

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswhite® Ortho (PF)**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : TQ/15053, TY/15082
Product name : Opalescence® Trèswhite® Ortho (PF)
Product description : Dental Bleaching Gel

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

Relevant identified uses : Dental Tooth Whitening Gel

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Opal® Orthodontics
 505 W 10200 S
 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 Directive 1999/45/EC**

Danger symbols : Xi
R phrases : R36/38

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]

Hazard pictogram(s) : 

Exclamation mark

Signal Word : WARNING

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswwhite® Ortho (PF)

Hazard statement(s) : H320: Causes eye irritation.
 H315: Causes skin irritation.

2.3. Other hazards

Immediate concerns : No other adverse human effects.

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
Carbamide Peroxide	124-43-6	204-701-4	< 10	Unlisted
Hydrogen Peroxide	7722-84-1	231-765-0	< 10	Xi;O; R41
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34
Sodium Fluoride	007681-49-4	231-667-8	< 0.3	T, Xi; R25; R32; R36/38

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** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswhite® Ortho (PF)

Notes to physician : N/A

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

General hazard : Not Determined

Hazardous combustion products : None known.

Explosion hazards : None known.

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 : N/A

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswhite® Ortho (PF)

7.3. Specific end use(s)

Specific end use(s) : Professional Use Dental Tooth Bleaching 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 : S36/37: 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 : Mint

pH : 5.8 to 7.2

Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable : Yes

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions : None known.

Hazardous polymerization : No

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 : None known.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswhite® Ortho (PF)

products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : Not Determined
Oral LD₅₀ : Not Determined
Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not yet Determined
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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswwhite® Ortho (PF)

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 : Not Dangerous Goods

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 : Not Determined

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.
 R36/38: Irritating to eyes and skin.
 R41: Risk of serious damage to eyes.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 4/29/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 14:** AIR (ICAO/IATA) (SPECIAL PROVISIONS), ROAD AND RAIL (ADR/RID) (PROPER SHIPPING NAME), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 16:** GENERAL STATEMENTS.

General statements : NA = Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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

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



Date Issued : 10/19/2011
SDS No : 145-001.6
Date Revised : 9/9/2014
Revision No : 6

Opalescence® Trèswhite® Ortho (PF)

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.