0	[-]	D
Fraction released to wastewater	Fwater	1	[-]	D
Fraction of inhabitants using a repellent product	Finh	0.2	[-]	D
Market share of repellent	Fpenetr	0.5	[-]	D
Specific density of the product	RHOform	1000	kg/m³	D

Calculations for Scenario 1

→ B and D2

$$Elocal_{wastewater} = Nlocal \times N_{appl} \times Qform_{appl} \times AREA_{skin} \times Cform_{weight} \times F_{inh} \times F_{water} \times Fpenetr \times 10^{-9}$$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Waste water	0.133	/

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Scenario 1b: Repellent treatment against mosquitoes or ticks applied on skin – STP release scenario

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario 1b: Repellent treatment against mosquitoes or ticks applied on skin – STP release scenario [ESD-PT19 – Section 3.1.4] **→ Use #1, 4, 6**				
Number of inhabitants per STP	N_{local}	10 000	[-]	Default value
Active substance in product	(B) $Cform_{weight}$	200	$g.kg^{-1}$	(20% technical)
Consumption per application	(D2) $Qform_{appl}$	0.8	$mg.cm^{-2}$	Maximum efficient dose
Number of applications per day	N_{appl}	4	d^{-1}	Default value, considering the efficacy of the product < 4h (ESD PT19, Table 3.2)
Treated area of human skin	$AREA_{skin}$	9130	cm²	HEAdoc recommendation (January 2018)

Fraction released to wastewater	F_{water}	1	[-]	Default value
Fraction of inhabitants using a repellent product	F_{inh}	0.2	[-]	Default value (ESD PT19, Table 3.5)
Market share of repellent	F_{penetr}	0.5	[-]	Default value

***Calculations for Scenario 1:* <u>Repellent treatment against mosquitoes of ticks applied on skin – STP release scenario</u>**

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	5.84E+00	/

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 2: Release to surface water bodies via swimming

In the assessment report for IR3535, in the paragraph on the elements to be taken into account when authorising products, it is mentioned that direct emissions to surface water by swimmers should be kept in mind and assessed. With this new scenario for the ESD for PT19, this requisite is taken into account.

Amount of product per application ($Qform_{appl}$)

Similarly as with scenario 1, the most important input parameter for this scenario is the amount of product that will be used per application ($Qform_{appl}$).

The same notes and thoughts can be applied as with scenario 1. Therefore, also here it is decided that the ESD default value will be applied.

$Qform_{appl}$ = 0.6 mg product/cm² skin

Treated area of human skin ($AREA_{skin}$)

Again, due to lack of a better value, the skin area for a head will be applied.

$AREA_{skin}$ = 1110 cm²

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Release of repellents used on human skin due to swimming activities in surface water bodies				
Daily number of swimmers	$N_{swimmer}$	1500	[-]	D
Fraction of swimmers using the repellent product	F_{swim}	0.1	[-]	P
Number of applications per day	N_{appl}	1	d^{-1}	D
Fraction released to surface water body	$F_{waterbody}$	1	[-]	D
Active substance in the product	(B) $C_{formweight}$	200	g/kg	(20%)
Consumption per application	(D2) $Qform_{appl}$	0.6	mg/cm²	(see above)
Treated area of human skin	$AREA_{skin}$	1110	cm²	(see above)

Specific density of product	RHOform	1000	kg/m³	D

Intermediate calculation for Scenario 2

→ B and D2

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

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Surface water	0.020	/

Final calculation for scenario 2

In the intermediate calculation a local daily emission to the surface water body due to swimmers treated with the repellent, was calculated. In order to assess the impact of this emission on the aquatic life in this waterbody, the actual concentration in active substance in this waterbody should be calculated.

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

Input parameters for calculating surface water concentration				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Release of repellents used on human skin due to swimming activities in surface water bodies				
Local emission to surface water body	$Elocal_{water}$	0.02	kg/d	O (Intermediate calculation)
Volume of water body	$V_{waterbody}$	435 000	m³	D
Number of emission days TIER 1	$T_{emission,\ 1d}$	1	d	D
Number of emission days TIER 2	$T_{emission,\ 91d}$	91	d	D
Number of emission events	$N_{emission,\ 91d}$	91	[-]	D

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

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

Resulting local concentrations in the waterbody		
Compartment	**Local concentration ($Clocal_{compartment}$) [kg/m³]**	**Remarks**
Surface water – after 1 day	4.59×10^{-8}	/
Surface water – after 91 days	4.18×10^{-6}	(without considering possible degradation)

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Scenario 2b: Repellent treatment against mosquitoes of ticks applied on skin – Swimming scenario

Input parameters for calculating the local emission

Input	Nomenclature	Value	Unit	Remarks
Scenario 2b: Repellent treatment against mosquitoes or ticks applied on skin – Swimming scenario [ESD-PT19 – Section 3.1.4] → **Use #1, 4, 6**				
Daily number of swimmers	$N_{swimmer}$	1500	[-]	Default value
Fraction of swimmers using the repellent product	F_{swim}	0.1	[-]	Default value
Number of applications per day	N_{appl}	1	d^{-1}	Default value
Fraction released to surface water body	$F_{waterbody}$	1	[-]	Default value
Active substance in the product	(B) $C_{formweight}$	200	g/kg	(20% technical)
Consumption per application	(D2) $Qform_{appl}$	0.8	$mg.cm^{-2}$	Maximum efficient dose
Treated area of human skin	$AREA_{skin}$	9130	cm^2	HEAdoc recommendation (January 2018)

