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)

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.

(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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/704. (See end of Document for details)*

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

1.2. **Product type(s)**

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

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	

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/704. (See end of Document for details)*

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