Safety data sheet
according to Regulation (EU) No. 2015/830

Printing date 23.12.2020 Revision: 23.12.2020

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

- **1.1 Product identifier**
- **Trade name: BRODITOP GEL**
- **Sds code/version:** 0/20
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
Ready for use rodenticide (biocidal product-PT14)
- **Application of the substance / the mixture** Ready for use rodenticide (biocidal product-PT14)
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Zapi S.p.A.
Via Terza Strada, 12
35026 Conselve (Pd)
Italy
Tel. +39 049 9597737 Fax +39 049 9597735

E-mail address of the competent person responsible for the SDS: techdept@zapi.it

- **Further information obtainable from:** Tech. dept.
- **1.4 Emergency telephone number:** Zapi customer service: tel. +39 049 9597737 (9:00-12:00/14:00-17:00)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Repr. 1A H360D May damage the unborn child.
STOT RE 2 H373 May cause damage to the blood through prolonged or repeated exposure.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
brodifacoum
- **Hazard statements**
H360D May damage the unborn child.
H373 May cause damage to the blood through prolonged or repeated exposure.
- **Precautionary statements**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P314 Get medical advice/attention if you feel unwell.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local regulation.

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- **Additional information:**
Restricted to professional users.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:**	
56073-10-0 brodifacoum	
PBT	Brodifacoum fulfils the P, B and T criteria.

- **vPvB:**	
56073-10-0 brodifacoum	
vPvB	Brodifacoum fulfils the vP criterion.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**		
CAS: 56073-10-0 EINECS: 259-980-5 Index number: 607-172-00-1	brodifacoum Acute Tox. 1, H300; Acute Tox. 1, H310; Acute Tox. 1, H330; Repr. 1A, H360D; STOT RE 1, H372; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10)	0.005%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:** Please refer to the instructions below for each specific way of exposure.

- **After inhalation:** Supply fresh air and to be sure call for a doctor.

- **After skin contact:**
Remove contaminated clothing.
Wash skin with water and then with water and soap.
If needed, seek for medical advice.

- **After eye contact:**
Rinse eyes with eye-rinse liquid or water, keep eyelids open at least 10 minutes.
If needed, seek medical advice.

- **After swallowing:**
Rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.

Contact a veterinary surgeon in case of ingestion by a pet.

- **4.2 Most important symptoms and effects, both acute and delayed**
This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

- **4.3 Indication of any immediate medical attention and special treatment needed**
The primary treatment are the antidote therapy and the clinical assessment. Antidote: Vitamin K1 (phytomenadione). The effectiveness of the treatment should be monitored by measuring the clotting time. Do not interrupt the treatment until the clotting time is back to normality and is stable.
Consult a Poison Control Centre.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO2, powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents:** To our knowledge, there are no unsuitable equipments.
- **5.2 Special hazards arising from the substance or mixture** In case of fire, toxic gases may be generated.
- **5.3 Advice for firefighters** Firefighters equipment in accordance with EN469 European standards.
- **Protective equipment:**
Do not inhale explosion gases or combustion gases.
Firefighters equipment in accordance with EN469 European standards.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
After cleaning up, ensure adequate ventilation.
Dispose of the material collected according to regulations.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Wash hands and directly exposed skin after using the product.
Wear appropriate protective gloves.
Do not smoke near the product.
When using the product, do not eat, drink or smoke.
Place inaccessible to children, companion animals and non-target animals.
Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.
- **Information about fire - and explosion protection:**
See Section 6.
See section 5.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Requirements to be met by storerooms and receptacles:**
Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
Store in places prevented from the access of children, birds, pets and farm animals.
Store only in original container.
- **Information about storage in one common storage facility:**
Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- **Further information about storage conditions:**
Protect from frost.
Protect from humidity and water.

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Do not store at temperature above 35°C.

- **7.3 Specific end use(s)** This product is a rodenticide bait for rodents' control.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any substances with critical values that have to be monitored at the workplace.

- PNECs		
56073-10-0 brodifacoum		
Oral	PNEC	0.0000128 mg/kg bw (bird)
		0.000011 mg/kg bw (mammal)
	PNEC	0.00004 mg/l (aquatic organisms)
		>0.0038 mg/l (microorganisms)
	PNEC	>0.88 mg/kg ww (soil)

- Other exposure limit values		
56073-10-0 brodifacoum		
Oral	AEL - short term	0.0000033 mg/kg bw (AEL)
	AEL - medium term	0.00000667 mg/kg bw (AEL)
	AEL - long term	0.0000033 mg/kg bw (AEL)

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from food, drink and animal feedingstuffs.
Wash hands before breaks and at the end of work.
Do not eat, drink, smoke or sniff while working.

- **Respiratory protection:** Not required during normal use of the product.

- **Protection of hands:**

Wear protective chemical resistant gloves during product handling phase (EN 374, category III).

