

Safety data sheet

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

1.1. Product identifier

Code: C302240/ C302242/ C302245
Product name: TROPICALGIN

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

Intended use: For professional use only. Alginate for dental impression.

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino
District and Country: 45021 Badia Polesine (RO)
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Tel. +39 0425-597611
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e-mail address of the competent person
responsible for the Safety Data Sheet: msds@zhermack.com

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN Tel.: 0551/19 240

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 EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:
Aquatic Chronic 3 H412

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments.

Danger Symbols:

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

2.2. Label elements.

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

Hazard pictograms:

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Signal words: --

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.

2.3. Other hazards.

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
DIPOTASSIUM HEXAFLUOROTITANATE			
CAS. 16919-27-0	1 - 3	Xn R22, Xi R37/38, Xi R41	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
EC. 240-969-9			
INDEX. -			
ZINC OXIDE			
CAS. 1314-13-2	0,5 - 2,5	N R50/53	Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410
EC. 215-222-5			
INDEX. 030-013-00-7			
Reg. no. 01-2119463881-32-XXXX			
PHENOLPHTHALEIN			
CAS. 77-09-8	0 - 0,2	Carc. Cat. 2 R45, Muta. Cat. 3 R68, Repr. Cat. 3 R62	Carc. 1B H350, Muta. 2 H341, Repr. 2 H361f

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EC. 201-004-7

INDEX. 604-076-00-1

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and 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. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

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.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

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. Avoid breathing vapours/mists/gases. 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.

Use spark-proof mechanical equipment to 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. Check incompatibility for container material in section 7. 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).

Information not available.

SECTION 8. Exposure controls/personal protection.**8.1. Control parameters.**

Regulatory References:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011.
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2012

ZINC OXIDE

Threshold Limit Value.					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
OEL	IRL	2			
TLV-ACGIH		2		10	

Legend:

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

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

VLA-ED 2,5 mg (F)/m3 INSHT guide

Indicatore biologico fluoruri nelle urine 8 mg/l INSHT guide

Prima del turno 4 mg/g creatinina dopo il turno 7 mg/g creatinina BAT.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment. (see standard EN 149).

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	powder
Colour	red
Odour	tropical
Odour threshold.	Not available.
pH.	Not available.

Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	NA
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	NA
Relative density.	Not available.
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Solid content. 71,73 %

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.

INTERNAL TEST CARRIED OUT ON A SIMILAR ALGINATE WITH A HIGHER CONTENT OF CORROSIVE COMPONENTS
Eye Irritation/Corrosion: Negative (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

11.1. Information on toxicological effects.

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.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation.

Vapour inhalation may moderately irritate the upper respiratory tract. Contact with skin may cause slight irritation.

Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.

ZINC OXIDE

LD50 (Oral). > 5000 mg/kg (OECD 401, rat, ECHA dossier).

LD50 (Dermal). > 2000 mg/kg (OECD 402, GLP, rat, ECHA dossier).

LD50 (Inhalation). > 5,7 mg/l (OECD 403, rat, ECHA dossier).

Irritation/Corrosion

Skin irritation: Not irritating (publication, in vivo, guinea pig, ECHA dossier).

Eye irritation: Not irritating (OECD 405, GLP, in vivo, rabbit, ECHA dossier).

Skin sensitization: Insufficient data (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).

STOT –

Repeated/single exposure: Negative (subchronic, inhalation exposure, rat, ECHA dossier).

Genotoxicity: Negative (in vivo, in vitro, ECHA dossier).

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

DIPOTASSIUM HEXAFLUOROTITANATE

LD50 (Oral). 200 mg/kg guinea pig

LD50 (Dermal). 360 mg/kg (subcutaneous, frog, MSDS supplier).

Acute Toxicity

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: No data available.

Eye irritation: Corrosive (according to OECD 405, in vivo, rabbit, ECHA dossier).

Skin sensitization: Not sensitising (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).

STOT Repeated/single exposure: No data available.

