

AUTHORISATION NUMBER: IE/BPA 70382

EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET, USE AND CONTROL OF BIOCIDAL PRODUCTS) REGULATIONS

CERTIFICATE OF AUTHORISATION

The Competent Authority for Biocides in Ireland, pursuant to the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, as amended by Regulation (EU) No 334/2014, and European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013), grants authorisation to:

Bayer CropScience Ltd 230 Cambridge Science Park Milton Road Cambridge, CB4 0WB UK

to make available on the market in Ireland, the biocidal product:

Ant Nest Killer

subject to the conditions detailed in the Annexes to this certificate.

Authorisation granted on behalf of the Competent Authority for Biocides in Ireland by

Pesticide Control Division (PCD)

Date of authorisation: 19 November 2015

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Food and the Business

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Official Stamp:

Ver1.2 – Change to manufacturer name

ANNEX I

Conditions of Authorisation

This authorisation may be subject to review in accordance with Regulation (EU) No 528/2012, as amended by Regulation (EU) No 334/2014, or the European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013). The outcome of such a review may lead to amendments to or the revocation of this authorisation.

The following conditions apply:

- 1. Product may **not** be made available on the market or used in the Republic of Ireland unless it complies with the Annexes of this authorisation.
- 2. The requirements and conditions, specified in the Annexes, of this authorisation may **not** be altered without prior approval of modifications by the Irish Competent Authority for Biocides in Ireland. Where any amendments are made to the original authorisation in another Member State, the Irish Competent Authority for Biocides in Ireland must be informed by the Authorisation Holder.
- 3. The holder of this certificate for authorisation must inform or provide the Irish Competent Authority for Biocides with any new or requested information/data, respectively, that shows this biocidal product and/or any of its active substances cause or may cause an adverse effect on human or animal health, ground water or the environment.
- 4. All product made available on the market in Ireland must comply with the classification, labelling and packaging requirements established in: Article 69 of Regulation (EU) No 528/2012; S.I. 624 (2001) transposing Directive 99/45/EC; the Chemicals Act 2008 (as amended) transposing Regulation (EC) No 1272/2008; and the Labelling and Safety Data Sheet Annex detailed in this certificate.
- 5. All biocidal products advertised must comply with Article 72 of Regulation (EU) No 528/2012.
- 6. A printed copy of the Irish label in accordance with the Annexes of this authorisation must be submitted to the Irish Competent Authority for Biocides prior to any product being made available on the market in Ireland. All product labels must carry the authorisation number of the form: IE/BPA 70382.
- 7. Safety Data Sheets (SDS) for the biocidal product(s) shall be prepared and made available in accordance with Article 70 of the Biocidal Products Regulation 528/2012 (as amended). Relevant sections of the SDS must be updated post-authorisation in accordance with Annex II of the authorisation certificate. In particular, Section 15 of the SDS should be updated to contain the authorisation number IE/BPA 70382. The SDS must be submitted to the Irish Competent Authority for Biocides and the National Poisons Information Centre of Ireland http://www.poisons.ie/manufacturers.asp before the product is made available on the market for sale or use.
- 8. On an annual basis, details of the quantities of this product (by pack size) manufactured in Ireland, imported into Ireland and/or exported from Ireland must be submitted to the Irish Competent Authority for Biocides by 31 January of the following year.
- 9. Fees are payable for the maintenance of the product on the Register of Biocidal Products and shall be paid by the 31st December of the following year and each year thereafter.

ANNEX II

Summary of Product Characteristics (SPC) for a biocidal product

1. Administrative information

1.1 Trade name of the product

Trade name	Country (if relevant)	
Ant Nest Killer	IE .	

1.2 Authorisation holder

Name and address of the	Name	Bayer Limited
authorisation holder	Address	The Atrium
		Blackthorn Road, Sandyford
		Dublin 18
		Dublin
		Ireland
Authorisation number	IE/BPA 70382	
Date of the authorisation	19/11/2015	
Expiry date of the authorisation	15/11/2025	

1.3 Manufacturer(s) of the product

Name of manufacturer	Bayer S.A.S. Bayer CropScience, Environmental Science Division
Address of manufacturer	16 rue Jean-Marie Leclair CS 90106 69266 Lyon Cedex 09 France
Location of manufacturing sites	Confidential (see Annex IV)

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

Active substance	Deltamethrin
Name of manufacturer	Bayer AG
Address of manufacturer	Alfred-Nobel-Str. 50 40789 Monheim am Rhein Germany
Location of manufacturing sites	Confidential (see Annex IV)

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 (%)
Deltamethrin	•	Active substance	52918-63-5	258-256-6	0.73
Confidential (see PAR R4BP)		Non-active substance ¹			

2.2 Type of formulation

SC - Suspension concentrate (= flowable concentrate)

3. Authorised use(s)

Product Type	PT18 (Insecticide)	
Where relevant, an exact description of the authorised use	A suspension concentrate product containing deltamethrin (0.73% w/w) for use as an insecticide by non-professionals for the curative control of workers and nests of the black ant and other commonly found garden ants by drenching.	
Target organism (including development stage)	Insects: Formicinae: Black ant, Garden ant Adults	
Field of use	Outdoor use (On terraces, patios, and pathways around private housing)	
Application method(s)	Drench: Apply with a watering can.	
Application rate(s) and frequency	Please Refer to Table 2: A	
Category(ies) of users	V.1 Non Professional/General public	
Pack sizes and packaging material	Product must not be decanted from packaging into unlabelled containers.	
	Please see Table I: Packaging below.	

