

Printing date 17.06.2020 Revision: 08.04.2019

### 1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: Consepsis™ Scrub

· Article number: 10969

· Index number: SDS 403-001.02

· Relevant identified uses of the substance or mixture and uses advised against

Professional Dental Chlorhexidine Gluconate Slurry

· Application of the substance / the mixture Professional Dental Chlorhexidine Gluconate Slurry

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@ultradent.com

EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany

Email: infoDE@ultradent.com

Emergency Phone: +49(0)2203-35-92-0

· Further information obtainable from: Customer Service

· Emergency telephone number:

CHEMTREC (NORTH AMERICA) : (800) 424-9300 (INTERNATIONAL) : +(703) 527-3887

## 2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



Skin Irrit. 2 H315 Causes skin irritation.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The Regulation EC 1272/2008 on classification, labeling 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 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- · Hazard pictograms GHS02, GHS07
- · Signal word Warning

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### · Hazard statements

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

### · Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

*P233* Keep container tightly closed.

*P240 Ground and bond container and receiving equipment.* 

P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

P242 Use non-sparking tools.

*P243* Take action to prevent static discharges.

*P264* Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P321 Specific treatment (see on this label).

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water

[or shower].

P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

*P403+P235* Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Additional information:

Contains Oils, Peppermint. May produce an allergic reaction.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

### 3 Composition/information on ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 14808-60-7	Silica Glass	>50-≤100%
EINECS: 238-878-4	♦ Acute Tox. 4, H332; Skin Irrit. 2, H315	
CAS: 64-17-5	Ethyl Alcohol	<i>≤</i> 6%
EINECS: 200-578-6	♦ Flam. Liq. 2, H225	
	Dimethicone	<i>≤</i> 1.5%
	<b>♦</b> Repr. 2, H361f; STOT RE 2, H373	
CAS: 8006-90-4	Oils, Peppermint	<1%
EINECS: 282-015-4	♦ Asp. Tox. 1, H304; ♦ Aquatic Chronic 2, H411; ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 18472-51-0	Chlorhexidine Gluconate	<i>≤</i> 2.5%
EINECS: 242-354-0	♠ Eye Irrit. 2, H319	

· Additional information: For the wording of the listed hazard phrases refer to section 16.

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### 4 First aid measures

- · Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## 5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO<sub>2</sub> powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters:
- · Protective equipment: No special measures required.

### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### 7 Handling and storage

- · Handling:
- Precautions for safe handling:

See product labeling.

Prevent formation of aerosols.

Open and handle receptacle with care.

Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection:

Keep respiratory protective device available.

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

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- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

See product labelling.

Keep container tightly sealed.

· Specific end use(s) Professional Dental Chlorhexidine Gluconate Slurry

### 8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

64-17-5 Ethyl Alcohol

WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not required.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

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· Body protection: Protective work clothing

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Physical and chemical properties	
Information on basic physical and chen	nical properties
· General Information	
· Appearance:	
Form:	Paste
Colour:	Green
· Odour:	Mint
· Odour threshold:	Not determined.
pH-value at 20°C:	5-7
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range	: Undetermined.
· Flash point:	34 °C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	363 °C
Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapo mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol %
Upper:	15 Vol %
· Vapour pressure:	Not determined.
Density at 20 °C:	$1.57 \text{ g/cm}^3$
Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
water:	Not miscible or difficult to mix.
Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Water:	<40 %
VOC (EC)	<10%
Solids content:	<30.0 %
· Other information	No further relevant information available.

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### 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid:

Ignition sources

Flames

Heat

- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products:

Hydrogen chloride (HCl)

Oxides of Carbon

Nitrogen oxides

Ammonia

## 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:			
ATE (Acu	te Toxicity I	Estimates)	
Inhalative	LC50/4 h	1.31 mg/l	
64-17-5 Et	hyl Alcohol		
Oral	LD50	5,600 mg/kg (Guinea pig)	
		3,400 mg/kg (mouse)	
		7,060 mg/kg (rat)	
	LC50 Fish	>10,000 mg/l (Fish)	
Inhalative	LC50/4 h	39 mg/l (mouse)	
		20,000 mg/l (rat)	
8006-90-4	Oils, Peppe	rmint	
Oral	LD50	2,490 mg/kg (mouse)	
		2,426 mg/kg (rat)	
D	vitant offoci	I.	

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

- · 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.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- 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.

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### 12 Ecological information

- · Toxicity
- · Aquatic toxicity:

64-17-5 Ethyl Alcohol

Algae Toxicity 1,000 mg/l (Algae)

- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

HP3 Flammable

HP4 Irritant - skin irritation and eye damage

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- · UN-Number
- · ADR, IMDG, IATA

UN1987

- · UN proper shipping name
- $\cdot ADR$

· IMDG, IATA

1987 ALCOHOLS, N.O.S. (Ethyl Alcohol) ALCOHOLS, N.O.S. (Ethyl Alcohol)

- · Transport hazard class(es)
- · ADR, IMDG, IATA



Class 3 Flammable liquids.

· Label

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Packing group	
ADR, ĬMDG, IATA	III
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	36
EMS Number:	F-E,S-D
Stowage Category	A
Transport in bulk according to Annex II of Mar	pol
and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
Transport category	3
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
·	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, III

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- \*REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### · Relevant phrases

- H225 Highly flammable liquid and vapour.
- H304 May be fatal if swallowed and enters airways.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H361f Suspected of damaging fertility.

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H373 May cause damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

- · Department issuing SDS: Regulatory Affairs
- · Contact: Customer Service
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity - inhalation - Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity - Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

GB2