CMR effects: No data available.

PHENOLPHTHALEIN

Acute toxicity: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (OECD 431, in vitro, ECHA dossier).

Eye irritation: Slightly irritating (OECD 437, in vitro, ECHA dossier).

Respiratory or skin Sensitization: Not sensitising (OECD 429, GLP, in vivo, Mouse local lymphnode assay, ECHA dossier).

STOT – Repeated exposure: Negative (OECD 407, oral, rat, ECHA dossier).

Genotoxicity in vitro: Negative (OECD 471, Ames test, ECHA dossier).

Carcinogenicity: Tumorigenic - Group 2B: Possibly carcinogenic to humans (IARC, oral, mouse and rat).

Toxicity to reproduction: No data available.

Aspiration toxicity: No data available.

SECTION 12. Ecological information.

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity.**DIPOTASSIUM HEXAFLUOROTITANATE**

EC50 = 18 mg/l (microorganisms, 24h, MSDS supplier).

ZINC OXIDE

LC50 - for Fish. 1,1 mg/l/96h *Oncorhynchus mykiss*

EC50 - for Crustacea. 1,7 mg/l/48h *Daphnia magna*

EC50 - for Algae / Aquatic Plants. 0,14 mg/l/72h

Chronic NOEC for Fish. 0,53 mg/l

Chronic NOEC for Algae / Aquatic Plants. 0,024 mg/l

PHENOLPHTHALEIN

EC50 - for Crustacea. 100 mg/l/48h (OECD 202, Daphnia magna, ECHA dossier).

EC50 - for Algae / Aquatic Plants. 8,9 mg/l/72h (OECD 201, Desmodesmus subspicatus, ECHA dossier).

12.2. Persistence and degradability.

ZINC OXIDE

Solubility in water. 2,9 mg/l

NOT rapidly biodegradable.

PHENOLPHTHALEIN

Rapidly biodegradable.

12.3. Bioaccumulative potential.

ZINC OXIDE

BCF. > 175

12.4. Mobility in soil.

Information not available.

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 greater than 0,1%.

12.6. 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.

Avoid littering. Do not contaminate soil, sewers and waterways.

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.

SECTION 15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**Seveso category.

None.

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

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Substances in Candidate List (Art. 59 REACH).

PHENOLPHTHALEIN

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 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.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

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

Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
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
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H361f	Suspected of damaging fertility.
H302	Harmful if swallowed.

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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.	
H412	Harmful to aquatic life with long lasting effects.	
Text of risk (R) phrases mentioned in section 2-3 of the sheet:		
R22	HARMFUL IF SWALLOWED.	
R37/38	IRRITATING TO RESPIRATORY SYSTEM AND SKIN.	
R41	RISK OF SERIOUS DAMAGE TO EYES.	
Carc. Cat. 2	Carcinogenicity, category 2.	
R45	MAY CAUSE CANCER.	
R50/53	VERY TOXIC TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT.	
R52/53	HARMFUL TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT.	
Repr. Cat. 3	Reproductive toxicity, fertility, category 3.	
R62	POSSIBLE RISK OF IMPAIRED FERTILITY.	
Muta. Cat. 3	Mutagenicity, category 3.	
R68	POSSIBLE RISK OF IRREVERSIBLE EFFECTS.	
LEGEND:		
- ADR: European Agreement concerning the carriage of Dangerous goods by Road - CAS NUMBER: Chemical Abstract Service Number - CE50: Effective concentration (required to induce a 50% effect) - CE NUMBER: Identifier in ESIS (European archive of existing substances) - CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit - TWA: Time-weighted average exposure limit - VOC: Volatile organic Compounds - vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation.		
GENERAL BIBLIOGRAPHY		
1. Directive 1999/45/EC and following amendments 2. Directive 67/548/EEC and following amendments and adjustments 3. Regulation (EC) 1907/2006 (REACH) of the European Parliament		

4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

Note for users:

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.

Changes to previous review:

The following sections were modified:

02 / 11.