



2024/2199

5.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2199

of 4 September 2024

amending Implementing Regulation (EU) 2021/1044 as regards administrative and minor changes to the 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 Article 50(2) thereof,

Whereas:

- (1) On 22 June 2021, a Union authorisation with authorisation number EU-0024951-0000 was granted to Sumitomo Chemical Agro Europe SAS for the making available on the market and use of the single biocidal product ‘Pesguard® Gel’ by Commission Implementing Regulation (EU) 2021/1044 ⁽²⁾. The Annex to that Implementing Regulation provides the summary of product characteristics (‘SPC’) for the single biocidal product ‘Pesguard® Gel’ in accordance with Article 22 of Regulation (EU) No 528/2012.
- (2) Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾ lays down the procedural rules for the different categories of changes referred to in Article 50(3) of Regulation (EU) No 528/2012. On receipt of an opinion from the European Chemicals Agency (‘the Agency’) on an application from an authorisation holder of a Union authorisation seeking to change any of the information submitted for the initial application for authorisation, the Commission is to decide whether the conditions of Article 19 or, where relevant, Article 25 of Regulation (EU) No 528/2012, are still met and whether the terms and conditions of the authorisation need to be amended.
- (3) On 8 April 2022, Sumitomo Chemical Agro Europe SAS submitted to the Agency an application for a minor change to the Union authorisation for the single biocidal product ‘Pesguard® Gel’ in accordance with Article 12(1) of Implementing Regulation (EU) No 354/2013, recorded in the register for biocidal products (‘the Register’) under case number BC-BL074962-31, for the increase of the concentration of two substances of concern in the product. In addition, the authorisation holder notified changes in the manufacturing site and administrative details of active substances manufacturers in accordance with Article 11(1) of that regulation.
- (4) On 31 July 2023, Sumitomo Chemical Agro Europe SAS submitted to the Agency a notification of further administrative change to add a trade name to the Union authorisation for the single biocidal product ‘Pesguard® Gel’, in accordance with Article 11(1) of Implementing Regulation (EU) No 354/2013, recorded in the Register under case number BC-RB088051-50.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) 2021/1044 of 22 June 2021 granting a Union authorisation for the single biocidal product ‘Pesguard® Gel’ (OJ L 225, 25.6.2021, p. 54, ELI: http://data.europa.eu/eli/reg_impl/2021/1044/oj).

⁽³⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

- (5) On 7 September 2023, the Agency submitted an opinion⁽⁴⁾ to the Commission on the notified administrative change to the Union authorisation for the single biocidal product 'Pesguard® Gel' of 31 July 2023, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013, together with a revised SPC. The opinion concludes that the proposed addition of a new trade name is an administrative change in accordance with Article 3(1), point (aa), of Regulation (EU) No 528/2012 and as specified in Title 1 of the Annex to Implementing Regulation (EU) No 354/2013, and that after the implementation of the change, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.
- (6) On 9 October 2023, the Agency submitted an opinion⁽⁵⁾ to the Commission on the application for minor changes to the Union authorisation for the biocidal product 'Pesguard® Gel' of 8 April 2022, in accordance with Article 12(4) of Implementing Regulation (EU) No 354/2013, together with a revised SPC and a revised assessment report. This opinion concluded that the increase of the concentration of two substances of concern in the product is not a minor change in accordance with Article 3(1), point (ab), of Regulation (EU) No 528/2012 and as specified in Title 2 of the Annex to Implementing Regulation (EU) No 354/2013. However, the Agency concluded that the changes related to the addition of a new manufacturing site for the active substance chlothianidin and a change in the address of the manufacturer of the two active substances are administrative changes in accordance with Article 3(1), point (aa), of Regulation (EU) No 528/2012 as specified in Title 1 of the Annex to Implementing Regulation (EU) No 354/2013, and that after the implementation of those changes, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.
- (7) On 10 November 2023, the Agency transmitted to the Commission the revised SPC of the Union authorisation for single the biocidal product 'Pesguard® Gel' in all official languages of the Union covering all administrative changes applied for, in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (8) The Commission concurs with the opinions of the Agency and therefore considers it appropriate to amend the Union authorisation for the single biocidal product 'Pesguard® Gel' to introduce the administrative changes requested by Sumitomo Chemical Agro Europe SAS and supported by the Agency.
- (9) The application for the increase of the concentration of two substances of concern in the product cannot be considered as a minor change in accordance with Article 3(1), point (ab), of Regulation (EU) No 528/2012 and as specified in Title 2, point 1, of the Annex to Implementing Regulation (EU) No 354/2013. Such a change would be a major change, for which an application for major change, in accordance with Article 13 of Implementing Regulation (EU) No 354/2013, would be necessary in order to ensure its appropriate evaluation. Due to the absence of such assessment, the Commission cannot determine whether the conditions of Article 19 of Regulation (EU) No 528/2012 would still be met and whether the authorisation could be amended. This part of the application for the increase of the concentration of two substances of concern should therefore be rejected.
- (10) Except for the amendments regarding the administrative changes, all other information included in the SPC of 'Pesguard® Gel' as set out in the Annex to Implementing Regulation (EU) 2021/1044 remains unchanged.
- (11) In order to enhance clarity and to ease the access of users and interested parties to the final consolidated version of the SPC which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2021/1044 should be replaced in its entirety.
- (12) Implementing Regulation (EU) 2021/1044 should therefore be amended accordingly,