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Surface water	0.219	/

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Scenario 3: Repellent treatment against mosquitoes of ticks applied on clothes – STP release scenario

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario 3: Repellent treatment against mosquitoes or ticks applied on clothes – STP release scenario [ESD-PT19 – Section 3.1.4]. → **Use #3, 5**				
Number of inhabitants per STP	N_{local}	10 000	[-]	Default value
Active substance in product	(B) $Cform_{weight}$	200	$g.kg^{-1}$	(20% technical)
Consumption per application	(D2) $Qform_{appl}$	0.85	$mg.cm^{-2}$	Maximum efficient dose
Number of applications per day	N_{appl}	1	d^{-1}	Default value for human clothes (ESD PT19, Table 3.2)
Treated area of clothes	$AREA_{clothes}$	17838	cm^2	Default value for human clothes (ESD PT19, Table 3.4)
Fraction released to wastewater	F_{water}	1	[-]	Default value
Fraction of inhabitants using a repellent product	F_{inh}	0.2	[-]	Default value (ESD PT19, Table 3.5)
Market share of repellent	F_{penetr}	0.5	[-]	Default value

Calculations for Scenario 3: Repellent treatment against mosquitoes of ticks applied on clothes – STP release scenario

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	3.03E+00	/

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Scenario 4: Repellent treatment against head lice or dust mites applied on fabric – Environment treatment scenario

In the ESD PT19, the only available scenario for treated surfaces is the indoor surface spray treatment scenario for spot treatments ($2m^2$) and barrier treatments ($9.3m^2$). These kinds of surfaces are not representative for the treatment of bed linen and underestimate the emissions. Then, the AREA treated was adapted to that kind of use (#7). Taking the different surfaces of a single bed linen (worst-case) and adding the surfaces of pillowcases (60cm*60cm*2 sides*2.5 inhabitants=1.8 m^2), fitted sheets (90cm*190cm*2.5 inhabitants=4.3 m^2), and duvet covers (180cm*220cm*2sides*2.5 inhabitants=19.8 m^2), a treated surface of **26 m^2** was calculated. This calculation is considering an average of 2.5 inhabitants per house (10000 inhabitants per STP divided by 4000 houses). Concerning the barrier treatment against human lice, the treated AREA (top of the bed linen and clothes in contact with the top of the body) is largely covered by the AREA of $26m^2$. As a worst-case, it was decided to use a treated AREA of $26m^2$ (Use #7) with the maximum efficient dose of $1.00kg.m^{-2}$ (Use #2).

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario 4: Repellent treatment against head lice or dust mites applied on fabric – environment treatment scenario [ESD-PT19 – Section 3.3.4] → **Use #2, 7**				
Quantity of product applied	Q_{prod}	1.00E-02	$kg.m^{-2}$	Maximum efficient dose
Fraction of active substance in the commercial product	F_{AI}	0.200	[-]	(20% technical)
Number of applications per day per building	$N_{appl,\ building}$	1	d^{-1}	Default value
Fraction emitted to air	$F_{application,air}$	0.02	[-]	Default value (ESD PT18, OECD 2008, Table 3.3-5)
Fraction emitted to applicator	$F_{application,applicator}$	0.02	[-]	
Fraction emitted to floor	$F_{application,floor}$	0.11	[-]	
Fraction emitted to treated surfaces	$F_{application,treated}$	0.85	[-]	
Area treated with the product	$AREA_{treated}$	26	m^2	Area calculated for the treatment of bed linen (cf calculation detail above).
Fraction emitted to wastewater from applicator after the application	F_{ww}	1	[-]	Default value (ESD PT18, OECD 2008, section 3.3.7)
Fraction emitted to wastewater from applicator after the application	$F_{applicator}$	1		
Cleaning efficiency	F_{CE}	1	[-]	Worst case, considering that treated surface (*e.g.* bed linen) is fully washed in a washing machine
Number of houses contributing to the same sewage treatment plant	N_{house}	4000	[-]	Default value
Simultaneity factor	$F_{simultaneity}$	0.0552	[-]	Worst case considering a daily treatment (ESD PT19, Table 3.17).

Calculations for Scenario 4: Repellent treatment against head lice or dust mites applied on fabric – Environment treatment scenario

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	11.25E+00	/

(III) Fate and distribution in exposed environmental compartments

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 1:

Applied product is removed from the body through showering or bathing. The wastewater from washing is then removed to the municipal waste water treatment plant, after which the effluent is emitted to the surface water where it can expose both fresh water and fresh water sediments.

Exposure to other compartments, such as soil and groundwater, is not considered relevant. The soil could be exposed through sludge application, but following the STP-distribution detailed in the third table below, sorption to sewage sludge is unlikely since IR3535 is almost completely degraded.

