

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



Date Issued : 06/05/2009
SDS No : 265-001.4
Date Revised : 08/25/2015
Revision No : 4

Opal® Seal™

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

1.1. Product identifier

Product code : OS/71022
Product name : Opal® Seal™
Product description : Primer and Sealant

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

Relevant identified uses : Professional Orthodontic Primer and Sealant

1.3. Details of the supplier of the safety data sheet

Manufacturer

Opal® Orthodontics
 505 W 10200 S
 South Jordan, UT 84095

Distributor

MPG Service GmbH
 Gereonstrasse 34-36
 D-50670 Cologne, Germany
 Email: mpgservicekoeln@googlemail.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 : F,Xi
R phrases : R36/37/38,R43

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

Health : Eye Irritation, Category 2
 Skin Sensitization, Category 1
 Target Organ Toxicity (Single exposure), Category 3
Physical : Flammable Liquids, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

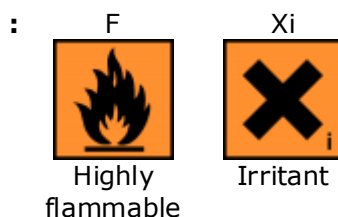
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Hazard pictogram(s)



R&S statement(s)

: R36/37/38: Irritating to eyes, respiratory system and skin.
 R43: May cause sensitization by skin contact.

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

Hazard pictogram(s)



Signal Word

: DANGER

Hazard statement(s)

: H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H225: Highly flammable liquid and vapour.

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.
 P337+P313: If eye irritation persists: 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.
 P301: IF SWALLOWED:
 P310: Immediately call a POISON CENTER or doctor/physician.
 P330: Rinse mouth.
 P331: Do NOT induce vomiting.
 P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P314: Get medical advice/attention if you feel unwell.

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

: Highly Flammable

SECTION 3: Composition / information on ingredients

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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]
Bis-GMA	1565-94-2	216-367-7	< 30	Xi; R36/37/38; R22	H315; H319; H317
HPMA	27813-02-1	248-666-3	< 15	Xi; R36/37/38; R41; R43	Skin Sens., Cat. 1; Eye Irr., Cat. 2; H317; H319
Ethyl Alcohol	64-17-5	200-578-6	< 10	F; R11	Flam. Liq., Cat. 2; H225; EUH 210
Methacrylic Acid	79-41-4	201-204-4	< 10	C; R34	EYE DMG., Cat. 1; Skin Irr., Cat. 2; STOT SE, CAT 3; H318

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. Get medical attention, if irritation persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.
- Following inhalation** : Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Causes eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : May be harmful if swallowed.

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Inhalation : Maybe 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 : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

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 : Foam, dry chemical, carbon dioxide (CO₂).

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 : Absorb liquid and place in sealed container for disposal. Vapors can travel to an ignition source.

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

Handling : Keep away from heat, sparks and flame.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

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7.3. Specific end use(s)

Specific end use(s) : Professional Orthodontic Primer and Sealant

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 : Use only in well-ventilated areas.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance : Light yellow opaque resin.

Odour : Acrylic, pungent

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Avoid light exposure.

10.5. Incompatible materials

Incompatible materials : None known.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

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11.1. Information on toxicological effects

Acute

Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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 : Stable when stored and handled under recommended conditions.

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 : 1987

14.2. UN proper shipping name

UN proper shipping name : Alcohols, n.o.s. (Ethyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

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Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : Not Applicable

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : N/A

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R11: Highly flammable.
 R22: Harmful if swallowed.
 R34: Causes burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R41: Risk of serious damage to eyes.
 R43: May cause sensitization by skin contact.
 EYE DMG., Cat. 1: Eye Damage, Category 1
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 STOT SE, CAT 3: Target Organ Toxicity (Single exposure), Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 EUH 210: Safety data sheet available on request.
 H225: Highly flammable liquid and vapour.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/24/2014 SDS. Revised: **Section 1:** GENERAL USE. **Section 2:** . **Section 3:** Wt.%. **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -

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SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 15:** SECTION 15: Regulatory information.

General statements

Manufacturer disclaimer

: N/A= Not Applicable

: FOR ORTHO 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.