

Revision nr. 6 Dated 26/09/2022 Printed on 26/09/2022 Page n. 1/15 Replaced revision:5

DERATION PELLET

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name Registration n° **DERATION PELLET** IT/2013/00097/AUT UV00-00H2-M00M-9U71

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use Ready-to-use rodenticide bait in pellet form. For professionals and trained professionals.

 Identified Uses
 Industrial
 Professional
 Consumer

 Rodenticide

Uses Advised Against

All uses other than those recommended

1.3. Details of the supplier of the safety data sheet

Name COLKIM S.r.l. Full address Via Piemonte, 50

District and Country 40064 OZZANO EMILIA (BO)

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Italia

Tel. 051 / 799445 Fax 051 / 797555

e-mail address of the competent person

responsible for the Safety Data Sheet

Supplier:

info@colkim.it

COLKIM S.r.I. - Via Piemonte, 50 - 40064 OZZANO E. (BO)

1.4. Emergency telephone number

For urgent inquiries refer to

Contact a poison control center:

Nane	City	Address	Zip code	Phone
CAV "Osp. Pediatrico Bambino Gesù"	Roma	P.zza Sant`Onofrio, 4	00165	06 68593726
Az. Osp. Univ. Foggia	Foggia	V.le Luigi pinto, 1	71122	0881 732326
Az. Osp. "A. Cardarelli"	Napoli	Via A. Cardarelli, 9	80131	081 7472870
CAV Policlinico "Umbero I"	Roma	V.le del policlinico, 155	00161	06 49978000
CAV Policlinico "A. Gemelli"	Roma	Largo Agostino Gemelli, 8	00168	06 3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica	Firenze	Largo Brambilla, 3	50134	055 7947819
CAV Centro Nazionale di Informazione Tossicologica	Pavia	Via Salvatore Maugeri, 10	27100	0382 24444
Osp. Niguarda Ca' Granda	Milano	P.zza Ospedale Maggiore,3	20162	02 66101029
Azienda Ospedaliera Papa Giovanni XXII	Bergamo	P.zza OMS, 1	24127	800883300
CAV centro antiveleni Verona	Verona	Piazzale Aristide Stefani,1	37126	800011858



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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Reproductive toxicity, category 1B H360D May damage the unborn child.

Specific target organ toxicity - repeated exposure, category 1 H372 Causes damage to organs through prolonged or repeated

exposure.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words: Danger

Hazard statements:

H360D May damage the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements:

P102 Keep out of reach of children.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

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

P280 Wear protective gloves / protective clothing / eye protection / face protection / hearing protection.

P308+P313 IF exposed or concerned: Get medical advice / attention.

P501 Dispose of contents / container to in accordance to national regulation.

Contains: BROMADIOLONE

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:



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Identification x = Conc. % Classification (EC) 1272/2008 (CLP)

CALCIUM SULPHATE DIHYDRATE

INDEX - $3 \le x < 3,5$

EC 231-900-3 CAS 10101-41-4

CALCIUM HYDROXIDE

INDEX - 0,35 ≤ x < 0,4 Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335

EC 215-137-3 CAS 1305-62-0

REACH Reg. 01-2119475151-45

BROMADIOLONE

EC 249-205-9

INDEX - x = 0,005 Repr. 1B H360D, Acute Tox. 1 H300, Acute Tox. 1 H310, Acute Tox. 1 H330,

STOT RE 1 H372, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1 Repr. 1B H360D: ≥ 0,003%, STOT RE 1 H372: ≥ 0,005%, STOT RE 2 H373:

≥ 0,0005%

CAS 28772-56-7 LD50 Oral: 0,56 ug/l, LD50 Dermal: 1,71 ug/l, STA Inhalation mists/powders:

0,005 mg/l

DENATONIUM BENZOATE

CAS. 3734-33-6 x = 0,001 Skin Irrit.2 H315, Eye Dam.1 H318, Aquatic Chronic.3 H412, Acute Tox.4

H302, Acute Tox.4 H332

CE 223-095-2 INDEX. -Nr. Reg.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately. INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Ingestion of excessive quantities may cause nausea, vomiting, loss of appetite, extreme thirst, lethargy, diarrhea, bleeding

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

If ingested, administer vitamin K1 orally or intramuscularly as indicated in the case of an overdose of bishydroxycoumarin. Repeat as needed based on monitoring of prothrombin times.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.



