



# Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO  
FARMACEUTICO  
Ufficio 8 – Biocidi e cosmetici  
Viale Giorgio Ribotta, 5 - 00144 Roma  
PEC: dgfdm@postacert.sanita.it

I.5.i.d.2/1873

<Spazio riservato per l'apposizione  
dell'etichetta di protocollo>

Spett.le  
**Bábolna Bioenvironmental Centre Private  
Limited Company**  
Szállás u. 6  
H-1107, Budapest (Hungary)  
kover.zita@babolna-bio.com

**OGGETTO: Prodotto biocida: Biopren 4 GR PLUS Larvicide granule, SOLFAC LARVICIDA,  
SOLFAC ANTILARVALE.  
Case number: BC-CL088306-34  
Trasmissione decreto di modifica amministrativa dell'autorizzazione  
n. IT/2022/00789/MRS.**

Si trasmette, in allegato, il decreto di modifica amministrativa relativo al prodotto biocida indicato in oggetto.

Si richiama l'attenzione di codesta società su quanto disposto dal Regolamento (CE) n. 1272/2008 del Parlamento europeo e del Consiglio, del 16 dicembre 2008 e ss.mm.ii., relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze e delle miscele.

Si rammenta, inoltre, che codesta società, fermo restando quanto previsto dall'articolo 6 del Regolamento (UE) 354/2013 e dalla sezione 2 del titolo I, punto 11 del relativo allegato, ha l'obbligo di adeguare autonomamente gli stampati del prodotto alla vigente normativa in materia di etichettatura e sue eventuali modifiche, ai sensi dell'articolo 6 del decreto del Ministero della salute del 10 febbraio 2015, recante, *“Disciplina dell'iter procedimentale ai fini dell'adozione dei provvedimenti autorizzativi da parte dell'autorità competente previsti dal Regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi”*.

IL DIRETTORE DELL'UFFICIO  
dott.ssa Raffaella Perrone\*

\*Firma autografa sostituita a mezzo stampa, ai sensi dell'art. 3, comma 2, del D. Lgs. 39/1993

Referente tecnico: Fabio Caporale - e-mail: f.caporale@sanita.it

Referente amministrativo: Massimiliano Pullo - e-mail: m.pullo-esterno@sanita.it



# Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO  
UFFICIO 8  
IT/2022/00789/MRS

IL DIRETTORE DELL'UFFICIO

**VISTO** l'art. 15 della Legge n. 97 del 06 agosto 2013 recante "Disposizioni per l'adempimento degli obblighi derivanti dall'appartenenza dell'Italia all'Unione europea – Legge europea 2013";

**VISTO** il Regolamento (UE) 528/2012 del Parlamento Europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi e, in particolare, gli artt.19 e ss.;

**VISTO** il Regolamento di esecuzione (UE) N. 354/2013 della Commissione del 18 aprile 2013 sulle modifiche dei biocidi autorizzati a norma del regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio;

**VISTO** il decreto di prima autorizzazione del prodotto biocida di cui al dispositivo del presente decreto, rilasciato in data 21 gennaio 2020;

**VISTA** l'istanza NA-ADC, case number BC-CL088306-34, presentata sul Registro Europeo R4BP3 in data 23 agosto 2023;

**RITENUTA** la conformità di detta documentazione alla normativa vigente in materia di immissione sul mercato di biocidi;

## DECRETA

la modifica amministrativa dell'autorizzazione del prodotto biocida:

|  |  |
|--|--|
| <b>DENOMINAZIONE</b>   | <b>Biopren 4 GR PLUS Larvicide granule, SOLFAC LARVICIDA, SOLFAC ANTILARVALE</b>                                   |
| <b>PRINCIPIO ATTIVO:</b>   | <b>S-Methoprene</b>  |
| <b>TITOLARE DELL'AUTORIZZAZIONE<br/>RESPONSABILE DELL'IMMISSIONE SUL<br/>MERCATO</b> | <b>Bábolna Bioenvironmental Centre Private Limited<br/>Company<br/>Szállás u. 6<br/>H-1107, Budapest (Hungary)</b> |
| <b>NUMERO DI AUTORIZZAZIONE</b>  | <b>IT/2022/00789/MRS</b>   |
| <b>SCADENZA DELL'AUTORIZZAZIONE</b>  | <b>31 gennaio 2030</b>   |
| <b>TIPOLOGIA DI PRODOTTO</b>   | <b>PT18</b>  |

La società **Bábolna Bioenvironmental Centre Private Limited Company** è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato 1 (ulteriori condizioni dell'autorizzazione) e nell'allegato 2 SPC - sommario delle caratteristiche del prodotto, aggiornato e caricato nel Registro Europeo.

Avverso il presente atto è ammesso ricorso giurisdizionale presso il Tribunale Amministrativo Regionale competente entro il termine di sessanta giorni, ovvero ricorso straordinario al Capo dello Stato entro il termine di centoventi giorni. Il presente decreto entra in vigore il quindicesimo giorno successivo alla data di notifica.

