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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Biopren 4 GR PLUS Larvicide granule

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number:

R4BP asset number: NL-0022257-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Biopren 4 GR PLUS Larvicide granule
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Bábolna Bioenvironmental Centre Private Limited Company
	Address	Szállás u. 6. H-1107 Budapest Hungary
Authorisation number		
<i>R4BP asset number</i>		NL-0022257-0000
Date of the authorisation		31/01/2020
Expiry date of the authorisation		31/01/2030

1.3. Manufacturer(s) of the product

Name of manufacturer	Bábolna Bioenvironmental Centre Private Limited Company
Address of manufacturer	Szállás utca 6 1107 Budapest Hungary
Location of manufacturing sites	Bábolna Bioenvironmental Centre Private Limited Company site 1 Köves J. u 1 2943 Bábolna Hungary

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

Active substance	S-Methoprene
Name of manufacturer	Bábolna Bioenvironmental Centre Private Limited Company
Address of manufacturer	Szállás u. 6 1107 Budapest Hungary
Location of manufacturing sites	Bábolna Bioenvironmental Centre Private Limited Company site 1 Szállás u 6 1107 Budapest Hungary

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
S-Methoprene	Isopropyl-(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	active substance	65733-16-6		0,421

2.2. Type(s) of formulation

GR Granule

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H412: Harmful to aquatic life with long lasting effects. EUH208: Contains Polyethyleneglycol-15-hydroxystearat. May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P273: Avoid release to the environment. P501: Dispose of contents to in accordance with national regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Fly larvae - general public and professional

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	insecticide
Target organism(s) (including development stage)	Scientific name: <i>Musca domestica</i> Common name: house fly Development stage: larvae Scientific name: <i>Stomoxys calcitrans</i> Common name: stable flies Development stage: larvae Scientific name: <i>Eristalis tenax</i> Common name: Drone fly Development stage: larvae
Field(s) of use	indoor use outdoor use Indoor: manure/litter in closed piggeries, cow and poultry houses, as well as in stables and other livestock breeding buildings. Outdoor: manure-pit which is leak-proof, insulated.
Application method(s)	Method: spreading Detailed description: The product has to be spread evenly onto the manure surface by hand, with a measuring cup or with an appropriate device, eg. hand held granule applicator according to the following instructions:
Application rate(s) and frequency	Application rate: 30 g/m ² Dilution (%): 0 Number and timing of application: Piggeries, Cattle Stables: -Slatted floor: Apply on the 3rd day after the introduction of new livestock. Treat the whole surface of manure/litter. It is necessary to repeat treatment after each removal of the manure.. -Deep litter: Apply on every new layer of litter and repeat the treatment after every 8 - 10 cm increase of the layer. Poultry Farms: -Cage: Treat the accumulated manure (every 10 cm thick layer) under the cages. -Deep litter: Apply on every new layer of litter and repeat the treatment after every 10 cm increase of the layer. In the case of very dry substrates (e.g. chicken litter), effect of the product may develop slower. Adding 100-200 mL water/m ² to the

	<p>substrate will facilitate development of the larvicidal effect in the case of very dry environmental conditions.</p> <p>Manure stored outdoors: it should only be treated if it is placed in a manure-pit which is leak-proof, insulated and corresponds to other requirements of safe manure storage. When treating manure stored outdoors, apply the product at the dosage of 30 g/m². Stop treating the manure with the larvicide at least two months before spreading/ processing the manure in the fields</p> <p>The product can inhibit the development of fly for a period of up to 12 weeks after treatment if above instructions for application are respected The maximum number of annual applications is six.</p>
Category(ies) of users	trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	<p>Professional:</p> <p>paper bag with LDPE inner layer 10, 15, 20, 25kg PP or HDPE Bag/sack 10, 15, 20, 25kg carton box with LDPE inner layer 100, 200, 250, 500, 750, 1000, 1500, 2000g PP or HDPE bucket 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 9, 10, 12.5, 15, 20, 25kg PP or HDPE box or bottle 100, 200, 250, 500, 1000g</p> <p>General public:</p> <p>carton box with LDPE inner layer 100, 200, 250, 500, 750, 1000, 1500, 2000g PP or HDPE bucket 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5 PP or HDPE box or bottle 100, 200, 250, 500, 1000g</p>

4.1.1. Use-specific instructions

See general instructions for use

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

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

See general instructions for use

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

See general instructions for use

4.2. Use description

Table 2. litter beetle larvae - general public and professional

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	insecticide
Target organism(s) (including development stage)	Scientific name: <i>Alphitobius diaperinus</i> Common name: litter beetle / Lesser mealworm Development stage: larvae
Field(s) of use	indoor use outdoor use Indoor: manure in closed poultry houses Outdoor: poultry manure-pit which is leak-proof, insulated.
Application method(s)	Method: spreading Detailed description: The product has to be spread evenly onto the manure surface by hand, with a measuring cup or with an appropriate device, eg. hand held granule applicator according to the following instructions:
Application rate(s) and frequency	Application rate: 30 g/m ² Dilution (%): 0 Number and timing of application: Poultry Farms: -Cage: Treat the accumulated manure (every 10 cm thick layer) under the cages.

