

Safety Data Sheet

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

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

1.1 Product Identifier:

Trade Name (as labeled): Versa-Temp[®] 2 Temporary Crown & Bridge Resin
Part/Item Number: 72041, 72051, 72056, 72061, 72066, 72071, 72076

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

Recommended Use: Fabrication of temporary dental crowns and bridges
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 17404
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)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Eye Irritation Category 2 (H319)	Not hazardous	Not hazardous

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

EU Risk (R) Phrases: R36

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

2.2 Labeling Elements:



Signal Word: Warning!

Hazard Statements	Precautionary Statements
H319 Causes serious eye irritation.	P264 Wash thoroughly after handling. P280 Wear eye protection and face protection. 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.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
<u>Base</u>				
Urethane dimethylacrylate	72869-86-4 / 276-957-5	reaction mass of 7,7,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate and 7,9,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate	Xi R43 Skin Sens. 1 (H317)	10-25
Catalyst	Proprietary	Not available	Xn, Xi R22, R41 Eye Dam 1 (H318) Acute Tox. 4 (H302)	<3

<u>Catalyst</u>				
Urethane dimethylacrylate	72869-86-4 / 276-957-5	reaction mass of 7,7,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate and 7,9,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate	Xi R43 Skin Sens. 1 (H317)	10-25
Benzoyl Peroxide	94-36-0 / 202-327-6	diphenylperoxyanhydride	E, O, Xi R3, R7, R36, R43 Org. Perox. B (H241) Eye Irrit. 2 (H319) Skin Sens. 1 (H317)	0.1-1

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

4. FIRST-AID MEASURES

The cured product is not hazardous and first aid will not be needed. The following should be used in case of contact with the uncured product:

4.1 Description of First Aid Measures:	
Routes of Exposure	First Aid Instructions
Eye	Flush eyes with large quantities of water for 15, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wipe off skin. Wash skin thoroughly with soap and water. If skin irritation occurs, get medical attention.
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:
Eye contact may cause eye irritation.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
None needed under normal conditions of use. If eye irritation occurs, get medical attention.
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 water spray, carbon dioxide or dry chemical. For large fires use water spray or alcohol foam.
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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 appropriate protective eye and skin protection as described in Section 8.

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. May cause a slip hazard. Wash spill area with soap and water.

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. Wash hands thoroughly after handling. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in accordance with package instructions.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Urethane dimethylacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Catalyst	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 glasses recommended if contact is possible.

Specific Skin Protection: Wear impervious gloves such as butyl rubber to prevent skin contact. Recommended glove: Butyl rubber. 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

Appearance:	Colored paste	Explosive limits:	Not applicable
Odor:	Characteristic odor	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility (ies)	Miscible
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not available	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 expected to be reactive.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

10.4 Conditions to Avoid: None known.

10.5 Incompatible materials: None known.

10.6 Hazardous Decomposition Products: None known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

The cured product is not hazardous and no effects are expected. The following applies to the uncured product:

Potential Health Effects:

Eyes: Direct contact with uncured product may cause irritation with redness and tearing.

Skin: Prolonged contact with uncured product may cause irritation.

Ingestion: Swallowing uncured product may cause gastrointestinal irritation and nausea. .

Inhalation: None expected from normal use.

Chronic Health Effects: None known.

Irritation: Urethane dimethylacrylate is not irritating to rabbit eyes or skin.

Corrosivity: The catalyst has been shown to cause severe irritation or eye damage. None of the other components are corrosive to skin or eyes.

Sensitization: The product was negative in a skin sensitization test with laboratory animals.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: Urethane dimethylacrylate was negative in the AMES test for mutagenicity.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Urethane dimethylacrylate: LD50 oral rat >5000 mg/kg

Catalyst: No toxicity data available

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

Specific Target Organ Toxicity (STOT):

Single Exposure No data available.

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

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Urethane dimethylacrylate .48 hr EC50 daphnia magna >1.2 mg/L (100% saturation)

12.2 Persistence and Degradability: Urethane dimethylacrylate is not readily biodegradable.

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		Not Regulated			Not applicable
ADR/RID		Not Regulated			Not applicable
IMDG		Not Regulated			Not applicable
IATA/ICAO		Not Regulated			Not applicable

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		

International Regulations

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

New Zealand Inventory of Chemicals: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Taiwan New and Existing Inventory of Chemicals: This product is a medical device and not subject to chemical notification requirements.

HMIS Hazard Rating:

Health – 2 Flammability – 0 Physical Hazard – 0

16. OTHER INFORMATION

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

E Explosive

O Oxidising

Xi Irritant

Xn Harmful

R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.

R7 May cause fire.

R22 Harmful if swallowed.

R36 Irritating to eyes.

R41 Risk of serious damage to eyes.

R43 May cause sensitization by skin contact.

Org. Perox. B Organic Peroxide Type B

Acute Tox. 4 Acute Toxicity Category 4

Skin Sens. 1 Skin Sensitizer Category 1

Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritation Category 2

H241 Heating may cause a fire or explosion.

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

Date of SDS Preparation/Revision: 25 February 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.