

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2109**of 30 November 2021****amending Implementing Regulation (EU) 2020/704 to make administrative changes to the Union authorisation of the biocidal product family 'INSECTICIDES FOR HOME USE'****(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) and Article 50(2) thereof,

Whereas:

- (1) On 26 May 2020, Commission Implementing Regulation (EU) 2020/704 ⁽²⁾ granted a Union authorisation with authorisation number EU-0021035-0000 to Agrobioters Laboratoire for the making available on the market and use of the biocidal product family 'INSECTICIDES FOR HOME USE'.
- (2) On 8 September 2020, Agrobioters Laboratoire submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾, regarding the administrative changes to the Union authorisation for the biocidal product family 'INSECTICIDES FOR HOME USE' referred to in Section 1 of Title 1 of the Annex to that Regulation.
- (3) Agrobioters Laboratoire proposed the addition of trade names in the third information level: individual products in the meta SPC 1, of the summary of the product characteristics for the biocidal product family 'INSECTICIDES FOR HOME USE' as set out in Annex II to Implementing Regulation (EU) 2020/704. The notification was recorded under the case number BC-DR061688-14 in the Register for Biocidal Products.
- (4) On 12 October 2020, the Agency submitted an opinion ⁽⁴⁾ on the proposed changes to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder fall under Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 of that Regulation are still met. On the same date, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'INSECTICIDES FOR HOME USE'.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2020/704 of 26 May 2020 granting a Union authorisation for the biocidal product family 'INSECTICIDES FOR HOME USE' (OJ L 164, 27.5.2020, p. 19).

⁽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).

⁽⁴⁾ ECHA opinion of 9 October 2020 on the administrative change of the Union authorisation of the biocidal product family 'INSECTICIDES FOR HOME USE', https://echa.europa.eu/documents/10162/22836226/opinion_for_ua-admin_change_bc-dr061688-14_en.pdf/90bc7c1f-ed8e-a127-982c-4f08b3af513f

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Implementing Regulation (EU) 2020/704 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, 30 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

ANNEX II

Summary of product characteristics for a biocidal product family

INSECTICIDES FOR HOME USE

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

Authorisation number: EU-0021035-0000

R4BP asset number: EU-0021035-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	INSECTICIDES FOR HOME USE
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1.2. Product type(s)

Product type(s)	PT18 – Insecticides, acaricides and products to control other arthropods (Pest control)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Agrobiothers Laboratoire
	Address	ZI Route des Platières, 71290 CUISERY, France
Authorisation number	EU-0021035-0000	
R4BP asset number	EU-0021035-0000	
Date of the authorisation	16 June 2020	
Expiry date of the authorisation	31 May 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Agrobiothers Laboratoire
Address of manufacturer	ZI Route des Platières, 71290 CUISERY France
Location of manufacturing sites	AF3 16 rue de l'Oberwald, 68360 Soultz France

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Ltd. (Art.95 List: LIMARU NV (Acting for Tagros Chemicals India Private Limited)
Address of manufacturer	Jhaver Centre, Rajah Annamalai Bldg., IV floor 72 Marshal's road Egmore, 600008 Chennai India
Location of manufacturing sites	A-4/1&2, Sipcot Industrial Complex, Pachayankuppam Cuddalore, 607 005 Tamilnadu India
Active substance	S-Methoprene
Name of manufacturer	Babolna bio Ltd.
Address of manufacturer	Szallas u.6 H-, 1107 Budapest Hungary
Location of manufacturing sites	Szallas u.6 H-, 1107 Budapest Hungary

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Permethrin		Active Substance	52645-53-1	258-067-9	0,177	0,177
S-Methoprene		Active Substance	65733-16-6		0,00225	0,00225
Propan-2-ol	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3,33475	3,33475
n-butane	n-butane	Non-active substance	106-97-8	203-448-7	63,458	63,458
propane	propane	Non-active substance	74-98-6	200-827-9	16,271	16,271
isobutane	isobutane	Non-active substance	75-28-5	200-857-2	4,068	4,068

2.2. **Type(s) of formulation**

Formulation(s)	AE – Aerosol dispenser
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PART II

SECOND INFORMATION LEVEL – META SPC(S)

Meta SPC 11. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

Identifier	Meta-SPC1: INSECTICIDE HOUSEHOLD SPRAY
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT18 – Insecticides, acaricides and products to control other arthropods (Pest control)
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Permethrin		Active Substance	52645-53-1	258-067-9	0,177	0,177
S-Methoprene		Active Substance	65733-16-6		0,00225	0,00225
Propan-2-ol	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3,33475	3,33475
n-butane	n-butane	Non-active substance	106-97-8	203-448-7	63,458	63,458
propane	propane	Non-active substance	74-98-6	200-827-9	16,271	16,271
isobutane	isobutane	Non-active substance	75-28-5	200-857-2	4,068	4,068

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	AE – Aerosol dispenser
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Extremely flammable aerosol. Pressurised container: May burst if heated May be fatal if swallowed and enters airways. Causes serious eye irritation. Very toxic to aquatic life with long lasting effects. Contains PERMETHRIN. May produce an allergic reaction.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Wash hands thoroughly after handling.

