

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 12 December 2008
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 Revision Number: 2

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	Aladdin ONE Universal Hybrid Composite
Part/Item Number:	99100, 99105, 99110, 99115, 99120, 99125, 99130, 99135, 99140, 999145, 99150, 99155 and 99160

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Restorative Composite
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture

GHS SDS Classification

Health	Environmental	Physical
Skin Irritation Category 2 H315 Eye Irritation Category 2 H319 Skin Sensitization Category 1 H317	Not Hazardous	Not Hazardous

EU Classification (1999/45/EC as amended): Irritant (Xi)

EU Risk (R) Phrases: R36/38, R43

Labeling Elements: Contains Urethane Modified Bis-GMA dimethacrylate, Polymerizable Dimethacrylate, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate



Signal Word: Warning!

Hazard Statements	Precautionary Statements
H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist, vapors or spray. P264 Wash skin thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing and eye protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %
Barium Boron Fluoro Alumino Silicate Glass	65997-18-4 / 266-047-6	None	Not applicable	50-80
Amorphous Silica	Mixture	Not applicable	Not applicable	1-10
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2 / 216-367-7	[2-hydroxy-3-[4-[2-[4-[2-hydroxy-3-(2-methylprop-2-enoyloxy)propoxy]phenyl]propan-2-yl]phenoxy]propyl] 2-methylprop-2-enoate	Xi R36/38, R43 Skin Irrit 2 H315 Skin Sens 1 H317 Eye Irrit 2 H319	1-10

Polymerizable Dimethacrylate	Mixture	Not applicable	Xi R36/38, R43 Skin Irrit 2 H315 Skin Sens 1 H317 Eye Irrit 2 H319	1-10
Urethane Modified Bis-GMA dimethacrylate	126646-17-1	Not applicable	Xi R36/38, R43 Skin Irrit 2 H315 Skin Sens 1 H317 Eye Irrit 2 H319	1-10

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES





4.1 Description of First Aid Measures:	
Routes of Exposure	First Aid Instructions
Eye	Flush eyes with large quantities of water several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wipe excess off skin. Wash skin thoroughly with soap and water. Get medical attention if irritation develops or persists.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air and get medical attention.
Ingestion	If small amount are swallowed, no adverse effects are expected. For large amounts, rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
Uncured product may cause eye and skin irritation. Uncured product may cause allergic skin reaction (sensitization).



4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
None required under normal conditions of use.
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media
Use media appropriate for surrounding fire.
5.2 Special Hazards Arising from the Substance or Mixture:
None known.
5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Cool fire exposed containers and structures with water.		
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Wear eye and skin protection.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Scoop or wipe up and place in appropriate containers for disposal.

6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:
Avoid contact with the eyes and skin. Use in accordance with package instructions.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store away direct sunlight

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Barium Boron Fluoro Alumino Silicate Glass	United States	5 mg/m ³ TWA OSHA PEL (respirable), 15 mg/m ³ TWA (total dust)
	Germany	None Established
	United Kingdom	4 mg/m ³ TWA UK OEL (respirable), 10 mg/m ³ TWA (inhalable)
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Amorphous Silica	United States	<u>80 mg/m³</u> TWA OSHA PEL % SiO ₂
	Germany	4 mg/m ³ TWA DFG (inhalable)
	United Kingdom	6 mg/m ³ TWA UK OEL
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Polymerizable Dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established

	European Union	None Established
Urethane Modified Bis-GMA dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)



Specific Eye/face Protection: Chemical safety goggles recommended for handling unreacted product.

Specific Skin Protection: Wear impervious gloves to prevent skin contact with unreacted product. Recommended glove: Nitrile gloves. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Various shades of viscous paste	Explosive limits:	Not applicable
Odor:	Characteristic sweet acrylic ester paste	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	1.8
Melting/freezing point:	Not available	Solubility:	Insoluble

Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive under normal use conditions.
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: Not expected to cause hazardous reactions.
10.4 Conditions to Avoid: None known.
10.5 Incompatible materials: Avoid oxidizing agents.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides, methacrylates, acrylates.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<u>Potential Health Effects:</u>
<u>Eyes:</u> Contact may cause irritation with redness and tearing.
<u>Skin:</u> May cause irritation with redness and itching. May cause allergic skin reaction (sensitization).
<u>Ingestion:</u> No adverse effects are expected from swallowing small amounts. Large amounts may cause gastric upset with nausea.
<u>Inhalation:</u> None expected from normal use.
<u>Chronic Health Effects:</u> None known.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: No mutagenic effects are expected.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Barium Boron Fluoro Alumino Silicate Glass: No toxicity data available

Amorphous Silica: No toxicity data available

1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate: No toxicity data available

Polymerizable Dimethacrylate; No toxicity data available

Urethane Modified Bis-GMA dimethacrylate: No toxicity data available

Reproductive Toxicity Data: No reproductive or teratogenic effects are expected.

Specific Target Organ Toxicity (STOT):

Single Exposure: Methacrylates has been shown to cause sensitization in humans.

Repeated Exposure: No data available, however, no adverse effects are expected.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No adverse effects are expected on aquatic organisms.

12.2 Persistence and Degradability: This product is expected to be removed by sedimentation or degradation.

12.3 Bio-accumulative Potential: This product is not expected to bio-accumulate.

12.4 Mobility in Soil: No data is available.

12.5 Other Adverse Effects: None known.

12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	Marine Pollutant-No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %

None		
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International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

Xi Irritant

R36/38 Irritating to eyes and skin.

R43 May cause sensitization by skin contact.

Skin Irrit 2 Skin Irritation Category 2

Skin Sens 1 Skin Sensitization Category 1

Eye Irrit 2 Eye Irritation Category 2

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Supersedes: 08 November 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 6 October 2014

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.