GREAT BRITAIN BIOCIDAL PRODUCT AUTHORISATION CERTIFICATE: NATIONAL AUTHORISATION EXPIRY DATE POSTPONEMENT

Product Name: Imidasect Ants
Authorisation Holder: Sharda Agrochem Limited

This certificate is granted in exercise of the powers conferred by Article 31 (7) 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 it has effect in Great Britain (referred to in this certificate as “Regulation 528/2012 GB”).

Regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 makes provision as to the appointment of competent authorities for the purposes of Article 81 of Regulation 528/2012 GB. These are, respectively, the Secretary of State (as regards England), the Scottish Ministers (as regards Scotland) and the Welsh Ministers (as regards Wales).

The Health and Safety Executive acts on behalf of the competent authorities, pursuant to Agency Agreements which came into force on 12 February 2021.

The Health and Safety Executive grants this authorisation with the following terms and conditions:

1. Subject to compliance with paragraph 2 the Authorisation Holder is authorised to place on the market the biocidal product(s) detailed in the Summary of the Product Characteristics in Appendices 1 and 2, for the use(s) set out in Appendix 1.

2. The Authorisation Holder shall complete, within the stated timeframe, the actions set out in the table below. If the actions have not been completed by the relevant due date, the biocidal product(s) covered by this certificate of authorisation may no longer be placed on the market as of that date.

Description	Due Date

3. This certificate revokes and replaces certificate document reference number 2023/150133.

4. Without prejudice to the duties imposed on the Authorisation Holder by Article 69 of Regulation 528/2012 GB, the Authorisation Holder must include on the product label(s) the information contained in Appendix 1 for the biocidal product(s), other than,
   - the list of all authorised trade names and their relevant suffix (however the relevant product trade name and suffix must be on the product label);
   - date of authorisation;
   - expiry date of the authorisation;
   - the name and address of the manufacturer(s) of the product (including site details);
   - the name and address of the manufacturer(s) of the active substance(s) (including site details);
   - the non-active substances, (however details of non-active substances specifically listed in the table in Section 2.1 or specifically referenced in Sections 3, 4 or 5 should be included on the product label);
   - any authorised uses outlined in Section 4 and 5 that are not relevant to the Authorisation Holder's current marketing strategy (however, for those uses which are included on the label, all the relevant conditions relating to those uses as outlined in the subsections of Sections 4 and 5 must be included in the labelling); and
   - the list of all authorised pack sizes and types (however the relevant pack size must be on the product label).

5. In accordance with Article 6 of Regulation (EU) No. 354/2013 (Changes Regulation), as it has effect in Great Britain, the Authorisation Holder may remove or update the information on the product label to implement Administrative Changes as defined in Section 2 of Title 1 of the Annex to Regulation (EU) No. 354/2013, as it has effect in Great Britain.

   The Authorisation Holder must notify these Administrative Changes to the GB Competent Authority within 12 months of implementation.

6. This certificate of authorisation may be amended in accordance with Article 48 or 50 of Regulation 528/2012 GB.

7. This certificate of authorisation may be cancelled in the circumstances set out in Articles 48 or 49 of Regulation 528/2012 GB.

8. Subject to paragraphs 6 to 7, this certificate of authorisation remains in force until 11:59pm on 1 April 2026.

Issued by

Colette Brockbank

Date of issue: 27 September 2023

Chemicals Regulation Division, Health and Safety Executive,
Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, United Kingdom

Explanatory notes:

i. 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 (and supplementary EU Regulations and EU Decisions) has been retained into Great Britain law by European Union (Withdrawal) Act 2018 (as amended). The retained Regulation (EU) No. 528/2012 has been amended by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 and the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

ii. Following the submission of the application to renew this authorisation by the Authorisation Holder, HSE decided that a full evaluation was required.

iii. For reasons beyond the control of the Authorisation Holder, this authorisation was likely to expire before a final decision on its renewal application could be made.

This certificate of authorisation has been granted to allow sufficient time to examine the renewal application in Great Britain only (which means England, Scotland and Wales).

This is not the final decision on the renewal of the product authorisation in Great Britain. Once the evaluation of the application has been completed in accordance with Article 31 of Regulation 528/2012 GB a final decision on the renewal application will be made in Great Britain.

