

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 03/02/2006  
SDS No : 38-001.9  
Date Revised : 06/02/2017  
Revision No : 8

## 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. Ultradent Drive (10200 South)  
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 Regulation(EC) No 1272/2008 [CLP]

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

Health : Skin Sensitization, Category 1  
Acute Toxicity (Oral), Category 4  
Acute Toxicity (Inhalation), Category 4

#### 2.2. Label elements

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

Hazard pictogram(s) :



Exclamation  
mark

Signal Word : WARNING

Hazard statement(s) : H317: May cause an allergic skin reaction.  
H302: Harmful if swallowed.  
H332: Harmful if inhaled.

##### Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P270: Do not eat, drink or smoke when using this product.  
P264: Wash hands thoroughly after handling.

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**Response** : P261: Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272: Contaminated work clothing should not be allowed out of the workplace.  
P271: Use only outdoors or in a well-ventilated area.  
: P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor/...if you feel unwell.  
P330: Rinse mouth.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364: Take off contaminated clothing and wash it before reuse.  
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P304+P312: IF INHALED: Call a POISON CENTER/doctor/...if you feel unwell.

**Storage** : P273: Avoid release to the environment.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-10/11/2003)

**2.3. Other hazards**

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Benzocaine	94-09-7	202-303-5	< 20	Skin Sens.,Cat. 1; Skin Irr.,Cat. 2; H317; H315
Ethyl Alcohol	64-17-5	200-578-6	< 5	Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 1; H225; H319; H315
Orange Creme flavor	NAP	NAP	< 5	Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; STOT SE,Cat 3; Eye Irr.,Cat. 2B; H225; H315; H317; H335; H319
Bubble Gum Flavor	NAP	NAP	≤ 1	Flam. Liq.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,Cat. 3; H225; H361; H315; H317; H335; H319

For full text of H-statements: 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** : Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation develops or persists. Wash contaminated clothing before reuse.

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**Following ingestion** : If swallowed rinse mouth out with water. Seek medical attention if you feel unwell.

**Following inhalation** : If inhaled, remove to fresh air. Get medical attention if you feel unwell.

**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** : May be harmful if inhaled.

**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 (CO<sub>2</sub>)

**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.

**Large Spill** : Remove all sources of ignition. Ventilate 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** : NAP

**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**

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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 : Ethyl Alcohol CAS: 64-17-5

Control Parameters	Exposure Limits
OSHA PEL General Industry	1000 ppm (1900 mg/m <sup>3</sup> ) TWA
OSHA PEL - Construction Industry	1000 ppm (900 mg/m <sup>3</sup> ) TWA
OSHA PEL Shipyard Employment	1000 ppm(1900 mg/m <sup>3</sup> ) TWA
NIOSH REL	1000 ppm(1900 mg/m <sup>3</sup> ) TWA
ACGIH TLV	1000 ppm(1880 mg/m <sup>3</sup> ) STEL
CAL/OSHA PEL	1000 ppm(1900 mg/m <sup>3</sup> ) TWA

**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. In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

Physical state : Gel  
 Colour : Flavor dependent  
 Odour : Flavor dependent  
 pH : NAP (non-aqueous)  
 Specific gravity : 1.15 - 1.17

**9.2. Other information**

Additional information : No further relevant information available

**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.

**10.3. Possibility of hazardous reactions**

**Hazardous polymerization** : None

**10.4. Conditions to avoid**

**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**

**Dermal LD<sub>50</sub>** : > 12700 mg/kg Rat/Rabbit

**Notes** : ~38% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 700 mg/kg Rat/Mouse

**Notes** : ~21% of the mixture consists of components of unknown toxicity (Oral).

**Inhalation LC<sub>50</sub>** : > 0.3 mg/L/4H Rat

**Notes** : ~39% of the mixture consists of components of unknown toxicity (Inhalation).  
 Although components of this mixture may have inhalation hazards, the product is a thick gel and is not able to be inhaled.

**Germ cell mutagenicity** : The components in this product are not reported to produce mutagenic effects in humans.

**Carcinogenicity** : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

**Reproductive toxicity** : WARNING! This product contains a substance to cause birth defects or other reproductive harm. Bubble Gum Flavor

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

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

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Mobility in soil : Not Available

**12.5. Results of PBT and vPvB assessment**

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

Environmental data : No further relevant information 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 : NAP

**14.2. UN proper shipping name**

UN proper shipping name : Not Dangerous Goods

**14.3. Transport hazard class(es)**

Hazard classification : NAP

**14.4. Packing group**

Packing group : NAP

**14.5. Environmental hazards**

Marine pollutant #1 : NAP

**14.6. Special precautions for user**

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

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

Transport in bulk : NAP

**SECTION 15: Regulatory information**

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

General information : Substances of very high concern (SVHC) according to REACH, Article 57:  
Contains no SVHC substances.

General comments : Please refer to the United states Food, Drug, and Cosmetic Act.

**15.2. Chemical safety assessment**

Chemical safety assessment : See Section 11

Additional information : WARNING! This product contains a substance known to cause birth defects or

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other reproductive harm. Bubble Gum Flavor.

**SECTION 16: Other information**

- Relevant H-statements (number and full text)** : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Eye Irr., Cat. 2B: Eye Irritation, Category 2B  
Eye Irr., Cat. 2: Eye Irritation, Category 2  
Flam. Liq., Cat. 2: Flammable Liquids, Category 2  
STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3  
STOT SE, Cat. 1: Target Organ Toxicity (Single exposure), Category 1  
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
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.  
H361: Suspected of damaging fertility or the unborn child (state specific effect if known)(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).
- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 03/23/2016 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 4:** INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INHALATION ), SKIN. **Section 6:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.
- General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit

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STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**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.