Scenario 2:

Applied product is removed from the body directly to the surface water through swimming, where it can expose both fresh water and fresh water sediments.

Exposure to other compartments is not considered relevant.

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

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

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 1b	Yes	Yes	No	No	Yes	No	No	No	No
Scenario 2b	Yes	Yes	No	No	No	No	No	No	No
Scenario 3	Yes	Yes	No	No	Yes	No	No	No	No
Scenario 4	Yes	Yes	No	No	Yes	No	No	No	No

- **FIRST AUTHORISATION – 2017 (BE CA)**

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	215.29	g/mol	
Melting point	-90	°C	
Boiling point	300	°C	
Vapour pressure (at 20 °C)	0.15	Pa	
Water solubility (at 20 °C)	70 000	mg/l	
Log Octanol/water partition coefficient	1.7	Log 10	
Organic carbon/water partition coefficient (Koc)	475.25	l/kg	
Henry's Law Constant (at 20 °C)	$4.613x10^{-4}$	Pa.m3/mol	
Biodegradability	Not readily biodegradable		

In the CAR for IR3535, calculations according to EUSES are available for the distribution in the STP, which in this case is only relevant for scenario 1. As a worst-case assessment the distribution presented in the CAR is taken over for the assumption that there is no degradation. As a TIER 2 evaluation, 99% degradation in STP is taken into consideration.

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

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Calculated fate and distribution in the STP			
Compartment	Percentage [%] – TIER 2 from the CAR only		Remarks
	Scenario 1b , 3 & 4	Scenario 2b	
Air	0	Not relevant	
Water	1		
Sludge	0		
Degraded in STP	99		

(IV) Calculated PEC values

- **FIRST AUTHORISATION – 2017 (BE CA)**

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

As mentioned before, for the scenario 2, possible degradation in surface water is not taken into account as a worst-case evaluation.

Summary table on calculated PEC values			
		PEC_{STP}	**PEC_{water}**
		[mg/l]	[mg/l]
Scenario 1	TIER 1	$6.59x10^{-2}$	$6.59x10^{-3}$
	TIER 2	$6.66x10^{-4}$	$6.66x10^{-5}$
Scenario 2	Day 1	n/a	$4.59x10^{-5}$
	Day 91	n/a	$4.18x10^{-3}$

- **MAJOR CHANGE FOR SPRAY REPULSIF IR200 – 2019 (FR CA)**

Summary table on calculated PEC values				
		PEC_{STP}	**PEC_{water}**	**PEC_{sed}**
		[mg/l]	[mg/l]	[mg/kg_{wwt}]
Scenario 1b	TIER 2	2.92E-02	2.92E-03	3.24E-02
Scenario 2b	Day 91*	Not relevant	4.14E-02	4.60E-01
Scenario 3	TIER 2	1.52E-02	1.52E-03	1.68E-02
Scenario 4	TIER 2	5.63E-02	5.62E-03	6.25E-02

**Calculated with $dt50_{surface,water}$=299,64 days.*

(V) Primary and secondary poisoning

a) Primary poisoning

Not applicable, since this product is a repellent and has no intention of killing.

b) Secondary poisoning

Not relevant, since no bioaccumulation is expected.

2.2.9.3 Risk characterisation

(I) Atmosphere

- **FIRST AUTHORISATION – 2017 (BE CA)**

Conclusion:
Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

(II) Sewage treatment plant (STP)

- **FIRST AUTHORISATION – 2017 (BE CA)**

Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{STP}$
Scenario 1	TIER 1	($6.59x10^{-2}$/100) = **$6.59x10^{-4}$**
	TIER 2	($6.66x10^{-4}$/100) = **$6.66x10^{-6}$**
Scenario 2	Day 1	**Not relevant**
	Day 91	**Not relevant**

Conclusion:
No adverse effect for the STP is expected

- **Major change for SPRAY REPULSIF IR200 - 2019**

Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{STP}$
Scenario 1b	TIER 2	2.92E-02/100 = **2.92E-04**
Scenario 2b	Day 91	Not relevant
Scenario 3	TIER 2	**1.52E-02**/ 100 = **1.52E-04**
Scenario 4	TIER 2	**5.63E-02**/ 100 = **5.63E-04**

Conclusion: No risk is identified for the sewage treatment plant.

(III) Aquatic compartment

- **FIRST AUTHORISATION – 2017 (BE CA)**

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

For the scenario 2, possible degradation in surface water is not taken into account as a worst-case evaluation.

Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{water}$
Scenario 1	TIER 1	($6.59x10^{-3}$/0.1) = **$6.59x10^{-2}$**
	TIER 2	($6.66x10^{-5}$/0.1) = **$6.66x10^{-4}$**

Scenario 2	Day 1	(4.59x10^{-9}/0.1) = **4.59x10^{-4}**
	Day 91	(4.18 x10^{-7}/0.1) = **4.18x10^{-2}**

Conclusion:
No adverse effect for the aquatic compartment is expected

- **Major change for SPRAY REPULSIF IR200 - 2019**

Summary table on calculated PEC/PNEC values			
		PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1b	TIER 2	2.92E-03 / 0.1 = **2.92E-02**	3.24E-02 / 1.11 = **2.92E-02**
Scenario 2b	Day 91	4.14E-02 / 0.1 = **4.14E-01**	4.60E-01 / 1.11 = **4.14E-01**
Scenario 3	TIER 2	1.52E-03 / 0.1 = **1.52E-02**	1.68E-02 / 1.11 = **1.52E-02**
Scenario 4	TIER 2	5.62E-03 / 0.1 = **5.62E-02**	6.25E-02 / 1.11 = **5.62E-02**

Conclusion: No risk is identified for the aquatic compartment.

(IV) Terrestrial compartment

- **FIRST AUTHORISATION – 2017 (BE CA)**

The terrestrial compartment is not considered a relevant receiving compartment (see point (III) above).

Exposure through sludge application is highly unlikely, since IR3535 almost completely degrades in the STP.

Conclusion

No adverse effects for the terrestrial compartment are expected

(V) Groundwater

- **FIRST AUTHORISATION – 2017 (BE CA)**

Since no exposure of the terrestrial compartment is expected, it follows that neither exposure to the groundwater is expected.

Conclusion

No adverse effects for the groundwater are expected.

(VI) Primary and secondary poisoning

- **FIRST AUTHORISATION – 2017 (BE CA)**

Primary poisoning is not applicable, since this product is a repellent and has no intention of killing.
Secondary poisoning is not relevant, since no bioaccumulation is expected.

(VII)Mixture toxicity

- **FIRST AUTHORISATION – 2017 (BE CA)**

Not relevant, since the product does not contain other components other than the active substance that could give a risk to the environment.

(VIII) Aggregated exposure

- **Major change for SPRAY REPULSIF IR200 - 2019**

Considering the scenarios that describe the additional uses of the product, aggregated exposure has to be estimated, as the corresponding releases to the environment could be overlapped in time and space. Scenario2b is not considered as relevant for aggregated exposure as it is very unlikely for the user to swim at the same place than wastewater releases of treatment plants.

Summary table on calculated ΣPEC/PNEC values			
	ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**
Scenario 1b (TIER2) + Scenario 3 (TIER 2) + Scenario 4 (TIER 2)	**1.01E-03**	**1.01E-01**	**1.01E-01**

Conclusion: Based on aggregated exposure, there is no risk for any of the relevant environmental compartments.

Overall conclusion on the risk assessment for the environment of the product
The use of the biocidal product does not induce risk for any of the environmental compartments.

2.2.10 Measures to protect man, animals and the environment

See §2.1.4 and §2.1.5

2.2.11 Assessment of a combination of biocidal products

Not applicable

2.2.12 Comparative assessment

Not applicable

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Author(s)	Year	Title	Report No.	Owner Company	Report date
Meinerling, M. and Herrmann, S.	2011	Determination of the Accelerated Storage Stability (8 weeks at 40 °C) of Pump Spray Lice IR 3535® 20 %	63172204	Merck KGaA	2011-08-08
Fieseler, A.	2011	Determination of the Relative Density of Pump Spray Lice IR 3535® 20 %	63171182	Merck KGaA	2011-06-27
Meinerling, M.	2009	EUS26-15 INSECT REPELLENT SPRAY – DETERMINATION OF THE STORAGE STABILITY AT AMBIENT TEMPERATURES	31232204	Merck KGaA	2009-05-27
Meinerling, M. and Herrmann, S.	2011	Determination of the Low Temperature Stability of Pump Spray Lice IR 3535® 20 %	63173204	Merck KGaA	2011-06-27
Aeropump	2005	Bericht zu den Tests mit dem Produkt INSECT REPELLENT im Auftrag der Fa. Merck KGaA	214-001	Merck KGaA	2005-12-14
Aeropump	2016	Bestimmung der Tröpfchengrößenverteilung per Laserbeugung	N/A	Merck KGaA	2016-04-25
Fieseler A.	2015	MDA-A-197-01 Verum 1: Accelerated Storage Stability	98322204	Merck KGaA	2015-08-04
Meinerling, M. and Fieseler, A.	2016	Statement to IBACON project	N/A	N/A	2016-21-06
Fieseler, A.	2011	Determination of the Flash Point of Pump Spray IR 3535® 20 %	63161189	Merck KGaA	2011-06-28
Dornhagen, J.	2011	FINAL REPORT (1st Original of 3) Pump Spray IR 3535® 20 % Batch No.: SM-0-1-1/090211 AUTO-IGNITION TEMPERATURE (LIQUIDS AND GASES) A.15	20110103.01	Merck KGaA	2011-07-04
zur Lage, J.	2016	IR3535_Ref Formulations Surface tension Viscosity_Reg.Aff	009093 - PM-PFC-RT	Merck KGaA	2016-07-04
[redacted]	[redacted]	Acute dermal irritation study of EUS26-15 Insect Repellent Spray in albino rabbits.	WIL-585006	[redacted]	[redacted]
[redacted]	[redacted]	Acute Eye Irritation Study of EUS26-15 Insect Repellent Spray in albino rabbits.	WIL-585007	[redacted]	[redacted]
[redacted]	[redacted]	Skin Sensitisation Study of EUS26-15 Insect Repellent Spray in albino guinea pigs (Modified Buehler Method).	WIL-585008	[redacted]	[redacted]
[redacted]	[redacted]	Acute dermal toxicity study of EUS26-15 Insect Repellent Spray in albino rats.	WIL-585005	[redacted]	[redacted]
Combescot, C.	1993	"Bioclinical in vivo trial to test the efficacy of repellent lotions (insect repellent 3535) in order to prevent re-infestation of lice on humans after the use of a pediculicidal shampoo; Akany Fianakaviana Masina Anhatiazo Centre, Antananarivo, Republic of Madagascar; Report No. AC 93-02; 05.07.1993"	336-1905	Merck KGaA	1993-07-05