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product 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.

- **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Not required during normal use of the product.

- **Limitation and supervision of exposure into the environment** See section 6.

- **Risk management measures** Follow the above-reported directions.

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SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties	
- General Information	
- Appearance:	
Form:	Solid
Colour:	Blue
- Odour:	Characteristic
- Odour threshold:	No data available.
- pH-value:	6.7 (CIPAC MT 75.3 - 1% aq.)
- Change in condition	
Melting point/freezing point:	No data available.
Initial boiling point and boiling range:	No data available.
- Flash point:	Not applicable.
- Flammability (solid, gas):	Not available (the product does not contain any ingredient classified as flammable).
- Ignition temperature:	No data available.
- Decomposition temperature:	No data available.
- Auto-ignition temperature:	Product is not selfigniting.
- Explosive properties:	Product does not present an explosion hazard.
- Explosion limits:	
Lower:	No data available.
Upper:	No data available.
- Oxidising properties	No data available.
- Vapour pressure:	Not applicable.
- Density:	No data available.
- Relative density	1.1788 g/ml (EU Method A.3)
- Vapour density	Not applicable.
- Evaporation rate	Not applicable.
- Solubility in / Miscibility with	
water:	Insoluble.
- Partition coefficient: n-octanol/water:	No data available.
- Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
- 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity Under standard handling and storing conditions, the product does not show any dangerous reaction.

- 10.2 Chemical stability Stable at room temperature and if used as recommended.

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.

- **10.4 Conditions to avoid**
Under standard handling and storing conditions, the product does not show any dangerous reaction.

- **10.5 Incompatible materials:**
Store only in original container.
Given the lack of information about possible incompatibilities with other substances, it is recommended not to use it in combination with other products.

- **10.6 Hazardous decomposition products:**
No dangerous decomposition products known under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**

- **Acute toxicity** Based on available data, the classification criteria are not met.

- LD/LC50 values relevant for classification:		
56073-10-0 brodifacoum		
Oral	LD50	0.4 mg/kg bw (male rat and mouse)
Dermal	LD50	3.16 mg/kg bw (rat)
Inhalative	LC50/4h	3.05 mg/m³ (rat)

- **Primary irritant effect:**

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**

- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

- **Carcinogenicity** Based on available data, the classification criteria are not met.

- Reproductive toxicity	
56073-10-0 brodifacoum	
developmental toxicity	Clear developmental toxicity was not observed in rabbits or rats. However, as a precaution, Brodifacoum should be considered teratogenic to humans because it contains the same chemical moiety responsible for the teratogenicity of warfarin, a known human teratogenic agent, and it has the same mode of action that is a known mechanism of teratogenicity in humans.

May damage the unborn child.

- **STOT-single exposure** Based on available data, the classification criteria are not met.

- STOT-repeated exposure		
56073-10-0 brodifacoum		
Oral	NOAEL	0.04 mg/kg bw/d (rat) The study reveals that repeated oral exposure results in toxic effects: prothrombin time prolongation, kaolin-caphalin time prolongation, haemorrhage. Based on the results of the acute dermal and inhalation toxicity studies and route-to-route extrapolation, it is justified to assume a similar concern for serious damage to health by prolonged exposure through dermal and inhalation routes also.

May cause damage to the blood through prolonged or repeated exposure.

- **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

- 12.1 Toxicity

- Aquatic and/or terrestrial toxicity:	
56073-10-0 brodifacoum	
LC50/14d	(eisenia foetida) >994 mg/kg dry weight >879.6 mg/kg wet weight
ErC50/72h	0.04 mg/l (selenastrum capricornutum)
EC10/3h	>0.058 mg/l (activated sludge) Based on water solubility at pH 7 and T=20°C.
EC10/6h	>0.0038 mg/l (pseudomonas putida) Based on water solubility at pH 5.2 and T=20°C.
LC50/96h	0.042 mg/l (oncorhynchus mykiss)
LC50 (diet)	0.72 mg/kg food (laughing gull)
NOEC (reproductive toxicity)	0.0038 mg/kg food (bird)
NOEL (reproductive toxicity)	0.000385 mg/kg bw/d (bird)
LD50	0.31 mg/kg bw (mallard duck)
EC50/48h	0.25 mg/l (daphnia magna)

- 12.2 Persistence and degradability

56073-10-0 brodifacoum	
biodegradability	Not easily biodegradable. Brodifacoum will probably partition into sewage sludge/sediment due to its high log Kow and poor water solubility.
photolytic half-life	0.083 days. Degrades rapidly by photolysis.
Hydrolitic half-life	> 1 year. Stable at pH 5, 7 and 9.

- 12.3 Bioaccumulative potential

56073-10-0 brodifacoum	
bioconcentration factor	BCF fish = 35645 (calculated according to TGD eq. 75, using log Kow = 6.12). BCF earthworm = 15820 (calculated according to TGD ed. 82d, using log Kow = 6.12).
octanol-water partition coefficient	log Kow = 6.12 (estimated from measured Koc).