⁽⁴⁾ ECHA Opinion on the administrative change of the Union authorisation of the single biocidal product 'Pesguard® Gel' of 7 September 2023, Opinion N° UAD-C-1680571-32-00/F (<https://echa.europa.eu/opinions-on-union-authorisation>).

⁽⁵⁾ Biocidal Products Committee (BPC) opinion on the minor change to the Union authorisation of the single biocidal product 'Pesguard® Gel' of 9 October 2023, ECHA/BPC/395/2023 (<https://echa.europa.eu/opinions-on-union-authorisation>).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2021/1044 is replaced by the text in the Annex to this Regulation.

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, 4 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Pesguard® Gel

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

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 GOLIATH®GEL NEW |
|---------------|----------------------------------|

1.2. Authorisation holder

| | | |
|--|-------------------|---|
| Name and address of the authorisation holder | Name | Sumitomo Chemical Agro Europe SAS |
| | Address | 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 | 25 September 2024 | |
| Expiry date of the authorisation | 30 June 2026 | |

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 (the) |
| Location of manufacturing sites | McLaughlin Gormley King Company, 4001 Peavey Road, MN 55318, Chaska, United States (the) |

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

| | |
|-------------------------|---|
| Active substance | (E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitro-guanidine (Clothianidin) |
| Name of manufacturer | Sumitomo Chemical Co. Ltd. |
| Address of manufacturer | 7-1, Nihonbashi 2-chome, Chuo-ku 103-6020 Tokyo, Japan |

| | |
|---------------------------------|---|
| Location of manufacturing sites | Sumitomo Chemical Company LTD, Oita Works, 2200, Tsurusaki, Oita City, 870-0106 Oita, Japan Jiangsu Flag Chemical Industry Co., Ltd., No. 309, Changfenghe Road, Nanjing Chemical, Industry Park 210047 Nanjing, China |
| Active substance | pyriproxyfen |
| Name of manufacturer | Sumitomo Chemical Co. Ltd. |
| Address of manufacturer | 7-1, Nihonbashi 2-chome, Chuo-ku 103-6020 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 (%) |
|--|---|----------------------|-------------|-----------|-------------|
| (E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin) | | 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(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|-------------------|---|
| Hazard statements | H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects. |
|-------------------|---|

| | |
|--------------------------|---|
| Precautionary statements | <p>P302 + P352: IF ON SKIN: Wash with plenty of water.</p> <p>P333 + P313: If skin irritation or rash occurs: Get medical advice.</p> <p>P280: Wear protective gloves.</p> <p>P273: Avoid release to the environment.</p> <p>P501: Dispose of container to in accordance with local regulations.</p> <p>P391: Collect spillage.</p> |
|--------------------------|---|

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Professional Use – RTU Bait

| | |
|--|---|
| 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>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 | <p>indoor use</p> <p>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.</p> |

| | |
|-----------------------------------|--|
| Application method(s) | Method: bait application Detailed description: A ready to use (RTU) insecticidal gel bait for the control of cockroaches in public hygiene |
| Application rate(s) and frequency | Application Rate: Pesguard® Gel should be applied as a number of spots of approximately 4 mm diameter (each spot comprising approximately 0,032 g of bait). Dilution (%): 0 Number and timing of application: 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 m ² in case of a light infestation) should be used. — Light infestation 1–2 (0,032–0,064 g) spots per m ² — Medium infestation 3–6 (0,096–0,192 g) spots per m ² — Heavy infestation 6–10 (0,192–0,320 g) spots per m ² The maximum number of annual applications is 11. |
| 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.

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

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 only be applied to areas inaccessible 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 areas 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.

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 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.

Likely direct or indirect effects

No adverse effects expected when used as directed.

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

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