Militão de Sousa, F. and Lang-Combescot, C.	2009	"Bioclinical Trial To study the efficacy of a product containing Repellent 3535; Veterinary Faculty State University of Ceara, Fortaleza, Brazil; Merck Protocol No. 09-01; 15.07.2009"	336-1920	Merck KGaA	2009-07-15

- **Major change application – 2019**

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
Serrano, B.	2018	LABORATORY ASSESSMENT OF A PERSONAL SKIN REPELLENT AGAINST MOSQUITOES - Trial against *Aedes aegypti*, *Culex quinquefasciatus* - Test product: SPRAY IR3535 20% ANTI POUX, Report No 2302-IR353520%-mosq-AIC/0118R	YES	Terrium	24/04/2018
Serrano, B.	2018	LABORATORY ASSESSMENT OF A PERSONAL SKIN REPELLENT AGAINST MOSQUITOES - Trial against *Aedes albopictus*, *Anopheles gambiae* - Test product: SPRAY IR3535 20% ANTI POUX, Report No 2302-IR353520%-mosq2-AIC/0118	YES	Terrium	06/06/2018
Serrano, B.	2018	LABORATORY ASSESSMENT OF A FABRIC TREATMENT INTENDED TO PROTECT FROM MOSQUITOES BITES - Trial against *Aedes aegypti, Aedes albopictus, Culex quinquefasciatus, Anopheles gambiae* - Test product: SPRAY IR3535 20% ANTI-POUX, Report No 2302-mosq/0118	YES	Terrium	28/02/2018
Serrano, B.	2018	LABORATORY ASSESSMENT OF A FABRIC TREATMENT INTENDED TO PROTECT FROM TICKS BITES - Trial against *Ixodes Ricinus* - Test product: SPRAY IR3535 20% ANTI-POUX, Report No 2302-tick/0118	YES	Terrium	28/02/2018
Serrano, B.	2018	LABORATORY ASSESSMENT OF A FABRIC TREATMENT INTENDED TO PROTECT FROM TICKS BITES - Trial against	YES	Terrium	30/04/2018

		Ixodes Ricinus - Test product: SPRAY IR3535 20% ANTI-POUX, Report No 2302-IR353520%-ticks/0118			
Serrano, B.	2018	LABORATORY ASSESSMENT OF A PERSONAL SKIN REPELLENT AGAINST TICKS - Test product: SPRAY IR3535 20% ANTI-POUX, Report No 2302-ticks/ 0118	YES	Terrium	29/06/2018
Serrano, B.	2018	LABORATORY ASSESSMENT OF A REPELLENT PRODUCT AGAINST HOUSE DUST MITES Test product: SPRAY IR3535 20% ANTI-POUX, Report No 2302-IR353520%-dustmites/0118	YES	Terrium	24/04/2018
Serrano, B.	2019	LABORATORY ASSESSMENT OF A FABRIC TREATMENT INTENDED TO PROTECT FROM MOSQUITOES BITES - Trial against *Aedes aegypti, Aedes albopictus, Culex quinquefasciatus, Anopheles gambiae* - Test product: SPRAY IR3535 20% ANTI-POUX	YES	Envirotech SAS	10/05/2019
Serrano, B.	2019	LABORATORY ASSESSMENT OF A FABRIC TREATMENT INTENDED TO PROTECT FROM TICKS BITES - Trial against *Ixodes Ricinus* - Test product: SPRAY IR3535 20% ANTI-POUX	YES	Envirotech SAS	25/04/2019
Toubaté, B.	2018	Efficacité repulsive du SPRAY IR3535 ANTI POUX rèf/LOT 20180118L1 pour la Société TERRIUM SAS	YES	Terrium	19/07/2018
Toubaté, B.	2019	Mise en évidence de la «Neutralité» des «supports» utilisés lors des essais réalisés et de l'absence d'effet insecticide du traitement répulsif société TERRIUM SAS – Analyses complémentaires	YES	Terrium	24/04/2019

- **Minor change application – 2021**

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed	Owner (PUB / ORG)	Date of first submission

