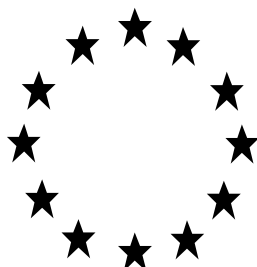


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product identifier in R4BP	OTC Antimosquitos Forte Aerosol Repelente
Product type(s):	19 (Repellent)
Active ingredient(s):	Ethyl butylacetylaminopropionate (IR3535)
Case No. in R4BP	BC-QR055242-23 (NA-MIC)
Asset No. in R4BP	ES-0021026-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/BB(MR)-2019-19-00639
Date	July 2019 (updated November 2020)

## Table of content

<b>1</b>	<b>Conclusion</b> .....	<b>4</b>
<b>2</b>	<b>Summary of the product assessment</b> .....	<b>5</b>
2.1	Administrative information .....	5
2.2	Composition and formulation.....	6
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008.....	6
2.4	Use(s) appropriate for further authorisation .....	<b>¡Error! Marcador no definido.</b>
2.5	General directions for use .....	9
<b>3</b>	<b>Assessment of the product</b> .....	<b>¡Error! Marcador no definido.</b>
<b>3.1</b>	<b><i>Use(s) considered appropriate for authorisation after former assessment (uses authorized by Spain)</i></b> .....	<b>¡Error! Marcador no definido.</b>
<b>3.2</b>	<b><i>Physical, chemical and technical properties</i></b> .....	<b>11</b>
<b>3.3</b>	<b><i>Physical hazards and respective characteristics</i></b> .....	<b>11</b>
<b>3.4</b>	<b><i>Methods for detection and identification</i></b> .....	<b>12</b>
<b>3.5</b>	<b><i>Efficacy against target organisms</i></b> .....	<b>12</b>
<b>3.6</b>	<b><i>Risk assessment for human health</i></b> .....	<b>12</b>
<b>3.7</b>	<b><i>Risk assessment for animal health</i></b> .....	<b>12</b>
<b>3.8</b>	<b><i>Risk assessment for the environment</i></b> .....	<b>12</b>
<b>3.9</b>	<b><i>Assessment of a combination of biocidal products</i></b> .....	<b>12</b>
<b>4</b>	<b>Confidential annex (Access level: “Restricted” to applicant and authority)</b> .....	<b>13</b>

<b>Application type</b>	<b>Ref MS</b>	<b>Case number/Asset number in the ref MS</b>	<b>Decision date</b>	<b>Assessment carried out (i.e. first authorisation / amendment /renewal)</b>
NA-MIC	ES	BC-QR055242-23	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 FORTE AEROSOL 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 Aerosol IR3535 30% (ES-0017368-0000). At the same time the product Insect Repellent Aerosol IR3535 30% is a mutual recognition of the Belgium APP Insect Repellent Aerosol IR3535 30% (BE-0012317-0000) Now a NAMIC 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 Aerosol IR3535 30%

Concerning the physical and chemical properties, the shelf-life has been increased from 24 months to 36 months based on the new information provided. This change has not been produced in the other mentioned products.

Therefore, OTC ANTIMOSQUITOS FORTE AEROSOL REPELENTE can be authorised as a repellent product against Mosquitoes (*Culicidae*) and ticks (*Ixodidae*). It is to be used indoors 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 Forte Aerosol Repelente
---

#### 2.1.2 Manufacturer(s) of the product

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

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

<b>Active substance</b>	Ethyl butylacetylaminopropionate (IR3535)
<b>Name of manufacturer</b>	Merck S.L.U.
<b>Address of manufacturer 1</b>	C/ María de Molina, 40 28006 Madrid Spain
<b>Location of manufacturing sites 1</b>	Polígono Merck 08100 – Mollet del Vallés (Barcelona) Spain
<b>Address of manufacturer 2</b>	Frankfurter Straße, 250 64293 – Darmstadt Alemania
<b>Location of manufacturing sites 2</b>	Polígono Merck 08100 - Mollet del Vallés (Barcelona) España

## 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

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

### 2.2.2 Information on the substance(s) of concern

Not applicable

### 2.2.3 Type of formulation


AE – Aerosol dispenser

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

Table 2

Classification	
Hazard classes, Hazard categories	Hazard statements
Flammable aerosol, category 2	H223: Flammable aerosol H229: Pressurized container
Eye irritation, category 2	H319: Causes serious eye irritation

Table 3

Labelling	Code	Pictogram / Wording
Pictograms	GHS02 GHS07	
Signal word		WARNING

Hazard statements	H223 H229 H319	Flammable aerosol Pressurised container: may burst if heated 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
	P251	Pressurised container – do not pierce or burn, even after use
	P264	Wash hands thoroughly after handling
	P410 + P412	Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122°F
	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 and ticks – General Public – Spray – Indoors and outdoors areas.**

