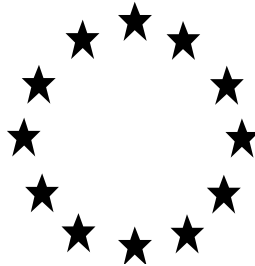


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE MINOR CHANGE OF A
NATIONAL AUTHORISATION**



Product identifier in R4BP	OTC Antimosquitos Familiar Spray Repelente
Product type(s):	19 (Repellent)
Active ingredient(s):	Ethyl butylacetylaminopropionate (IR3535)
Case No. in R4BP	BC-UM055243-27 (NA-MIC)
Asset No. in R4BP	ES-0021198-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/BB(MR)-2019-19-00647
Date	August 2019 (updated November 2020)

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Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-MIC	ES	BC-UM055243-27	November 2020	Shelf-life

1 Conclusion

The assessment presented in this report includes the minor change submitted by the applicant.

It is concluded that the product, OTC ANTIMOSQUITOS FAMILIAR SPRAY REPELENTE, with the active substance IR3535, at a level of 20% w/w, may be authorised for use as a repellent (product-type 19). This product is a same biocidal product (BB) of Insect Repellent Pump Spray IR3535 20% (ES-0017370-0000). At the same time the product Insect Repellent Pump Spray IR3535 20% is a mutual recognition of the Belgium APP Insect Repellent Pump Spray IR3535 20% (BE-0012319-0000) Now a NA-MIC has been submitted and a PAR has been done.

Regarding toxicology, efficacy, exposure and environment assessment the conclusions are the same as the product Insect Repellent Pump Spray IR3535 20%.

Concerning the physical and chemical properties, the shelf-life has been increased from 18 months to 36 months based on the new information provided. This change has not been produced in the other mentioned products.

Therefore, OTC ANTIMOSQUITOS FAMILIAR SPRAY REPELENTE can be authorised as a repellent product against Mosquitoes (*Culicidae*). It is to be used in well ventilated indoor areas and outdoors. The users are non-professional (General public).

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

OTC Antimosquitos Familiar Spray Repelente
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2.1.2 Manufacturer(s) of the product

Name of manufacturer	Ferrer Internacional, S.A.
Address of manufacturer	Gran Vía Carlos III, 94 08028 Barcelona Spain
Location of manufacturing sites	Joan XXIII, 10 08950 Esplugues de Llobregat (Barcelona) Spain

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

Active substance	Ethyl butylacetylaminopropionate (IR3535)
Name of manufacturer	Merck S.L.U.
Address of manufacturer	C/ María de Molina, 40 28006 Madrid Spain
Location of manufacturing sites	Polígono Merck 08100 – Mollet del Vallés (Barcelona) Spain

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

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
Ethanol		Non-active substances	64-17-5	200-578-6	35

- Information on the full composition is provided in the confidential annex (see chapter 3).

2.2.2 Information on the substance(s) of concern

The biocidal product contains the following substances of concern (SoC):

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethanol 96%	Ethanol	Solvent	64-17-5	200-578-6	35

During the referral discussions concerning this product, it was decided that ethanol should be considered as a substance of concern (SoC).

According to the definition in the BPR (Article (3)(f)), a SoC is a substance which has an inherent capacity to cause an adverse effect. In this product, ethanol is the cause for the classification as a flammable liquid and during the referral discussions it was agreed that flammability can be considered as a cause to provoke an adverse effect and, therefore, ethanol should be considered as a SoC.

Due to the lack of guidance in relation to physical-chemical endpoints, the methodology described in the guidance for human health assessment of SoC, can be applied by analogy. Accordingly, the label of the product should include the corresponding H/P statements but a qualitative/quantitative risk assessment is not necessary. Ethanol will be indicated in the SPC Section 2.1.

Related to the submission of the analytical method for determining the concentration of the SoC, Article 21 of the BPR is applicable and waiving of the data requirements is allowed and accepted.

2.2.3 Type of formulation


AL – Any other liquid

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008

Table 3

Classification	
Hazard classes, Hazard categories	Hazard statements
Flammable liquid, category 3 Eye irritation, category 2	H226: Flammable liquid and vapour H319: Causes serious eye irritation

Table 4

Labelling		
	Code	Pictogram / Wording
Pictograms	GHS02 GHS07	
Signal word		WARNING
Hazard statements	H226 H319	Flammable liquid and vapour Causes serious eye irritation
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	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
	P501	Dispose of contents/container in accordance with local/regional/national/international regulations
Note	-	

2.4 Authorised use (s)

Table 1. Use # 1 – Repellent – Mosquitoes – General Public – Spray – Well ventilated indoor areas and outdoors

Product Type(s)	19
Where relevant, an exact description of the use	Repellent against mosquitoes for humans
Target organism(s) (including development stage)	<i>Culicidae</i> (Mosquitoes)
Field(s) of use	Use indoors only in well ventilated areas and outdoors.

