

# Summary of product characteristics for a biocidal product

**Product name:** IR 35/10

**Product type(s):** PT19 - Repellents and attractants (Pest control)

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

**Authorisation number:** FR-2019-0044

**R4BP 3 asset reference number:** FR-0013223-0000

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## Administrative information

### 1.1. Trade names of the product

|                 |
|-----------------|
| IR 35/10        |
| ANTI MOSQUITO   |
| MOSQUITO SHIELD |
| INSECT STOP     |
| MÜCKENSCHUTZ    |
| INSEKTENBREMSE  |

### 1.2. Authorisation holder

|   |                 |  |
|---|-----------------|--|
| <b>Name and address of the authorisation holder</b> | Name            | Arthur Schopf Hygiene GmbH & Co. KG          |
|   | Address         | Pfaffensteinstraße 1 83115 Neubeuern Germany |
| <b>Authorisation number</b>                         | FR-2019-0044    |  |
| <b>R4BP 3 asset reference number</b>                | FR-0013223-0000 |  |
| <b>Date of the authorisation</b>                    | 11/04/2019      |  |
| <b>Expiry date of the authorisation</b>             | 16/05/2027      |  |

### 1.3. Manufacturer(s) of the biocidal products

|  |  |
|--|--|
| <b>Name of the manufacturer</b>        | Arthur Schopf Hygiene GmbH & Co. KG          |
| <b>Address of the manufacturer</b>     | Pfaffensteinstraße 1 83115 Neubeuern Germany |
| <b>Location of manufacturing sites</b> | Pfaffensteinstraße 1 83115 Neubeuern Germany |
|  | Elektronstraße 8 06749 Bitterfeld Germany    |

#### 1.4. Manufacturer(s) of the active substance(s)

|  |   |
|--|---|
| <b>Active substance</b>                | 1320 - Ethyl butylacetylaminopropionate                 |
| <b>Name of the manufacturer</b>        | Merck S.L.U.  |
| <b>Address of the manufacturer</b>     | Calle Maria de Molina, 40 28006 Madrid Spain            |
| <b>Location of manufacturing sites</b> | Polígono Merck 08100 Mollet de Vallés, Barcelone Spain  |
| <b>Active substance</b>                | 1320 - Ethyl butylacetylaminopropionate                 |
| <b>Name of the manufacturer</b>        | Merck KGaA  |
| <b>Address of the manufacturer</b>     | Frankfurter Straße 250 64293 Darmstadt Germany          |
| <b>Location of manufacturing sites</b> | Polígono Merck 08100 Mollet del Vallés, Barcelone Spain |

## 2. Product composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the biocidal product

| Common name                      | IUPAC name | Function             | CAS number | EC number | Content (%) |
|----------------------------------|------------|----------------------|------------|-----------|-------------|
| Ethyl butylacetylaminopropionate |            | Active Substance     | 52304-36-6 | 257-835-0 | 20          |
| Ethanol 96%                      | Ethanol    | Non-active substance | 64-17-5    | 200-578-6 | 35          |

## 2.2. Type of formulation

AL - Any other liquid

## 3. Hazard and precautionary statements

### Hazard statements

Flammable liquid and vapour.

Causes serious eye irritation.

### Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice.

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - Spray to repel mosquitoes and ticks from human skin (general public)

### Product type

PT19 - Repellents and attractants (Pest control)

### Where relevant, an exact description of the authorised use

Repellent

### Target organism(s) (including development stage)

Scientific name: Culex spp  
Common name: Mosquitoes  
Development stage: Adults

Scientific name: Aedes spp  
Common name: Aedes mosquitoes  
Development stage: Adults

Scientific name: Anopheles spp  
Common name: Anopheles mosquitoes  
Development stage: Adults

Scientific name: Ixodes ricinus  
Common name: Ticks

|  |  |
|--|--|
|  | Development stage: Adults<br>Scientific name: Ixodes scapularis<br>Common name: Ticks<br>Development stage: Adults   |
| <b>Field(s) of use</b>                     | Indoor<br>Outdoor<br>Indoor and/or outdoor   |
| <b>Application method(s)</b>               | Method: Spraying<br>Detailed description:<br>Spray directly onto the exposed skin and distribute the liquid on the skin by hand.   |
| <b>Application rate(s) and frequencies</b> | Application Rate: Mosquitoes : 0.00067 g/cm <sup>2</sup> skin ; Ticks : 0.00067 g/cm <sup>2</sup> skin<br>Dilution (%): -<br>Number and timing of application:<br>Mosquitoes : 0,00067 g/cm <sup>2</sup> skin<br>Protection time : 8 hours<br><br>Ticks : 0,00067 g/cm <sup>2</sup> skin<br>Protection time : 12 hours |
| <b>Category(ies) of users</b>              | General public (non-professional)  |
| <b>Pack sizes and packaging material</b>   | HDPE bottles from 25 to 750 mL   |

