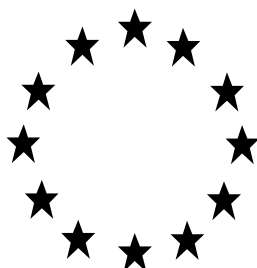


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR NATIONAL
AUTHORISATION APPLICATIONS
(version 2)**



Shampouxrepel

Product type 19

Ethyl butylacetylaminopropionate
(Further referred to as IR3535®)

Case Number in R4BP NA-MIC: BC-PR013536-21

Evaluating Competent Authority: Belgium

Date: finalised on 19/11/2019

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1 DOCUMENT HISTORY

Note to the reader

October 2018 : the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is *Insect Repellent Pump Spray Lice IR3535® 20%* - Asset number: BE-0012318-0000 / Authorisation number: BE2017-0015.

May 2019 : an application for a minor change was introduced for the product of SHAMPOUXREPEL. The product assessment report (PAR) is based on the first PAR of *Insect Repellent Pump Spray Lice IR3535® 20%* (rMS : BE - finalised on 28/03/2017).

Version	Comments	Decision date	R4BP3 case number
Version 1 – Please refer to the reference product.	no PAR available (same biocidal product)	Completed on 09/10/2018	BC-GB020118-69 (source case – NA-BBP)
Version 2 - PAR integrated the MIC	Minor change application for change of the shelf life	Completed on 24/01/2020	(NA-MIC): BC-DP051820-38

2 CONCLUSION

Shampouxrepel can be authorised 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.

Conclusion considering the minor change :

The minor change, submitted in May 2019, consists in the change of the shelf life from 18 months to 30 months; the previous conclusion remains valid.

3 ASSESSMENT REPORT

3.1 SUMMARY OF THE PRODUCT ASSESSMENT

3.1.1 Administrative information

3.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Shampouxrepel	Belgium

3.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Laboratoria Qualiphar N.V./S.A.
	Address	Rijksweg 9 2880 Bornem Belgium
Authorisation number	BE2017-0041	
Date of the authorisation	29/03/2017	
Expiry date of the authorisation	06/04/2027	

3.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Cosmade BVBA
Address of manufacturer	Impulsstraat 3A 2220 Heist-op-den-Berg Belgium
Location of manufacturing sites	Belcofill BVBA Impulsstraat 7 2220 Heist-op-den-Berg Belgium

3.1.1.4 Manufacturer(s) of the active substance

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck S.L.U.
Address of manufacturer	Calle Maria de Molina 40 28006 Madrid Spain
Location of manufacturing sites	Poligono Merck 08100 Mollet de Vallés Barcelona Spain
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strasse 250 64293 Darmstadt Germany
Location of manufacturing sites	Poligono Merck 08100 Mollet de Vallés Barcelona Spain

3.1.2 Product composition and formulation

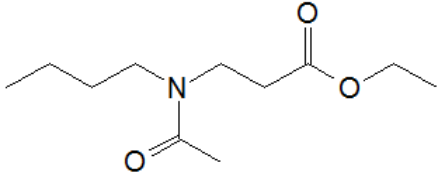
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

3.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	IR3535
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	

3.1.2.2 Candidate(s) for substitution

The active substance IR3535[®] is not a candidate for substitution.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
IR3535 [®]	ethyl 3-[N-acetyl-N-butyl] aminopropionate	Active substance	52304-36-6	257-835-0	20 purity: ≥99%

Full composition is available in the confidential annex.

3.1.2.4 Information on technical equivalence

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

3.1.2.5 Information on the substance(s) of concern

Not applicable

3.1.2.6 Type of formulation

AL -Any other liquid

3.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	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
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P264 Wash hands thoroughly after handling. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P501 Dispose of contents/container in accordance with local/regional/national/international regulations
Note	

3.1.4 Authorised use(s)

3.1.4.1 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	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 Shampouxrepel is a ready to use repellent product to prevent reinfestation with human head lice (<i>Pediculus humanus capitis</i>) only after a pediculicidal treatment. It is to be applied on hair, the nape of the neck and behind the ears.		
Application method(s)	Spraying: The ready to use product is a pump spray which is sprayed directly onto the hair.		
Application rate(s) and frequency	RTU leave-on product Timing: Shampouxrepel is intended to be used to prevent reinfestation with human head lice (<i>Pediculus humanus capitis</i>) only after a pediculicidal treatment. Reapply after washing the hair and at the latest after 2 days. Dose per application: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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.		
Category(ies) of users	General public		
Pack sizes and packaging material	Type Bottle	Material Plastic: HDPE	Size ≥25.0 - ≤250.0 mL

3.1.4.2 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. When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.

