



Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE, DEI DISPOSITIVI MEDICI,
DEL FARMACO E DELLE POLITICHE IN FAVORE DEL SERVIZIO
SANITARIO NAZIONALE
EX DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL
SERVIZIO FARMACEUTICO
Ufficio 8 – Biocidi e cosmetici
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<Spazio riservato per l'apposizione
dell'etichetta di protocollo>

I.5.i.d.2/602

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OGGETTO: Prodotto biocida: Vespamayer Schiumogeno Plus
Case number: BC-AE092031-67
Trasmissione decreto di trasferimento di titolarità dell'autorizzazione
n. IT/2017/00401/AUT

Si trasmette, in allegato, il decreto di trasferimento di titolarità dell'autorizzazione relativa al biocida indicato in oggetto.

Si richiama l'attenzione di codesta società su quanto disposto dal Regolamento (CE) n. 1272/2008 del Parlamento europeo e del Consiglio, del 16 dicembre 2008 e ss.mm.ii., relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze e delle miscele.

Si rammenta, inoltre, che codesta società, fermo restando quanto previsto dall'articolo 6 del Regolamento (UE) 354/2013 e dalla sezione 2 del titoli I, punto 11 del relativo allegato, ha l'obbligo di adeguare autonomamente gli stampati del prodotto alla vigente normativa in materia di etichettatura e sue eventuali modifiche, ai sensi dell'articolo 6 del decreto del Ministero della salute del 10 febbraio 2015, recante, *“Disciplina dell'iter procedimentale ai fini dell'adozione dei provvedimenti autorizzativi da parte dell'autorità competente previsti dal Regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi”*.

IL DIRETTORE DELL'UFFICIO
dott.ssa Raffaella Perrone*

*Firma autografa sostituita a mezzo stampa, ai sensi dell'art. 3, comma 2, del D. Lgs. 39/1993

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Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE, DEI DISPOSITIVI MEDICI, DEL FARMACO E
DELLE POLITICHE IN FAVORE DEL SERVIZIO SANITARIO NAZIONALE
EX DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL
SERVIZIO FARMACEUTICO - UFFICIO 8
IT/2017/00401/AUT

IL DIRETTORE DELL'UFFICIO

VISTO il Regolamento (UE) 528/2012 del Parlamento Europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi e, in particolare, gli artt.19 e ss.;

VISTO il Regolamento di esecuzione (UE) N. 354/2013 della Commissione del 18 aprile 2013 sulle modifiche dei biocidi autorizzati a norma del regolamento (UE) n. 528/2012 del Parlamento europeo e del Consiglio;

VISTA l'istanza NA-TRS, case number BC-AE092031-67, presentata sul Registro Europeo R4BP3 in data 26 gennaio 2024;

VISTA la documentazione presentata dalla società richiedente a sostegno della suddetta istanza e accertata la conformità di detta documentazione alla normativa vigente in materia di immissione sul mercato di biocidi;

DECRETA

il trasferimento di titolarità dell'autorizzazione del prodotto biocida:

DENOMINAZIONE	Vespamayer Schiumogeno Plus
PRINCIPIO ATTIVO:	etofenprox
TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO	MAYER BRAUN SRL via Brigata Marche 129 31030 Carbonera (TV)
NUMERO DI AUTORIZZAZIONE	IT/2017/00401/AUT
SCADENZA DELL'AUTORIZZAZIONE	30 giugno 2025
TIPOLOGIA DI PRODOTTO	PT18

La società **MAYER BRAUN SRL** è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato 1 SPC - sommario delle caratteristiche del prodotto, aggiornato e caricato nel Registro Europeo.

Avverso il presente atto è ammesso ricorso giurisdizionale presso il Tribunale Amministrativo Regionale competente entro il termine di sessanta giorni, ovvero ricorso straordinario al Capo dello Stato entro il termine di centoventi giorni.

Roma

IL DIRETTORE DELL'UFFICIO
dott.ssa Raffaella Perrone

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Vespamayer Schiumogeno Plus

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number:

R4BP asset number:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Vespamayer Schiumogeno Plus
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	
	Address	
Authorisation number		
<i>R4BP asset number</i>		
Date of the authorisation		
Expiry date of the authorisation		

1.3. Manufacturer(s) of the product

Name of manufacturer	MAYER BRAUN DEUTSCHLAND S.R.L.
Address of manufacturer	VIA BRIGATA MARCHE 129 31030 CARBONERA Italy
Location of manufacturing sites	MAYER BRAUN DEUTSCHLAND S.R.L. site 1 TOSVAR SRL - Via del Lavoro 10 20060 Pozzo D'Adda (MI) Italy MAYER BRAUN DEUTSCHLAND S.R.L. site 2 BERGEN SRL Via Roma 90 37060 Castel d'Azzano Italy

