

In compliance with EC Regulation no. 453/2010

Rev. 0 of 15/05/2012

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1Product identifier: MEGALON WAX BLOCKS

1.2 Relevant identified uses of the substance or mixture and uses advised against: rodenticidal bait

1.3 Details of the supplier of the safety data sheet

I.N.D.I.A. INDUSTRIE CHIMICHE S.p.A. Address: Nona Strada 55/57 35129 Padova

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 $e\text{-mail address of the competent } person \ responsible \ for the \ MSDS: laboratorio@indiacare.it$

1.4 Emergency contacts: +39 049.807.61.44 from 8.30 to 12.30 and from 14.00 to 18.00

2.HAZARD IDENTIFICATION

2.1 Classification of mixture: is not classified dangerous

2.2 Label elements:

Pictograms: none

Hazard statements: none Precautionary statements:

S2 Keep out of the reach of children

S13 Keep away from food, drink and animal feedingstuffs.

S37 Wear suitable gloves

2.3 Other hazards:

PBT:

vPvB:

Harmful effects, if any, are described at section 9 and 12

3.COMPOSITION/INFORMATION ON INGREDIENTS

NAME	Conc. % w/w	EINECS no.	CAS no.	Classification according to 67/548/CE	Classification according to CLP
Bromadiolone	0.0050	249-205-9	28772-56-7	T+,N; R26/27/28 R48/23/24/25,R50/53	Acute Tox H300,H310, H330 STOT.RE H372 Aquatic Acute1 H400
Denatonium benzoate	0.001	223-095-2	3734-33-6	Xn,Xi; R20/22,R41,R38,R52/53	Aquatic Chronic 1H410 Eye damage 1 H318 Skin irrt. 2 H315
				NZU/ZZ,N41,N36,N3Z/33	Acute Tox. 4 H302, H332 Aquatic Chronic 3 H412
Other non-dangerous substances	Up to 100				

The full text of risk phrases (R) and of hazard phrases (H) can be found at section $16\,$

4. FIRST AID MEASURES

4.1 Description of first aid measures

Page 1 of 6

INDIA

SAFETY DATA SHEET

Rev. 0 of 15/05/2012

In compliance with EC Regulation no. 453/2010

Way of exposure:

- General indications: In any case, seek medical advice. Do not administer anything through mouth to unconscious people.
- Skin contact: wash skin immediately with soap and plenty of water.
- Eye contact: Flush eyes immediately with plenty of water for at least 15/20 minutes with open eyelids. If smarting or irritation
 persists consult an oculist.
- If swallowed: flush mouth with water
- Inhalation: remove patient to fresh air

4.2 Most important symptoms and effects, both acute and delayed

Bromadiolone is a single-feed second generation anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in profuse internal haemorrhage and death.

- Harmful to skin contact; could be absorbed and cause internal haemorrhage.
- Harmful if swallowed; serious risk of internal haemorrhage
- Harmful if inhaled; serious risk of internal haemorrhage
- Soil and water could be contaminated.
- Symptoms may be associated to increased bleeding tendency.

4.3 Indication of any immediate medical attention and special treatment needed:

Medical information: like all anticoagulant rodenticides, Bromadiolone structure is similar to that of vitamin K. In the affected spot, a blood clot is formed because of a complex cascading system involving several blood coagulation factors synthesized in the liver as inactive precursors, converted into active and annexed to blood circulation. Vitamin K is used in the liver in the activation process and is used in a continuous cyclic process involving several enzymes. Anticoagulant rodenticides block these enzymes preventing vitamin K regeneration and the activation of coagulation factors.