	<p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>If eye irritation persists: Get medical advice.</p> <p>Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F.</p> <p>Store at temperatures not exceeding 40 °C/104 °F.</p> <p>Avoid release to the environment.</p> <p>Collect spillage.</p> <p>Dispose of contents/container in accordance with local regulation</p>
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4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1. Use # 1 – Insecticide household spray

Product type	PT18 – Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Fleas (larvae and adults): e.g. <i>Ctenocephalides felis</i></p> <p>Ticks: <i>Ixodes ricinus</i> <i>Rhipicephalus sanguineus</i></p>
Field(s) of use	<p>Indoor</p> <p>Targeted treatment of non-washable furniture and home textile such as carpets, mats, arm chairs</p>
Application method(s)	<p>Spraying</p> <p>After vacuuming the surface to be treated, the product is sprayed at a distance of 30 cm.</p>
Application rate(s) and frequency	<p>1, 3 second spray treat for approximately 1 m² (2,1 g/m²)</p> <p>The minimum time interval between two treatments is 6 months.</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	<p>Tin plate aerosol can with internal coating made of epoxy phenolic protective lacquer (250mL or 500mL)</p> <p>Tin plate aerosol can without internal coating (300 mL)</p>

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 direction 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

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1**

5.1. **Instructions for use**

- The product is to be used for targeted treatment of non-washable furniture and home textile as carpets, mats, arm chairs.
- Always read the label or leaflet before use and respect all the instructions provided.
- Respect the recommended application doses.
- Residual efficacy until up to 6 months that can be lowered in case of normal cleaning (e.g. vacuum on carpets) or extensive use of the surfaces (e.g., walking, friction).
- In case of continuous infestation, use alternate products containing active substances with a different mode of action in order to avoid the occurrence of resistance. This is to remove the resistant individuals from the population.
- If the infestation persists despite following the instructions of the label/leaflet, contact a pest control professional.
- Do not use on cats and other animals or pet baskets for cats.
- Inform the authorisation holder if the treatment is ineffective.

5.2. **Risk mitigation measures**

- Do not use on wet washable surfaces and textile.
- Do not wash furniture with wet wiping clothes and do not wet clean carpets or mats to avoid discharges into the sewer system.
- Remove all food, feed and drinks prior treatment.
- Do not use on surfaces and facilities in the vicinity or likely to be in contact with food, feed and drinks.
- Avoid contact with eyes.
- After spraying, leave the room and let act for 1 hour before airing.
- Remove or cover terrariums, aquariums and animal cages before application.
- Turn off aquarium air-filter while spraying.
- Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.
- Keep children and pets away during treatment.

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

- Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.

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

- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- Keep the container or label available.
- Permethrin may be dangerous for cats. If signs of poisoning occur, seek veterinary advice immediately and show the package to a veterinarian.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 24 months
- Do not store at a temperature higher than 40 °C
- Do not expose to direct sunlight
- Protect from frost

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	
	FRONTLINE PET CARE SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT SPRAY ANTIPARASITAIRE POUR L'HABITAT 300 ML FRISKIES INSECTICIDE HABITAT/HOME VETOCANIS FRONTLINE HOMEGARD SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT INSECTICIDE HABITAT/HOME VITALVETO SPRAY INSECTICIDE POUR L'HABITAT VITALVETO/INSECTICIDE HOUSEHOLD SPRAY VITALVETO SPRAY INSECTICIDE POUR L'HABITAT VETOCANIS/INSECTICIDE HOUSEHOLD SPRAY VETOCANIS FRONTLINE HOMEGARD Husholdningssspray med insekticid og acaricid FRONTLINE HOMEGARD Insecticide and acaricide household spray FRONTLINE HOMEGARD Hyönteisten ja punkkien torjuntasuihke kotitalouksille FRONTLINE HOMEGARD insektizides und akarizides Haushaltsspray FRONTLINE HOMEGARD Spray εντομοκτόνο και ακαρεοκτόνο σπρέι οικιακής χρήσης FRONTLINE HOMEGARD Spray insetticida e acaricida per l'ambiente domestico FRONTLINE HOMEGARD Insecticide en acaricidespray voor huishoudelijk gebruik FRONTLINE HOMEGARD Husholdningssspray med insekticid og acaricid FRONTLINE HOMEGARD INSETICIDA E ACARICIDA EM SPRAY PARA USO DOMÉSTICO

FRONTLINE HOMEGARD Hushålls-spray med insekticid och akaricid					
Authorisation number	EU-0021035-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin		Active Substance	52645-53-1	258-067-9	0,177
S-Methoprene		Active Substance	65733-16-6		0,00225
Propan-2-ol	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3,33475
n-butane	n-butane	Non-active substance	106-97-8	203-448-7	63,458
propane	propane	Non-active substance	74-98-6	200-827-9	16,271
isobutane	isobutane	Non-active substance	75-28-5	200-857-2	4,068'