#### 4.1.1 Use-specific instructions for use

|  |
|--|
| Apply on the different parts of the body the described spray :<br>- Toddlers from 1 to 2 years old : 2 to 3 for the head and neck, 2 by arm, 2 by leg. Do not apply more than once a day.<br>- Child from 2 to 6 years old : 3 for the head and neck, 2 by arm, 3 by leg. Do not apply more than once a day.<br>- Child from 6 to 12 years old : 3 for the head and the neck, 3 by arm, 4 by leg. Do not apply more than twice a day.<br>- Adult and child from 12 years old : 7 for the head and the neck, 5 by arm, 2 to 3 by hand, 8 by leg, 3 by foot. Do not apply more than twice a day.<br>- In case of application of a sunscreen, wait minimum 20 minutes after its application to apply the repellent product.<br>- Consider the use of personal vector protection in combination with a biocidal repellent. |
|--|

#### 4.1.2 Use-specific risk mitigation measures

|  |
|--|
| - Apply only to uncovered areas of the skin.<br>- Do not spray directly on the face but spray on hands and then apply on the face.<br>- For adults and children over 6 years old, the product needs to be applied twice a day maximum.<br>- For children from 1 to 5 years old : the product needs to be applied maximum once a day.<br>- Do not apply on hands of children.<br>- For children, the product needs to be applied by an adult. |
|--|

**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**

Refer to the general conditions of use.

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

Refer to the general conditions of use.

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

Refer to the general conditions of use.

**4.2 Use description**

**Use 2 - Application on horses/ponies**

**Product type**

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

**Where relevant, an exact description of the authorised use**

Repellent to be applied on horses/ponies

**Target organism(s) (including development stage)**

Scientific name: *Musca domestica*  
Common name: House fly  
Development stage: Adults

Scientific name: *Stomoxys calcitrans*  
Common name: Stable flies  
Development stage: Adults

Scientific name: *Tabanus sudeticus*  
Common name: Horse Fly  
Development stage: Adults

Scientific name: *Haematopota pluvialis*  
Common name: Horse fly  
Development stage: Adults

Scientific name: *Simulium venustum*  
Common name: Blackflies  
Development stage: Adults

Scientific name: *Simulium nyssa*  
Common name: Blackflies  
Development stage: Adults

Scientific name: *Prosimulium mixtum*  
Common name: Blackflies  
Development stage: Adults

Scientific name: Culicoides spp  
 Common name: Biting midges  
 Development stage: Adults

Scientific name: Phlebotomus spp  
 Common name: Sandflies  
 Development stage: Adults

Scientific name: Culex spp  
 Common name: House mosquito  
 Development stage: Adults

Scientific name: Hyalomma marginatum  
 Common name: African tick  
 Development stage: Adults

Scientific name: Ixodes ricinus  
 Common name: Castor bean tick  
 Development stage: Adults

**Field(s) of use**

Outdoor

The product must be applied outdoor when the animal to be treated will be on paved ground in order to protect the soil compartment.

**Application method(s)**

Method: Spraying  
 Detailed description:  
 Direct spraying on the horses/ponies.

Method: Spraying  
 Detailed description:  
 Direct spraying on the horses/ponies.

Method: Spraying  
 Detailed description:  
 Direct spraying on the horses/ponies.

**Application rate(s) and frequencies**

Application Rate: 5 g/m<sup>2</sup>  
 Dilution (%): -  
 Number and timing of application:

House fly  
 Protection time up to 4h  
 Stable fly  
 Protection time up to 3h



Horse flies  
Protection time up to 2h  
Biting midges  
Protection time up to 4h  
Black flies  
Protection time up to 5h  
Sandflies  
Protection time up to 3h  
Common house mosquito  
Protection time up to 4h  
Castor bean tick  
Protection time up to 6h  
African tick  
Protection time up to 3h

1 application per day.

Application Rate: 10 g/m<sup>2</sup>  
Dilution (%): -  
Number and timing of application:

House fly  
Protection time up to 5h  
Stable fly  
Protection time up to 4h  
Horse flies  
Protection time up to 3h  
Biting midges  
Protection time up to 5h  
Black flies  
Protection time up to 7h  
Sandflies  
Protection time up to 4h  
Common house mosquito  
Protection time up to 5h  
Castor bean tick  
Protection time up to 8h  
African tick  
Protection time up to 4h

1 application per day.

