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 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 (EU) Regulation 2015/830.
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 organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe dust / fume / gas / mist / vapours / spray.
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

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
CRISTOBALITE		
CAS 14464-46-1	5 ≤ x < 8,5	STOT RE 1 H372
EC 238-455-4		
INDEX -		
DIPOTASSIUM HEXAFLUOTOTITANATE		
CAS 16919-27-0	1 ≤ x < 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 ≤ x < 2,5	Aquatic Acute 1 H400 M=1, Aquatic Chronic 1

H410 M=1

EC 215-222-5
INDEX 030-013-00-7
Reg. no. 01-2119463881-32-XXXX

PHENOLPHTALEIN

CAS 77-09-8 | 0 ≤ x < 0,2 | Carc. 1B H350, Muta. 2 H341, Repr. 2 H361f
EC 201-004-7
INDEX 604-076-00-1
Reg. no. 01-2119498295-24-XXXX

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

Specific information on symptoms and effects caused by the product are unknown.

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.
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 (Storage conditions: 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:

BGR	България	МИНИСТЕРСТВО НА ТРУДА И СОЦИАЛНАТА ПОЛИТИКА МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО НАРЕДБА No 13 от 30 декември 2003 г
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci

DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveysministeriön julkaisuja 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
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 RODZIN Y, PRAC Y I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
ROU	România	Monitorul Oficial al României 44; 2012-01-19
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007
SVN	Slovenija	Uradni list Republike Slovenije 04.06.2015 (1602) - Pravilnik o spremembah in dopolnitvah Pravilnika o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2018

CRISTOBALITE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min			
		mg/m3	ppm	mg/m3	ppm		
TLV	DNK	0,15					
VLA	ESP	0,05				RESP	
VLEP	FRA	0,05				RESP	(aerosol).
AK	HUN	0,15				RESP	(aerosol).
MAC	NLD	0,075				RESP	
MAK	SWE	0,05				RESP	

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 for water, intermittent release	0,108	mg/l
Normal value of STP microorganisms	1,5	mg/l
Normal value for the terrestrial compartment	19,1	mg/kg

Health - Derived no-effect 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					VND	5,2 mg/m3	5,2 mg/m3	5,2 mg/m3
Skin	NPI	37,5 mg/kg bw/d	NPI	37,5 mg/kg bw/d	NPI	75 mg/kg bw/d	NPI	75 mg/kg bw/d

ZINC OXIDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	5		10	
TLV	CZE	1		2	
MAK	DEU	1		1	
TLV	DNK	4			

VLA	ESP	2	10	
HTP	FIN	2	10	
VLEP	FRA	5		
TLV	GRC	5	10	
AK	HUN	5	20	
MAC	NLD	5		
TLV	NOR	5		
NDS	POL	5	10	
TLV	ROU	5	10	
NPHV	SVK	1		
MV	SVN	5	20	RESP
MAK	SWE	5		
TLV-ACGIH		2	10	

Predicted no-effect concentration - PNEC		
Normal value in fresh water	117	mg/l
Normal value in marine water	0,0061	mg/l
Normal value for fresh water sediment	117	mg/kg
Normal value for marine water sediment	56,5	mg/kg
Normal value of STP microorganisms	0,052	mg/l
Normal value for the terrestrial compartment	35,6	mg/kg

Health - Derived no-effect 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
Oral				0,83 mg/kg/d				
Inhalation				2,5 mg/m3				5 mg/m3
Skin				87 mg/kg/d				87 mg/kg/d

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.

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.

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.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
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, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

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	red
Odour	tropical
Odour threshold	Not available
pH	Not applicable
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	Not available
Evaporation Rate	Not available
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	Not available
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

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.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

LC50 (Inhalation) of the mixture:
Not classified (no significant component)
LD50 (Oral) of the mixture:
>2000 mg/kg
LD50 (Dermal) of the mixture:
Not classified (no significant component)

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 (INTERNAL TEST Bridging Principle, OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

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

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

May cause damage to organs

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

CRISTOBALITE
Acute Toxicity: No data available.
Irritation/Corrosion
Skin irritation: Not irritating (MSDS supplier).
Eye irritation: Slightly irritating (MSDS supplier).
Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: Does not meet the classification criteria for this hazard class (MSDS supplier).
Carcinogenicity: IARC (group 1), NTP (RAHC), ACGIH (A2) (IARC).
Toxicity to reproduction: Does not meet the classification criteria for this hazard class (MSDS supplier).
Toxicity for aspiration: Not applicable.
STOT Repeated Exposure: Adverse effects on lungs (fibrosis-silicosis)(MSDS supplier).
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 HEXAFLUOROTITANATE
LD50 (Dermal(. 324 mg/kg (OECD 401, rat, SDS supplier).
Acute Toxicity
Inhalation: No data available.
Dermal: No data available.
Irritation/Corrosion
Skin irritation: Not irritating (OECD 404, in vivo, rabbit, MSDS supplier).
Eye irritation: Corrosive (OECD 405, in vivo, rabbit, MSDS supplier).
Skin sensitization: Not sensitising (OECD 406, GLP, Guinea pig maximisation test, MSDS supplier).
STOT Repeated/single exposure: No data available.
Genotoxicity in vitro: Negative (OECD 471, Test di Ames); Positive (OECD 487,476; chromosomic aberration) (MSDS supplier).
Genotoxicity in vivo: Positive (OECD 474, rat, SDS supplier).
Carcinogenicity: No data available.
Toxicity to reproduction: No data available.

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: Not sensitizing (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).
STOT – Single/Repeated exposure: No data available.
Genotoxicity in vitro: Negative (OECD 471, ECHA dossier).
Genotoxicityin vivo: Negative (OECD 474, GLP, mouse, ECHA dossier).
Carcinogenicity: No data available.
Toxicity to reproduction: No data available.
Toxicity for aspiration: Not applicable.

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

ZINC OXIDE

EC50 - for Algae / Aquatic Plants	0,17 mg/l/72h (Pseudokirchnerella subcapitata, SDS supplier).
Chronic NOEC for Algae / Aquatic Plants	0,017 mg/l (Pseudokirchnerella subcapitata, SDS supplier).

PHENOLPHTALEIN

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

DIPOTASSIUM HEXAFLUOTOTITANATE

LC50 - for Fish	172 mg/l/96h (OECD 203, Danio rerio, ECHA dossier).
EC50 - for Crustacea	48,2 mg/l/48h (OECD 203, Daphnia magna, ECHA dossier).
EC50 - for Algae / Aquatic Plants	10,81 mg/l/72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).
Chronic NOEC for Algae / Aquatic Plants	1,31 mg/l (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

12.2. Persistence and degradability

ZINC OXIDE
Degradability: information not available

NOT rapidly degradable

PHENOLPHTALEIN
Degradability: information not available

CRISTOBALITE
NOT rapidly degradable

DIPOTASSIUM HEXAFLUOTOTITANATE
NOT rapidly degradable

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

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

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 Marpol 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 - Directive 2012/18/EC: None

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

Product
None

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:

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.

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
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.
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.

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 (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 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
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)
- 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
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

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.

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.

Changes to previous review:
The following sections were modified:
01 / 02 / 03 / 04 / 08 / 11 / 12 / 14 / 15.