Table I - Packaging

Packaging type/description	Packaging material ¹	Pack size
Non-professional/General public		
Plastic bottle with "easy-dose"/measuring	Container: HDPE	Max. 250 ml
device		

Page 4 of 9 14 July 2020

¹ Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to non-active substance.

Table II - Authorised uses

Application Rate	Dilute 20 ml of product with water to obtain a total amount of 5 Liters of solution. Use 5 L of solution for 5 m² per ant nest. Timing: If the treatment has not succeeded in reducing the number of ants to an acceptable level, retreatment can be performed after 1 month at the earliest. Not more than 2 treatments per nest should be performed in a season to avoid negative effects on the environment.
Usage target	Curative
Application Method	Drench: Apply with a watering can.
Usage area	Outdoor use (On terraces, patios, and pathways around private housing)
Stages of development	Adults
Target Organism	Formicinae: Black ant, Garden ant
User category	Non Professional /General public/Amateur
PT	86

4. Hazard and precautionary statements²

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Aquatic Chronic 1
	Aquatic Acute 1
Hazard statement	H410 Very toxic to aquatic life with long lasting effects.
	EUH208 Contains 1,2-benzisothiazol-3(2H)-one, Reaction
	mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-
	isothiazol-3-one (3:1). May produce an allergic reaction.
Labelling - Please refer	to Annex III for additional labelling requirements.
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects.
	EUH208 Contains 1,2-benzisothiazol-3(2H)-one, Reaction
	mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-
	isothiazol-3-one (3:1). May produce an allergic reaction.
Precautionary statements	P273 Avoid release to the environment
	P391 Collect spillage
	P501 Dispose of contents/container to in accordance with local
	regulations.
Note	Pictogram: GHS09

5. Directions for use

5.1 Instructions for use³

- Fill the watering can with half the required volume of water. Measure desired quantity of product and pour carefully in the watering can avoiding splashing. Complete the filling of the watering can with water, to a total amount of 5 L.
- Dilute with water only.
- Identify the ant nest's location and the entrance(s) carefully. Please note that an ant nest may have several entrances which all need to be treated for successful eradication.
- Drench ant nest by pouring diluted solution into and around the nest entrance(s).
- Use 5 L of solution per ant nest, and divide over all entrances.
- Do not store diluted solution.
- After the outdoor watering application, rinse the watering can several times with a little water. Apply the rinse water on the ant nest.
- Do not re-use the watering can for other purposes after application without prior cleaning.

² For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Page 6 of 9

³ Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

Cutaneous sensations may occur, such as burning or stinging on the face and mucosae. However, these sensations cause no lesions and are of a transitory nature (max. 24 hours).

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

First Aid:

GENERAL: In case of accident, suspected exposure or if you feel unwell, seek medical advice immediately (show the label where possible).

Remove contaminated clothing immediately and dispose of safely.

IF SWALLOWED: Do NOT induce vomiting. Seek medical advice/attention immediately.

IF ON SKIN: Wash off thoroughly with plenty of soap and water for approximately 15 minutes. Call a physician if irritation develops and persists.

IF IN EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician if irritation develops and persists.

IF INHALED: Move the patient to fresh air and keep at rest. Call a physician or poison control centre immediately.

Note to Physician:

Treat symptomatically. If large quantities of product have been swallowed or inhaled contact a poison treatment specialist immediately.

Poison Information:

For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference.

5.3 Instructions for safe disposal of the product and its packaging

This material and its container must be disposed of safely as hazardous waste.

Any product collected during application that is not re-used must be disposed of safely as hazardous waste.

Do NOT dispose of unwanted product down drains or in to waterbodies or watercourses.

Dispose of packaging and of unused product in accordance with local regulations.

If required, consult a professional waste operator or local authority.

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

Shelf life of 2 years.

Keep container tightly closed.

Keep away from direct sunlight.

Protect from freezing.

Keep away from food, drink and animal feedingstuffs.

Keep out of reach of children.

6. Other information

Name and address of the marketing company if different to the Authorisation Holder:

The active substance in the product is known to develop resistance in some organisms (i.e. the product becomes less effective if used frequently). Ants are not one of these organisms,

but the product should be used with care and in accordance with the instructions for use, in order to limit the development of resistance in other organisms.

Batch number and expiry date: Must be printed or embossed on label or packaging

ANNEX III

Other Labelling Requirements

Please note:

Article 69 of the BPR indicates the minimum labelling requirements for the product. Authorisation holders may place additional label information as they consider necessary, which must be in accordance with relevant labelling legislation. Any claims made must be supported by data.

Special labelling provisions for Ireland

Use Biocides Safely and Sustainably.

It is illegal to use this product for uses or in a manner other than that prescribed on this label.

Full statement of use must be placed on the label.

Additional safety Information:

To avoid risks to human health and the environment, comply with the instructions for use.

Contains 1,2-benzisothiazol-3(2H)-one, Reaction mass 5-chloro-2-methyl-2Hisothiazol-3-one and 2-methyl-2Hisothiazol-3-one (3:1). May produce an

allergic reaction.