

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

Manufacturer: Ultradent Products Inc.

SDS Expiry: 8 May 2024

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

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-2017-HSR002556

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

Date Prepared: This coversheet was prepared on 2 June 2020

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 1907/2006/EC, Article 31

Printing date 17.05.2019

Revision: 08.05.2019

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

- **Product identifier**
- **Trade name:** Consepsis™, Consepsis™ V
- **Article number:** 10772, 10796
- **Index number:** SDS 33-001.10
- **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. 10200 S.
South Jordan, UT 84095

Ultradent Australia PTY Ltd.
P.O. Box 111
Coogee, NSW 2034
Email: info.anz@ultradent.com
Emergency Phone: 1-800-290929
- **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**



flame

Flam. Liq. 3 H226 Flammable liquid and vapour.

- **Label elements**
- **GHS label elements**
Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS02
- **Signal word** Warning
- **Hazard statements**
Flammable liquid and vapour.
- **Precautionary statements**
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read label before use.
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting equipment.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **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:**

64-17-5	Ethyl Alcohol	>10-≤20%
	⚠ Flam. Liq. 2, H225	
	Dimethicone	<3%
	⚠ Repr. 2, H361; STOT RE 2, H373	
18472-51-0	Chlorhexidine Gluconate	≤2.5%
	⚠ Eye Irrit. 2A, H319	
8006-90-4	Oils, Peppermint	<1%
	⚠ Asp. Tox. 1, H304; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	
25322-68-3	Polyethylene Glycol	>10-≤15%

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

4 First aid measures

- **Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
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:**
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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- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
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:**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.
- **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 2% Chlorhexidine Solution

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	
NES	Long-term value: 1880 mg/m ³ , 1000 ppm
WES	Long-term value: 1880 mg/m ³ , 1000 ppm
· Additional information: The lists valid during the making were used as basis.	

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- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Store protective clothing separately.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **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

- **Information on basic 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:**

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

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· Flammability (solid, gas):	Not applicable.
· 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.
· 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:	<80 %
VOC (EC)	0.00 %
Solids content:	<40.0 %
· Other information	No further relevant information available.

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:**
 - Heat
 - Ignition sources
 - Flames
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
 - Oxides of Carbon
 - Nitrogen oxides
 - Hydrogen chloride (HCl)
 - Ammonia

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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	>20,311-22,096 mg/kg (mouse)
Inhalative	LC50/4 h	>233-253 mg/l (mouse)

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)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.

12 Ecological information

- **Toxicity**

· **Aquatic toxicity:**

64-17-5 Ethyl Alcohol

Algae Toxicity	1,000 mg/l (Algae)
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- **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** Do not allow product to reach sewage system.

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

14 Transport information

· 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	
	
· Class	3 Flammable liquids.
· Label	3
· Packing group	
· ADG, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	30
· EMS Number:	F-E,S-D
· Stowage Category	A
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADG	
· 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

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Chemical Substances**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **GHS label elements**

Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).

· **Hazard pictograms** GHS02

· **Signal word** Warning

· **Hazard statements**

Flammable liquid and vapour.

· **Precautionary statements**

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

Keep out of reach of children.

Read label before use.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Ground/bond container and receiving equipment.

Use explosion-proof electrical/ventilating/lighting equipment.

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

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

· **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

· **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.

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.

H361 Suspected of damaging fertility or the unborn child.

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

· **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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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*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**Flam. Liq. 4: Flammable liquids – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 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*

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