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]

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)

P270: Do not eat, drink or smoke when using this product.
P264: Wash hands thoroughly after handling.
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Ultracare® (All Flavors)

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.

Response

: 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


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

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

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.
Ultracare® (All Flavors)

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 (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.

**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
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Ultracare® (All Flavors)

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

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>1000 ppm (1900 mg/m³) TWA</td>
</tr>
<tr>
<td>OSHA PEL - Construction Industry</td>
<td>1000 ppm (900 mg/m³) TWA</td>
</tr>
<tr>
<td>OSHA PEL Shipyard Employment</td>
<td>1000 ppm (1900 mg/m³) TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>1000 ppm (1900 mg/m³) TWA</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>1000 ppm (1880 mg/m³) STEL</td>
</tr>
<tr>
<td>CAL/OSHA PEL</td>
<td>1000 ppm (1900 mg/m³) TWA</td>
</tr>
</tbody>
</table>

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
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\textsubscript{50} : > 12700 mg/kg Rat/Rabbit
Notes : ~38% of the mixture consists of components of unknown toxicity (Dermal).
Oral LD\textsubscript{50} : > 700 mg/kg Rat/Mouse
Notes : ~21% of the mixture consists of components of unknown toxicity (Oral).
Inhalation LC\textsubscript{50} : > 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
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


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.


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

Ultracare® (All Flavors)
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: Personal Protective Equipment - Respiratory. Section 9: Comments, Percent Volatile, pH, Specific Gravity. Section 11: ACUTE (DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), ORAL LD50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat), INHALATION LC50 (rat), INHALATION LC50 (rat), ORAL LD50 (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 EC50, 96-HOUR EC50), 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
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

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

Ultracare® (All Flavors)

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.