

Safety data sheet

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

1.1. Product identifier

Code: C302241
Product name: TROPICALGIN NORMAL SET

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 100
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-597689

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: 0039 0425597611

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.

Hazard classification and indication:

| | | |
|--|------|--|
| Specific target organ toxicity - repeated exposure, category 2 | H373 | May cause damage to organs through prolonged or repeated exposure. |
| Hazardous to the aquatic environment, chronic toxicity, category 3 | H412 | Harmful to aquatic life with long lasting effects. |

2.2. Label elements.

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

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

Hazard pictograms:



Signal words: Warning

Hazard statements:

H373 May cause damage to lungs through prolonged or repeated exposure. Route of exposure: Inhalation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe dust.
P273 Avoid release to the environment.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice / attention if you feel unwell.

Contains: CRISTOBALITE

2.3. Other hazards.

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

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 1272/2008 (CLP). |
|---------------------------------------|-----------|--|
| CRISTOBALITE | | |
| CAS. 14464-46-1 | 1 - 8 | STOT RE 1 H372 |
| EC. 238-455-4 | | |
| INDEX. - | | |
| DIPOTASSIUM HEXAFLUOTOTITANATE | | |
| CAS. 16919-27-0 | 1 - 3 | Acute Tox. 4 H302, Eye Dam. 1 H318 |
| EC. 240-969-9 | | |
| INDEX. - | | |
| Reg. no. 01-2119978268-20-XXXX | | |
| ZINC OXIDE | | |
| CAS. 1314-13-2 | 0,5 - 2,5 | 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

PHENOLPHTALEIN

CAS. 77-09-8

0 - 0,2

Carc. 1B H350, Muta. 2 H341, Repr. 2 H361f

EC. 201-004-7

INDEX. 604-076-00-1

Note: Upper limit is not included into the range.

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.

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 and dry place, away from direct sunlight (storage temperature: 5-27°C). Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

See section 1.2.

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

Regulatory References:

| | | |
|-----|-----------------|---|
| CZE | Česká Republika | Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci |
| DEU | Deutschland | MAK-und BAT-Werte-Liste 2012 |
| DNK | Danmark | Graensevaerdier per stoffer og materialer |
| ESP | España | INSHT - Límites de exposición profesional para agentes químicos en España 2015 |
| FIN | Suomi | HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveystieteiden tutkimuskeskus julkaisuja 2012:5 |
| FRA | France | JORF n°0109 du 10 mai 2012 page 8773 texte n° 102 |
| ITA | Italia | Decreto Legislativo 9 Aprile 2008, n.81 |
| NLD | Nederland | Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18 |
| NOR | Norge | Veiledning om Administrative normer for forurensning i arbeidsatmosfære |
| POL | Polska | ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r |
| SWE | Sverige | Occupational Exposure Limit Values, AF 2011:18 |
| | TLV-ACGIH | ACGIH 2014 |

CRISTOBALITE

Threshold Limit Value.

| Type | Country | TWA/8h | | STEL/15min | | |
|-----------|---------|--------|-----|------------|-----|-------------|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| TLV | DNK | 0,15 | | | | RESP. |
| VLEP | FRA | 0,05 | | | | RESP. |
| TLV | ITA | 0,05 | | | | (USA-NIOSH) |
| MAC | NLD | 0,075 | | | | RESP. |
| MAK | SWE | 0,05 | | | | RESP. |
| TLV-ACGIH | | 0,025 | | | | |

DIPOTASSIUM HEXAFLUOTOTITANATE

Predicted no-effect concentration - PNEC.

| | | |
|--|-------|---------|
| Normal value in fresh water | 0,131 | mg/l |
| Normal value in marine water | 0,131 | mg/l |
| Normal value for fresh water sediment | 24,45 | mg/kg/d |
| Normal value for marine water sediment | 4,89 | mg/kg/d |
| Normal value of STP microorganisms | 1,51 | mg/l |
| Normal value for the terrestrial compartment | 19,1 | mg/kg |

Health - Derived no-effect level - DNEL / DMEL

| Route of exposure | Effects on consumers. Acute local | Acute systemic | Chronic local | Chronic systemic | Effects on workers | | | |
|-------------------|--------------------------------------|----------------|---------------|------------------|--------------------|----------------|---------------|------------------|
| | | | | | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Inhalation. | | | | | VND | 5,2 mg/m3 | 5,2 mg/m3 | 5,2 mg/m3 |
| Skin. | | | | | VND | 75 mg/kg bw/d | VND | 75 mg/kg bw/d |

ZINC OXIDE

Threshold Limit Value.

| Type | Country | TWA/8h | | STEL/15min | |
|-----------|---------|--------|-----|------------|-----|
| | | mg/m3 | ppm | mg/m3 | ppm |
| TLV | CZE | 1 | | 2 | |
| MAK | DEU | 1 | | 1 | |
| TLV | DNK | 4 | | | |
| VLA | ESP | 2 | | 10 | |
| HTP | FIN | 2 | | 10 | |
| VLEP | FRA | 5 | | | |
| MAC | NLD | 5 | | | |
| TLV | NOR | 5 | | | |
| NDS | POL | 5 | | 10 | |
| MAK | SWE | 5 | | | |
| TLV-ACGIH | | 2 | | 10 | |

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.

