

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1044
of 22 June 2021
granting a Union authorisation for the single biocidal product ‘Pesguard® Gel’

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 21 September 2016, Sumitomo Chemical Agro Europe SAS submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a single biocidal product named ‘Pesguard® Gel’ of product-type 18, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-HS027052-37 in the Register for Biocidal Products.
- (2) ‘Pesguard® Gel’ contains pyriproxyfen and clothianidin, as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 31 March 2020, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 13 October 2020, the Agency submitted to the Commission an opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Pesguard® Gel’ and the final assessment report on the single biocidal product in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Pesguard® Gel’ is a biocidal product, that it is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 26 October 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Pesguard® Gel’.
- (8) According to the opinion of the Agency, as regards the non-active substances cis CTAC and dichloromethane contained in ‘Pesguard® Gel’, it was not possible to conclude whether they meet the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ⁽³⁾ within the period for the evaluation of the application. Further examination of cis CTAC and dichloromethane should therefore take place. If it is concluded that either cis CTAC or dichloromethane or both are considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for ‘Pesguard® Gel’ in accordance with Article 48 of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 8 October 2020 on the Union authorisation of the biocidal product ‘Pesguard® Gel’ (ECHA/BPC/269/2020), <https://echa.europa.eu/it/opinions-on-union-authorisation>

⁽³⁾ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0024951-0000 is granted to Sumitomo Chemical Agro Europe SAS for the making available on the market and use of the single biocidal product 'Pesguard® Gel' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 15 July 2021 until 30 June 2031.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Pesguard® Gel

Product type 18 – Insecticides, acaricides and products to control other arthropods (Pest control)

Authorisation number: EU-0024951-0000

R4BP asset number: EU-0024951-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	Pesguard® Gel
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sumitomo Chemical Agro Europe SAS
	Address	Parc d'Affaires de Crécy 10A, rue de la Voie Lactée, 69370 Saint Didier au Mont d'Or, France
Authorisation number	EU-0024951-0000	
R4BP asset number	EU-0024951-0000	
Date of the authorisation	15 July 2021	
Expiry date of the authorisation	30 June 2031	

1.3. Manufacturer(s) of the product

Name of manufacturer	McLaughlin Gormley King Company (MGK)
Address of manufacturer	8810 10th Avenue North, MN 55427 Minneapolis United States
Location of manufacturing sites	McLaughlin Gormley King Company, 4001 Peavey Road, MN 55318 Chaska United States

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

Active substance	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3- methyl-2-nitroguanidine (Clothianidin)
Name of manufacturer	Sumitomo Chemical Co. Ltd
Address of manufacturer	27-1, Shinkawa 2-chome, Chuo-ku, 104-8260 Tokyo Japan
Location of manufacturing sites	Sumitomo Chemical Company LTD, Oita Works, 2200, Tsurusaki, Oita City,, 870-0106 Oita Japan

Active substance	pyriproxyfen
Name of manufacturer	Sumitomo Chemical Co. Ltd
Address of manufacturer	27-1, Shinkawa 2-chome, Chuo-ku, 104-8260 Tokyo Japan
Location of manufacturing sites	Sumitomo Chemical Company LTD, Misawa Works, Aza-Sabishirotaira, Oaza-Misawa, Misawa,, 033-0022 Aomori Japan

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 (%)
Clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	Active Substance	210880-92-5	433-460-1	0,526
pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	Active Substance	95737-68-1	429-800-1	0,515
Acetic acid	Ethanoic acid	Non-active substance	64-19-7	200-580-7	0,3
Potassium sorbate	potassium (E,E)-hexa-2,4-dienoate	Non-active substance	24634-61-5	246-376-1	0,5

2.2. Type of formulation

RB – Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects.
Precautionary statements	IF ON SKIN:Wash with plenty of water. If skin irritation or rash occurs: Get medical advice. Wear protective gloves. Avoid release to the environment. Dispose of container in accordance with local regulations. Collect spillage.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – Professional Use – RTU Bait