- Monitor prothrombin activity continuously for several days, especially if the amount swallowed is large. Treatment: vitamin K1.
- In animals and particularly in pets, vitamin K1 can be administered even in absence of symptoms, because of the haemorrhage that can appear after swallowing

Other medical data (bromadiolone):

1991-1999 the calls received by the Poison-Control Centre in Milan (Italy) amounted to 98, involving both people and animals. 55% of cases was swallowing by children below 4 years of age. Symptoms: 11 cases showed vomiting, gastric pyrosis and 1 case haematological troubles

5. FIREFIGHTING MEASURES

5.1 Extinguishing means

Appropriate means: chemical powder, CO₂, foam, inert gases Means not to be used for safety reasons: direct water jets

5.2 Special hazards arising from the substance or mixture

in a fire toxic fumes are released

5.3 Advice for firefighters

wear protective fire-proof clothing and mask

6.ACCIDENTAL RELEASE MEASURES

- **6.1 Personal precautions, protective equipment and emergency procedures:** avoid contact with eyes and skin. Block the access to children and pets
- 6.2 Environmental precautions: Keep away from drains, surface and underground waters. Avoid contamination of foodstuffs.
- **6.3 Methods and material for containment and cleaning up:** collect with mechanical means, store in tight containers and dispose of according to indications given at section 13.

Page 2 of 6

INDIA

SAFETY DATA SHEET

In compliance with EC Regulation no. 453/2010

Rev. 0 of 15/05/2012

7. HANDLING AND STORAGE

- **7.1 Precautions for safe handling:** wear all suitable protective devices to avoid contact. Protect eyes and skin. When handling, do not eat, drink or smoke
- **7.2 Conditions for safe storage, including any incompatibilities:** to be stored in ventilated cool premises, away from direct sunlight. Keep out of the reach of children and pets. Protect from direct sunlight. Keep away from any combustion source. Keep in original closed containers, away from foodstuffs and beverages and out of the reach of children and pets. Provide accurate ventilation/suction on work premises.
- 7.3 Specific end use: rodenticidal bait

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

National:

EU:

Bio:ogical threshold values

DNEL: PNEC:

8.2 Exposure controls:

Protection of eyes/face: wear protective goggles

Protection of skin: wear suitable clothing. Replace periodically.

Protection of hands: wear protective gloves for chemicals. Replace periodically

Respiratory protection: not required

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information:

Physical state: solid

Colour : red

Odour: characteristic

Important information for human health, safety and the environment

Flammability: not highly flammable

9.2 Other information:

10. STABILITY AND REACTIVITY

10.1 Reactivity: none

10.2 Chemical stability: Stable in original sales pack when complying to instructions given on the label

10.3 Possibility of hazardous reactions: none

10.4 Conditions to avoid: none

10.5 Incompatible materials: none



In compliance with EC Regulation no. 453/2010

Rev. 0 of 15/05/2012

10.6 Hazardous decomposition products: none

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Rabbit skin irritation: not irritating (JFR study) Rabbit eye irritation: not irritating (JFR study)

The product is not dangerous for health; toxicological information is provided below on the active ingredient Bromadiolone:

Acute oral toxicity: LD50 rat 1.31 mg/kg bw
 Oral acute toxicity: LD50 dog 8.1 mg/kg bw
 Dermal acute toxicity: LD50 rat 23.31 mg/kg bw
 Acute inhalation toxicity: LC50 rat 0.43 μg/kg bw/day

NOAEL rat: 2.5 μg/dayNOAEL rabbit: 0.5 μg/kg/day

Maternal toxicity (rabbit): LOAEL 2 μg/kg/day
 Growth toxicity: LOAEL 2 μg/kg/day
 NOAEL 4 μg/kg/day

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Bromadiolone: toxic effects on fish, plankton and other organisms. Limited risk for waters.