- 12.4 Mobility in soil

56073-10-0 brodifacoum	
DT50	157 days. Persistent.
organic carbon partition coefficient	Koc = 9155 l/kg (pH 7,1-7.6). Immobile in soil.
soil mobility	Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule. Under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

- General notes:
Hazardous to wildlife.
Do not allow the product to reach ground water, water course or sewage system.

- 12.5 Results of PBT and vPvB assessment

- PBT:	
56073-10-0 brodifacoum	
PBT	Brodifacoum fulfils the P, B and T criteria.

- vPvB:	
56073-10-0 brodifacoum	
vPvB	Brodifacoum fulfils the vP criterion.

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- **12.6 Other adverse effects**

56073-10-0 brodifacoum

. The major environmental concern of Brodifacoum is primary and secondary poisoning of non-target animals.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.

- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with local requirements.

SECTION 14: Transport information

- **14.1 UN-Number**	
- **ADR, ADN, IMDG, IATA**	Not applicable
- **14.2 UN proper shipping name**	
- **ADR, ADN, IMDG, IATA**	Not applicable
- **14.3 Transport hazard class(es)**	
- **ADR, ADN, IMDG, IATA**	
- **Class**	Not applicable
- **14.4 Packing group**	
- **ADR, IMDG, IATA**	Not applicable
- **14.5 Environmental hazards:**	Not applicable.
- **14.6 Special precautions for user**	Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
- **UN "Model Regulation":**	Not applicable

SECTION 15: Regulatory information

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

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **Seveso category** This product is not subject to Seveso directive dispositions.

- **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)**
The product does not contain any substance included in annex XIV.

- **REGULATION (EC) No 1907/2006 ANNEX XVII** Restrictions: 30

- **Other regulations, limitations and prohibitive regulations** No further information available.

- **Substances of very high concern (SVHC) according to REACH, Article 59** None.

- **Regultion (EC) n. 1005/2009: substances that deplete the ozone layer** None.

- **Regulation (EC) n. 850/2004: persistent organic pollutants** None.

- **Substances listed in Regulation (EC) n. 649/2012 (PIC):** None.

- **15.2 Chemical safety assessment:**
A Chemical Safety Assessment according to Regulation (EC) No. 1907/2006 has not been carried out for the mixture.

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SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Any responsibility derived from misuse of the product or in case of violation of current regulations is refused.

- Relevant phrases

H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H330 Fatal if inhaled.
H360D May damage the unborn child.
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.

- Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is based on the calculation method stated in annex I of Regulation (CE) n. 1272/2008, using components data.

- Abbreviations and acronyms:

NOELR: No Observed Effect Loading Rate
RD50: Respiratory Decrease, 50 percent
LC0: Lethal concentration, 0 percent
NOEC: No Observed Effect Concentration
IC50: Inhibitory concentration, 50 percent
NOAEL: No Observed Adverse Effect Level
EC50: Effective concentration, 50 percent
EC10: Effective concentration, 10 percent
AEC: Acceptable Exposure Concentration
LL0: Lethal Load, 0 percent
AEL: Acceptable Exposure Limit
LL50: Lethal Load, 50 percent
EL0: Effective Load, 0 percent
EL50: Effective Load, 50 percent
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 1: Acute toxicity – Category 1
Repr. 1A: Reproductive toxicity – Category 1A
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

- References

- Biocidal Products Committee (BPC) opinion June 2016 on the active substance;
- Assessment Report on the active substance (available at ECHA website);

- Sources

1. The E-Pesticide Manual 2.1 Version (2001)
2. Regulation (EC) 1907/2006 and following amendments
3. Regulation (EC) 1272/2008 and following amendments
4. Regulation (EU) 2015/830
5. Regulation (EU) 528/2012
6. Regulation (EC) 790/2009 (1st ATP CLP)
7. Regulation (EU) 286/2011 (2nd ATP CLP)
8. Regulation (EU) 618/2012 (3rd ATP CLP)
9. Regulation (EU) 487/2013 (4th ATP CLP)
10. Regulation (EU) 944/2013 (5th ATP CLP)
11. Regulation (EU) 605/2014 (6th ATP CLP)
12. Regulation (EU) 2015/1221 (7th ATP CLP)
13. Regulation (EU) 2016/918 (8th ATP CLP)
14. Regulation (EU) 2016/1179 (9th ATP CLP)
15. Regulation (EU) 2017/776 (10th ATP CLP)

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16. Regulation (EU) 2018/669 (11th ATP CLP)
17. Regulation (EU) 2019/521 (12th ATP CLP)
18. Regulation (EU) 2018/1480 (13th ATP CLP)
19. Directive 2012/18/EU (Seveso III)
20. ECHA web site