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5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)



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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

ITA GBR EU

United Kingdom OEL EU

Decreto Legislativo 9 Aprile 2008, n.81

EH40/2005 Workplace exposure limits (Fourth Edition 2020)
Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983;
Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive

2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.

TLV-ACGIH

Threshold Limit Value Type	Country	TWA/8h		STEL/15min		Remarks		
		mg/m3	ppm	mg/m3	ppm	Observati	ons	
WEL	GBR	10	FF···		FF		Particulat	es
Predicted no-effect concentrate								
Normal value in fresh water				260	mg	<u></u>		
Normal value in marine water				26	mg	ı/I		
Normal value for fresh water s	sediment			572	mg	ı/kg		
Normal value for marine water	r sediment			57,2	mg	ı/kg		
Normal value for water, interm	nittent release			183	mg	ı/I		
Normal value of STP microorg	ganisms			20000	mg	ı/I		
Normal value for the terrestria	l compartment			50	mg	ı/kg		
Health - Derived no-effec		OMEL			Effects on			
	Effects on consumers				workers			
Route of exposure		Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation	consumers Acute local	Acute systemic	Chronic local 10 mg/m3				Chronic local	systemic
Inhalation CALCIUM SULPHATE DI Threshold Limit Value	consumers Acute local	Acute systemic		systemic		systemic Remarks	10 mg/m3	systemic
nhalation CALCIUM SULPHATE DI Threshold Limit Value	consumers Acute local HYDRATE	·		systemic 50 mg/m3		systemic	10 mg/m3	systemic
nhalation CALCIUM SULPHATE DI Threshold Limit Value Type	consumers Acute local HYDRATE	TWA/8h	10 mg/m3	systemic 50 mg/m3 STEL/15min	Acute local	systemic Remarks	10 mg/m3	systemic
CALCIUM SULPHATE DI Threshold Limit Value Type WEL	Acute local HYDRATE Country	TWA/8h mg/m3	10 mg/m3	systemic 50 mg/m3 STEL/15min	Acute local	systemic Remarks Observati	10 mg/m3	systemic
CALCIUM SULPHATE DI Threshold Limit Value Type WEL	Consumers Acute local HYDRATE Country GBR	TWA/8h mg/m3	10 mg/m3	systemic 50 mg/m3 STEL/15min	Acute local	Remarks Observati	10 mg/m3	systemic
CALCIUM SULPHATE DI Threshold Limit Value Type WEL WEL TLV-ACGIH	Consumers Acute local HYDRATE Country GBR GBR	TWA/8h mg/m3 10 4	10 mg/m3	systemic 50 mg/m3 STEL/15min	Acute local	Remarks Observati	10 mg/m3	systemic
Route of exposure Inhalation CALCIUM SULPHATE DI Threshold Limit Value Type WEL WEL TLV-ACGIH Predicted no-effect concentral Normal value of STP microorg	Consumers Acute local HYDRATE Country GBR GBR tion - PNEC	TWA/8h mg/m3 10 4	10 mg/m3	systemic 50 mg/m3 STEL/15min	Acute local	Remarks Observati INHAL RESP	10 mg/m3	systemic
Inhalation CALCIUM SULPHATE DI Threshold Limit Value Type WEL TLV-ACGIH Predicted no-effect concentration	Consumers Acute local HYDRATE Country GBR GBR GBR tion - PNEC ganisms	TWA/8h mg/m3 10 4 10	10 mg/m3	systemic 50 mg/m3 STEL/15min mg/m3	Acute local	Remarks Observati INHAL RESP	10 mg/m3	systemic
CALCIUM SULPHATE DI Threshold Limit Value Type WEL TLV-ACGIH Predicted no-effect concentrat Normal value of STP microore Health - Derived no-effect	CONSUMERS ACUTE IOCAL HYDRATE COUNTRY GBR GBR GBR tion - PNEC ganisms ct level - DNEL / E Effects on	TWA/8h mg/m3 10 4 10	10 mg/m3	systemic 50 mg/m3 STEL/15min mg/m3 100 Chronic	ppm mg	Remarks Observati INHAL RESP	10 mg/m3	systemic 168 mg/m3 Chronic
CALCIUM SULPHATE DI Threshold Limit Value Type WEL WEL TLV-ACGIH Predicted no-effect concentral Normal value of STP microorg	CONSUMERS ACUTE LOCAL HYDRATE COUNTRY GBR GBR tion - PNEC ganisms ct level - DNEL / E Effects on consumers	TWA/8h mg/m3 10 4 10	10 mg/m3	systemic 50 mg/m3 STEL/15min mg/m3	ppm Effects on workers	Remarks Observati INHAL RESP	10 mg/m3 / ons	systemic 168 mg/m3



