

SAFETY DATA SHEET

Product name: ProphyCare® HAp Page: 1/10
Supersedes date: Issuing date 2021-02-01
Product No.: SDS-ID: GB-EN/1.0

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

1.1. Product identifier

Product name: ProphyCare® HAp

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

Identified use(s): Paste for polishing teeth. Medical device. Directly invasive.

1.3. Details of the supplier of the safety data sheet

Supplier: Directa AB
Box 723
SE-194 27 Upplands Väsby
Tel:+46 850650575
info@directadental.com

1.4. Emergency telephone number

Emergency telephone: 08-33 12 31 or NHS: 111

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: The product is not classified.

2.2. Label elements

This product is a medical device and does not require a hazard label. The information which would have appeared on the label is shown here.

EUH210 Safety data sheet available on request.

Contains L-menthan-3-one. May produce an allergic reaction.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

CLP:

%:	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
30-60	56-81-5	200-289-5	-	Glycerol	-	#
10-20	112926-00-8		-	Silica, amorphous		#
1-5	122-99-6	204-589-7	-	2-Phenoxyethanol	Acute Tox. 4;H302 Eye Irrit. 2;H319	
<5	13463-67-7	236-675-5	-	Titanium dioxide	-	#
0.1-<1	14073-97-3	237-926-1	-	L-menthan-3-one	Skin Irrit. 2;H315 Skin Sens. 1B;H317	

Notes: #: The substance has been assigned an exposure limit.

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References: The full text for all hazard statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Not relevant.

Skin contact: Flush skin thoroughly with water.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Rinse mouth with water. Contact physician if larger quantity has been consumed.

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

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

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

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow precautions for safe handling described in this safety data sheet.

Protective equipment: For personal protection, see section 8.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Small spillages: Collect spillage with a moist cloth.
Large Spillages: Absorb spilled substance with sand or earth. Sweep up and place into an appropriate container.

6.4. Reference to other sections

References: For personal protection, see section 8. For waste disposal, see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Avoid contact with eyes and prolonged skin contact. Observe good chemical hygiene practices. Ventilate well. Wash hands before breaks and before smoking, eating or drinking.

Technical measures: Keep the workplace clean.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in tightly closed original container in a well-ventilated place. Store at room temperature.

7.3. Specific end use(s)

Specific use(s): Not relevant.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

<u>CAS-No.:</u>	<u>Chemical name:</u>	<u>As:</u>	<u>Exposure limits:</u>	<u>Type:</u>	<u>Notes:</u>	<u>References:</u>
56-81-5	Glycerol, mist	-	10 mg/m3	TWA	-	EH40
112926-00-8	Silica, amorphous, inhalable dust	-	6 mg/m3	TWA	-	EH40
112926-00-8	Silica, amorphous, respirable dust	-	2.4 mg/m3	TWA	-	EH40
13463-67-7	Titanium dioxide, respirable dust	-	4 mg/m3	TWA	-	EH40
13463-67-7	Titanium dioxide, total inhalable dust	-	10 mg/m3	TWA	-	EH40

Notes: EH40: EH40/2005.

DNEL/PNEC: Not available.

8.2. Exposure controls

Engineering measures: Observe occupational exposure limits and minimise the risk of inhalation of vapours.

Personal protection: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: Under normal conditions of use respiration protection should not be required. In case of inadequate ventilation use suitable respirator.

Hand protection: Risk of contact: Wear protective gloves. The most suitable glove must be chosen in consultation with the gloves supplier, who can inform about the breakthrough time of the glove material.

Eye protection: Risk of splashes: Wear approved safety goggles.

Skin protection: Wear appropriate clothing to prevent repeated or prolonged skin contact.

Hygiene measures: Wash hands after handling. Wash contaminated clothing before reuse.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: Paste.
Colour: Blue.
Odour: Mint
Odour threshold: Not available.
pH: 7
Melting point / freezing point: Not available.
Boiling point: Not available.
Flash point: Not available.
Evaporation rate: Not available.
Flammability (solid, gas): Not available.
Explosive limits Not available.
Vapour pressure: Not available.
Vapour density: Not available.
Relative density: Not available.
Solubility: Not available.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature (°C): Not available.
Decomposition temperature (°C): Not available.
Viscosity: Not available.
Explosive properties: Not available.
Oxidising properties: Not available.

9.2. Other information

Other data: Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not reactive.

10.2. Chemical stability

Stability: Stable under normal temperature conditions. (3years)

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: Extremes of temperatures. (>25°C - <0°C)

10.5. Incompatible materials

Incompatible materials: Strong oxidising substances and strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products: None under normal conditions.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

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

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

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

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

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

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

Inhalation: Not relevant at normal room temperatures. When heated, irritating vapours may be formed.

Skin contact: Prolonged contact may cause redness and irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.

Eye contact: May irritate and cause redness and pain.

Ingestion: May cause irritation to the mouth and throat.

Toxicological data:
LD50 (oral, rat):
Glycerol: 12600 mg/kg
Titanium dioxide: >5000 mg/kg

LD50 (dermal rabbit):
Glycerol: >10000 mg/kg

11.2. Information on other hazards

Endocrine disrupting properties: None.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Not classified as dangerous to the environment.

Titanium dioxide:
LC50 (Fish): >1000 mg/l (96h)
EC50 (Daphnia magna, 48 hours): >1000 mg/l

12.2. Persistence and degradability

Degradability: This product mainly consists of inorganic compounds which are not biodegradable. The remaining compounds of the product are expected to be easily biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: None.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

Waste from residues: EWC-code: 18 01 07

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SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Environmentally Hazardous substance: -

14.6. Special precautions for user

Special precautions: -

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

Transport in bulk: -

SECTION 15: REGULATORY INFORMATION

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

National regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.
The Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002 No. 2677) with amendments.
EH40/2005, Workplace exposure limits 2005, with amendments.
The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

Abbreviations and acronyms used in the safety data sheet: PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.
LD50 = Lethal Dose 50%.
EC50 = Effective Concentration 50%.
LC50 = Lethal Concentration 50%.
CSA= Chemical Safety Assessment.

Wording of H-statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
