

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Consepsis™ - Consepsis™ V

Manufacturer: Ultradent

SDS Expiry: 3 August 2028

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
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Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 3 / 6

HSNO Group Standard: Dental Products Flammable Group Standard 2020 HSR002556

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – September 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Safety Data Sheet
according to WHS Regulations

Printing date 03.08.2023

Revision: 03.08.2023

1 Identification

- **Product identifier**
- **Trade name:** *Consepsis™ - Consepsis™ V*
- **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*
- **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*

2 Hazard(s) Identification

- **Classification of the substance or mixture**



Flam. Liq. 3

H226 Flammable liquid and vapour.



Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS02, GHS07*
- **Signal word** *Warning*
- **Hazard statements**
*H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.*
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.

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- P102 Keep out of reach of children.
 P103 Read label before use.
 P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
 P241 Use explosion-proof electrical/ventilating/lighting equipment.
 P303+P361+P353 **IF ON SKIN (or hair):** Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P403+P235 Store in a well-ventilated place. Keep cool.
 P501 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	≥0-<10%
	⚠ Serious eye damage/irritation – Category 2A, H319	
8006-90-4	Oils, Peppermint	≥0.1-<1%
	⚠ Asp. Tox. 1, H304; ⚠ 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 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.
 - **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.

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· **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.

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· **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

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **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/vapour 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.

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- **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.

· LD/LC50 values relevant for classification:

64-17-5 Ethyl Alcohol

Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)
8006-90-4 Oils, Peppermint		
Oral	LD50	2,490 mg/kg (mouse)
		2,426 mg/kg (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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.

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· **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.

14 Transport information

· **UN-Number**· **ADG, IMDG, IATA**

UNI987

· **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**· **Class**

3 Flammable liquids.

· **Label**

3

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

· 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 for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

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**

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- **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.**