Product type	PT18 – Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	<p>Scientific name: <i>Blattella germanica</i> Common name: German cockroach Development stage: Nymphs</p> <p>Scientific name: <i>Blattella germanica</i> Common name: German cockroach Development stage: Adults</p> <p>Scientific name: <i>Supella longipalpa</i> Common name: Brown-banded cockroach Development stage: Nymphs</p> <p>Scientific name: <i>Supella longipalpa</i> Common name: Brown-banded cockroach Development stage: Adults</p> <p>Scientific name: <i>Blatta orientalis</i> Common name: Oriental Cockroach Development stage: Nymphs</p> <p>Scientific name: <i>Blatta orientalis</i> Common name: Oriental Cockroach Development stage: Adults</p> <p>Scientific name: <i>Periplaneta americana</i> Common name: American Cockroach Development stage: Nymphs</p> <p>Scientific name: <i>Periplaneta americana</i> Common name: American Cockroach Development stage: Adults</p>
Field(s) of use	Indoor In cracks and crevices, or in concealed locations inaccessible to humans or domestic animals: behind refrigerators cupboards and shelves, under kitchen appliances, in electrical control boxes, voids and ducting and under bathroom fixtures etc.
Application method(s)	Bait application A ready to use (RTU) insecticidal gel bait for the control of cockroaches in public hygiene
Application rate(s) and frequency	<p>Pesguard® Gel should be applied as a number of spots of approximately 4 mm diameter (each spot comprising approximately 0,032 g of bait). In cases of severe infestation, where larger cockroach species are present (<i>B. orientalis</i> or <i>P. americana</i>), in areas that are particularly dirty or cluttered or where alternative sources of food cannot be entirely eliminated the higher application rate (e.g. 2 instead of 1 spot per m² in case of a light infestation) should be used.</p> <ul style="list-style-type: none"> • Light infestation 1 – 2 (0,032 – 0,064 g) spots per m² • Medium infestation 3 – 6 (0,096 – 0,192 g) spots per m² • Heavy infestation 6 – 10 (0,192 – 0,320 g) spots per m² <p>The maximum number of annual applications is 11.</p>

Category(ies) of users	Professional
Pack sizes and packaging material	30 g Polypropylene (PP) syringe Screw top cap High Density Poly Ethylene (HDPE)

4.1.1. *Use-specific instructions for use*

See the general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See the 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 the general directions for use.

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

See the 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 the general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

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

Do not expose bait drops to sunlight or heat (e.g. radiator).

The pre-filled plastic reservoir containing Pesguard® Gel is intended for use with the plunger provided or a specific bait application device common to the pest control industry. Refer to the manufacturer's instructions for directions on the use of the applicator.

Inject the bait into cracks and crevices, void spaces, or in concealed locations inaccessible to humans or domestic animals where insects may live, feed and breed. Such areas are generally warm/damp and dark (behind refrigerators, cupboards and shelves, under kitchen appliances, in electrical control boxes, voids and ducting and under bathroom fixtures etc.). Inspection or trapping to confirm infestation is recommended prior to treatment. Ensure that any alternative food sources are removed and concentrate the bait placements as individual spots at cockroach activity sites. The product should not be applied to areas accessible to children and pets.

Do not apply Pesguard® Gel where it will come into contact with water or in areas that are routinely cleaned. Typically cockroaches will die a few hours after a single feed on Pesguard® Gel. In infested premises, dead cockroaches will normally be seen within 24 hours of treatment.

Remove the cap from the nozzle, touch the top to the surface to be treated, and push down on the plunger. Replace the cap on the dispenser after treatment is completed.

The bait will adhere to non-greasy or non-dusty surfaces and will remain pliable and palatable to cockroaches as long as it is visibly present.

Treated area's should be visually inspected after 1-2 weeks. Where initial infestation was heavy a second Pesguard® Gel application may be required if the first treatment has been consumed and live cockroaches are still present.

A second visual inspection of bait placements is recommended 2-4 weeks after the initial treatment. Reapply when bait is no longer visibly present, according to the level of infestation (light, medium or heavy). Replace bait before it is completely consumed to keep cockroaches from returning.

Inform the registration holder if the treatment is ineffective.

Spills and residues containing the product need to be removed as chemical waste.

Care should be taken to avoid depositing gel onto exposed surfaces. If gel contacts an exposed surface, remove gel with a paper towel and clean the area with disposable wet wipes.

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

During follow-up visits, inspect bait placements and re-apply when necessary.

Do not place bait in locations that are routinely washed, as bait will be removed by washing. Do not use this product in or on electrical equipment where a possibility of shock hazard exists. Avoid contact with textiles and clothing, as bait may stain.

5.2. Risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Do not apply bait in areas where repellent insecticides have been used without thoroughly cleaning the surface with disposable wet tissue. Do not apply repellent insecticides after application of the bait.

Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

Spills and residues containing the product must be removed as chemical waste.

Avoid placing gel on fabrics or carpets since it may stain some absorbent materials. To prevent staining, exposed bait should be cleaned up immediately with disposable wet wipes.

Cleaning materials must be disposed of as to solid waste.

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

This biocidal product contains clothianidin, which is dangerous to bees.

Description of first aid measures

Skin contact: Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation persists after washing.

Eye contact: If symptoms occur, rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Ingestion: If swallowed: If symptoms occur call a POISON CENTRE or a doctor.

If inhaled: not applicable.

Most important symptoms and effects, both acute and delayed

Eyes: May cause temporary eye irritation.

Emergency measures to protect the environment

Avoid release of the product to the environment.

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

Only pass on empty containers/packaging for recycling.

Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Protect from frost. Store away from direct sunlight.

Shelf life: 2 years.

6. **OTHER INFORMATION**