	<p>-Deep litter: Apply on every new layer of litter and repeat the treatment after every 10 cm increase of the layer.</p> <p>Only for general public, non professional users: Apply the product after each cleaning event, on the top of the first new layer of manure / fresh litter.</p> <p>In the case of very dry substrates (e.g. chicken litter), effect of the product may develop slower. Adding 100-200 mL water/m² to the substrate will facilitate development of the larvicidal effect in the case of very dry environmental conditions.</p> <p>The product can inhibit the development of litter beetle Lesser mealworm for a period of up to 12 weeks after treatment if above instructions for application are respected The maximum number of annual applications is six.</p>
Category(ies) of users	trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	<p>Professional:</p> <p>paper bag with LDPE inner layer 10, 15, 20, 25kg PP or HDPE Bag/sack 10, 15, 20, 25kg carton box with LDPE inner layer 100, 200, 250, 500, 750, 1000, 1500, 2000g PP or HDPE bucket 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 9, 10, 12.5, 15, 20, 25kg PP or HDPE box or bottle 100, 200, 250, 500, 1000g</p> <p>General public:</p> <p>carton box with LDPE inner layer 100, 200, 250, 500, 750, 1000, 1500, 2000g PP or HDPE bucket 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5 PP or HDPE box or bottle 100, 200, 250, 500, 1000g</p>

4.2.1. Use-specific instructions

See general instructions for use

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

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

See general instructions for use

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

See general instructions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

Avoid continuous use of the product.

Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.

Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).

Alternate the use of this product with products containing active substances with a different mode of action, (to remove resistant individuals from the population).

It is important to disperse the granules over the surface of the dung within 3 days after introduction of livestock and then treat every new 10 cm thick dung layer. Disperse the granules evenly over the surface of the remaining dung after each removal of the dung.

The product has to be spread onto the manure's surface either with a measuring cup, or with an appropriate device, eg. hand held granule applicator according to the following dosing:

Piggeries, Cattle Stables:

Slatted floor: Apply on the 3rd day after the introduction of new livestock. Treat the whole floor of manure-pit.

It is necessary to

repeat treatment after each removal of dung.

Deep litter: Apply on every new layer of litter and repeat the treatment after every 8 - 10 cm increase of the layer.

Poultry Farms:

Cage: Treat the accumulated manure (every 10 cm thick layer) under the cages.

Deep litter: Apply on every new layer of litter and repeat the treatment after every 10 cm increase of the layer. In the case of very dry substrates (e.g. chicken litter), effect of the product may develop slower. Adding 100-200 mL water/m² to the substrate will facilitate development of the larvicidal effect in the case of very dry environmental conditions

Goat manure application in goat-folds and sheep-pens will not be authorized.

Dung stored outdoors:

it should only be treated if it is placed in a dung-pit which is leak-proof, insulated and corresponds to other requirements of safe dung storage. When treating dung stored outdoors, apply the product at the dosage of 30 g/m².

Stop treating the dung with the larvicide at least two months before spreading/ processing the dung in the fields.

The product can control the number of newly hatched adult flies for a period up to 12 weeks after treatment if above instructions for application are respected.

5.2. Risk mitigation measures

During application, observe the relevant regulations in order to avoid risk the environment or human health.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Prevent livestock from getting in contact with the product. Should this not be feasible, remove livestock for the duration of the treatment. Treat the dung accumulated under the slatted floor, metal grid, deep litter system or the cages.

Do not disperse the granules in the immediate surroundings of feeding and watering places or where the animals may consume the product. In the event that the animal's feed or drinking water might be contaminated, empty or cover the feeder and the water dispenser before treating the area.

Keep out of reach of children and domestic animals.

Keep away from food, drink and animal feedingstuffs.

DO NOT store with food, feedstuffs, seed and fertilisers.

Do not use in animal housings where exposure to a STP or direct emission to surface water cannot be prevented.

Resistance management

To prevent the development of resistance it is advised to use insecticides with a different mode of action as well in the pest control

program. In the case of Biopren 4 GR larvicide granule it is advised to use an adulticidal product, sticky traps and UV lamps after a few applications of the larvicidal product. Sticky traps can also be used for monitoring purposes.

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

Likely direct or indirect adverse effects:

- Repeated exposure may cause allergic disorders.

First aid measures:

- IF IN EYES: Rinse cautiously with water for 15 minutes. Remove contact lenses, if present and easy to do.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- IF exposed or concerned: Get medical advice/attention.

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

The empty containers and the remains of product should be disposed as hazardous waste.

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

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tore in original closed packaging in a dry and cool place protected from radiant heat and at max. 35 °C.

Store unused product in a well ventilated area and out of direct sunlight.

Shelf life: 3 years.

6. OTHER INFORMATION