8.2. Exposure controls.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate not 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.

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.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

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 II 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 (see standard EN 149) or equivalent device, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS.

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 | yellow |
| Odour | tropical |
| Odour threshold. | Not available. |
| pH. | Not applicable. |
| Melting point / freezing point. | Not available. |
| Initial boiling point. | Not applicable. |
| Boiling range. | Not applicable. |
| Flash point. | Not available. |
| Evaporation Rate | Not applicable. |
| 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 applicable. |
| Vapour density | Not applicable. |
| Density | 0,2-0,5 g/cm ³ |
| Solubility | partially soluble in water, colloidal solution |
| Partition coefficient: n-octanol/water | Not available. |
| Auto-ignition temperature. | Not available. |
| Decomposition temperature. | Not available. |
| Viscosity | Not applicable. |
| Explosive properties | Not available. |
| Oxidising properties | Not available. |

9.2. Other information.

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.

The powders are potentially explosive when mixed with air.

10.4. Conditions to avoid.

Avoid environmental dust build-up. Avoid moisture and high temperature.

10.5. Incompatible materials.

Not known.

10.6. Hazardous decomposition products.

Not known.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

INTERNAL TEST (Bridging Principle)

Eye Irritation/Corrosion: Negative (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

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.

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous.

ZINC OXIDE

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

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

LC50 (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.

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.

CRISTOBALITE

LD50 (Oral).> 2000 mg/kg (OECD 401, rat, MSDS supplier)

LC50 (Inhalation).> 2,6 mg/l (OECD 403, rat, MSDS supplier)

Irritation/Corrosion

Skin irritation: Not irritating (MSDS supplier).

Eye irritation: Not irritating (MSDS supplier).

Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: No data available (MSDS supplier).

Carcinogenicity: No data available (MSDS supplier).

Toxicity to reproduction: No data available (MSDS supplier).

STOT Repeated Exposure:

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

DIPOTASSIUM HEXAFLUOTOTITANATE

LD50 (Oral).324 mg/kg (OECD 401, rat, SDS 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 (Carcinogenic, Mutagenic, Toxic for reproduction): 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.

ZINC OXIDE

EC50 - for Crustacea. 0,83 mg/l/48h (pH< 7; Ceriodaphnia dubia, SDS supplier).

EC50 - for Algae / Aquatic Plants. 0,27 mg/l/72h (pH> 7; Pseudokirchnerella subcapitata, SDS supplier).

PHENOLPHTALEIN

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).

DIPOTASSIUM

HEXAFLUOTOTITANATE

LC50 - for Fish. 172,4 mg/l/96h (OECD 203, Brachydanio rerio, SDS supplier).

EC50 - for Crustacea. 48,2 mg/l/48h (OECD 203, Daphnia magna, SDS supplier).

EC50 - for Algae / Aquatic Plants. 0,646 mg/l/72h (OECD 202, Pseudokirchneriella subcapitata, SDS supplier).

12.2. Persistence and degradability.

ZINC OXIDE

Biodegradability: Information not available.

NOT rapidly biodegradable.

PHENOLPHTALEIN

Rapidly biodegradable.

CRISTOBALITE

NOT rapidly biodegradable.

DIPOTASSIUM

HEXAFLUOTOTITANATE

NOT rapidly biodegradable.

12.3. Bioaccumulative potential.

Information not available.

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 (HP 5). 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.

14.1. UN 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.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

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.

Point. 28 PHENOLPHTALEIN

Substances in Candidate List (Art. 59 REACH).

PHENOLPHTALEIN

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

C302241 - TROPICALGIN NORMAL SET

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.
Product not intended for uses provided for by Dir. 2004/42/CE.

U.S. State Regulations California Proposition 65.

WARNING: This product can expose you to silica, crystalline (airborne particles of respirable size) and phenolphthalein, which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

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 |
| STOT RE 1 | Specific target organ toxicity - repeated exposure, category 1 |
| STOT RE 2 | Specific target organ toxicity - repeated exposure, category 2 |
| Eye Dam. 1 | Serious eye damage, category 1 |
| Eye Irrit. 2 | Eye irritation, category 2 |
| 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. |
| H372 | Causes damage to organs through prolonged or repeated exposure. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H400 | Very toxic to aquatic life. |

C302241 - TROPICALGIN NORMAL SET

- H410** Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting 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
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. 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
- 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
 - ECHA website

Note for users:

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.
This safety data sheet has been created on a voluntary basis.

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:

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