

SAFETY DATA SHEET

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



Date Issued : 07/31/2007
SDS No : 166-001.05
Date Revised : 03/16/2018
Revision No : 3

Gishy Goo™

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

1.1. Product identifier

Product code : 1005221, 1005222
Product name : Gishy Goo™
Product description : Silicone bracket relief aid

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

Ultradent Products, Inc.
505 W. Ultradent Drive (10200 South)
South Jordan, UT 84095

EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

: This mixture is not classified as hazardous according to Regulation(EC) No 1272/2008 [CLP].

Health : Not Classified

2.2. Label elements

Additional advice on labelling

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

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.
P337+P313: If eye irritation persists: Get medical advice/attention.
P301: IF SWALLOWED:
P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of container and unused contents in accordance with federal, state, and local requirements.

2.3. Other hazards

SAFETY DATA SHEET

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No risks worthy of mention.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Preparation of silicone polymers and fillers with platinum-catalyst (ppm range)	NAP	NAP	100	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

Following skin : In general the product is not skin irritative.

Following ingestion : Seek medical attention if problems persist.

Following inhalation : Not applicable

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 : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water fog, Foam, Carbon dioxide (CO₂)

5.2. Special hazards arising from the substance or mixture

General hazard : Advice on protection against fire and explosion
No special precautionary measures are necessary.

Explosion hazards : Not Explosive

5.3. Advice for firefighters

Fire fighting procedures : Advice for firefighters
Extinguishing materials should be selected according to the surrounding area.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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General procedures : Not required.

6.2. Environmental precautions

Water spill : Do not empty into drains or the aquatic environment.

6.3. Methods and material for containment and cleaning up

Large Spill : Collect mechanically.

6.4. Reference to other sections

Reference to other sections : No release of hazardous substances.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Advice on safe handling
 No special precautionary measures are necessary.
 Advice on protection against fire and explosion
 No special precautionary measures are necessary.
 Further information on handling
 No special precautionary measures are necessary.

Storage : Conditions for safe storage, including any incompatibilities
 Requirements for storage rooms and vessels
 No special requirements
 Advice on storage compatibility
 Not required
 Further information on storage conditions
 No special requirements.

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 Orthodontic Silicone Bracket Relief Aid

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Occupational exposure controls
 not applicable

8.2. Exposure controls

Engineering controls : Not Applicable
 Protective and hygiene measures : The usual precautions when handling
 chemicals have to be obtained.
 Avoid contact with skin, eye and clothing.

Eye/face protection : Not required.

Skin protection : Hand protection
 Single-use gloves.
 Suitable material: PE (polyethylene).

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Unsuitable materials: NR (Natural rubber (Caoutchouc), Natural latex).
 In the cases of special applications, it is recommended to check the chemical resistance with the manufacturer of the gloves.

Skin protection: Not required

Respiratory protection : With correct and proper use, and under normal conditions, breathing protection is not required.

Other precautions : Environmental Exposure Controls.
 Not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste

Colour : Base paste: white. Catalyst: light grey

Odour : Bubble Gum (Base); Odorless (Catalyst)

pH : Neutral

Melting temperature : NAP

Boiling temperature : NAP

Density : 20°C : 1.5-1.6 g/cm³

Solubility in water : Insoluble

Explosive properties : Not explosive

9.2. Other information

Additional information : No further relevant information available

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 : None by intended use.

10.5. Incompatible materials

Incompatible materials : None by intended use

10.6. Hazardous decomposition products

Hazardous decomposition products : None by intended use.

Additional information : Further information
 Please pay attention to the Directions for Use

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Gishy Goo™

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Oral LD₅₀	: > 2000 mg/kg Rat
Skin corrosion/irritation	: Irritant effect on the skin: Not an irritant.
Serious eye damage/irritation	: Irritant effect on the eye: Not an irritant.
Respiratory or skin sensitisation	: No danger of sensitization.
Other information	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity	: Product has not been tested.
Aquatic toxicity (acute)	: Do not empty into drains or the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability	: Information not available.
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12.3. Bioaccumulative potential

Bioaccumulative potential	: Information not available
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12.4. Mobility in soil

Mobility in soil	: Information not available
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	: Conclusion(I) The substance does not fulfill the PBT and vPvB criteria for screening assessment there is no indications of P or B properties.
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12.6. Other adverse effects

Environmental data	: Doesn't get into the sewage water as long as the process is carried out according to regulations.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method	: Advice on disposal Remove according to the regulations. Additional information: Waste disposal number of waste from residues/unused products 070217 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; wastes containing silicones other than those mentioned in 07 02 16 Waste disposal number of used product 200399 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal
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wastes not otherwise specified
Contaminated packaging
 Completely emptied packings can be recycled.

SECTION 14: Transport information

14.1. UN number

UN number : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

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

Transport in bulk : NAP

Additional information : Not a hazardous material with respect to these transportation regulations.

SECTION 15: Regulatory information

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

General information : Substances of very high concern (SVHC) according to REACH, Article 57:
 Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : National regulatory information
 Water contaminating class (D): 1 - slightly water contaminating

SECTION 16: Other information

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/29/2016 SDS. Revised: **Section 1:** MSDS
 No. **Section 4:** NOTES TO PHYSICIAN. **Section 5:** EXTINGUISHING MEDIA,
 FIRE FIGHTING PROCEDURES, GENERAL HAZARD. **Section 8:** . **Section**
9: APPEARANCE, COLOR, pH. **Section 10:** COMMENTS. **Section 12:**

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ECOTOXICOLOGICAL INFORMATION, SECTION 12: Ecological information. **Section 14:** COMMENTS. **Section 15:** COMMENTS.

General statements

: NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment
 AMU = Atomic Mass Unit

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.