This certificate of authorisation is not applicable/valid in Northern Ireland.

iv. If the Authorisation Holder fails to comply with the action(s) as outlined in term/condition 2 they cannot place the biocidal product(s) on the GB market as of the date stated. Any stock of the biocidal product(s) they have already placed on the GB market prior to the date(s) stated in term/condition 2 can continue to be made available on the GB market by any company other than the Authorisation Holder and used in accordance with the terms and conditions of this authorisation.

v. While the information in term/condition 4 is not required to be included on the product label(s) by Regulation 528/2012 GB the Authorisation Holder may choose to include it if they wish.

vi. The power to amend or cancel this certificate of authorisation is exercisable at any time by HSE where the conditions specified in Regulation 528/2012 GB are not met.

vii. A failure to comply with any terms and/or conditions contained in this certificate of authorisation may result in cancellation of the authorisation under Article 48 of Regulation 528/2012 GB. Non-compliance with the law may result in enforcement action, including prosecution.

viii. This authorisation will expire on the date shown unless the Authorisation Holder submits a valid application for renewal in accordance with Article 31 of Regulation 528/2012 GB at least 550 days before the expiry date of this authorisation.

Appendix 1: Summary of Product Characteristics for a Biocidal Product

1. Administrative information

1.1. Trade name(s) of the product

Imidasect Ants Xtermin8 Prob Ant Bait Station MoBe Ant Gel MoBe Ant Station

1.2. Authorisation holder

Name and address of the authorisation holder

Authorisation holder name	Sharda Agrochem Limited
Authorisation holder address	201, Cervantes House, 5-9, Headstone Road, Harrow, Middlesex, HA1 1PD

Authorisation number

GB-2016-1043

Suffixes to the authorisation number linked to trade names

GB-2016-1043-0001 - Xtermin8 Prob Ant Bait Station GB-2016-1043-0002 - MoBe Ant Gel GB-2016-1043-0003 - MoBe Ant Station

Date of the authorisation

23 November 2016 (as amended 27 September 2023)

Expiry date of the authorisation

1 April 2026

1.3. Manufacturer(s) of the product

Manufacturer 1

Name of manufacturer		Sharda Cropchem Limited
Address of manufacturer		Dominic Holm, 29th Road, Bandra 400050 Mumbai India
Location of manufacturing sites	***Site 1***	Dominic Holm, 29th Road, Bandra 400050 Mumbai India
	Site 2	DTS OABE S.Lv., Poligono Industrial Zabale, Parcela 3, 48410 Orozco (Vizcaya) Spain

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

Manufacturer 1

Active substance	Imidacloprid
Name of manufacturer	Sharda Worldwide Exports Pvt. Ltd
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai India
Location of manufacturing sites	Hebei Veyong Bio-Chemical Co.Ltd - 393 East Heping Road - Shijizhang China

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 (% w/w)***
Imidacloprid		Active substance	138261-41-3	428-040-8	0.01
Confidential - see Appendix 2		Non-active substance			99.99

2.2. Type of formulation

Gel

3. Hazard and precautionary statements

The following classification and labelling information was originally provided by the reference Member State, prior to the end of the Transition Period following the UK's Exit from the EU, in accordance with Regulation (EC) No. 1272/2008 of the 16th December 2008 (Classification, Labelling and Packaging of substances and mixtures Regulation) and the outcomes of the product risk assessment.

Classification of the product according to Regulation (EC) No. 1272/2008 as it applies in Great Britain (GB) (GB Classification, Labelling and Packaging of substances and mixtures Regulation (GB CLP))

Hazard category	Aquatic Chronic 2

Hazard statement	H411: Toxic to aquatic life with long lasting effects

Labelling of the product according to Regulation (EC) No. 1272/2008 as it applies in Great Britain (GB) (GB Classification, Labelling and Packaging of substances and mixtures Regulation (GB CLP))

Signal words	None
Hazard statements	H411: Toxic to aquatic life with long lasting effects
Precautionary statements	P273: Avoid release to the environment P391: Collect spillage. P501: Dispose of contents/containers according to national legislation
Note	-

NB: It is the responsibility of the Authorisation Holder to label the product in accordance with Regulation (EC) No. 1272/2008 of the 16 December 2008 (Classification, Labelling and Packaging of substances and mixtures Regulation), as it has effect in Great Britain, and include the relevant classification and labelling information from this section.