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

Active substance	etofenprox
Name of manufacturer	Mitsui Chemicals Agro, Inc.
Address of manufacturer	1-5-2 Higashi-shimbashi, Minato-Ku 105-7117 Tokyo Japan
Location of manufacturing sites	Mitsui Chemicals Agro, Inc. site 1 Omuta Works, 30 Asamuta-machi, Ohmuta-shi 836-8610 Fukuoka 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 (%)
etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether	active substance	80844-07-1	407-980-2	0,5

2.2. Type(s) of formulation

AE Aerosol dispenser

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H222 : Extremely flammable aerosol, H229 : Pressurised container: May burst if heated H229: Pressurised container: May burst if heated H362: May cause harm to breast-fed children. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P260: Do not breathe spray. P263: Avoid contact during pregnancy and while nursing. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P403: Store in a well-ventilated place. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C/ 122°F. P501: Dispose of container to local rules. P102: Keep out of reach of children. P251: Do not pierce or burn, even after use.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Nest application

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	No authorized use. New product.
Target organism(s) (including development stage)	Scientific name: Hymenoptera: Vespinae: Hymenoptera: Vespinae: Common name: common wasp Development stage: adults
Field(s) of use	indoor use outdoor use Vespamayer Schiumogeno Plus is an indoor/outdoor spray can insecticide specific for wasps.
Application method(s)	Method: foam application Detailed description: The biocide product must be spray at least 2-3 meters from the target area in order to irrogate the nest.
Application rate(s) and frequency	Application rate: 15 g for nest / application Dilution (%): 0 Number and timing of application: One application for nest. In case repeat the application after 2/4 days.
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	Aerosol can, Tin , 200, 250, 300, 350, 400, 450, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950, 1000 mL None None

4.1.1. Use-specific instructions

The product is a ready to use spray aerosol. Spray at a distance of 2-3 meters from the target area and being careful to spray accurately the wasp nest so that the foam wrap them. Before use on specific surface, it is recommended to try in a limited area of the surface in order to check eventually stains and spots formed. Mayer Braun Deutschland srl disclaims anyliability.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

None

4.1.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No episodes of damage to personnel using the product . However , in case of need , we adopt the Following General measures :

- INHALATION : Move to fresh air . If breathing is difficult , administer artificial respiration and seek medical advice .
- INGESTION: seek medical attention ; Induce vomiting only if indicated by the doctor ; Never give anything by mouth to an unconscious person .
- EYES and SKIN: Wash with plenty of water ; If irritation persists , consult a doctor.

Environmental precautions: prevent product from entering the sewers, surface water , ground water and neighboring areas

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

- Product residues are considered hazardous waste . The hazard level of waste containing this product should be evaluated according to applicable regulations .
- Disposal must be performed through an authorized waste management , in compliance with national and local regulations.
- Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations .

4.1.6. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Precautions for safe handling: Avoid the accumulation of electrostatic charges . No smoking. Do not spray on a naked flame or incandescent . Vapors can ignite with explosion ,therefore necessary to avoid accumulation keeping the windows and doors open and ensuring a good ventilation . Without adequate ventilation , the vapors may accumulate on theground and ignite at a distance, if triggered , with danger of backfiring .

Conditions for safe storage , including any incompatibilities . Store in a well ventilated place, away from direct sunlight at a temperature below 50 ° C , away from sources of ignition .

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Vespermayer Schiumogeno Plus is an outdoor/indoor spray can insecticide specific for wasps. The product is a ready to use spray aerosol. Spray at a distance of 2-3 meters from the target area and being careful to spray accurately the wasp nest so that the foam wrap them. Before use on specific surface, it is recommended to try in a limited area of the surface in order to check eventually stains and spots formed. Mayer Braun Deutschland srl disclaims any liability.

5.2. Risk mitigation measures

None

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

No episodes of damage to personnel using the product. However, in case of need, we adopt the following General measures:

- **INHALATION**: Move to fresh air. If breathing is difficult, administer artificial respiration and seek medical advice.
- **INGESTION**: seek medical attention; Induce vomiting only if indicated by the doctor; Never give anything by mouth to an unconscious person.
- **EYES and SKIN**: Wash with plenty of water; If irritation persists, consult a doctor.

Environmental precautions: prevent product from entering the sewers, surface water, ground water and neighboring areas

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

- Product residues are considered hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
- Disposal must be performed through an authorized waste management, in compliance with national and local regulations.
- Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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

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

Precautions for safe handling: Avoid the accumulation of electrostatic charges . No smoking. Do not spray on a naked flame or incandescent . Vapors can ignite with explosion ,therefore necessary to avoid accumulation keeping the windows and doors open and ensuring a good ventilation . Without adequate ventilation , the vapors may accumulate on theground and ignite at a distance, if triggered , with danger of backfiring .

Conditions for safe storage , including any incompatibilities . Store in a well ventilated place, away from direct sunlight at a temperature below 50 ° C , away from sources of ignition .

6. OTHER INFORMATION