The 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.

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.

3.1.4.3 *Use-specific risk mitigation measures*

Use repellent safely. Always read the label and product information before use.

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.

Avoid breathing vapours/spray.

Synthetic materials should be protected during spraying.

The users should inform if the treatment is ineffective and report straightforward to the registration holder

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

Causes serious eye irritation.

After inhalation: fresh air.

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Most important symptoms and effects, both acute and delayed: irritant effects

Indication of any immediate medical attention and special treatment needed: No information available

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Environmental precautions: Do not discharge superfluous fluids to the drain.

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

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Do not discharge superfluous fluids to the drain

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

Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

The product should not be stored for prolonged times at temperatures >40 °C.

Shelf-life: 30 months

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

3.1.5 General directions for use

There is only one authorised used. All directions can be found in the use-specific section.

3.1.5.1 Instructions for use

See §2.1.4.2

3.1.5.2 Risk mitigation measures

See §2.1.4.3

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

See §2.1.4.4

3.1.5.4 Instructions for safe disposal of the product and its packaging

See §2.1.4.5

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

See §2.1.4.6

3.1.6 Other information

/

3.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	≥25 mL - ≤250 mL	plastic: HDPE	pump head covered by a cap	non-professional	Yes

3.1.8 Documentation

3.1.8.1 Data submitted in relation to product application

The applicant provided the necessary information according art. 2 of COMMISSION IMPLEMENTING REGULATION (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

In addition, for the minor change dossier, applicant provided study on the biocidal product. See §4.1 list of studies for the biocidal product.

3.1.8.2 Access to documentation

The applicant provided a letter of access to all the data supporting the authorisation of the related reference product.

3.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015.

3.2.2 Clarification on product composition and compositions tested

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015.

3.2.3 Physical, chemical and technical properties

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

Conclusion on the physical, chemical and technical properties of the product
<p>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 18 months. 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.</p>

Following the NA-MIC dossier:

The storage stability was revised in accordance with provided new data:

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – accelerated storage	CIPAC MT 46.3 HPLC methods (as validated, see hereunder in PAR) Organoleptic European Pharmacopoeia Monographs 2.2.3 and 2.2.5	Shampouxrepel - IR3535® 20%	- No change in colour, odour, or structure. - No change in packaging appearance. - Mass changes (average, n=2): - 0.14% (dry), - 0.06% (75% RH)	Verstraeten, K. 2019. Laboratoria Qualiphar N.V./S.A.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			<ul style="list-style-type: none"> - Change in A.S. (average, n=2): 201.5 mg/g -> 200.5 mg/g(dry), 198 mg/g (75% RH) - Free acid content (=hydrolysis product) (average, n=2): 0.02% -> 0.15% (dry), 0.16% (75% RH) - pH (average, n=2): 7.25 -> 6.5 (both dry and 75% RH) - Relative density (average, n=2): 0.95 -> 0.955 (both dry and 75% RH) [8 weeks at 40°C. Packaging: HDPE pump spray bottle - 100 mL] 	
Storage stability test – long term storage at ambient temperature	<p>HPLC methods (as validated, see hereunder in PAR)</p> <p>Organoleptic</p> <p>European Pharmacopoeia Monographs 2.2.3 and 2.2.5</p>	Shampouxrepel - IR3535® 20%	<ul style="list-style-type: none"> - No change in colour, odour, or structure. - No change in packaging appearance. - Mass changes (average, n=2): T6m: -0.035% T12m: -0.075% T18m: -0.115% T24m: -0.15% T30m: -0.205% - Change in A.S. (average, n=2): T0: 201.5 mg/g T6m: 202.5 mg/g T12m: 202.5 mg/g T18m: 202.5 mg/g T24m: 201.5 mg/g T30m : 203 mg/g - Free acid content 	Verstraeten, K. 2019. Laboratoria Qualiphar N.V./S.A.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			(=hydrolysis product) (average, n=2): T0: 0.02% T6m: 0.075% T12m : 0.14% T18m : 0.23% T24m : 0.36% T30m : 0.545% - pH (average, n=2): T0: 7.25 T6m : 6.6 T12m : 6.25 T18m : 6 T24m: 5.9 T30m: 5.55 - Relative density (average, n=2): T0: 0.95 T6m : 0.955 T12m : 0.955 T18m: 0.95 T24m: 0.955 T30m : 0.955 [30 months weeks at 25°C and 60% R. Packaging: HDPE pump spray bottle - 100 mL]	