			(Yes/No)		
Demangel, B.	2021	Chemical analyses during and after a storage procedure for 30 months at 20 °C ± 2 °C on Spray Antipoux IR3535 Merck Batches No. CTG 181101/00/02 and No. CTG 181101/00/04 DEFITRACES Report No. 18-905023-002 GLP; Unpubished	YES	Envirotech	07/2021
Demangel, B.	2021	Physico-chemical tests and chemical analyses before, during and after a storage procedure for 36 months at 20 °C ± 2 °C on Spray Antipoux IR3535 Merck Batch No. CTG 181101/00/04 DEFITRACES Report No. 19-905023-001 Intermediary GLP; Unpublished	YES	Envirotech	07/2021
Padilla, P.	2020	Physico-chemical tests before and after an accelerated storage procedure for 8 weeks at 40 °C ± 2 °C on SPRAY ANTIPOUX IR3535 MERCK DEFITRACES Report No. 20-905023-001 GLP; Unpublished	YES	Envirotech	07/2021

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

3.2.1 Human exposure calculations

- **FIRST AUTHORISATION – 2017 (BE CA)**

Scenario 1: Primary exposure: Dermal exposure assessment for adults, children, toddlers and infants.

a. Adult:

3 applications/day of biocidal product results in the following dermal exposure:

3.15 g product x 20 % of a.s. = 630 mg of IR3535®/day.

Thereof 14 % penetrates the skin resulting in a systemic exposure of:

630 mg IR3535®/day x 14 % = 88.2 mg IR3535®/day.

Taking into account a body weight of 60 kg for an adult the dermal systemic exposure is calculated to be:

88.2 mg IR3535®/day / 60 kg = 1.47 mg IR3535®/kg bw/day.

b. Child 6-11 years:

When 3 applications/ day of biocidal product results in the following dermal exposure:

1.5 g product x 20 % IR3535® = 300 mg IR3535®/day

Thereof 14 % penetrates the skin resulting in a systemic exposure of:

300 mg IR3535®/day x 14 % = 42 mg IR3535®/day.

Taking into account a body weight of 23.9 kg for a child the dermal systemic exposure is calculated to be:

42 mg IR3535®/day / 23.9 kg = 1.76 mg IR3535®/kg bw/day

c. Toddler 1-2 years:

When 3 applications/ day of biocidal product results in the following dermal exposure:

1.5 g product x 20 % IR3535® = 0.3 g IR3535®/day

Thereof 14 % penetrates the skin resulting in a systemic exposure of:

300 mg IR3535®/day x 14 % = 42 mg IR3535®/day.

Taking into account a body weight of 10 kg for a toddler the dermal systemic exposure is calculated to be:

42 mg IR3535®/day / 10 kg = 4.2 mg IR3535®/kg bw/day

d. Infant 6-12 months:

When 3 applications/ day of biocidal product results in the following dermal exposure:

1.5 g product x 20 % IR3535® = 0.300 g IR3535®/day

Thereof 14 % penetrates the skin resulting in a systemic exposure of:

300 mg IR3535®/day x 14 % = 42 mg IR3535®/day.

Taking into account a body weight of 8 kg for an infant the dermal systemic exposure is calculated to be:

42 mg IR3535®/day / 8 kg = 5.25 mg IR3535®/kg bw/day

When 2 applications/ day of biocidal product results in the following dermal exposure:

1.0 g product x 20 % IR3535® = 0.200 g IR3535®/day

Thereof 14 % penetrates the skin resulting in a systemic exposure of:

200 mg IR3535®/day x 14 % = 28 mg IR3535®/day.

Taking into account a body weight of 8 kg for an infant the dermal systemic exposure is calculated to be:

28 mg IR3535®/day / 8 kg = 3.5 mg IR3535®/kg bw/day

Scenario 2: Primary exposure: Inhalation exposure assessment for adults, children, toddlers and infants..

a. Adult:

inhaled product = 1.25 m^3 x 3 applications x 4 min. / 60 min. x 10.5 mg/m^3 = 2.625 mg

inhaled active substance = 2.625 x 20 % = 0.525 mg

inhalation systemic exposure:

11.21% x 0.525 x 100% / 60 = 0.000981 mg/kg bw

Oral systemic exposure:

88.79 % x 0.525 x 100% / 60 = 0.00777 mg/kg bw

b. Child

inhaled product = 1.32 m^3 x 3 applications x 4 min. / 60 min. x 10.5 mg/m^3 = 2.772 mg
inhaled active substance = 1.848 x 20 % = 0.5544 mg
inhalation systemic exposure:
11.21% x 0.5544 x 100% / 23.9 = 0.0026 mg/kg bw
Oral systemic exposure:
88.79 % x 0.5544 x 100% / 23.9 = 0.021 mg/kg bw

c. Toddler

inhaled product = 1.26 m^3 x 3 application x 4 min. / 60 min. x 10.5 mg/m^3 = 2.646 mg
inhaled active substance = 2.646 x 20 % = 0.5292 mg
inhalation systemic exposure:
11.21% x 0.5292 x 100% / 10 = 0.00593 mg/kg bw
Oral systemic exposure:
88.79 % x 0.5292 x 100% / 10 = 0.0470 mg/kg bw