Fish (Oncorhynchus mykiss): LC50 96 h: 2.86 mg/l Invertebrates (Daphnia magna): EC50 48 h: 5.79 mg/l

Pesudokichneriella sub capitata 72 h growth inhibition (g) ErC50 1.14 mg/l Activated sludge 3 h, breathing inhibition EC50 132.8 mg/l (calculated) Effects on earthworms and other non-target organisms in soil:

Acute toxicity on Eisenia foetida: 13 day LC50 918 mg/kg dwt

Effects on terrestrial vertebrates:

Acute toxicity in mammals: LD50 1.31 mg/kg bw (rat)
Bird acute toxicity: LD50 134 mg/kg bw (Japanese quail)

Bird toxicity 10-day diet LC50 28.9 mg/kg food

Bird reproduction toxicity: NOEC 0.26mg/kg drinking water (Japanese quail)

Denatonium benzoate: Fish LC50 (96 h): >1000 mg/l LC50 (shrimp) (96 h): >400 mg/l Daphnia magna EC50 (48 h): 13 mg/l

12.2 Persistence and degradability:.

Bromadiolone is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes. Route and rate of degradation in water: No hydrolysis was found at the investigated pH 7 and 10, so hydrolysis of bromadiolone is not expected to be a significant process in the environment. pH 9, 50°C: no hydrolysis of bromadiolone during the 120 days test.

Photolytic/photo-oxidative degradation Natural sunlight at latitude 52° N, aqueous solution:

DT50 = 2.98 minutes (summer) and 30.4 minutes (winter) at a quantum yield of 0.25. DT50 = 74.5 minutes (summer) and 768 minutes (winter) at a quantum yield of 0.01.

Denatonium benzoate: in water: 10% anaerobic degradation after 30 days at 25°C at all pH values

12.3 Bioaccumulative potential:

Bromadiolone: Bioconcentration tests failed due to high mortalities. BCF (calculated from a log Kow of 3.8) = 339

Denatonium benzoate: LogPow 0.9

Page 4 of 6

of 15/05/2012

Rev. 0

In compliance with EC Regulation no. 453/2010

12.4 Mobility in soil:

Bromadiolone: Soil distribution (partition) coefficient (KD): 71.2-1250 mL/g (adsorption)Soil adsorption coefficient normalized for organic carbon content (KOC): 3530 to 41600 mL/g (adsorption), average value 14770 mL/g used for calculations.No pH dependence observed. Bromadiolone is considered slightly mobile to non-mobile in soil

Denatonium benzoate: N.D.

12.5 Results of PBT and vPvB assessment:

Bromadiolone: P screening criterion for water is fulfilled and in addition, bromadiolone fulfils the soil P criterion of REACH taking the toxic and persistent metabolites into consideration.

B screening is under revision. T criterion is fulfilled for bromadiolone. To summarize, the uncertainties with regard to the B-criterion cannot be clarified at the moment and bromadiolone should be considered as a potential PBT substance.

Denatonium benzoate: N.D.

12.6 Other adverse effects:

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods: dispose of as toxic waste. The correct classification is an obligation of the waste holder

14. TRANSPORT INFORMATION

14.1 UN number:

14.2 UN proper shipping name:

14.3 Transport hazard class:

14.4 Packing group:

Transport classification:

Marine pollutant:

IMO: 9

IATA: 9

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Seveso category: 9i

Substances in Candidate List (Art. 59 REACH): none

Substance subject to authorization (Annex XIV REACH): none

15.2 Chemical safety assessment: no chemical safety assessment has been conducted for the compound and the substances therein contained.

16. OTHER INFORMATION

Integral text of H and R phrases

H300 fatal if swallowed

H302 harmful if swallowed

H310 Fatal in contact with skin

H315 Causes skin irritation

H318 Causes serious eye damage

H372 Causes damage to organs through prolonged or repeated exposure

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects

Page 5 of 6



gulation no. 453/2010 of 15/05/2012

Rev. 0

In compliance with EC Regulation no. 453/2010

H412 Harmful to aquatic life with long lasting effects

R26/27/28 Very toxic in contact with skin, if swallowed and inhaled

R48/23/24/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed R50/53 very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

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Bibliography: The Pesticide Manual HSDB Hazardous Substances Data Bank MSDS of raw materials