Therefore, the conclusion on the physical, chemical and technical properties of the product SHAMPOUXREPEL, after assessment of the MIC, become:

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

The SHAMPOUXREPEL 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 for up to and including 30 months, and is stable under cold and accelerated storage conditions. 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.

3.2.4 Physical hazards and respective characteristics

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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.

3.2.5 Methods for detection and identification

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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.

3.2.6 Efficacy against target organisms

3.2.6.1 Function and field of use

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process.

3.2.6.3 Effects on target organisms, including unacceptable suffering

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray

Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.6.4 *Mode of action, including time delay*

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.6.5 *Efficacy data*

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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.

3.2.6.6 *Occurrence of resistance and resistance management*

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.6.7 *Known limitations*

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.6.8 *Evaluation of the label claims*

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.7 Risk assessment for human health

3.2.7.1 Assessment of effects on Human Health

(I) Skin corrosion and irritation

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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**a. Acute toxicity by oral route**

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

b. Acute toxicity by inhalation

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

c. Acute toxicity by dermal route

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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)		

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(IX) Available toxicological data relating to a mixture

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(X) Other

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.7.2 Exposure assessment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(II) List of scenarios

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(III) Industrial exposure

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(IV) Professional exposure

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(V) Non-professional exposure

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(VI) Exposure of the general public

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(VII) Monitoring data

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(VIII) Dietary exposure

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray

Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(X) Aggregated exposure

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Not applicable

(XI) Summary of exposure assessment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.7.3 Risk characterisation for human health

(I) Risk for industrial users

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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).

(II) Risk for professional users

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Not applicable

(III) Risk for non-professional users

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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.

(IV) Risk for the general public

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Not applicable

(V) Risk for consumers via residues in food

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Not applicable

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

Not applicable

3.2.8 Risk assessment for animal health

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

3.2.9 Risk assessment for the environment

3.2.9.1 Effects assessment on the environment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. The related reference product is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015. Conclusion is available below :

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray

Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(VII) Foreseeable routes of entry into the environment on the basis of the use envisaged

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(IX) Leaching behaviour (ADS)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(X) Testing for distribution and dissipation in soil (ADS)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(XII) Testing for distribution and dissipation in air (ADS)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(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)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

(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)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.9.2 Exposure assessment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

3.2.9.3 Risk characterisation

(I) Atmosphere

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Conclusion:

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

(II) Sewage treatment plant (STP)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Conclusion:

No adverse effect for the STP is expected

(III) Aquatic compartment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Conclusion:

No adverse effect for the aquatic compartment is expected

(IV) Terrestrial compartment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Conclusion

No adverse effects for the terrestrial compartment are expected

(V) Groundwater

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Conclusion

No adverse effects for the groundwater are expected.

(VI) Primary and secondary poisoning

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

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

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

Not relevant, since the product does not contain other components other than the active substance that could give a risk to the environment.

3.2.10 Measures to protect man, animals and the environment

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

See §2.1.4 and §2.1.5

3.2.11 Assessment of a combination of biocidal products

Not applicable

3.2.12 Comparative assessment

Not applicable

4 ANNEXES

4.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Author(s)	Year	Title	Report No.	Owner Company	Report date
Verstraeten, K.	2019	Shampouxrepel: Storage Stability Report	N/A	Laboratoria Qualiphar N.V./S.A.	2019-07-29

4.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

4.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

Not applicable.

4.4 RESIDUE BEHAVIOUR

Not applicable.

4.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Not relevant as the product SHAMPOUXREPEL was first authorized according NA-BBP process. Please refer to the related reference product which is Insect Repellent Pump Spray Lice IR3535® 20% - Asset number: BE-0012318-0000 / Authorisation number:BE2017-0015 for additional information.

4.6 CONFIDENTIAL ANNEX

No

4.7 OTHER

Not applicable.