d. Infant

inhaled product = 0.84 m^3 x 3 application x 4 min. / 60 min. x 10.5 mg/m^3 = 1.764mg
inhaled active substance = 1.764 x 20 % = 0.3528 mg
inhalation systemic exposure:
11.21% x 0.3528 x 100% / 8 = 0.00494 mg/kg bw
Oral systemic exposure:
88.79 % x 0.3528 x 100% / 8 = 0.0392 mg/kg bw

inhaled product = 0.84 m^3 x 2 application x 4 min. / 60 min. x 10.5 mg/m^3 = 1.176mg
inhaled active substance = 1.176 x 20 % = 0.2352 mg
inhalation systemic exposure:
11.21% x 0.2352 x 100% / 8 = 0.0033mg/kg bw
Oral systemic exposure:
88.79 % x 0.2352 x 100% / 8 = 0.0261 mg/kg bw

Scenario 3: Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure

Calculations for scenario 3

a. Adult:

External dermal dose for adult per application:
1050 mg X 20 % /60 kg = 3.5 mg/kg bw/application
Oral systemic exposure via hand-mouth transfer is:
3.5 x 40% = 1.4 mg/kg bw/ application.
As a consequence, an adult is allowed to apply the repellent 3.57 times before the AEL is exceeded through hand-mouth transfer per day (5/1.4= 3.57).

b. Child

External dermal dose for adult per application:

500 mg X 20 % / 23.9 kg = 4.18 mg/kg bw/application

Oral systemic exposure via hand-mouth transfer is:

4.18 x 40 % = 1.67 mg/kg bw/ application.

As a consequence, it is allowed to apply the repellent to a 6-11 year-old child 2.99 times before the AEL is exceeded through hand-mouth transfer per day (5/1.67= 2.99).

c. Toddler

External dermal dose for adult per application:

500 mg X 20 % / 10 kg = 10 mg/kg bw/application

Oral systemic exposure via hand-mouth transfer is:

10 x 29 % = 2.9 mg/kg bw/ application.

As a consequence, it is allowed to apply the repellent to a 1-2 year-old toddler 1.72 times before the AEL is exceeded through hand-mouth transfer per day (5/2.9 = 1.72).

d. Infant

External dermal dose for adult per application:

500 mg X 20 % / 8 kg = 12.5 mg/kg bw/application

Oral systemic exposure via hand-mouth transfer is:

12.5 x 29% = 3.625 mg/kg bw/ application.

As a consequence, it is allowed to apply the repellent to an infant 1.38 times before the AEL is exceeded through hand-mouth transfer per day (5/3.625 = 1.38).

Scenario 4: Parent treating two children and himself/herself (spraying) (combined inhalative and oral exposure)

Calculations for scenario 4

a. Adult:

inhaled product = 1.25 m^3 x 9 applications x 4 min. / 60 min. x 10.5 mg/m^3 = 7.875 mg

inhaled active substance = 7.875 x 20 % = 1.575 mg

inhalation systemic exposure:

11.21% x 1.575 x 100% / 60 = 0.00294 mg/kg bw

Oral systemic exposure:

88.79 % x 1.575 x 100% / 60 = 0.0233 mg/kg bw

Combined inhalative and oral systemic exposure:

0.00294 + 0.0233 = 0.0262 mg/kg bw

Scenario 5: Inhalation of volatilised residues after application (inhalative exposure)

Calculations for scenario 5

a. Adult:

Report for assessment PUMP SPRAY LICE 20% ConsExpo Web	
Substance	
Name	IR3535
Molecular weight	215 g/mol

K_{OW}	–
Product	
Name	IR PS Lice 20
Weight fraction substance	20 %
Population	
Name	ADULT
Body weight	kg
Scenario Inhalation of volatilised residues	
Frequency	–
Description	
Inhalation	
Exposure model	Exposure to vapour - Instantaneous release
Exposure duration	24 hour
Product amount	3.15 g
Weight fraction substance	20 %
Room volume	20 m³
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m³/hr
Limit concentration to saturated air concentration	No
Absorption model	Fixed fraction
Absorption fraction	100 %
Dermal	
Exposure model	n.a.
Absorption model	n.a.
Oral	
Exposure model	n.a.
Absorption model	n.a.
Results for scenario Inhalation of volatilised residues	
Inhalation	
Mean event concentration	2.2 mg/m³
Mean concentration on day of exposure	–
Year average concentration	–
External event dose	1.1 mg/kg bw
External dose on day of exposure	–
Internal event dose	1.1 mg/kg bw
Internal dose on day of exposure	–
Internal year average dose	–
Integrated	
Internal event dose	1.1 mg/kg bw
Internal dose on day of exposure	–
Internal year average dose	–

b. Child

Report for assessment PUMP SPRAY LICE 20% ConsExpo Web - Mon Feb 13 2017	
Substance	
Name	IR3535
Molecular weight	215 g/mol
K_{OW}	–
Product	

Name	IR PS Lice 20
Weight fraction substance	20 %
Population	
Name	CHILD
Body weight	23.9 kg

