

# Summary of product characteristics for a biocidal product

**Product name:** REPEL By UNI-PHARMA Spray

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

**Authorisation number:** Ky-0135

**R4BP 3 asset reference number:** CY-0019587-0000

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## Administrative information

### 1.1. Trade names of the product

REPEL By UNI-PHARMA Spray

### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A. (Distinctive Title: UNI-PHARMA)
	Address	14th km National Road 1 14564 Athens Greece
<b>Authorisation number</b>		Ky-0135
<b>R4BP 3 asset reference number</b>		CY-0019587-0000
<b>Date of the authorisation</b>		27/09/2018
<b>Expiry date of the authorisation</b>		16/05/2027

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

<b>Name of the manufacturer</b>	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A. (Distinctive Title: UNI-PHARMA)
<b>Address of the manufacturer</b>	14th km National Road 1 14564 Athens Greece
<b>Location of manufacturing sites</b>	14th km National Road 1 14564 Athens Greece

### 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, Barcelona 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, Barcelona 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	ethanol		64-17-5	200-578-6	36
denatonium benzoate	N-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate hydrate		3734-33-6	223-095-2	0,0088
Polyoxypropylene monostearyl ether	1-octadecoxypropan-2-ol		25231-21-4		1
polyglycol	Not applicable, ingredient is a UVCB substance		25322-68-3	500-038-2	4
PVP/VA copolymer E-735	ethenyl acetate;1-ethenylpyrrolidin-2-one		25086-89-9		1
water	water		7732-18-5		31,5
polyglycol	Not applicable, ingredient is a UVCB substance		25322-68-3	500-038-2	5

polysorbate	2-[2-[3,4-bis(2-hydroxyethoxy)oxolan-2-yl]-2-(2-hydroxyethoxy)ethoxy]eth	9005-64-5	500-018-3	1,5
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## 2.2. Type of formulation

AL - Any other liquid
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## 3. Hazard and precautionary statements

<b>Hazard statements</b>	Flammable liquid and vapour. Causes serious eye irritation.
<b>Precautionary statements</b>	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.

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - 1-Application to skin

<b>Product type</b>	PT19 - Repellents and attractants (Pest control)
<b>Where relevant, an exact description of the authorised use</b>	Insect repellent pump spray IR3535® 20 % is a ready to use product. The repellent is sprayed onto the skin. 3 g Product is sufficient for the application to approximately 50% of the body surface (face, hands, arms and legs as assessed in the CAR for IR3535). 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. Relevant codes: VI.1.1 and VI.9 (manual distribution over skin).
<b>Target organism(s) (including development stage)</b>	Scientific name: Culicidae: Common name: Mosquitoes Development stage: Adults  Scientific name: Ixodidae: Common name: Ticks Development stage: Nymphs  Scientific name: Ixodidae: Common name: Ticks Development stage: Adults

#### Field(s) of use

	Other  use in well ventilated areas
<b>Application method(s)</b>	Spraying - The ready to use product is a pump spray which is sprayed directly onto the exposed skin.
<b>Application rate(s) and frequencies</b>	3.0 gram - 100 - Insect Repellent Pump Spray IR3535 20% is intended to be used in summer when insects are frequent. It is usually applied once a day depending on outdoor activities, weather and presence of insects. The application can be repeated when necessary (noticeable reduction in repellence). The pump spray can be applied up to 3 times per day for adults, up to 2 times by children between the age of 3 and 10 years and maximally 1 time per day for children below 3 years.
<b>Category(ies) of users</b>	General public (non-professional)
<b>Pack sizes and packaging material</b>	Bottle - Plastic: HDPE - > 25.0 - < 750.0 mL

#### 4.1.1 Use-specific instructions for use

Spray the product evenly onto exposed skin. 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. An adult should apply the product to children below 10 years of age. Do not apply the product to the hands of children. In case of strong perspiration and after having taken a swim, the repellent will need to be reapplied early. The product should not be used under clothing. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non visible part of clothes before use.

#### 4.1.2 Use-specific risk mitigation measures

Use in well-ventilated areas.

#### 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

After inhalation: fresh air. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower.  
 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 let product enter drains. Risk of explosion. Methods and material for containment and cleaning up  
 Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions. Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® H, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

#### 4.1.4 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.

#### **4.1.5 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. Recommended storage temperature see product label.

Advice on safe handling: Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures: Change contaminated clothing. Wash hands after working with substance. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection Safety glasses

Hand protection required

Other protective equipment: Flame retardant antistatic protective clothing.

Respiratory protection required when vapours/aerosols are generated. Recommended Filter type: filter ABEK The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls Do not let product enter drains. Risk of explosion.

## **5. General directions for use**

### **5.1. Instructions for use**

Spray the product evenly onto exposed skin. 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. An adult should apply the product to children below 10 years of age. Do not apply the product to the hands of children. In case of strong perspiration and after having taken a swim, the repellent will need to be reapplied early. The product should not be used under clothing. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non visible part of clothes before use.

### **5.2. Risk mitigation measures**

Do not apply the product to the hands of children. Use in well-ventilated areas. Do not spray into the face.

### **5.3. 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. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower. 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 let product enter drains. Risk of explosion. Methods and material for containment and cleaning up. Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions. Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® H, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

### **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. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

## 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.  
Recommended storage temperature see product label.  
Shelf-life: at least 2 years

## 6. Other information

Merck KGaA is not a formulator of biocidal products. Merck KGaA holds data for reference formulations and authorises these formulations. Merck KGaA clients that actually produce these formulations can make reference to this authorisation and apply for same products authorisation.

The product can be used three times per day by adults and two times per day for children between 3 and 10 years of age. In small children and infants, the use of Insect Repellent Pump Spray IR3535® 20 % must be limited to one application per day. The use for children 1 year is not recommended unless disease vectors are present. Physical protection (clothing and mosquito nets) is to be preferred.

The product should be applied sparingly and only to skin areas which are not covered by clothes and therefore accessible for insects. The label shall therefore state 'ONLY apply to arms, hands, legs, and face'. Only intact skin should be treated.

To children and infants, the product should only be applied by adults. To avoid oral uptake, care must be taken not to apply the product to the hands of the children or the infants and to the regions around the mouth.

It is further recommended to use the product only in well-ventilated areas and to avoid breathing in spray. It is further recommended not to use creams or perfumes on top of the applied repellents.