

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

1 Identification

- **Product identifier**
- **Trade name:** Consepsis™, Consepsis™ V
- **Article number:** 10772, 10796
- **Index number:** SDS 33-001.10
- **Application of the substance / the mixture** Professional Dental 2% Chlorhexidine Gluconate 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
- **Information department:** 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**



GHS02 Flame

Flam. Liq. 3 H226 Flammable liquid and vapor.



GHS08 Health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**
Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS02, GHS07, GHS08
- **Signal word** Warning
- **Hazard-determining components of labeling:**
Dimethicone
Oils, Peppermint
- **Hazard statements**
Flammable liquid and vapor.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
May cause damage to organs through prolonged or repeated exposure.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: **Consepsis™, Consepsis™ V**

(Contd. of page 1)

· **Precautionary statements**

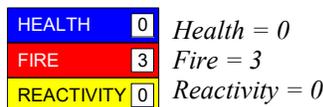
- If medical advice is needed, have product container or label at hand.*
Keep out of reach of children.
Read label before use.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting/equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Do not breathe dust/fume/gas/mist/vapors/spray.
Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
In case of fire: Use for extinction: CO2, powder or water spray.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
 · **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

64-17-5	Ethyl Alcohol	>10-≤20%
25322-68-3	Polyethylene Glycol	>10-≤15%
	Dimethicone	<3%
18472-51-0	Chlorhexidine Gluconate	≤2.5%

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: **Consepsis™, Consepsis™ V**

(Contd. of page 2)

8006-90-4 Oils, Peppermint

<1%

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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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**
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

64-17-5	Ethyl Alcohol	1,800 ppm
25322-68-3	Polyethylene Glycol	30 mg/m ³

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: Consepsis™, Consepsis™ V

(Contd. of page 3)

· PAC-2:

64-17-5	Ethyl Alcohol	3300* ppm
25322-68-3	Polyethylene Glycol	1,300 mg/m ³

· PAC-3:

64-17-5	Ethyl Alcohol	15000* ppm
25322-68-3	Polyethylene Glycol	7,700 mg/m ³

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 protection against explosions and fires:

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 receptacle tightly sealed.

· Specific end use(s) Professional Dental 2% Chlorhexidine Gluconate Solution

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

· Control parameters

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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

64-17-5 Ethyl Alcohol

PEL Long-term value: 1900 mg/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

STEL Short-term value: 1000 mg/m³

TLV Short-term value: 1880 mg/m³, 1000 ppm

TWA Short-term value: 1900 mg/m³

25322-68-3 Polyethylene Glycol

WEEL Long-term value: 10 mg/m³
(H); MW>200

· Additional information: The lists that were valid during the creation were used as basis.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: **Consepsis™, Consepsis™ V**

(Contd. of page 4)

- **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.

Store protective clothing separately.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **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 is based 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

Color: Blue Green
Green

- **Odor:** Mint

- **Odor threshold:** Not determined.

- **pH-value at 20 °C:** 5.2-6.2

- **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: *Consepsis™, Consepsis™ V*

(Contd. of page 5)

· Flash point:	36 °C
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
Lower:	3.3 Vol %
Upper:	19 Vol %
· Vapor pressure at 20 °C:	552 hPa
· Density at 20 °C:	0.99-1.02 g/cm ³
· Relative density	Not determined
· Vapor 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 content:	0.00 %
	15.7 g/l / 0.13 lb/gal
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

US

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: **Consepsis™, Consepsis™ V**

(Contd. of page 6)

11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

ATE (Acute Toxicity Estimate)

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)

25322-68-3 Polyethylene Glycol

Oral	LD50	19,600 mg/kg (Guinea pig) 17,300 mg/kg (mouse) >10,000 mg/kg (rat)
Dermal	LC50 Fish	>100 mg/l (Fish)
	LD50	>20,000 mg/kg (rabbit)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)

8006-90-4 Oils, Peppermint

Oral	LD50	2,490 mg/kg (mouse) 2,426 mg/kg (rat)
------	------	--

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

64-17-5	Ethyl Alcohol	1
2353-45-9	FD&C Green <u>3</u>	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

US

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: *Consepsis™, Consepsis™ V*

(Contd. of page 7)

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.

- **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packagings:**

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

14 Transport information

- **UN-Number**

- **DOT, IMDG, IATA**

UN1987

- **UN proper shipping name**

- **DOT**

Alcohols, n.o.s. (Ethyl Alcohol)

- **IMDG, IATA**

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

- **Transport hazard class(es)**

- **DOT**



- **Class**

3 Flammable liquids

- **Label**

3

(Contd. on page 9)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: *Consepsis™, Consepsis™ V*

(Contd. of page 8)

· **IMDG, IATA**

· Class	3 Flammable liquids
· Label	3
· Packing group	III
· DOT, 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 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· DOT	
· Quantity limitations	On passenger aircraft/rail: 60 L On cargo aircraft only: 220 L
· 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
- Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **TSCA new (21st Century Act) (Substances not listed)**

Dimethicone

· **Proposition 65**· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

(Contd. on page 10)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: **Consepsis™, Consepsis™ V**

(Contd. of page 9)

· Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:
64-17-5 Ethyl Alcohol

· Carcinogenic categories
· EPA (Environmental Protection Agency)
None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)	
64-17-5 Ethyl Alcohol	A3

· NIOSH-Ca (National Institute for Occupational Safety and Health)
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, GHS07, GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Dimethicone

Oils, Peppermint

- **Hazard statements**

Flammable liquid and vapor.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

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

Keep out of reach of children.

Read label before use.

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

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

Keep container tightly closed.

Ground/bond container and receiving equipment.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

Do not breathe dust/fume/gas/mist/vapors/spray.

Contaminated work clothing must not be allowed out of the workplace.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF exposed or concerned: Get medical advice/attention.

Get medical advice/attention if you feel unwell.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

In case of fire: Use for extinction: CO2, powder or water spray.

Store in a well-ventilated place. Keep cool.

Store locked up.

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

(Contd. on page 11)

Safety Data Sheet

acc. to OSHA HCS

Printing date 04/29/2019

Reviewed on 12/10/2018

Trade name: Consepsis™, Consepsis™ V

(Contd. of page 10)

· **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.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Date of preparation / last revision** 04/29/2019 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 3: Flammable liquids – Category 3

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

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