Scenario Inhalation of volatilised residues

Frequency	–
Description	

Inhalation

Exposure model	Exposure to vapour - Instantaneous release
Exposure duration	24 hour
Product amount	1.5 g
Weight fraction substance	20 %
Room volume	20 m³
Ventilation rate	0.6 per hour
Inhalation rate	1.32 m³/hr
Limit concentration to saturated air concentration	No
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario Inhalation of volatilised residues

Inhalation

Mean event concentration	1.0 mg/m³
Mean concentration on day of exposure	–
Year average concentration	–
External event dose	1.4 mg/kg bw
External dose on day of exposure	–
Internal event dose	1.4 mg/kg bw
Internal dose on day of exposure	–
Internal year average dose	–

Integrated

Internal event dose	1.4 mg/kg bw
Internal dose on day of exposure	–
Internal year average dose	–

c. Toddler

Report for assessment PUMP SPRAY LICE 20%
ConsExpo Web - Mon Feb 13 2017

Substance

Name	IR3535
Molecular weight	215 g/mol
K_{OW}	–

Product

Name	IR PS Lice 20
Weight fraction substance	20 %

Population		
Name	TODDLER	
Body weight	10 kg	
Scenario Inhalation of volatilised residues		
Frequency	–	
Description		
Inhalation		
Exposure model		Exposure to vapour - Instantaneous release
Exposure duration		24 hour
Product amount		1.5 g
Weight fraction substance		20 %
Room volume		20 m³
Ventilation rate		0.6 per hour
Inhalation rate		1.26 m³/hr
Limit concentration to saturated air concentration		No
Absorption model		Fixed fraction
Absorption fraction		100 %
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Inhalation of volatilised residues		
Inhalation		
Mean event concentration		1.0 mg/m³
Mean concentration on day of exposure		–
Year average concentration		–
External event dose		3.1 mg/kg bw
External dose on day of exposure		–
Internal event dose		3.1 mg/kg bw
Internal dose on day of exposure		–
Internal year average dose		–
Integrated		
Internal event dose	3.1 mg/kg bw	
Internal dose on day of exposure	–	
Internal year average dose	–	

d. Infant

Report for assessment PUMP SPRAY LICE 20%	
ConsExpo Web - Mon Feb 13 2017	
Substance	
Name	IR3535
Molecular weight	215 g/mol
K_{OW}	–
Product	
Name	IR PS Lice 20
Weight fraction substance	20 %
Population	
Name	INFANT

Body weight	8 kg	
Scenario Inhalation of volatilised residues		
Frequency	–	
Description		
Inhalation		
Exposure model		Exposure to vapour - Instantaneous release
Exposure duration		24 hour
Product amount		1.5 g
Weight fraction substance		20 %
Room volume		20 m³
Ventilation rate		0.6 per hour
Inhalation rate		0.84 m³/hr
Limit concentration to saturated air concentration		No
Absorption model		Fixed fraction
Absorption fraction		100 %
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Inhalation of volatilised residues		
Inhalation		
Mean event concentration		1.0 mg/m³
Mean concentration on day of exposure		–
Year average concentration		–
External event dose		2.6 mg/kg bw
External dose on day of exposure		–
Internal event dose		2.6 mg/kg bw
Internal dose on day of exposure		–
Internal year average dose		–
Integrated		
Internal event dose	2.6 mg/kg bw	
Internal dose on day of exposure	–	
Internal year average dose	–	

Scenario 6: Mixing and Loading model – worst case for the production, formulation and disposal of the biocidal product

Calculations for scenario 6

Dermal exposure via clothing:

101 x 0.99 x 10 x 1 = 999.9 mg/d

Dermal exposure via hands:

2.02 x 0.99 x 10 x 1 = 19.998 mg/d

Dermal systemic exposure:

(999.9 + 19.998) x 0.5 / 60 = 8.49915 mg/kg bw/d

Inhalation exposure:

0

Systemic exposure:

8.49915 + 0 = 8.5 mg/kg bw/d

Dermal exposure via clothing:
101 x 0.99 x 10 x 1 x (1-0.75) = 249.975 mg/d
Dermal exposure via hands:
2.02 x 0.99 x 10 x 1 = 19.998 mg/d
Dermal systemic exposure:
(249.975 + 19.998) x 0.5 / 60 = 2.25 mg/kg bw/d
Inhalation exposure:
0
Systemic exposure:
2.25 + 0 = 2.25 mg/kg bw/d

Dermal exposure via clothing:
101 x 0.99 x 10 x 1 x (1-0.75) = 249.975 mg/d
Dermal exposure via hands:
2.02 x 0.99 x 10 x 1 x (1-0.9) = 1.9998 mg/d
Dermal systemic exposure:
(249.975 + 1.9998) x 0.5 / 60 = 2.09979 mg/kg bw/d
Inhalation exposure:
0
Systemic exposure:
2.09979 + 0 = 2.1 mg/kg bw/d

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

Not applicable.

3.4 RESIDUE BEHAVIOUR

Not applicable.

3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Not relevant, IUCLID file available.

3.6 CONFIDENTIAL ANNEX

Yes, see seperate document.

3.7 OTHER

Not applicable.