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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Biopren 50 LFL Fly larvicide concentrate

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number:

R4BP asset number: NL-0027015-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Biopren 50 LFL PLUS larvicide concentrate Biopren 50 LFL PLUS larvicide concentraat LarvenOI Caps CS LarvO CS LarvOcide CS LarvOx Caps CS
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	LODI S.A.S.
	Address	Parc d'Activités des Quatre Routes 35390 Grand Fougeray France
Authorisation number		
<i>R4BP asset number</i>	NL-0027015-0000	
Date of the authorisation	04/06/2021	
Expiry date of the authorisation	04/06/2031	

1.3. Manufacturer(s) of the product

Name of manufacturer	Babolna Bioenvironmental Centre Plc
Address of manufacturer	Szállás utca 6 H-1107 Budapest Hungary
Location of manufacturing sites	Dr Köves János út 1-3 H-2943 Bábolna Hungary

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

Active substance	S-Methoprene
Name of manufacturer	Babolna Bioenvironmental Centre Plc
Address of manufacturer	Szállás utca 6 H-1107 Budapest Hungary
Location of manufacturing sites	Szállás utca 6 H-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		5,26
Polyethylene glycol (15)-hydroxystearate		Non-active substance	70142-34-6		11,58

2.2. Type(s) of formulation

ZW A mixed formulation of CS and EW

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long lasting effects.
Precautionary statements	P261: Avoid breathing spray. P280: Wear protective gloves. P280: Wear protective clothing. P302+P352: IF ON SKIN: Wash with plenty of water. P333+P313: If skin irritation or rash occurs: Get medical advice. P363: Wash contaminated clothing before reuse. P391: Collect spillage. P501: Dispose of contents to in accordance with local/regional/national/international regulation. P501: Dispose of container to in accordance with local/regional/national/international regulation. P273: Avoid release to the environment.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Insecticide – Professional use - larvicide

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)	<p>Scientific name: <i>Musca domestica</i> Common name: house fly Development stage: larvae</p> <p>Scientific name: <i>Stomoxys calcitrans</i> Common name: Stable fly Development stage: larvae</p> <p>Scientific name: <i>Eristalis tenax</i> Common name: Drone fly Development stage: larvae</p>
Field(s) of use	<p>indoor use outdoor use</p> <p>To be used in closed livestock buildings (poultry farms, piggeries, sheepfolds and cattle farms). Outdoor use only concerns the treatment of manure/slurry kept in a concrete basin (leak-proof insulated).</p>
Application method(s)	<p>Method: spraying</p> <p>Detailed description: 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: Treat the litter before the introduction of new livestock. Repeat the treatment by each manure layer of 8 - 10 cm thick.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.Maximum number of applications: six per year</p>
Application rate(s) and frequency	<p>Application Rate: Dosage to be applied to treat 100 m2 surface: 230-240 ml of BIOPREN 50 LFL concentrate diluted to 5 litres with water. Note: apply this dosage on approx. 10 cm thick manure Application rate: 2.3-2.4 g/m2. Maximum sprayer flow rate: 0.3-0.5 L/min</p> <p>Dilution (%): -</p> <p>Number and timing of application: The product can control the number of newly hatched adult flies up to 12 weeks after treatment. Expected time delay from the beginning of the application to the beginning of decrease in number of flies emerging is 2 -4 weeks. The biocidal effect is fully demonstrated after 8-12 weeks.</p>
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Bottle: coex PE/PA or HDPE , up to 10 L

Drum: HDPE drum up to 55 L Can: Coex PE/PA or HDPE , up to 10 L
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4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use

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 general directions for use

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

See general directions for use

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

See general directions for use

4.2. Use description

Table 2. Litter beetle - Professional use - larvicide

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: Alphetobius diaperinus Common name: 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: spraying Detailed description: 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.Maximum number of applications: six per year
Application rate(s) and frequency	Application Rate: Dosage to be applied to treat 100 m2 surface: 230-240 ml of BIOPREN 50 LFL concentrate diluted to 5 litres with water. Note: apply this dosage on approx. 10 cm thick manure Application rate: 2.3-2.4 g/m2. Maximum sprayer flow rate: 0.3-0.5 L/min Dilution (%): - Number and timing of application: 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.

Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	Bottle: coex PE/PA or HDPE , up to 10 L Drum: HDPE drum up to 55 L Can: Coex PE/PA or HDPE , up to 10 L

4.2.1. Use-specific instructions for use

See general directions for use

4.2.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Shake the concentrate well before use. Once the required quantity of concentrate is poured, close the bottle immediately.

Fill the sprayer with water to half of its volume, measure the quantity of concentrate given in the table and pour into the sprayer. After that, fill the sprayer to the desired volume, then mix the solution thoroughly. Keep the prepared working solution closed and use it up within 24 hours after preparation.

Shake the working solution from time to time during treatment or every time following longer standing.

Rinse the empty container three times and add rinses to the spray tank.

Contact of livestock with the product should be avoided. If this is not feasible, remove the animals during treatment. Treat the manure accumulated under the slatted floor and the cage or the deep litter system. Do not spray the working solution directly next to the feeding or drinking place or places where the animals may consume the product.

It is important to spray the surface of the manure within 3 days after the introduction of livestock, then treat every newly formed manure layer of 10 cm thick. After each removal of the manure, evenly treat the surface of the manure remaining in the stable.

In the case of very dry substrates effect of the product may develop slower. Adding 100-200 mL water/m² to the substrate may facilitate development of larvicide effect in the case of very dry environmental conditions.

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: Treat the litter before the introduction of new livestock. Repeat the treatment by each manure layer of 8 - 10 cm thick.

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.

Dosage to be applied to treat 100 m² surface: 230-240 ml of BIOPREN 50 LFL concentrate diluted to 5 litres with water. Note: apply this dosage on approx. 10 cm thick manure

Application rate: 2.3-2.4 g/m². Maximum sprayer flow rate: 0.3-0.5 L/min

-Inform the registration holder if the treatment is ineffective.

-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.

-Do not apply the product in areas where resistance to the active substance (s) contained in this product is suspected or established

5.2. Risk mitigation measures

Wear appropriate personal protection during mixing, loading and application of the product, including cleaning of the spray equipment (gloves and coverall).

To avoid any risk to humans and the environment, observe the directions for use and the provisions concerning health at work. Do not eat or smoke during work. Avoid contact with skin and eyes. Wash hands thoroughly with hot water and soap after use.

It is forbidden to use BIOPREN 50 LFL FLY LARVICIDE CONCENTRATE in case effluent/wastewater of the stable and/or manure deposit can directly leach into the sewer.

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.

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

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

The remnants of the product should be disposed of as hazardous waste.

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

Store in the closed, original container in a dry, cool, well ventilated area out of direct sunlight. Store product at temperatures between 5 and 40 °C.

Shelf life: 30 months.

6. OTHER INFORMATION

To prevent the development of insecticide resistance it is advised to:

- Products should always be used in accordance with label instructions.
- It is advised to use insecticides with different mode of action in rotation during the pest control program, especially if an extended period of control is required.
- Where possible, chemical treatments should be recommended to be combined with application of non-chemical measures (e.g. sticky traps or fly traps with UV lamps).
- Sufficient elimination of pest insects should be attempted in infested areas.
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance in the frame of IPM programs.