

COMMISSION IMPLEMENTING REGULATION (EU) 2020/704**of 26 May 2020****granting a Union authorisation for 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) thereof,

Whereas:

- (1) On 6 October 2016, Agrobiothers Laboratoire, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'INSECTICIDES FOR HOME USE' of product-type 18, as described in Annex V to that Regulation, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under the case number BC-TW023858-93 in the Register for Biocidal Products.
- (2) 'INSECTICIDES FOR HOME USE' contains permethrin and S-Methoprene, 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 10 December 2018, 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 11 July 2019, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics ('SPC') of 'INSECTICIDES FOR HOME USE' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'INSECTICIDES FOR HOME USE' is a 'biocidal product family' within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 25 July 2019, 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 'INSECTICIDES FOR HOME USE'.
- (8) In the opinion the Agency recommends that a new shelf-life study of INSECTICIDE HOUSEHOLD SPRAY in packagings in which the product will be made available on the market, be conducted by the authorisation holder as a condition of the authorisation. The study should determine the active substance contents, the cis/trans ratio of permethrin and the technical properties of INSECTICIDE HOUSEHOLD SPRAY before and after storage. The Commission agrees with that recommendation and considers that the submission of the results of that study should be a condition relating to the making available on the market and use of the biocidal product family pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1)(d) of that Regulation on the basis of the existing data.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 26 June 2019 on the Union authorisation of 'INSECTICIDES FOR HOME USE' (ECHA/BPC/228/2019), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

- (9) According to the opinion of the Agency, as regards the non-active substance nitromethane contained in the biocidal product family 'INSECTICIDES FOR HOME USE', it was not possible to conclude whether it meets 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 nitromethane should therefore take place. If it is eventually concluded that nitromethane is considered as having endocrine-disrupting properties, the Commission will consider whether the Union authorisation for the biocidal product family 'INSECTICIDES FOR HOME USE' has to be cancelled or amended in accordance with Article 48 of Regulation (EU) No 528/2012.
- (10) 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-0021035-0000 is granted to Agrobiothers Laboratoire for the making available on the market and use of the biocidal product family 'INSECTICIDES FOR HOME USE' subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 16 June 2020 until 31 May 2030.

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, 26 May 2020.

For the Commission

The President

Ursula VON DER LEYEN

⁽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).

ANNEX I

Terms and conditions (EU-0021035-0000)

The authorisation holder shall conduct a shelf life study of INSECTICIDE HOUSEHOLD SPRAY in packagings in which the product will be made available on the market. The study shall determine the active substance contents, the cis/trans ratio of permethrin, the spray pattern, the functioning of the trigger device, the discharge rate and the mass median aerodynamic diameter, before and after storage.

By 16 December 2022 the authorisation holder shall submit the results of the study to the Agency.

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 1

1. 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. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F.

	Store at temperatures not exceeding 40 °C/104 °F. Avoid release to the environment. Collect spillage. Dispose of contents/container in accordance with local regulation
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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)	Fleas (larvae and adults): e.g. <i>Ctenocephalides felis</i> Ticks: <i>Ixodes ricinus</i> <i>Rhipicephalus sanguineus</i>
Field(s) of use	Indoor Targeted treatment of non-washable furniture and home textile such as carpets, mats, arm chairs
Application method(s)	Spraying After vacuuming the surface to be treated, the product is sprayed at a distance of 30 cm.
Application rate(s) and frequency	1,3 second spray treat for approximately 1 m ² (2,1 g/m ²) The minimum time interval between two treatments is 6 months.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Tin plate aerosol can with internal coating made of epoxy phenolic protective lacquer (250 mL or 500 mL) Tin plate aerosol can without internal coating (300 mL)

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 no 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 one 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.
- 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.

⁽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.

- 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				
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
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