Roma

IL DIRETTORE DELL'UFFICIO  
dott.ssa Raffaella Perrone

## Allegato 1

### Ulteriori Condizioni dell'Autorizzazione

#### ETICHETTATURA

- L'etichetta del prodotto biocida oggetto della presente autorizzazione dovrà essere redatta nel rispetto delle disposizioni di cui all'articolo 69 del Regolamento (UE) n.528/2012 riportando le informazioni di cui al sommario delle caratteristiche del prodotto riportato in Allegato I.
- Tutte le etichette del prodotto biocida devono riportare il numero di autorizzazione attribuito dal presente decreto, con la seguente dicitura:

***“PRODOTTO BIOCIDA (PT18)***

***AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2022/00789/MRS”***

- Per ogni categoria di utilizzatore autorizzata (Professionisti/ Professionisti formati/ Utilizzatori non professionisti) deve essere predisposta una etichetta distinta.
- L'etichetta dovrà contenere l'indicazione dell'officina di produzione e sito produttivo del formulato autorizzato.
- Nell'etichetta l'esatta denominazione del biocida dovrà comunque essere individuabile attraverso una colorazione e un carattere unici in contrasto con le altre eventuali colorazioni e caratteri usati nel testo degli stampati autorizzati.
- L'etichetta del prodotto non contiene le formule «biocida a basso rischio», «non tossico», «innocuo», «naturale», «rispettoso dell'ambiente», «rispettoso degli animali» o indicazioni analoghe comportanti una sottovalutazione degli effetti potenziali del prodotto da parte dell'utilizzatore e non devono riportare dizioni riferite al prodotto che possano generare confusione per quanto concerne i rischi che il prodotto comporta per l'uomo o l'ambiente.

È consentita l'immissione sul mercato dei biocidi a condizione che le indicazioni dell'etichetta siano redatte in lingua italiana.

## **Summary of product characteristics for a biocidal product**

# 1. Administrative information

## 1.1. Trade names of the product

| Market area | Trade name(s)                       |
|-------------|-------------------------------------|
| Italy       | Biopren 4 GR PLUS Larvicide granule |
| Italy       | SOLFAC LARVICIDA                    |
| Italy       | SOLFAC ANTILARVALE                  |

## 1.2. Authorisation holder

Authorisation number

Not defined

Date of the authorisation

Not defined

Expiry date of the authorisation

Not defined

Name and address of the  
authorisation holder

Name  
Address

Not defined

Not defined

## 1.3. Manufacturers of the product

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

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

BAS number: 1386

|                                 |   |
|---------------------------------|---|
| Name of the manufacturer        | Bábolna Bioenvironmental Centre Private Limited Company |
| Address of the manufacturer     | Szállás u. 6 1107 Budapest Hungary                      |
| Location of manufacturing sites | Szállás u 6 1107 Budapest Hungary                       |

# 2. Product composition and formulation

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

| BAS number | EC number | CAS number | Common name  | IUPAC name  | Function         | Content (%) |
|------------|-----------|------------|--------------|---|------------------|-------------|
| 1386       |           | 65733-16-6 | S-Methoprene | Isopropyl-(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate | Active Substance | 0.421       |

## 2.2. Type of formulation

GR - Granule

# 3. Hazard and precautionary statements

**Hazard statements** Contains *Polyethyleneglycol-15-hydroxystearat*. May produce an allergic reaction.  
Harmful to aquatic life with long lasting effects.

**Precautionary statements** If medical advice is needed, have product container or label at hand.  
Keep out of reach of children.

Avoid release to the environment.

Dispose of contents to in accordance with national regulations.

## 4. Authorised use(s)

### 4.1. Fly larvae - general public and professional

**Product type(s)** PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

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

**Field(s) of use** Indoor, Outdoor  
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.

**Category(ies) of users** Trained professional, Professional, General public (non-professional)

| Target organisms | Scientific name     | Common name  | Development stage |
|------------------|---------------------|--------------|-------------------|
|                  | Musca domestica     | House fly    | Larvae            |
|                  | Stomoxys calcitrans | Stable flies | Larvae            |
|                  | Eristalis tenax     | Drone fly    | Larvae            |

**Application method(s)**

**Method** Spreading

**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:

**Rate:** 30 g/m<sup>2</sup>

**Dilution:** 0%

**Timing:**

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<sup>2</sup> to the substrate will facilitate development of the larvicidal effect in the case of very dry environmental conditions.

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/m<sup>2</sup>.

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

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.

**Pack sizes and packaging material** Professional:

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

General public:

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

#### 4.1.1. Use-specific instructions for use

See general instructions for use

#### 4.1.2. Use-specific risk mitigation measures

See general instructions 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 instructions for use

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

See general instructions 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 instructions for use

### 4.2. litter beetle larvae - general public and professional

**Product type(s)** PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

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

**Field(s) of use** Indoor, Outdoor  
Indoor: manure in closed poultry houses

Outdoor: poultry manure-pit which is leak-proof, insulated.

**Category(ies) of users** Trained professional, Professional, General public (non-professional)

| Target organisms | Scientific name        | Common name                     | Development stage |
|------------------|------------------------|---------------------------------|-------------------|
|                  | Alphitobius diaperinus | litter beetle / Lesser mealworm | Larvae            |

**Application method(s)**

**Method** Spreading

**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:

**Rate:** 30 g/m<sup>2</sup>

**Dilution:** 0%

**Timing:**  
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.

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.

In the case of very dry substrates (e.g. chicken litter), effect of the product may develop slower. Adding 100-200 mL water/m<sup>2</sup> to the substrate will facilitate development of the larvicidal effect in the case of very dry environmental conditions.

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.

**Pack sizes and packaging material** Professional:

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

General public:

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

#### 4.2.1. Use-specific instructions for use

See general instructions for use

#### 4.2.2. Use-specific risk mitigation measures

See general instructions 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 instructions for use

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

See general instructions 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 instructions for use

## 5. General directions for use

### 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/m<sup>2</sup> 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/m<sup>2</sup>.

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.

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

S

Store 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

Not defined