

NOTICE OF AUTHORIZATION IN TERMS OF THE BIOCIDAL PRODUCT REGULATION

27/06/2016

In exercise of the powers conferred by the Legal Notice 348 of 2013 and Regulation (EU) No 528/2012 concerning the placing of biocidal products on the market, the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority hereby acknowledges the authorization of the following biocidal product.

PRODUCT: Protect Sewer Block

ACTIVE INGREDIENT: Bromadiolone

PRODUCT TYPE: 14

IDENTITY OF APPLICANT: Babolna Bio Ltd

REGISTRATION REFERENCE NUMBER: 2013-05-20-B01

APPROVED PACKAGING SIZES FOR PROFESSIONAL USE:

Disc 75 g: 100 pcs/ paper carton box (7.5 kg)
Disc 120 g: 100 pcs/ paper carton box (12 kg)
Disc 200 g: 20 pcs/ PE foil (4 kg)
Block 100 g: 150 pcs/ paper carton box (15 kg)
Block 200 g: 80 pcs/ paper carton box (16 kg)

Subject to the conditions set out below:

- (a) **Label:** Products to be sold or supplied with the draft labels attached to this document. Any amendments to the label should be approved beforehand by the Head of the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority.
- (b) **Product Composition:** Product to be sold or supplied in the composition approved by this authorization. The composition should be the same as approved by the Reference Member State; unless the change is minor and does not significantly change the properties of the product. Such a change has to be approved by the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority.
- (c) **Retail Packaging Sizes:** Products to be sold or supplied in the retail packaging sizes specified in this authorization. Any modifications should be approved beforehand by the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority.
- (d) **Placing on the Market:** Products shall only be placed on the market by authorized dealers as specified in the Legal Notice 348 of 2013 (as amended).
- (e) **Entry into Malta:** The Technical Regulations Division of the Malta Competition and Consumer Affairs Authority shall be notified of any consignment of Biocides brought into Malta as specified in Legal Notice 348 of 2013.

(f) **Renewal of Authorization:** Unless previously revoked, the authorization is renewable on application by the holder made at least three months before expiry of the validity period. The authorization will be revoked with immediate effect upon expiry in case of failure of submission of an application for renewal.

(g) **Other:** The Technical Regulations Division of the Malta Competition and Consumer Affairs Authority may impose other conditions as deemed necessary to ensure that the conditions specified in the Regulations are satisfied.

Information to the Applicant:

This authorization shall not exempt the applicant and/or any other person authorised to act on his behalf from any other obligation under the Biocide Regulations or any other relevant legislation or administrative provision. It shall be the sole and exclusive responsibility of the applicant and/or any other person authorised to act on his behalf to consult the L.N. 348/2013 together with its relevant amendments.

Failure to provide any supporting documentation, as may be required by the Technical Regulations Division, in accordance with the Biocides Regulations, shall constitute an offence under those regulations.

The authorisation holder is reminded of the obligation to submit a fresh application in the event of any change in the composition of the product and/or its labelling.

Without prejudice to Decisions already taken pursuant to L.N. 348/2013 of the Biocides Regulations, an authorization shall be cancelled if it is established that the requirements for obtaining the authorization are not or are no longer satisfied, or that false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted, or it shall be modified if it is established that on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified.



Director General

Valid until 30/06/2018

AVVIŻ TA' AWTORIZZAZZJONI SKOND IR-REGOLAMENTI DWAR PRODOTT BIOĊIDA

27/06/2016

Fl -eżerċizzju tas -setgħat mogħtija bl -Avviż Legali 348 tal- 2013 u r- Regolament (UE) Nru. 528/2012 dwar it-tqegħid fis-suq u l-użu tal-prodotti bijoċidali, id-Diviżjoni dwar Regolamenti Tekniċi tal- Awtorità ta' Malta għall-Kompetizzjoni u Affarijiet tal-Konsumatur, qiegħed hawnhekk jirrikonoxxi l-awtorizzazzjoni tal-prodott bijoċidali li ġej.

PRODOTT: Protect Sewer Block

INGREDJENT ATTIV: Bromadiolone

TIP TA' PRODOTT: 14

IDENTITÀ TAL- APPLIKANT: Babolna Bio Ltd

NUMRU TA' REFERENZA REĠISTRAZZJONI: 2013-05-20-B01

QIES TA' IPPAKKJAR AWTORIZZAT (għall- użu professjonali) :

Diska 75 g: 100 biċċa/ kaxxa tal-kartun (7.5 kg)
Diska 120 g: 100 biċċa/ kaxxa tal-kartun (12 kg)
Diska 200 g: 20 biċċa/ fojl tal- PE (4 kg)
Blokka 100 g: 150 biċċa/ kaxxa tal-kartun (15 kg)
Blokka 200 g: 80 biċċa/ kaxxa tal-kartun (16 kg)

Suġġett għall-kundizzjonijiet msemmija hawn taħt :

(a) **Label:** Prodotti li għandhom jiġu mibjugħa jew ipprovduti l-abbozz tikketti mehmuża ma 'dan id-dokument. Kwalunkwe emendi għall -tikketta għandhom ikunu approvati minn qabel mill- Kap tad- Diviżjoni dwar Regolamenti Tekniċi tal-Awtorità ta 'Malta għall-Kompetizzjoni u Affarijiet tal-Konsumatur.