4. Authorised use(s)

4.1. Use description

Table1. Use #1 – General public

Product type	18
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Tropical ants (Pharaoh ants (Monomorium pharaonis); argentine ants (Linepithema humile)) Lasius niger (black ant) (eggs; larvae; nymphs; pupae; imagines, adults)
Field(s) of use	Indoor use Outdoor use as a barrier around buildings (Application aim: Health protection)

Application method(s)	Open application of a gel bait from a syringe ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2-0.4g/m2; 0.2g/m (open application- indoor) 0.2g/lair entry or foraging trial; 0.2g/m building perimeter (open application- outdoor) Max. 0.35g/m² (bait tray-indoor) Max. 0.23 g /m building perimeter (bait tray-outdoor) Product can be used continuously for 2 - 3 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Non-professional
Pack sizes and packaging material	3g, 5g, 10g, 15g syringe 0.75g, 1g, 1.2g, 1.4g in bait tray 5mL ampoule 4mL, 10mL dropper

4.1.1. Use-specific instructions for use – Use #1 – General public

See section 5.1

4.1.2. Use-specific risk mitigation measures – Use #1 – General public

See section 5.2

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 – Use #1 – General public

See section 5.3

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging – Use #1 – General public

See section 5.4

4.1.5. Where-specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Use #1 – General public

See section 5.5

4.2. Use description

Table 2. Use #2 – Professional use

Product type	18
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Tropical ants (Pharaoh ants (Monomorium pharaonis); argentine ants (Linepithema humile)) Lasius niger (black ant) (eggs; larvae; nymphs; pupae; imagines, adults)
Field(s) of use	Indoor use Outdoor use as a barrier around buildings (Application aim: Health protection)
Application method(s)	Open application of a gel bait from a cartridge, ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2-0.4g/m2; 0.2g/m (open application- indoor) 0.2g/lair entry or foraging trial; 0.2g/m building perimeter (open application- outdoor) Max. 0.35g/m² (bait tray-indoor) Max. 0.23 g /m building perimeter (bait tray-outdoor) Product can be used continuously for 2 - 3 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	30g, 35g, 50g, 75g, 100g cartridge 5mL ampoule 4mL, 10mL dropper

4.2.1. Use-specific instructions for use – Use #2 – Professional use

See section 5.1

4.2.2. Use-specific risk mitigation measures – Use #2 – Professional use

See section 5.2

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment – Use #2 – Professional use

See section 5.3

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging – Use #2 – Professional use

See section 5.4

4.2.5. Where-specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Use #2 – Professional use

See section 5.5

5. General directions for use

5.1. Instructions for use

Before treatment, remove all natural source of food for ants (waste, food scraps...) from the infested area to encourage the ingestion of the gel.
Where ants are present indoors, place the gel in drops or thin lines near ant trails, points of entry and their nests.
Where ants are present outdoors, place the gel in drops or thin lines in the ant nests or trails.
Where presence of ants is only suspected or detected sporadically, it is recommended to use the gel in a bait tray.
Check the bait trays once a week.
During inspections, check the treated area and if necessary, replace the gel.
Do not apply the product on absorbing surfaces.
Apply the product away from direct sunlight or heat sources (e.g. do not place it under a radiator).
Avoid continuous use of the product.
If the infestation persists despite following the instructions of the label, contact a pest control professional.
Inform the authorisation holder if the treatment is ineffective.

5.2. Risk mitigation measures

Avoid any unnecessary contact to the preparation. Misuse may cause health damage.
Keep away from food, drink and animal feeding stuffs.
Do not contaminate food, feed, eating utensils or food contact surfaces.
Keep out from reach of children
Avoid release to the environment.
The outdoor application should only be conducted on paved surfaces (do not apply on bare soil).
Remove bait trays when the plague ceases or is eliminated.

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

None

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

Dispose of Container/content in a safe way and according to national legislation

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

Shelf-life: 24 months

6. Other information

The product contains a bittering agent.

Appendix 2: Confidential Biocidal Product Characteristics

In accordance with Article 66 (2) of Regulation 528/2012 GB these biocidal product characteristics are considered to be confidential but are also part of the Summary of the biocidal Product Characteristics (SPC).

1. Product composition and formulation

1.1. Qualitative and quantitative confidential information on the composition of the biocidal product

Common name	*IUPAC name*	*Function*	*CAS number*	*EC number*	*Content (% w/w)*
Denatonium benzoate	N-(2-((2,6-Dimethylphenyl) amino)2-oxoethyl)-N,N-diethyl (phenylmethyl)ammonium benzoate	Bittering agent	3734-33-6	223-095-2	0.001
ProClin® 300		Preservative			0.001
Bronopol	2-Bromo-2-nitro-1,3-propanediol	Preservative	52-51-7	200-143-0	0.5
Bone protein		Thickener			0.5
Glycerine	Propane-1,2,3-triol	Antifreeze	56-81-5	200-289-5	8.0
Casein		Rheological additive	9000-71-9	232-555-1	0.3
Liquid glucose		Bait	8029-43-4	232-436-4	70.0
Water		Solvent	7732-18-5	231-791-2	20.688

2. Other confidential biocidal product characteristics

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