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



Date Issued: 01/23/2007 SDS No: 131-001.10

Date Revised: 10/29/2015

Revision No: 10

Opalescence® Go™ 6% HP (All flavors)

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

1.1. Product identifier

Product code : SN/71162, 3I/1002795

Product name : Opalescence® Go™ 6% HP (All flavors)

Product description: Dental Teeth Bleaching 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

Distributor

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 : R36/38

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

Health : Skin Irritation, Category 2

Eye Irritation, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin. Classification according to Regulation(EC) No 1272/2008 [CLP]

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Hazard pictogram(s)

Exclamation

Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H315: Causes skin irritation.

H319: Causes serious eye 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.

P313: Get medical advice/attention.

P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation 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 : None

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]
Poly Acrylic acid	9003-01-4	N/A	< 10	Xi; R36/37/38	Not classified
Hydrogen Peroxide	7722-84-1	231-765-0	≤ 6	Xi; R36	Acute Tox. (O),Cat. 4; EYE DMG.,Cat. 1; Skin Irr.,Cat. 2; H302; H318; H315
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2

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Sodium Fluoride	007681-49-4	231-667-8	0.25	Not classified	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),Cat 3; EUH032; H301; H315; H319
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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: Flush eye with water for 15 minutes. Get medical attention.

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. 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

Eyes : Causes eye irritation.

Skin : May cause skin irritation.

Ingestion: May be harmful if swallowed in large quantities.

Inhalation: None Expected.

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: Please see Fire Fighting Equipment under Section 5.3.

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.

Fire fighting equipment: Water spray only.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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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

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 : 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 : Colorless

Odour: Flavor dependent

pH : 5.0 to 7.2

Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Volatile

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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 : 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

Notes: This product meets the toxicologic profile required for cosmetics per

the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

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 LC50: Not Determined48-hour EC50: Not Determined96-hour EC50: 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 : Not Determined

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assessment

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

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 Regulation 1223/2009 on Cosmetics

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-: R34: Causes burns.

statements (number and full R36/37/38: Irritating to eyes, respiratory system and skin.

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text) R36: Irritating to eyes.

Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4

EYE DMG., Cat. 1: Eye Damage, Category 1 Eye Irr., Cat. 2: Eye Irritation, Category 2 Skin Irr., Cat. 2: Skin Irritation, Category 2

EUH032: Contact with acids liberates very toxic gas.

H301: Toxic if swallowed.H302: Harmful if swallowed.H315: Causes skin irritation.H318: Causes serious eye damage.H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary: This SDS replaces the 07/21/2015 SDS. Revised: Section 1:

Section 5: EXPLOSION HAZARDS, FIRE EXPLOSION, GENERAL

HAZARD, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO

IMPACT.

General statements: N/A= Not Applicable

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.