(b) **Komposizzjoni tal-Prodott :** Prodott li jinbiegħu jew fornuti fit-kompożizzjoni approvata minn din l-awtorizzazzjoni . Il-kompożizzjoni għandha tkun l- istess kif approvat mill-Istat Membru ta 'Referenza ; sakemm il- bidla hija minuri u ma jbidlilx b'mod sinifikanti l- proprjetajiet tal-prodott . Tali bidla għandha tiġi approvata mid-Diviżjoni dwar Regolamenti Tekniċi tal- Awtorità ta 'Malta għall-Kompetizzjoni u Affarijiet tal-Konsumatur .

(ċ) **Ippakkjar bl-imnut Daqsijiet:** Prodotti li jiġu mibjugħa jew ipprovduti fid-daqsijiet ippakkjar bl-imnut speċifikati f'din l-awtorizzazzjoni. Kwalunkwe tibdila għandha tiġi approvata minn qabel mill- Diviżjoni dwar Regolamenti Tekniċi tal-Awtorità ta 'Malta għall-Kompetizzjoni u Affarijiet tal-Konsumatur .

- (d) **Tqegħid fis- Suq:** Il-prodotti għandhom jitqiegħdu biss fis-suq minn negozjanti awtorizzati kif speċifikat fl-Avviż Legali 348 tal-2013 (kif emendat) .
- (e) **Dħul fis- suq Malti:** Il- Diviżjoni dwar Regolamenti tekniċi tal- Malta għall-Kompetizzjoni u lill-Awtorità Affarijiet tal-Konsumatur għandha tkun notifikata kull kunsinna ta ' Bijocidi miġjuba f'Malta kif speċifikat fl-Avviż Legali 348 tal-2013.
- (f) **Tiġdid ta ' Awtorizzazzjoni :** Sakemm revokata qabel, l-awtorizzazzjoni jista' jiġġedded fuq applikazzjoni tad-detentur mill-inqas tliet xhur qabel jiskadi l-perjodu ta ' validità . L-awtorizzazzjoni għandha tiġi revokata b'effett immedjat meta jiskadu fil-każ ta ' falliment tas-sottomissjoni ta ' applikazzjoni għal tiġdid .
- (g) **Oħrajn :** L- Diviżjoni dwar Regolamenti Tekniċi tal- Malta għall-Kompetizzjoni u għall-Affarijiet tal-Konsumatur tista ' timponi kundizzjonijiet oħra kif jitqies meħtieġ sabiex jiġi żgurat li l-kondizzjonijiet speċifikati fir-Regolamenti huma sodisfatti .

Informazzjoni lill- Applikant:

Din l-awtorizzazzjoni m'għandhiex teżenta lill -applikant u / jew kwalunkwe persuna oħra awtorizzata li taġixxi f'ismu minn kwalunkwe obbligazzjoni oħra taħt ir-Regolamenti bijocida jew kwalunkwe leġiżlazzjoni oħra rilevanti jew diżpożizzjoni amministrattiva . Għandha tkun ir-responsabbiltà unika u esklussiva tal- applikant u / jew kwalunkwe persuna oħra awtorizzata li taġixxi f'ismu li jikkonsulta l LN 348/2013 flimkien mal-emendi rilevanti.

Nuqqas li tiġi pprovduta kwalunkwe dokumentazzjoni ta ' appoġġ , kif jista' jkun meħtieġ mid- Diviżjoni dwar Regolamenti Tekniċi , skond ir- Regolamenti dwar il-Bijocidi , għandu jikkostitwixxi reat taħt dawn ir-regolamenti .

Id- detentur tal-awtorizzazzjoni għandu jzomm f'moħħu l- obbligu li jissottomettu applikazzjoni ġdida fil- każ ta ' kwalunkwe bidla fil-kompożizzjoni tal-prodott u / jew it-tikkettar tiegħu.

Mingħajr preġudizzju għal Deċiżjonijiet li jkunu diġa ttieħdu skond LN 348/2013 tar-Regolamenti dwar il-Bijocidi , awtorizzazzjoni għandha tiġi kkanċellata jekk jiġi stabbilit li r-rekwiżiti għall-kisba tal- awtorizzazzjoni m'humiex issodisfati jew m'għadhomx jiġu sodisfatti , jew li dettalji foloz jew qarrieqa jkunu ġew mgħoddija dwar il- fatti li abbażi tagħhom l- awtorizzazzjoni ngħatat , jew għandu modifikata jekk jiġi stabbilit illi fuq il- bażi ta ' żviluppi fit-tagħrif xjentifiku u tekniku il-mod ta' użu u l-ammonti użati jistgħu jiġu modifikati .



