



Safety Data Sheet

Cleanic Prophy paste for cleaning and polishing mint flavour without fluoride - tube

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Cleanic Prophy paste for cleaning and polishing mint flavour without fluoride - tube

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

Relevant identified uses

Use of the substance/mixture : Preparation intended for dental medical use

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T 00-800-41-050-505

Manufacturer

KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T 00-800-41-050-505

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements : EUH208 - Contains trans-menthone. May produce an allergic reaction

Extra phrases : A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis
The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
glycerol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 56-81-5 (EC-No.) 200-289-5	15 - 45	Not classified
titanium dioxide substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 13463-67-7;13463-67-7 (EC-No.) 236-675-5 (REACH-no) 01-2119489379-17	1 - 5	Not classified
ethanol, ethyl alcohol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	1 - 5	Flam. Liq. 2, H225

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general	: Move to fresh air. Get medical attention if any discomfort continues.
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: On ingestion in large quantities: Drink plenty of water, Get medical advice/attention. Rinse mouth. Do NOT induce vomiting.

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

No additional information available

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

No specific measures identified.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non flammable.
Hazardous decomposition products in case of fire	: Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment	: See Heading 8.
Emergency procedures	: Evacuate unnecessary personnel.

For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store in a closed container. Keep cool. Store in original container. Keep container closed when not in use.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

titanium dioxide (13463-67-7;13463-67-7)		
EU	Local name	Titanium dioxide
EU	Notes	SCOEL Recommendations (Ongoing)
Ireland	Local name	Titanium dioxide
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ total inhalable dust 4 mg/m ³ respirable dust
United Kingdom	Local name	Titanium dioxide
United Kingdom	WEL TWA (mg/m ³)	4 mg/m ³ respirable 10 mg/m ³ total inhalable
glycerol (56-81-5)		
Ireland	Local name	Glycerol, mist
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³
United Kingdom	Local name	Glycerol
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³ mist
ethanol, ethyl alcohol (64-17-5)		
Ireland	Local name	Ethanol
Ireland	OEL (15 min ref) (ppm)	1000 ppm
United Kingdom	Local name	Ethanol
United Kingdom	WEL TWA (mg/m ³)	1920 mg/m ³
United Kingdom	WEL TWA (ppm)	1000 ppm

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Hand protection : Not required for normal conditions of use

Eye protection : Not required

Skin and body protection : Not required

Respiratory protection : Not required

Other information : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state : Liquid

Appearance : Paste.

Colour : Blue.

Odour : mint.

Odour threshold	: Not determined
pH	: 7 - 7.5
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Non flammable
Vapour pressure	: Not determined
Relative vapour density at 20 °C	: Not determined
Relative density	: 1.4 - 1.7 (g/ml)
Solubility	: Not determined.
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Not explosive.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

No incompatible groups noted.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Acute toxicity : Not classified

titanium dioxide (13463-67-7;13463-67-7)	
LD50 oral rat	> 100000 mg/kg
(±)-2-isopropyl-5-methylcyclohexanol (89-78-1)	
LD50 oral rat	2900 mg/kg
LD50 dermal rabbit	> 5000 mg/kg
(R)-p-mentha-1,8-diene, d-limonene (5989-27-5)	
LD50 oral rat	4400 mg/kg
LD50 dermal rabbit	> 5000
glycerol (56-81-5)	
LD50 oral rat	12600 mg/kg
LD50 dermal rabbit	> 10000 mg/kg
ethanol, ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LD50 dermal rabbit	> 20000 mg/m ³
LC50 inhalation rat (Vapours - mg/l/4h)	124.7 mg/l/4h

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: 7 - 7.5
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: 7 - 7.5
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

titanium dioxide (13463-67-7;13463-67-7)	
LC50 fish 1	> 1000 mg/l Fundulus heteroclitus
EC50 Daphnia 1	> 1000 mg/l (48 hours - Daphnia magna)
(±)-2-isopropyl-5-methylcyclohexanol (89-78-1)	
LC50 fish 1	96 mg/l
(R)-p-mentha-1,8-diene, d-limonene (5989-27-5)	
LC50 fish 1	0.7 mg/l 96h (Pimephales promelas)
EC50 Daphnia 1	0.73 mg/l 48h (Daphnia pulex)
glycerol (56-81-5)	
LC50 fish 1	67500 mg/l (96 hours - Rainbow trout)
IC50 algae	2900 mg/l
ethanol, ethyl alcohol (64-17-5)	
LC50 fish 1	13500 mg/l (96 hours - Pimephales promelas)
EC50 Daphnia 1	54000 mg/l (48 hours - Daphnia magna)
IC50 algae	> 10.9 mg/l (IC50, 72 hours - Skeletonema costatum)

12.2. Persistence and degradability

Cleanic Prophy paste for cleaning and polishing mint flavour without fluoride - tube	
Persistence and degradability	Not established.
glycerol (56-81-5)	
Chemical oxygen demand (COD)	1
Biodegradation	63 % (15 days, method: OECD 301C)
ethanol, ethyl alcohol (64-17-5)	
BOD (% of ThOD)	≥ 0.4 % ThOD BOD5/COD
Biodegradation	85 % (OECD 301D method)

12.3. Bioaccumulative potential

Cleanic Prophy paste for cleaning and polishing mint flavour without fluoride - tube	
Log Pow	Not determined
Bioaccumulative potential	Not established.
(±)-2-isopropyl-5-methylcyclohexanol (89-78-1)	
Bioconcentration factor (BCF REACH)	69.18
Log Pow	3.3

(R)-p-mentha-1,8-diene, d-limonene (5989-27-5)	
Bioconcentration factor (BCF REACH)	660.69
Log Pow	4.23
glycerol (56-81-5)	
Bioconcentration factor (BCF REACH)	0.017
Log Pow	-1.76

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Cleanic Prophy paste for cleaning and polishing mint flavour without fluoride - tube
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects : None to our knowledge.
 Additional information : No other effects known. Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector's sorting instructions.
 Waste treatment methods : Do not discharge into drains.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.
 European List of Waste (LoW) code : 18 01 07 - chemicals other than those mentioned in 18 01 06

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number	
Not regulated for transport	
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
No supplementary information available	

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

IBC code : Not applicable.

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

Contains no REACH substances with Annex XVII restrictions
 Contains no substance on the REACH candidate list
 Contains no REACH Annex XIV substances

National regulations

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Indication of changes:

Composition/information on ingredients. Physical and chemical properties.

1.2	Function or use category	Removed	
2.1	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
3.2	Composition/information on ingredients	Modified	
3.2	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	
9.1	Physical and chemical properties	Modified	

Data sources : EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

Other information : None.

Date of issue : 24/03/2011

Revision date : 30/04/2017

Supersedes : 20/05/2014

Date of total revision : 30/04/2017

Version : 4.0

Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour
EUH208	Contains . May produce an allergic reaction

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.