

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/01/2006

SDS No : 33-001.9

Date Revised : 10/29/2015

Revision No : 8

Consepsis®, Consepsis® V & Consepsis® Scrub**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : CB/10969, CR/10796, CS/10772
Product name : Consepsis®, Consepsis® V & Consepsis® Scrub
Product description : 2% Chlorhexidine Gluconate Solution

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Antibacterial Solution

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

Distributor

Ultradent Products GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300
(INTERNATIONAL) :+1(703) 527 - 3887

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols : Xi,F

R phrases : R11,R36/38

Classification according to Regulation(EC) No 1272/2008 [CLP]

Health : Eye Damage, Category 1

Environmental : Flammable Liquids, Category 2
 Acute Hazards to the Aquatic Environment, Category 1

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi F



Irritant



Highly flammable

R&S statement(s) : R11: Highly flammable.

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ULTRADENT
 PRODUCTS, INC.

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R36/38: Irritating to eyes and skin.

Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s)



Signal Word

: DANGER

Hazard statement(s)

: H225: Highly flammable liquid and vapour.
 H400: Very toxic to aquatic life.
 H319: Causes serious eye irritation.

Precautionary statement(s)

Prevention

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

Response

: P305: IF IN EYES:
 P351: Rinse cautiously with water for several minutes.
 P315: Get immediate medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P301: IF SWALLOWED:
 P331: Do NOT induce vomiting.

Storage

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

Disposal

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: Flammable

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Ethyl Alcohol	64-17-5	200-578-6	< 20	F+; R11	Flam. Liq.,Cat. 2; H225; EUH 210
Chlorhexidine Gluconate	18472-51-0	242-354-0	< 5	Xi; R36/38	EYE DMG.,Cat. 1; Aquatic Tox.,Acute, Cat. 1; H318; H400

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- Following skin** : Wash with soap and water.
- Following ingestion** : Give large volumes of water. Do not induce vomiting. Consult a physician if ingested in large amounts.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Causes severe eye irritation.
- Skin** : May cause skin irritation.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Irritating to eyes.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Ammonia, hydrogen chloride, oxides of carbon and nitrogen

5.3. Advice for firefighters

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- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO₂).

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

- General procedures** : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

- Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Small spill** : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.
- Large spill** : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

- Reference to other sections** : Not Applicable

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

- Handling** : Use suitable protective equipment.
- Storage** : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

- Shelf life** : See product labeling

7.3. Specific end use(s)

- Specific end use(s)** : Professional Dental Antibacterial Solution

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

- Control parameters** : Not Determined

8.2. Exposure controls

- Eye/face protection** : Wear eye protection
- Skin protection** : Wash thoroughly after handling.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

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Physical state	: Consepsis Scrub-very viscous paste, Consepsis V-medium viscosity liquid, Consepsis-low viscosity liquid
Colour	: Green
Odour	: Mint

9.2. Other information

Percent volatile	: Not Determined
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SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity	: Stable
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10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: Heat, flames, ignition sources, direct light.
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10.5. Incompatible materials

Incompatible materials	: Not Determined
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10.6. Hazardous decomposition products

Hazardous decomposition products	: Ammonia, hydrogen chloride, oxides of carbon and nitrogen.
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SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**

Notes	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.
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SECTION 12: Ecological information**12.1. Toxicity**

Toxicity	: Not Determined
Aquatic toxicity (acute)	: Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀	: Not Determined
48-hour EC₅₀	: Not Determined
96-hour EC₅₀	: Not Determined

12.2. Persistence and degradability

Persistence and degradability	: Not Determined
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12.3. Bioaccumulative potential

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Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Harmful to aquatic life with long lasting effects.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information**14.1. UN number**

UN number : 1987

14.2. UN proper shipping name

UN proper shipping name : Alcohols, n.o.s. (Ethyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : N/A

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

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Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R11: Highly flammable.
 R36/38: Irritating to eyes and skin.
 Aquatic Tox., Acute, Cat. 1: Aquatic Toxicity, Acute, Category 1
 EYE DMG., Cat. 1: Eye Damage, Category 1
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 EUH 210: Safety data sheet available on request.
 H225: Highly flammable liquid and vapour.
 H318: Causes serious eye damage.
 H400: Very toxic to aquatic life.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 05/19/2015 SDS. Revised: **Section 1:** . **Section 2:** . **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - EYES. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** WATER SPILL. **Section 10:** CONDITIONS TO AVOID. **Section 12:** ENVIRONMENTAL DATA, AQUATIC TOXICITY (ACUTE).

General statements : N/A= Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.