Id- Direttur Ġenerali

Valida sa 30/06/2018

PROTECT[®] Sewer Block

Ready-to-use wax-coated bait containing 0.005 % Bromadiolone for the control of rats, including use in wet and humid places.

Only for professional pest controllers!

For control of the Brown/Norway rat (*Rattus norvegicus*).

For use in and around buildings including animal houses (farm buildings), at sewage treatment plants, at recycling centres in urban environments and in sewers, supplied with built in wire hook.

Protect[®] Sewer Blocks are specially formulated highly palatable wax-coated weatherproof blocks for the control of rats in damp and humid conditions. Effective against warfarin-resistant rats.

INSTRUCTIONS FOR SAFE USE



Protect[®] Sewer Blocks are ready for use. Blocks must be placed in tamper resistant and secured, fixable bait boxes in well-protected situations inaccessible to children, non-target animals and birds, at frequent intervals about 5 – 10 m apart along rat runs, in hides or where rats are feeding. Use 75 to 200 grams per feeding point (see Use chart). Always consider the level of infestation and availability of alternative feeding sources. Ensure that baits are well positioned and fixed. Protect the bait from weather and from possible access by children, domestic animals, livestock and wildlife.

Use the built-in wire for fixing the bait to prevent removal.

For use around buildings; bait must be placed within 50 metres of the building to be protected.

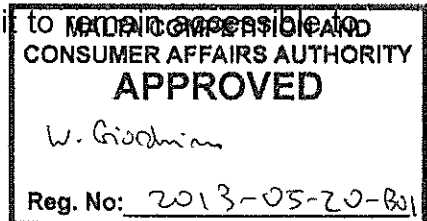
It is good practice to remove or reduce the availability of other food material on which the rats can feed, in order to maximise the consumption of **Protect[®] Sewer Blocks**. Inspect the bait at regular, frequent intervals (e.g. every 3 – 7 days) and replenish if

all or most of the bait has been eaten; replace bait that has deteriorated (e.g. if mouldy). Replace blocks until no more bait is consumed.

Note: Generally no immediate consumption can be expected because of bait-shyness. If rats are present and the consumption has not begun after 2 – 3 days, re-establish the baiting point.

USE IN SEWERS, MANHOLES, SINKHOLES, GULLIES

Protect[®] Sewer Blocks can be used in sewer ducts, manholes and sinkholes. The usage of special baiting stations is highly recommended where possible (e.g. in sewer manholes)! In ducts suspend the block using the supplied wire and fix it securely to the grid. The wire should be long enough for bait to remain accessible to rodents, but avoid direct contact with water.



Use chart

Place of use	Quantity per baiting point
In sewers, manholes, sinkholes	75 - 200 grams
In/around buildings for control of rats	100, 120 grams
In recycling centres in urban environments	100, 120 grams

The resistance status of the target rat population should be taken into account when considering the choice of rodenticide to be used.

Regularly search for and remove dead rats during the period of the campaign, at least as frequently as for monitoring and/or replacing the bait. To reduce the risk of secondary poisoning, all used baiting stations and unused bait must be removed after the campaign or treatment. Dispose of used bait, bait stations and carcasses by incineration (or according to local requirements).

Bait stations placed outdoors should be billed with the following information:

- Date of placing out the bait and inspection dates
- Contact information
- The name and authorisation number of the product

- Information on the active substance and its antidote
- Warning to prevent children and domestic animals from reaching the bait
- Reference to the national poison centre

Contains denatonium benzoate to prevent accidental human consumption.


WARNING: Use only for rat control and follow the directions for use. Store in a cool and dry place, in the original pack, away from foodstuffs and feed, and beyond the reach of non-competent persons, children and domestic animals. If poisoning is suspected the patient should be examined by a doctor without delay.

Content:

Date of manufacture:.....



CLASSIFICATION ACCORDING TO CLP: STOT RE 2; H373

 WARNING	<p>H373 May cause damage to organs through prolonged or repeated exposure.</p> <p>P102 Keep out of reach of children.</p> <p>P262 Do not get in eyes, on skin, or on clothing.</p> <p>P270 Do not eat, drink or smoke when using this product.</p> <p>P280 Wear protective gloves</p> <p>P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor</p> <p>P501 Dispose of contents and container in accordance with the local requirements / the instruction of the label</p>
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To avoid risks to man and the environment, comply with the instructions for use

ACTIVE SUBSTANCE: 0.005 % w/w Bromadiolone

AUTHORIZATION NUMBER:

ANTIDOTE: Vitamin K₁ /Vitaplex Inj./Konakion Inj.

SHELFLIFE: Two years if kept in original packing in a dry and cool place.

WEIGHT: 75, 100, 120, 200 gram

DISTRIBUTED BY:

ORTIS LTD., INDUSTRIAL ZONE, TA' QALI ATD4000, MALTA Tel.: 21 418236

MANUFACTURED BY:

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