Application Rate: 16.7 g/m<sup>2</sup>  
 Dilution (%): -  
 Number and timing of application:  
 House fly  
 Protection time up to 5h  
 Stable fly  
 Protection time up to 5h  
 Horse flies  
 Protection time up to 5h  
 Biting midges  
 Protection time up to 6h  
 Black flies  
 Protection time up to 9h  
 Sandflies  
 Protection time up to 5h  
 Common house mosquito  
 Protection time up to 6h  
 Castor bean tick  
 Protection time up to 8.5h  
 African tick  
 Protection time up to 5h

1 application per day.

**Category(ies) of users**

Professional  
 General public (non-professional)

**Pack sizes and packaging material**

3L and 5L HDPE canister  
 100 mL to 2L PET spray bottle (Versaplast EU 28/410)  
 100 mL to 2L HDPE spray bottle (Versaplast EU 28/410)  
 3L and 5L PET canister

**4.2.1 Use-specific instructions for use**

- The product is only intended to be sprayed on the horse or pony body, no spreading is needed.
- For use all over the horse's or pony's body, apply the dosage of 5 g of product per m<sup>2</sup>, avoiding contact with eyes and nostrils.
- When used at a dose rate of 10 g of product per m<sup>2</sup>: treat the animal on the most exposed parts of its body (not all of it) by avoiding contact with eyes and nostrils. As example, for a ride in the forest, in order to avoid tick bites, it is recommended to treat the lower parts of the animal: chest, shoulders, forearms, front legs, hips, thighs and hind legs.
- When used at a dose rate of 16.7 g of product per m<sup>2</sup>: treat the animal on the most exposed parts of its body (not all of it) by avoiding contact with eyes and nostrils. For example, to repel flies during a day's riding, treat the most exposed parts of the horse, such as the head, chest, shoulders, forearms, lower parts of the hind legs and front legs. In order to avoid possible insect bites on other parts of the horse, a quarter blanket must be used as a physical and mechanical protection (the areas usually covered by the blanket are the back, ribs, rump, hips, thighs and part of the top of the hind legs).

#### 4.2.2 Use-specific risk mitigation measures

- Do not use near or on animals intended for consumption.
- Spray the product outdoor or in a well ventilated area.
- Spray the product downwards below the eye level.
- Wash hands after application of the product.
- Avoid the animal's eyes and eye area.
- Children should not treat the horse themselves. An adult must do it for them.
- The animals must be treated on sealed/paved ground in order to prevent direct releases to soil.
- Treated horses must be hosed down/rinsed only on sealed/paved ground in order to prevent direct releases to soil.

#### 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

Refer to the general conditions of use.

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

Refer to the general conditions of use.

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

Refer to the general conditions of use.

## 5. General directions for use

### 5.1. Instructions for use

- Comply with instructions of use.
- Efficacy in tropical conditions is not demonstrated.
- Respect dosages of the product.
- Always read the label and follow all instructions given therein.
- If exceptionally, the treatment seems to show too low efficacy, inform the marketing authorisation holder.
- Do not mix with other repellents.
- The protection time is given as indication. Environmental factors (temperature, wind, etc.) can modify the duration of protection.
- Reapply after exposure to water, but do not exceed the recommended maximum number of applications.

### 5.2. Risk mitigation measures

- Keep out of the reach of children.
- Avoid breathing of vapor or spray mists.
- Treat outdoors in a well ventilated place only.
- Wash hands before any food manipulation.
- Do not use the product close to foodstuffs and surfaces which can be in contact with food or drink intended for human consumption.

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

In case of contact with the user's eyes: rinse the eyes with plenty of warm water, keeping the eyelids open, then continue rinsing under a stream of warm water for 10 minutes. If wearing lenses: rinse immediately with warm water, then remove the lenses if there is no contraindication and continue rinsing under a thin stream of warm water for 10 minutes. If signs of irritation persist or visual disturbances happen, consult a doctor.

If skin lesions, redness or pain appear after application of the product, consult a doctor.

In the event of inhalation of high concentrations: rest in a half-sitting position; if symptoms appear contact the poison center or call 15/112.

In case of contact with the mouth: rinse thoroughly with water and contact the poison center or call 15/112.

In the event of disturbance of consciousness, place the subject in a lateral safety position (lying on his side); call 15/112. Do not drink or vomit.

#### 5.4. Instructions for safe disposal of the product and its packaging

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

#### 5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Keep the container tightly closed.
- Store at less than 40 ° C.
- Storage period: 18 months.

#### 6. Other information

- If exceptionally, the treatment seems to show low efficacy, inform the marketing authorisation holder.
- The product for animals and the product for humans have to be put on the market in different packaging.
- In order to guarantee the effectiveness of the product when applied, the number of sprays of the product and the doses at which it is to be used must appear on the label.