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Туре	Country	TWA/8h		STEL/15min		Remarks Observat	•	
		mg/m3	ppm	mg/m3	ppm			
VLEP	ITA	1		4		RESP		
WEL	GBR	5				INHAL		
WEL	GBR	1		4		RESP		
OEL	EU	1		4		RESP		
TLV-ACGIH		5						
Predicted no-effect concent	tration - PNEC							
Normal value in fresh water	r			49	mg	/I		
Normal value in marine wat	er			32	mg	/I		
Normal value for water, inte	ermittent release			49	mg	/I		
Normal value of STP micro	organisms			3	mg	/I		
Normal value for the terrest	rial compartment			1080	mg	/kg		
Health - Derived no-eff	fect level - DNEL /	DMEL						
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation	4 mg/m3		1 mg/m3	•	4 mg/m3		1 mg/m3	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

8.2. Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

8.2.1 APPROPRIATE ENGINEERING CONTROLS

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range Upper end of the range



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1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood - local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2 PERSONAL PROTECTION











Eye and face protection

Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

Skin protection

See Hand protection below

Hands/feet protection

Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber NOTE: The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be

observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact
- chemical resistance of glove material
- glove thickness
- dexterity.

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- -When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- -Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- Excellent when breakthrough time > 480 min.
- Good when breakthrough time > 20 min.
- Fair when breakthrough time < 20 min.
- Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times. Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers' technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example: -Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. -Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential.



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	Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of
	a non-perfumed moisturiser is recommended.
Body protection	See Other protection below
Other protection	Overalls.P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit.
Environmental	Emissions from manufacturing processes, including those from ventilation equipment, should be controlled for compliance with
exposure controls	environmental protection legislation. Product residues must not be discharged without control into wastewater or water
	courses.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance Colour Odour Odour threshold	solid red sweetish not available	Method:OPPTS 830.6303 Method:OPPTS 830.6302 Method:OPPTS 830.6304 Reason for missing data:Determination not
Melting point / freezing point	not available	required for safe use of the product Reason for missing data: Determination not
Initial boiling point	not available	required for safe use of the product Reason for missing data: Determination not required for safe use of the product Reason for missing data: Determination not required for safe use of the product
Flammability	not applicable	Reason for missing data:The product is not flammable
Lower explosive limit	not applicable	Reason for missing data:Not applicable to solids
Upper explosive limit	not applicable	Reason for missing data:Not applicable to solids
Flash point	not available	Reason for missing data:Not applicable to solids
Auto-ignition temperature	not applicable	Reason for missing data:Not applicable to solids
Decomposition temperature	not available	Reason for missing data:The mixture is not self-reactive
pH Kinematic viscosity	6,9 not applicable	Method:OECD test 122 Reason for missing data:Not applicable to solids
Dynamic viscosity	not available	Reason for missing data:Not applicable to solids
Solubility	immiscible with water	
Partition coefficient: n-octanol/water	not applicable	Reason for missing data: Not determinable for mixtures
Vapour pressure	not available	Reason for missing data:Determination not required for safe use of the product
Density and/or relative density Relative vapour density	1,276 g/cm3 not applicable	Method:OECD test 109 Reason for missing data:Not applicable to solids
Particle characteristics		
Median equivalent diameter		
Remark:	The product is presented as a single compact block	

