

NOTICE OF AUTHORIZATION IN TERMS OF THE BIOCIDAL PRODUCT REGULATION

09/06/2016

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 Wax Block Extruded

ACTIVE INGREDIENT: Bromadiolone

PRODUCT TYPE: 14

IDENTITY OF APPLICANT: Babolna Bio Ltd

REGISTRATION REFERENCE NUMBER: 2014-03-24-B01

APPROVED PACKAGING SIZES FOR PROFESSIONAL USE:

- (1) 20g blocks supplied inside plastic bucket in multiples of 50/150/400. Up to 8kg.
- (2) 25g blocks supplied inside a plastic bucket in multiples of 40/120/320. Up to 8kg.
- (3) 50g blocks supplied inside a plastic box in multiples of 20/60/160. Up to 8kg.

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.

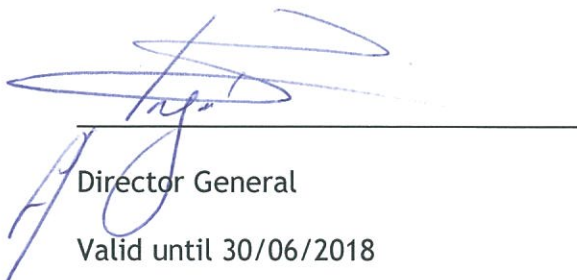
Information to the Applicant:

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' AWTORIZAZZJONI SKOND IR-REGOLAMENTI DWAR PRODOTT BIOĊIDA

09/06/2016

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 Wax Block Extruded

INGREDJENT ATTIV: Bendiocarb

TIP TA' PRODOTT: 14

IDENTITÀ TAL- APPLIKANT: Babolna Bio Ltd

NUMRU TA' REFERENZA REĠISTRAZZJONI: 2014-03-24-B01

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

- (1) Blokki ta' 20g fornuti ġewwa barmil tal- plastik f'multipli ta' 50/150/400. Sa 8kg.
- (2) Blokki ta' 25g fornuti ġewwa barmil tal- plastik f'multipli ta' 40/120/320. Sa 8kg.
- (3) Blokki ta' 50g fornuti f'kaxxa tal-plastik f'multipli ta' 20/60/160. Sa 8kg.

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 jbidilx 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 ' Bijoċidi miġjuba f'Malta kif speċifikat fl-Avviż Legali 348 tal-2013.

(f) **Tiġdid ta' Awtorizzazzjoni** : Sakemm revokata qabel, l-awtorizzazzjoni jista' jiġgedded 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) **Oñrajn** : L- Diviżjoni dwar Regolamenti Tekniċi tal- Malta għall-Kompetizzjoni u għall-Affarijiet tal-Konsumatur tista' timponi kundizzjonijiet oñra kif jitqies meħtieġ sabiex jiġi żgurat li l-kondizzjonijiet speċifikati fir-Regolamenti huma sodisfatti .

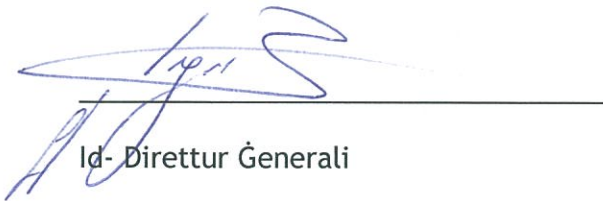
Informazzjoni lill- Applikant:

Din l-awtorizzazzjoni m'għandhiex teżenta lill -applikant u / jew kwalunkwe persuna oñra awtorizzata li taġixxi f'ismu minn kwalunkwe obligazzjoni oñra taħt ir-Regolamenti bijoċida jew kwalunkwe leġislazzjoni oñra rilevanti jew dispożizzjoni amministrattiva . Għandha tkun ir-responsabbiltà unika u esklussiva tal- applikant u / jew kwalunkwe persuna oñra 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-Bijoċidi , għandu jikkostitwixxi reat taħt dawn ir-regolamenti .

Id- detentur tal-awtorizzazzjoni għandu jżomm 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-Bijoċidi , 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[®] Wax Block Extruded

A ready-to-use Wax Block bait containing 0.05 g/kg bromadiolone

Intended uses: against Brown rat (*Rattus norvegicus*) and House mouse (*Mus domesticus/musculus*)

For indoor & outdoor (around buildings) use.

