

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : FF/39025, FG/39029, FH/39013, FI/39019, FJ/39005, FK/39009, FP/13514, FQ/13509, FR/13518, SC/71178, SD/71179, SG/71180

Product name : Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

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 : Eye Irritation, Category 2
Skin Irritation, Category 2

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

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

ULTRADENT
 PRODUCTS, INC.

Date Issued : 02/02/2006
 SDS No : 14-001.14
 Date Revised : 08/11/2015
 Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

R&S statement(s) : R36/38: Irritating to eyes and skin.

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

Hazard pictogram(s) :



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.
 P315: Get immediate 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.
 (EC1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Carbamide Peroxide	000124-43-6	204-701-4	≤ 20	Xi; R36	Skin Corr.,Cat. 1B; Oxid. Sol.,Cat. 3; H272; H314
Poly Acrylic acid	9003-01-4	N/A	< 10	Xi; R36/37/38	Not classified
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr.,Cat. 1B; H314
Sodium Fluoride	007681-49-4	231-667-8	0.25	T, Xi; R25; R32; R36/38	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),CAT 3; EUH032; H301; H315; H319

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** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate 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** : Irritating to eyes.
- Skin** : May cause skin irritation.
- Ingestion** : Maybe harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel**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** : Not Determined**Explosion hazards** : Not Determined**Fire explosion** : Not Determined**Sensitive to static discharge** : Not Determined**Sensitivity to impact** : 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.**Fire fighting equipment** : Water spray only.**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****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**

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

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 : ~ 6.5

Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Determined

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel**SECTION 12: Ecological information****12.1. Toxicity**

Aquatic toxicity (acute)	: Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀	: Not Determined
48-hour EC₅₀	: Not Determined
96-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 assessment	: Not Determined
---	------------------

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.14

Date Revised : 08/11/2015

Revision No : 16

Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

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-statements (number and full text) : R25: Toxic if swallowed.
 R32: Contact with acids liberates very toxic gas.
 R34: Causes burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/38: Irritating to eyes and skin.
 R36: Irritating to eyes.
 Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Category 3
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Oxid. Sol., Cat. 3: Oxidizing Solids, Category 3
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 EUH032: Contact with acids liberates very toxic gas.
 H272: May intensify fire; oxidizer.
 H301: Toxic if swallowed.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 03/18/2015 SDS. Revised: **Section 1:** .

General statements : N/A= Not Applicable

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.