

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/24/2006

SDS No : 9-001.11

Date Revised : 10/14/2016

Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

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

1.1. Product identifier

Product code : OE/10320, OM/11592
 Product name : Opalescence® 10% Bleaching Gel (All Flavors)
 Product description : Dental Teeth Whitening Gel

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

Relevant identified uses : Professional Dental Teeth Whitening Gel

1.3. Details of the supplier of the safety data sheet

Manufacturer

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

EC Responsible Person

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

R phrases : R36

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

Health : Eye Irritation, Category 2
 Skin Irritation, Category 2
 Acute Toxicity (Inhalation), Category 4

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]

SAFETY DATA SHEET

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



Date Issued : 01/24/2006
SDS No : 9-001.11
Date Revised : 10/14/2016
Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

Hazard pictogram(s) :



Exclamation
mark

Signal Word :

DANGER

Hazard statement(s) :

H319: Causes serious eye irritation.
H315: Causes skin irritation.
H335: May cause respiratory 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.
P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
P363: Wash contaminated clothing before reuse.
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

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 Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Carbamide Peroxide	124-43-6	204-701-4	10	Xi; R41	Skin Corr., Cat. 1B; Oxid. Sol., CAT 3; H272; H314
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr., Cat. 1B; Eye Irr., Cat. 1; Cor. Metal, Cat. 1; H314; H290
Poly Acrylic acid	9003-01-4	N/A	< 10	Xi; R36/37/38	Not classified

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

SECTION 4: First aid measures

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/24/2006

SDS No : 9-001.11

Date Revised : 10/14/2016

Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

4.1. Description of first aid measures

- After eye contact.** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- After skin contact** : Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.
- After ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- After 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

- General notes** : Irritating to eyes.
: Irritating to skin.
: May be harmful if swallowed in large quantities.
: May be harmful if inhaled.

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

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Water Spray Only

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : None known.

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 with cloth, soap and 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

SAFETY DATA SHEET

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



Date Issued : 01/24/2006
SDS No : 9-001.11
Date Revised : 10/14/2016
Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.
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 Teeth Whitening Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Sodium Hydroxide CAS: 1310-73-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	2 mg/m ³ TWA
OSHA PEL - Construction Industry	2 mg/m ³ TWA
OSHA PEL - Shipyard Employment	2 mg/m ³ TWA
NIOSH REL	2 mg/m ³ Ceiling
ACGIH TLV	2 mg/m ³ Ceiling
CAL/OSH A PEL	2 mg/m ³ Ceiling

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 : Clear gel with bubbles
Colour : Colorless
Odour : Mint or odorless
pH : 6.1 - 6.7
Specific gravity : 1.2 - 1.3
Solubility in water : Partially Soluble
Viscosity : < = 3,762,000 cp

9.2. Other information

Percent volatile : Not Volatile

SECTION 10: Stability and reactivity

SAFETY DATA SHEET

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



Date Issued : 01/24/2006
SDS No : 9-001.11
Date Revised : 10/14/2016
Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

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 : Avoid strong bases, metals, excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 7800 mg/kg Rabbit

Notes : ~7% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 2500 mg/kg Rat/Mouse

Notes : There are no components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 1.0 mg/L/4H Dust/Mist Rat

Notes : ~10% of the mixture consists of components of unknown toxicity (Inhalation).

Other information : This product meets the toxicologic profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/3009.

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/24/2006

SDS No : 9-001.11

Date Revised : 10/14/2016

Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

Environmental data : Do not flush to sewer.

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 comments : Please refer to Regulation 1223/2009 on Cosmetics

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R34: Causes burns.
R36/37/38: Irritating to eyes, respiratory system and skin.
R41: Risk of serious damage to eyes.
Cor. Metal, Cat. 1: Corrosive to Metals, Category 1

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/24/2006

SDS No : 9-001.11

Date Revised : 10/14/2016

Revision No : 14

Opalescence® 10% Bleaching Gel (All Flavors)

Eye Irr., Cat. 1: Eye Irritation, Category 1
 Oxid. Sol., CAT 3: Oxidizing Solids, Central Nervous System Category 3
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 H272: May intensify fire; oxidizer.
 H290: May be corrosive to metals.
 H314: Causes severe skin burns and eye damage.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 10/29/2015 SDS. Revised: **Section 1:** MSDS No, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** ODOR, pH, PHYSICAL STATE, SPECIFIC GRAVITY, VISCOSITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, 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
 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.