For professional use.

The rodenticide wax block extruded bait contains denatonium benzoate - an extremely bitter substance - which helps preventing incidental consumption by humans.

Instructions for use:

Place baits manually in the rodent infested area. The method of deployment is dependant on the particular circumstances, however a priority should be to exclude non-target exposure as much as possible.

Bait may be deployed in bait stations (tamper proof baiting boxes), at bait points (a makeshift arrangement using materials and/or the local environment to restrict access to the bait), and loose but inaccessible (using the local environment only to restrict access to the bait).

These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non-target organisms) of a particular site must be assessed in the decision for the deployment method to be used.

Bait can be placed in bait boxes, which may be fixed to the ground. Such bait should be secured in place on the built-in spikes, to minimise removal and dispersal by rodents. Bait may also be placed on trays under a tile, or located in such a way that access by non-target organisms is restricted.

The product must never be placed indiscriminately.

The resistance status of the target population should be taken into account

when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

When tamper resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Rate of use:

For rat infestations use bait points of up to 200 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations.

For mouse infestations use bait points of up to 40g to 50 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations.

Death of the rodents starts after 3-5 days from the beginning of consumptions. Make regular inspections of the bait points (regularly every 7 – 10 days) and replace any bait that has been eaten by rodents, damaged by water or contaminated by dirt. If bait is totally consumed then the quantity of the bait at each bait point should be replenished.

Precautions for use:

Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry). Where possible, secure baits so that they cannot be dragged away.

Use anticoagulant rodenticides as permanent baits only under the supervision of a pest control operator or other competent person. In most

cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined. Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children.

First aid:

Bromadiolone is an anticoagulant which may produce bleeding; the onset of bleeding may be delayed for several days after exposure. If there is no active bleeding the INR (prothrombin time) should be measured on presentation and 48-72 hours after exposure. If the INR is greater than 4, administer Vitamin K1 (phytomenadione) 5-10 mg by slow intravenous injection (100 µg/kg body weight for a child). Treatment with phytomenadione (orally or intravenously) may be required for several weeks.

Antidote Vitamin K1 (under medical supervision).

Waste disposal:

Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.

Dispose of dead rodents in accordance with local requirements.

Remove all baits after treatment and dispose of them in accordance with local requirements.

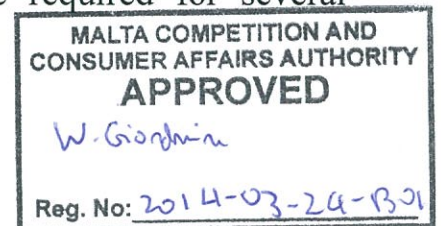
Storage and shelf-life:

Keep in a cool, dry, well-ventilated area. Shelf life up to 24 months.

Contains:

Pack contains:

(Possible packaging:



– 20 g blocks supplied inside a plastic bucket in multiples of 50/150/400.

Up to 8kg.

– 25 g blocks supplied inside a plastic bucket in multiples of 40/120/320.

Up to 8kg.

– 50 g blocks supplied inside a plastic box in multiples of 20/60/160. Up to 8kg.)

Authorisation number: 2014-03-24-B01

Formulator, Authorisation Holder & Marketing Company:

Babolna Bio Limited, H-1107 Budapest, Szállás út 6, Hungary

Telephone: +36-1-432 0400 Fax: +36-1-4320-401

Email: info@babolna-bio.com www.babolna-bio.com

DISTRIBUTED IN MALTA BY: ORTIS LTD.,

INDUSTRIAL ZONE, TA' QALI ATD4000,

MALTA Tel.: 21 418236

Nru. tal-Emergenza / Emergency No: 112

® = Trademark

Date of Manufacture / Batch nr:



WARNING

Hazard statements:

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P102 Keep out of reach of children.

P262 Do not get in eyes, on skin, or on clothing.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves (only for professionals)

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor

P501 Dispose of contents and container in accordance with the local requirements / the instruction of the label

To avoid risks to man and the environment, comply with the instructions for use

