

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



**Date Issued :** 07/31/2007  
**SDS No :** 167-001.3  
**Date Revised :** 08/11/2015  
**Revision No :** 2

**Gishy Goo!™, Part 2 of 2 (Catalyst)**

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

**1.1. Product identifier**

**Product code** : GJ/71039  
**Product name** : Gishy Goo!™, Part 2 of 2 (Catalyst)  
**Product description** : Silicone material for tissue relief

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

**Relevant identified uses** : Professional Orthodontic Silicone Bracket Relief Aid

**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.  
 This material is not considered hazardous to health.

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

**Health** : Not Classified

**2.2. Label elements**

**Classification according to Directive 1999/45/EC:** This material is not considered to be hazardous for the health. Please note that this material is not considered hazardous for the health according to the Classification according to Regulation(EC) No 1272/2008[CLP]

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

**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.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.

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**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** : There is no exposure to breathable , free crystalline silica during normal use of this product. For more information see Section 11.

**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]
Silica, Cristobalite	14464-46-1	238-455-4	≤ 10	Xn; R48/20	STOT RE,Cat 1; H372

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** : Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes.  
**Following skin** : Wash with soap and water.  
**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** : Non-Irritating to the eyes.  
**Skin** : Non-irritating to the skin.  
**Ingestion** : Poses little or no immediate hazard.  
**Inhalation** : None expected for this product.

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

**Notes to physician** : Not Applicable

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**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** : Do not breathe combustion products.

**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, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

**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 small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with 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**

**Handling** : Before handling the product, consult all the other sections of the SDS. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothing and ppe before entering places in which people eat.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

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**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Orthodontic Silicone Bracket Relief Aid

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Cristobalite: Type: OEL. Country: IRL. TWA/8h: 0,1 mg/m<sup>3</sup>. Type: TLV-ACGIH: TWA/8h: 0,025 mg/m<sup>3</sup>.

**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** : Paste

**Colour** : White

**Odour** : Odorless or no characteristic odor

**Solubility in water** : Insoluble

**9.2. Other information**

**Percent volatile** : Not Volatile

**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** : Acids and Alkaline substances

**10.5. Incompatible materials**

**Incompatible materials** : Acids and alkaline substances

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

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**SECTION 11: Toxicological information**

**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**

**Toxicity** : Information not available  
**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.  
**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Cristobalite  
 Not rapidly biodegradable

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Information not available

**12.4. Mobility in soil**

**Mobility in soil** : Information not available

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1%.

**12.6. Other adverse effects**

**Environmental data** : Information 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

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**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 Medical Devices Directive 93/42/EEC

**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)** : R48/20: Harmful : danger of serious damage to health by prolonged exposure through inhalation.  
 STOT RE, Cat 1: Target Organ Toxicity (Repeated exposure), lungs, Category 1  
 H372: Causes damage to lungs.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 07/16/2014 SDS. Revised: **Section 1:** Date-Revised. **Section 16:** GENERAL STATEMENTS.

**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.

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