

Page 1/8

Safety Data Sheet according to WHS Regulations

Printing date 03.08.2023

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Revision: 03.08.2023

Identification	
Product identifier	
Trade name: <u>ConsepsisTM - ConsepsisTM V</u>	
Article number: SDS 33-001.10R02, 10796, 10772 Relevant identified uses of the substance or mixture and uses advised against Professional Dental 2% Chlorhexidine Gluconate Solution Application of the substance / the mixture Professional Dental 2% Chlorhexidine Solution	1
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	
Ultradent Australia Pty Ltd. Level 22/2 Market Street Sydney NSW 2000 Australia Email: info.anz@ultradent.com Toll Free: 1-800-290929	
Further information obtainable from: Customer Service Emergency telephone number: CHEMTREC (NORTH AMERICA) :(800) 424-9300 (INTERNATIONAL) : +(703) 527-3887	
Hazard(s) Identification	
<i>Hazard(s) Identification Classification of the substance or mixture</i>	
Classification of the substance or mixture	
Classification of the substance or mixture	
Classification of the substance or mixture flame Flam. Liq. 3 H226 Flammable liquid and vapour.	

Printing date 03.08.2023

Revision: 03.08.2023

Trade name: ConsepsisTM - ConsepsisTM V

(Contd. of page 1)
Keep out of reach of children.
Read label before use.
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Use explosion-proof electrical/ventilating/lighting equipment.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin
with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
present and easy to do. Continue rinsing.
Store in a well-ventilated place. Keep cool.
Dispose of contents/container in accordance with local/regional/national/international
regulations.

3 Composition and Information on Ingredients

· Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
64-17-5 Ethyl Alcohol	≥10-<30%	
🚸 Flam. Liq. 2, H225; 🚸 Serious eye damage/irritation – Category 2A, H319		
Dimethicone	<3%	
🚸 Repr. 2, H361f; STOT RE 2, H373		
18472-51-0 Chlorhexidine Gluconate	<i>≥</i> 0-<10%	
Serious eye damage/irritation – Category 2A, H319		
8006-90-4 Oils, Peppermint	≥ 0.1-<1%	
Asp. Tox. 1, H304; (1) Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227		
Additional information. For the wording of the listed hazard physics refer to section 16		

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

4 First Aid Measures

· General information: Immediately remove any clothing soiled by the product.

• After inhalation: Supply fresh air; consult doctor in case of complaints.

- After skin contact: Immediately rinse with water.
- After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

· Suitable extinguishing agents:

CO₂ 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.

(Contd. on page 3)

AU

Printing date 03.08.2023

Revision: 03.08.2023

(Contd. of page 2)

Trade name: ConsepsisTM - ConsepsisTM V

· 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: No special precautions are necessary if used correctly.
- Information about fire and explosion protection:

Keep ignition sources away - Do not smoke. Protect against electrostatic charges.

· 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 2% Chlorhexidine Solution

8 Exposure controls and personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· Ingredients with limit values that require monitoring at the workplace:

64-17-5 Ethyl Alcohol

WES Long-term value: 1880 mg/m³, 1000 ppm

• Additional information: The lists valid during the making were used as basis.

· 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 eyes.

Avoid contact with the eyes and skin.

• **Respiratory protection:** Not required.

(Contd. on page 4)

AU —

Printing date 03.08.2023

Revision: 03.08.2023

Trade name: ConsepsisTM - ConsepsisTM V

(Contd. of page 3)

ΑU



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.



Tightly sealed goggles

· Body protection: Protective work clothing

Physical and Chemical Propertion	
General Information	
Appearance:	
Form:	Consepsis V: Clear medium viscosity liquid
	Consepsis: Clear to Cloudy low viscosity liquid
Colour:	Consepsis: Blue Green
	Consepsis V: Green
Odour:	Consepsis V: Strong mint
Odour threshold:	Not determined.
pH-value at 20 °C:	5.2-6.2
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
Flash point:	36 °C
Flammability (solid, gas):	Flammable.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapou
	mixtures are possible.
Explosion limits:	
Lower:	3.3 Vol %
Upper:	19 Vol %
Vapour pressure at 20 °C:	552 hPa
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

Printing date 03.08.2023

Revision: 03.08.2023

Trade name: ConsepsisTM - ConsepsisTM V

	(Contd. of page
· 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.
• Other information	No further relevant information available.

10 Stability and Reactivity

· *Reactivity* No further relevant information available.

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid: Heat Ignition sources Flames
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products:
- Oxides of Carbon Nitrogen oxides Hydrogen chloride (HCl) Ammonia

11 Toxicological Information

· Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

	thyl 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	ermint	
Oral	LD50	2,490 mg/kg (mouse)	
		2,426 mg/kg (rat)	
Skin corro	sion/irritati	on Based on available data, the classification criteria are not met.	
Serious ey	e damage/ii	ritation Causes serious eye irritation.	
Respirator	y or skin se	nsitisation Based on available data, the classification criteria are not met.	
~	mutacaniai	ty 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.

(Contd. on page 6)

[—] AU

Printing date 03.08.2023

Revision: 03.08.2023

(Contd. of page 5)

Trade name: ConsepsisTM - ConsepsisTM V

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

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

Disposal should be in accordance with applicable regional, national and local laws and regulations. Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

UN-Number		
ADG, IMDG, IATA	UN1987	
UN proper shipping name		
ADG	1987 ALCOHOLS, N.O.S. (Ethyl Alcohol)	
IMDG, IATA	ALCOHOLS, N.O.S. (Ethyl Alcohol)	
Transport hazard class(es)		
ADG, IMDG, IATA		
3		
Class	3 Flammable liquids.	
Label	3	

Printing date 03.08.2023

Revision: 03.08.2023

Trade name: ConsepsisTM - ConsepsisTM V

	(Contd. of pag
Packing group	
ADG, IMDG, IATA	111
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	30
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:	
ADG	
Limited quantities (LQ)	5L
Excepted quantities $(\tilde{E}Q)$	Code: El
	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: El
	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

• Australian I	· Australian Inventory of Industrial Chemicals		
7732-18-5	Water		
64-17-5	Ethyl Alcohol		
25322-68-3	Polyethylene Glycol		
18472-51-0	Chlorhexidine Gluconate		
8006-90-4	Oils, Peppermint		
89-78-1	Menthol		
5949-29-1	Citric Acid Monohydrate		
2353-45-9	FD&C Green <u>3</u>		
· Standard fo	Standard for the Uniform Scheduling of Medicines and Poisons		
None of the	None of the ingredients is listed.		
· Australia: P	· Australia: Priority Existing Chemicals		
None of the	None of the ingredients is listed.		
	• Directive 2012/18/EU • Named dangerous substances - ANNEX I None of the ingredients is listed.		

• Seveso category P5c FLAMMABLE LIQUIDS

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

(Contd. on page 8)

AU

Printing date 03.08.2023

Revision: 03.08.2023

(Contd. of page 7)

Trade name: ConsepsisTM - ConsepsisTM V

- \cdot Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · 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 from Section 3 H225 Highly flammable liquid and vapour. H227 Combustible liquid. 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. H361f Suspected of damaging fertility. H373 May cause damage to organs through prolonged or repeated exposure. · Department issuing SDS: Environmental, Health, and Safety · Contact: Customer Service · Abbreviations and acronyms: ADR: Accord relatif au transport international 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 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) 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 Flam. Liq. 4: Flammable liquids - Category 4 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A 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 • * Data compared to the previous version altered.