9.2. Other information

9.2.1. Information with regard to physical hazard classes



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9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

BROMADIOLONE

Oral LD50 (rat): 1,12 mg/Kg.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure



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Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:

ATE (Oral) of the mixture:

Not classified (no significant component)

Not classified (no significant component)

ATE (Dermal) of the mixture:

Not classified (no significant component)

CALCIUM SULPHATE DIHYDRATE

LD50 (Oral): > 1581 mg/kg LC50 (Inhalation mists/powders): > 3,26 mg/l/4h

CALCIUM HYDROXIDE

LD50 (Dermal): > 2500 mg/kg Rabbit LD50 (Oral): > 2000 mg/kg Rat - female

BROMADIOLONE

 LD50 (Dermal):
 1,71 mg/kg

 LD50 (Oral):
 0,56 mg/kg

 LC50 (Inhalation vapours):
 0,43 ug/l

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

May damage the unborn child

STOT - SINGLE EXPOSURE



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Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Causes damage to organs

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

BROMADIOLONE

LC50 - for Fish > 8 mg/l/96h SPECIE RAINBOW TROUT
EC50 - for Crustacea 2 mg/l/48h SPECIE DAPHNIA MAGNA

EC50 - for Algae / Aquatic Plants 1,14 mg/l/72h

CALCIUM HYDROXIDE

LC50 - for Fish 457 mg/l/96h Gasterosteus aculeatus

EC50 - for Algae / Aquatic Plants 18457 mg/l/72h Pseudokirchneriella subcapitata

CALCIUM SULPHATE DIHYDRATE

LC50 - for Fish > 56000 mg/l/96h Gambusia affinis EC50 - for Crustacea 6,6 mg/l/48h Daphnia magna

EC50 - for Algae / Aquatic Plants > 79 mg/l/72h Selenastrum capricornutum

12.2. Persistence and degradability

BROMADIOLONE

NOT rapidly degradable

CALCIUM HYDROXIDE

Solubility in water 1000 - 10000 mg/l

12.3. Bioaccumulative potential

BROMADIOLONE

Partition coefficient: n-octanol/water 4,07 Log Kow

BCF 575

12.4. Mobility in soil



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12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable



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14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Contained substance

Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

This safety data sheet contains one or more Exposure Scenarios in an integrated form. Contents have been included in sections 1.2, 8, 9, 12, 15 and 16 of this safety data sheet.



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SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Repr. 1B Reproductive toxicity, category 1B

Acute Tox. 1 Acute toxicity, category 1

STOT RE 1 Specific target organ toxicity - repeated exposure, category 1

Eye Dam. 1 Serious eye damage, category 1

Skin Irrit. 2 Skin irritation, category 2

STOT SE 3 Specific target organ toxicity - single exposure, category 3

Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1

Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1

H360D May damage the unborn child.

H300 Fatal if swallowed.H310 Fatal in contact with skin.

H330 Fatal if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure.

H318 Causes serious eye damage.

H315 Causes skin irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

I EGEND.

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament



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- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
- Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
- 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- **FCHA** website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control: therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11. Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Decreto Legislativo 25 Febbraio 2000, n. 174 "Attuazione della direttiva 98/8/CE in materia di immissione sul mercato di biocidi"

Decreto del Presidente della Repubblica 6 Ottobre 1998, n. 392 "Regolamento recante norme per la semplificazione dei procedimenti di autorizzazione alla produzione ed all'immissione in commercio di presidi medico-chirurgici, a norma dell'articolo 20, comma 8, della legge 15 Marzo 1997, n. 59.

Changes to previous review:

The following sections were modified:

01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.