

NOTICE OF AUTHORIZATION IN TERMS OF THE BIOCIDAL PRODUCT REGULATION

2016-05-17

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: Facorat Wax Blocks

ACTIVE INGREDIENT: Brodifacoum

PRODUCT TYPE: 14

IDENTITY OF APPLICANT: I.N.D.I.A. Industrie Chimiche S.r.L.

REGISTRATION REFERENCE NUMBER: 2014-04-02-B01

APPROVED PACKAGING SIZES FOR PROFESSIONAL USE:

Type: Box

Material: Paper, cardboard

Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25 kg

Type: Bag/ Sack

Material: Plastic: composite

Size: 40-60-100-160-200-260-280-300-320-340-360-380-400-420-440-460-480-500 g

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 31/01/2017

AVVIŻ TA' AWTORIZAZZJONI SKOND IR-REGOLAMENTI DWAR PRODOTT BIOĊIDA

2016-05-17

Fl -eżercizzju 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 Affarjiet tal-Konsumatur , qiegħed hawnhekk jirrikonoxxi l-awtorizzazzjoni tal-prodott bijoċidali li ġej.

PRODOTT: Facorat Wax Blocks

INGREDJENT ATTIV: Brodifacoum

TIP TA' PRODOTT: 14

IDENTITÀ TAL- APPLIKANT: I.N.D.I.A. Industrie Chimiche S.r.L.

NUMRU TA' REFERENZA REĠISTRAZZJONI: 2014-04-02-B01

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

Tip: Kaxxa

Materjal: Karta, kartun

Daqs: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25 kg

Tip: Borża/ Xkora

Materjal: Plastik: Kompst

Daqs: 40-60-100-160-200-260-280-300-320-340-360-380-400-420-440-460-480-500 g

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 Affarjiet 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 Affarjiet 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 Affarjiet 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) **Dhul fis- suq Malti:** Il- Diviżjoni dwar Regolamenti tekniċi tal- Malta għall-Kompetizzjoni u lill-Awtorità Affarjiet 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' 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-Affarjiet 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 obligazzjoni oħra taħt ir-Regolamenti bijoċida jew kwalunkwe leġiżlazzjoni oħra rilevanti jew dispożizzjoni 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-Bijoċidi , 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 Deciżjonijiet 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'humix issodisfatti jew m'għadhomx jiġu sodisfatti , jew li dettalji foloz jew qarrieqa jkunu ġew mghoddija 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 31/01/2017

FACORAT WAX BLOCKS

COMPOSITION

100 g of product contain:
Brodifacoum (CAS No. 56073-10-0) 0.005 g
Denatonium Benzoate 0.001 g
Palatable substances and co-formulants: up to 100 g

CAUTION RECOMMENDATIONS

P102 Keep out of reach of children.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves.
P301+310 IF SWALLOWED: Immediately call a POISON CENTER or a doctor.
P401 Store away from food, drink and animal feeding stuff.
P501 Dispose of contents to hazardous waste facilities in accordance with national regulations.

BIOCIDAL PRODUCT (PT14)

MCCAA Authorisation No. 2014-04-02-B01

Authorisation holder:

I.N.D.I.A. Industrie Chimiche S.r.l, Via Sorgaglia 25, 35020 Arre (PD) – Italy Tel. +39.049.8076144

Production, packing and controlling plant:

INDUSTRIALCHIMICA S.r.l, Via Sorgaglia 40, 35020 Arre (PD) - Italy

Batch No.:

Production date:

Shelf-life: 24 months (If stored in original unopened container, in a cool dry place, away from direct sunlight)

Net content: 1-3-5-10-20-25 kg

(containing wax blocks of 6 or 20 g each)

FACORAT WAX BLOCKS

Ready-for-use rodenticidal wax blocks

For professional use

Before use, carefully read the label instructions

CHARACTERISTICS OF THE PRODUCT

FACORAT WAX BLOCKS is a ready-for-use rodenticidal bait containing Brodifacoum, an active ingredient effective against mice and rats even after a single feed.

The product is formulated as wax blocks, particularly palatable for all the species of rodents indicated under the paragraph "directions for use".

The product does not arise the suspicion of the rodents' colony.

FACORAT WAX BLOCKS contains an aversive substance to prevent children from swallowing the product.

FACORAT WAX BLOCKS can be used in and around industrial, rural and civilian buildings (including goods warehouses and ship holds), houses, cellars, garages, utility rooms and relating gardens or outdoor areas.

DIRECTIONS FOR USE

The product is ready for use and must be used according to usage rates given below. The rodenticide bait must be placed in a bait box, weather-resistant, tamper-resistant, inaccessible to non-target animals and preventing bait release in the environment.

Inspect the infested area and place the sealed bait boxes close to dens, along tracks and in most densely populated areas. Avoid touching the product with bare hands and wear appropriate gloves.

The product is effective against:

House mouse (*Mus musculus*)

Grey rat (*Rattus norvegicus*)

Black rat (*Rattus rattus*)

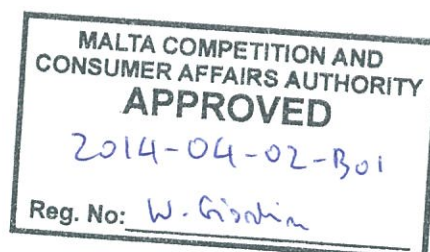
Recommended rates are:

House mouse: 40 g/100 sqm

Grey rat: 60-100 g/100 sqm

Black rat: 60-100 g/100 sqm

Clearly signal the area being treated



Replace bait boxes weekly, if necessary. Remove dead rodents as soon as possible and dispose of according to the rules in force. The product is not aimed at permanent use. Treatments should be scheduled to last for 6 weeks max. At the end of treatment, dispose of the bait boxes containing remaining baits according to the rules in force. Carefully read the safety data sheet.

MEDICAL INFORMATION

Mode of action: the active ingredient in the product is an antagonist of Vitamin K and reduces the hepatic synthesis of K-dependent factors.

Symptoms: serious poisoning if swallowed. Inhibits vitamin K and causes skin and mucosae bleeding. Symptoms for other systems and apparatus are mainly haemorrhagic.

Therapy: in case of ingestion of large amounts, induce vomiting, carry out a gastric lavage and monitor prothrombin activity (if reduced, administer vitamin K). Follow a suitable medical protocol.

Counter-indications: anticoagulants

Warning: consult a poison-control centre.

WARNING

Bait boxes must be safely placed so as to minimise tampering risks and accidental swallowing risks by children and non-target animals. Make sure the bait boxes are properly fixed and that baits cannot be dragged away by rodents. Avoid treatments in the presence of exposed foodstuffs and feedingstuffs. Do not use in agriculture. In case of contamination, wash hands with plenty of water and soap. Do not re-use the container and do not release it in the environment. Dispose of it in compliance with regulations in force. If swallowing is suspected to have occurred, consult a Poison-Control Centre. The product can be dangerous if swallowed by pets or other non-target. If the product has been swallowed, induce vomiting. Immediately seek a veterinarian's attention and show this container or label.