	<p>The product is a ready-to-use insect repellent used to protect humans against mosquitoes in temperate areas only. The product is not intended to be used in tropical areas.</p> <p>The repellent is sprayed onto the skin, only on uncovered parts of the face, hands, arms, legs and feet.</p>
Application method(s)	Spray directly onto the exposed skin and distribute the liquid on the skin by hand.
Application rate(s) and frequency	<p>Apply sparingly to uniformly cover uncovered parts of the face, hands, arms, legs and feet.</p> <p>Dose per application:</p> <ul style="list-style-type: none"> • adult: 6.12 g or approx. 53 sprays • child (between 6 and 12 years): 3.39 g or approx. 29 sprays • child (between 2 and 6 years): 2.51 g or approx. 21 sprays • toddler (between 1 and 2 years): 1.77 g or approx. 15 sprays <p>The product is intended to be used in summer when insects are frequent.</p> <p>It can only be applied once a day depending on the outdoors activities, the weather and the presence of insects.</p> <p>The product is suitable only for children older than 1 year.</p>
Category(ies) of users	General public
Pack sizes and packaging material	<p>Plastic Bottle (HDPE) from 25 mL to 750 mL.</p> <p>The bottle is closed with a pumping head covered by a cap.</p>

2.4.1.1 Use-specific instructions for use

See section 2.5.1

2.4.1.2 Use-specific risk mitigation measures

See section 2.5.2

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

See section 2.5.3.

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

See section 2.5.4

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

See section 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

Apply the product evenly onto exposed skin and distribute the applied spray liquid on the skin by hand. ONLY apply to uncovered parts of the body, limited to arms, hands, legs, feet and face.

Do not spray directly on the face. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes. Do not spray into the eyes or apply to eye area.

An adult should apply the product to children below 12 years of age. Do not use on children's hands. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing. Only for external use.

Only children older than 1 year can use this product.

Caution must be taken when using these products on children. Use products very responsibly. Mechanical protection (clothing, mosquito nets) is to be preferred at all times.

Avoid contact with synthetic materials. Synthetic materials should be protected during spraying.

Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

The product is not intended for use on animals/pets.

2.5.2 Risk mitigation measures:

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

Suitable only for children older than 1 year. Keep out of reach of children.

Avoid breathing spray. Do not spray directly on the face.

Use only outdoors or in a well-ventilated area.

ONLY apply to uncovered parts of the face, hands, arms, legs and feet. Do not use under clothing.

Mechanical protection (clothing, mosquito nets) is to be preferred at all times. Only for external use. Use only as directed.

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

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

•The clinical manifestations that can occur in case of exposure and / or contact are:

Causes serious eye irritation.

•Basic action measures:

After eye contact: rinse out with plenty of water for several minutes, remove contact lenses if possible and continue rinsing

•Therapeutic advice for doctors and health personnel:

-Symptomatic and support treatment

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

2.5.4 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. (*Spain: Dispose of the content and / or its container as hazardous waste by delivering it to a clean point (P501)*).

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.

2.5.5 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: 36 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.

2.5.6 Other information

- Non-professional use (general public) is considered to be someone who uses the product in their private life

2.6 Physical, chemical and technical properties

• Long-term stability test:

$$[C]_0 = 20.27\% - [C]_{3M} = 20.68\% - \Delta[C] = +2.02\%$$

$$[C]_0 = 20.27\% - [C]_{6M} = 20.43\% - \Delta[C] = +0.79\%$$

$$[C]_0 = 20.27\% - [C]_{12M} = 20.50\% - \Delta[C] = +1.13\%$$

$$[C]_0 = 20.27\% - [C]_{18M} = 21.03\% - \Delta[C] = +3.75\%$$

$$[C]_0 = 20.27\% - [C]_{24M} = 20.74\% - \Delta[C] = +2.32\%$$

$$[C]_0 = 20.27\% - [C]_{30M} = 20.84\% - \Delta[C] = +2.81\%$$

$$[C]_0 = 20.27\% - [C]_{36M} = 20.69\% - \Delta[C] = +2.07\%$$

Conclusion: The results fulfil the Guidance criteria and therefore the shelf-life can be increased from 18 months to 36 months

For the rest of physical, chemical and technical properties, see INSECT REPELLENT PUMP SPRAY IR3535 20%.

2.7 Physical hazards and respective characteristics

See INSECT REPELLENT PUMP SPRAY IR3535 20% physical hazards evaluation.

2.8 Methods for detection and identification

See INSECT REPELLENT PUMP SPRAY IR3535 20% analytical methods evaluation.

2.9 Efficacy against target organisms

See INSECT REPELLENT PUMP SPRAY IR3535 20% efficacy evaluation

2.10 Risk assessment for human health

2.10.1 Assessment of effects of the active substance on human health

See INSECT REPELLENT PUMP SPRAY IR3535 20% Risk assessment for human health evaluation.

2.10.2 Assessment of effects of the product on human health

See INSECT REPELLENT PUMP SPRAY IR3535 20% Risk assessment for human health evaluation.

2.10.3 Exposure assessment

See INSECT REPELLENT PUMP SPRAY IR3535 20% Exposure assessment evaluation.

2.10.4 Risk characterisation for human health

See INSECT REPELLENT PUMP SPRAY IR3535 20% Risk characterisation for human health evaluation.

2.11 Risk assessment for animal health

See INSECT REPELLENT PUMP SPRAY IR3535 20% Risk assessment for animal health evaluation.

2.12 Risk assessment for the environment

See INSECT REPELLENT PUMP SPRAY IR3535 20% Risk assessment for the environment evaluation

2.13 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3 Confidential annex (Access level: “Restricted” to applicant and authority)

This product is identical to INSECT REPELLENT PUMP SPRAY IR3535 20% . A letter of access has been submitted in order to use the information/data.