SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use

ULTRADENT PRODUCTS, INC.

Date Issued : 03/02/2006
SDS No : 38-001.8
Date Revised : 03/23/2016
Revision No : 7

Ultracare® (All Flavors)

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : BG/10329, CM/10332, WB/11436, CE/1002996

Product name : Ultracare® (All Flavors)

Product description : Topical Oral Anesthetic

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

Relevant identified uses : Oral Anesthetic Gel

1.3. Details of the supplier of the safety data sheet

Manufacturer

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

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

R phrases : R36

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

Health : Skin Sensitization, Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi

Irritant

R& statement(s) : R36: Irritating to eyes.

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

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Hazard pictogram(s) :

Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H317: May cause an allergic skin reaction.

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.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

Storage : P273: Avoid release to the environment.

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

2.3. Other hazards

Immediate concerns : May cause skin irritation and sensitization.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Benzocaine	94-09-7	202-303-5	20	Xi; R36/37/38	Skin Sens.,Cat. 1; H317
Ethyl Alcohol	64-17-5	200-578-6	< 5	F; R11	Flam. Liq.,Cat. 2; H225; EUH 210
Orange Creme flavor	N/A	N/A	< 5	Xi; F+; R11; R36/37/38	Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; STOT SE,CAT 3; Eye Irr.,Cat. 2B; H225; H315; H317; H335;

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					H319

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 : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

Eyes : May cause mild irritation.

Skin : May cause skin irritation and sensitization.

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 : May cause skin irritation and sensitization.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO2)

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Not Determined

5.3. Advice for firefighters

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.

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.

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Large Spill : Remove all sources of ignition. Ventillate area of leak or spill. Pick up spill for recovery or disposal and place into sealed containers.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Avoid contact with eyes.

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) : Oral Anesthetic Gel

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 : Wear suitable protective clothing and gloves.

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

Physical state : Gel

Colour : Flavor dependent

Odour : Flavor dependent

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

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Conditions to avoid : High Temperatures

10.5. Incompatible materials

Incompatible materials : Acids and Alkalis

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon monoxide, carbon dioxide, and oxides of nitrogen

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : This product meets the toxicologic requirements of US OTC drugs per 21 CFR 356.

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 LC_{50} : Not Determined

48-hour EC_{50} : Not Determined

96-hour EC_{50} : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

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 : Not Available

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 : N/A

14.2. UN proper shipping name

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UN proper shipping name	**:** Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification	**:** N/A

14.4. Packing group

Packing group	**:** N/A

14.5. Environmental hazards

Marine pollutant #1	**:** N/A

14.6. Special precautions for user

ADR - road	**:** Not Dangerous Goods
RID - rail	**:** Not Dangerous Goods
IMDG - sea	**:** Not Dangerous Goods
IATA - air	**:** Not Dangerous Goods

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

Transport in bulk	**:** Not Dangerous Goods

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS	**:** Please refer to the United States Food, Drug, and Cosmetic Act.

15.2. Chemical safety assessment

Chemical safety assessment	**:** See Section 11
Additional information	**:** This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text)	**:** R11: Highly flammable. R36/37/38: Irritating to eyes, respiratory system and skin. Eye Irr., Cat. 2B: Eye Irritation, Category 2B Flam. Liq., Cat. 2: Flammable Liquids, Category 2 STOT SE, CAT 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3 Skin Irr., Cat. 2: Skin Irritation, Category 2 Skin Sens., Cat. 1: Skin Sensitization, Category 1 EUH 210: Safety data sheet available on request. H225: Highly flammable liquid and vapour. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H335: May cause respiratory irritation.
Prepared by	**:** Anu Kattoju
Revision summary	**:** This SDS replaces the 09/24/2015 SDS. Revised: **Section 1:** MSDS No, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** Wt.%. **Section 4:** EYES, NOTES TO

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	PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** HANDLING. **Section 11:** ACUTE (ORAL LD_{50} (rat), INHALATION LC_{50} (rat) ACUTE. **Section 15:** COMMENTS, SECTION 15: Regulatory information.
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.