

**Safety Data Sheet**  
*acc. to OSHA HCS*

Printing date 09/29/2020

Reviewed on 09/11/2020

**1 Identification**

- **Product identifier**
- **Trade name:** Ultracare™
- **Article number:** 10329, 10332, 11436
- **Index number:** SDS 38-001.10
- **Application of the substance / the mixture** *Topical Oral Anaesthetic*
- **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**



GHS07

*Eye Irrit. 2A H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **GHS label elements**  
*Medical Devices, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).*
- **Hazard pictograms** GHS07
- **Signal word** *Warning*
- **Hazard-determining components of labeling:**  
*Benzocaine  
Bubble Gum Flavor  
Creme De Menthe*
- **Hazard statements**  
*Causes serious eye irritation.  
May cause an allergic skin reaction.*
- **Precautionary statements**

<i>P261</i>	<i>Avoid breathing dust/fume/gas/mist/vapors/spray</i>
<i>P264</i>	<i>Wash thoroughly after handling.</i>
<i>P272</i>	<i>Contaminated work clothing must not be allowed out of the workplace.</i>
<i>P280</i>	<i>Wear protective gloves / eye protection / face protection.</i>
<i>P302+P352</i>	<i>If on skin: Wash with plenty of water.</i>
<i>P305+P351+P338</i>	<i>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i>
<i>P333+P313</i>	<i>If skin irritation or rash occurs: Get medical advice/attention.</i>
<i>P321</i>	<i>Specific treatment (see on this label).</i>
<i>P337+P313</i>	<i>If eye irritation persists: Get medical advice/attention.</i>

(Contd. on page 2)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 1)

P363 Wash contaminated clothing before reuse.  
 P501 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:**

25322-68-3	Polyethylene Glycol	>50-≤100%
56-81-5	Glycerine	>10-≤25%
	Eye Irrit. 2B, H320	
94-09-7	Benzocaine	>10-≤25%
	⚠ Skin Sens. 1, H317	
64-17-5	Ethyl Alcohol	>2.5-≤10%
	⚠ Flam. Liq. 2, H225	
	Strawberry Flavor	≤2.5%
	⚠ Flam. Liq. 3, H226; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
	Bubble Gum Flavor	≤2.5%
	⚠ Flam. Liq. 2, H225; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
	Creme De Menthe	≤2.5%
	⚠ Flam. Liq. 3, H226; ⚠ Skin Sens. 1, H317	

### 4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:**  
 Immediately wash with water and soap and rinse thoroughly.  
 If skin irritation continues, consult a doctor.
- **After eye contact:**  
 Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If swallowed in large quantities seek medical attention.

(Contd. on page 3)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 2)

- **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:**  
Water spray, fog, or mist, foam, dry chemical, carbon dioxide  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**  
Carbon monoxide (CO)  
Nitrogen oxides (NOx)
- **Advice for firefighters**  
General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- **Protective equipment:** Wear fully protective suit.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**  
Dilute with plenty of water.  
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:**

25322-68-3	Polyethylene Glycol	30 mg/m <sup>3</sup>
56-81-5	Glycerine	45 mg/m <sup>3</sup>
64-17-5	Ethyl Alcohol	1,800 ppm

- **PAC-2:**

25322-68-3	Polyethylene Glycol	1,300 mg/m <sup>3</sup>
56-81-5	Glycerine	180 mg/m <sup>3</sup>
64-17-5	Ethyl Alcohol	3300* ppm

- **PAC-3:**

25322-68-3	Polyethylene Glycol	7,700 mg/m <sup>3</sup>
56-81-5	Glycerine	1,100 mg/m <sup>3</sup>
64-17-5	Ethyl Alcohol	15000* ppm

US

(Contd. on page 4)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 3)

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **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)** Topical Oral Anaesthetic

## 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:**

### 25322-68-3 Polyethylene Glycol

WEEL	Long-term value: 10 mg/m <sup>3</sup> (H); MW>200
------	--

### 56-81-5 Glycerine

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.
TWA	Short-term value: 15 mg/m <sup>3</sup>

### 64-17-5 Ethyl Alcohol

PEL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
REL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
STEL	Short-term value: 1000 mg/m <sup>3</sup>
TLV	Short-term value: 1880 mg/m <sup>3</sup> , 1000 ppm
TWA	Short-term value: 1900 mg/m <sup>3</sup>

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

- **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.  
Avoid contact with the eyes.  
Avoid contact with the eyes and skin.
- **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.

(Contd. on page 5)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 4)

· **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:**

· <b>Form:</b>	Gel
· <b>Color:</b>	According to product specification
· <b>Odor:</b>	Flavor Dependent
· <b>Odor threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined

· **Flash point:** Not applicable

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** 400 °C

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

(Contd. on page 6)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 5)

· <b>Vapor pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.15-1.17 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Partly miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	<30 %
<b>VOC content:</b>	<10 %
	28.2 g/l / 0.24 lb/gal
<b>VOC (EC)</b>	<10%
<b>Solids content:</b>	<60 %
· <b>Other information</b>	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity** Stable when stored and handled under recommended conditions.
- **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** No further relevant information available.
- **Incompatible materials:**
  - Alkalis
  - Acids
- **Hazardous decomposition products:**
  - Carbon monoxide and carbon dioxide
  - Nitrogen oxides

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

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

### ATE (Acute Toxicity Estimate)

Oral	LD50	8,621 mg/kg
Inhalative	LC50/4 h	>0.71 mg/l

### 25322-68-3 Polyethylene Glycol

Oral	LD50	19,600 mg/kg (Guinea pig)
		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)

(Contd. on page 7)

US

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 6)

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)
<b>56-81-5 Glycerine</b>		
Oral	LD50	7,750 mg/kg (Guinea pig)
		4,100 mg/kg (mouse)
		5,570 mg/kg (rat)
		27,000 mg/kg (rabbit)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)
<b>94-09-7 Benzocaine</b>		
Oral	LD50	3,042 mg/kg (rat)
<b>64-17-5 Ethyl Alcohol</b>		
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)

- **Primary irritant effect:**

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

- **on the eye:** 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	I
---------	---------------	---

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

**56-81-5 Glycerine**

EC50	>10,000 mg/l (Bacteria)
------	-------------------------

	>10,000 mg/l (daphnia)
--	------------------------

(Contd. on page 8)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 7)

**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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | not regulated   |
| · <b>Packing group</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>Environmental hazards:</b>  | Not applicable. |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | not regulated   |

US

(Contd. on page 9)



# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

Trade name: Ultracare™

(Contd. of page 8)

## 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 components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **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.

· **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, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).

· **Hazard pictograms GHS07**

· **Signal word Warning**

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

Benzocaine

Bubble Gum Flavor

Creme De Menthe

· **Hazard statements**

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

P264 Wash thoroughly after handling.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves / eye protection / face protection.

P302+P352 If on skin: Wash with plenty of water.

(Contd. on page 10)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/29/2020

Reviewed on 09/11/2020

**Trade name: Ultracare™**

(Contd. of page 9)

P305+P351+P338 *If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*

P321 *Specific treatment (see on this label).*

P337+P313 *If eye irritation persists: Get medical advice/attention.*

P363 *Wash contaminated clothing before reuse.*

P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

**Chemical safety assessment:**

*This product meets the toxicological requirements of the US OTC drugs per 21 CFR 355.*

## 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:** Environmental, Health & Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 09/29/2020 / -

· **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. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B

Skin Sens. 1: Skin sensitisation – Category 1

STOT/SE 3: Specific target organ toxicity (single exposure) – Category 3