Product Type(s)	19
Where relevant, an exact description of the use	Repellent against mosquitoes and ticks for humans
Target organism(s) (including development stage)	<i>Culicidae</i> (Mosquitoes) <i>Ixodidae</i> (Ticks)
Field(s) of use	Use indoors in well ventilated areas and outdoors.  The product is authorised as a repellent product against Mosquitoes ( <i>Culicidae</i> ) and ticks ( <i>Ixodidae</i> ) in temperate areas only. The product is not intended to be used in tropical areas.  The repellent is sprayed onto the skin, only on uncovered parts of the face, hands, arms, legs and feet.
Application method(s)	Apply directly onto the exposed skin by spraying on the skin by hand.
Application rate(s) and frequency	Apply sparingly to uniformly cover uncovered parts of the face, hands, arms, legs and feet.  Dose per application: • adult: spraying 3 g of product or approx. during 1.4 to 2.39 secs. • child: spraying 1.6 g of product or approx. during 0.7 to 1.2 secs. • toddler (between 1 and 2 years): spraying 0.83 g of product or approx. during 0.4 to 0.6 secs  The product is intended to be used in summer when insects are frequent.

	It can only be applied once a day depending on the outdoors activities, the weather and the presence of insects. Application can be repeated if necessary (noticeable reduction in repellency) and when allowed (see label instructions). The spray will be applied up to twice a day for adults, and once a day for children older than 1 year The product is suitable only for children older than 1 year.
Category(ies) of users	General public
Pack sizes and packaging material	Metallic aerosol container, from 25ml to 250ml. The spray has a pumping head covered by a cap

#### **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 11 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.

The repellent should be reapplied in case of excessive perspiration and also after bathing. The re-application is authorized for adults only. Reapply only when a noticeable reduction in repellency is observed and no later than ten hours after the first application

When reapplying the product, observe the maximum number of applications allowed per day: twice for adults and once for children over 1 year

The product is suitable only for children over 1-year-old. Care should be taken when using these products on children. Use the products in a very responsible way. Mechanical protection (clothing, mosquito nets) is preferable 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

Pressurized gas bottle: discard only in empty state

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 a 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 >35°C. The product should not be exposed to temperatures above 50°C / 122°F

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:

$$[C]_0 = 30.85\% - [C]_{3M} = 31.96\% - \Delta[C] = +3.60\%$$

$$[C]_0 = 30.85\% - [C]_{6M} = 31.62\% - \Delta[C] = +2.50\%$$

$$[C]_0 = 30.85\% - [C]_{12M} = 31.60\% - \Delta[C] = +2.43\%$$

$$[C]_0 = 30.85\% - [C]_{18M} = 31.31\% - \Delta[C] = +2.62\%$$

$$[C]_0 = 30.85\% - [C]_{24M} = 31.66\% - \Delta[C] = +2.62\%$$

$$[C]_0 = 30.85\% - [C]_{30M} = 30.51\% - \Delta[C] = -1.102\%$$

$$[C]_0 = 30.85\% - [C]_{36M} = 29.28\% - \Delta[C] = -5.08\%$$

**Conclusion:** The results fulfil the Guidance criteria and therefore the shelf-life can be increased from 24 months to 36 months

For the rest of physical, chemical and technical properties, see Insect Repellent Aerosol IR3535 30%

## 2.7 Physical hazards and respective characteristics

See Insect Repellent Aerosol IR3535 30% physical hazards evaluation.

## **2.8 Methods for detection and identification**

See Insect Repellent Aerosol IR3535 30% analytical methods evaluation.

## **2.9 Efficacy against target organisms**

See Insect Repellent Aerosol IR3535 30% 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 Aerosol IR3535 30% Risk assessment for human health evaluation.

### **2.10.2 Assessment of effects of the product on human health**

See Insect Repellent Aerosol IR3535 30% Risk assessment for human health evaluation.

### **2.10.3 Exposure assessment**

See Insect Repellent Aerosol IR3535 30% Exposure assessment evaluation.

### **2.10.4 Risk characterisation for human health**

See Insect Repellent Aerosol IR3535 30% Risk characterisation for human health evaluation.

## **2.11 Risk assessment for animal health**

See Insect Repellent Aerosol IR3535 30% Risk assessment for animal health evaluation.

## **2.12 Risk assessment for the environment**

See Insect Repellent Aerosol IR3535 30% 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 Aerosol IR3535 30%. A letter of access has been submitted in order to use the information/data.