

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. PRODUCT IDENTIFICATION

Trade Name (as labeled): Versa-Temp[®] Temporary Crown & Bridge Material

Chemical Name/Classification: Mixture

Product Identifier (Part/Item Number): 72010, 72015, 72020, 72025, 72030, 72035, 72040, 72050, 72055, 72060, 72065, 72070, 72075, 72080, 72085, 72090

U.N. Number: None

U.N. Dangerous Goods Classification: None

Recommended Use: Temporary Cement for Restorations

Restrictions on Use: For professional use only

Manufacturer/Supplier Name: Sultan Healthcare

Manufacturer/Supplier Address: 411 Hackensack Avenue, 9th Floor
Hackensack, NJ

Manufacturer/Supplier Telephone Number: 1-201-871-1232 or 800-637-8582 (Product Information)-

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

Email address: customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

Hazard/Danger Classification (Regulation EC) No. 1272/2008 [CLP] / Hazcom 2012:

Health	Environmental	Physical
Skin Sensitizer Category 1	Not hazardous	Not hazardous

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

EU Risk (R) Phrases: R43

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

Labeling Elements: Contains: Urethane Bismethacrylate, Urethane Acrylate, Alkyl Methacrylate



Signal Word: Warning!

Hazard Statements	Precautionary Statements
H317 May cause an allergic skin reaction.	P261 Avoid breathing vapours. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents and container in accordance with local and national regulations.

Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
<u>Catalyst</u>				
Urethane Bismethacrylate	Proprietary	Not available	Xi R43 Skin Sens. 1 (H317)	50-60
Urethane Acrylate	Proprietary	Not available	Xi R43 Skin Sens. 1 (H317)	20-30
Alkyl Methacrylate	Proprietary	Not available	Xi, R43 Skin Sens. 1 (H317)	1-5
Dibenzoyl peroxide	94-36-0 / 202-327-6	benzoyl benzenecarboperoxoate	E, O, Xi R3, R7, R36, R43 Org. Perox. B (H241) Eye Irrit. 2 (H319) Skin Sens. 1 (H317)	1-2





<u>Base</u>				
Urethane Acrylate	Proprietary	Not available	Xi R43 Skin Sens. 1 (H317)	30-40
Urethane Bismethacrylate	Proprietary	Not available	Xi R43 Skin Sens. 1 (H317)	20-30
Alkyl Methacrylate	Proprietary	Not available	Xi, R43 Skin Sens. 1 (H317)	1-5

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

4. 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.
Most important symptoms of exposure	Uncured product may cause mild eye and skin irritation. Uncured product may cause allergic skin reaction (sensitization).
Other	None known.
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

Suitable Extinguishing Media:	Use media appropriate for surrounding fire.		
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.		
Specific Hazards Arising from the Chemical:	None known.		
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

Personal Precautions, PPE and Emergency Procedures: Wear eye and skin protection.

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

Methods and Materials for Containment and Clean-up: Scoop or wipe up and place in appropriate containers for disposal. May cause a slip hazard. Wash spill area with soap and water.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE



Precautions for Safe Handling: Avoid contact with the eyes and skin. Use in accordance with package instructions.

Conditions for Safe Storage: Store away from extreme heat and sunlight

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Urethane 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
Urethane Acrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established

	France	None Established	
	Spain	None Established	
	Italy	None Established	
	European Union	None Established	
Alkyl Methacrylate	United States	None Established	
	Germany	None Established	
	United Kingdom	None Established	
	France	None Established	
	Spain	None Established	
	Italy	None Established	
	European Union	None Established	
Dibenzoyl peroxide	United States	5 mg/m3 TWA OSHA PEL 5 mg/m3 TWA ACGIH TLV	
	Germany	5 mg/m3 DFG MAK (inhalable fraction)	
	United Kingdom	5 mg/m3 TWA UK OEL	
	France	5 mg/m3 TWA INRS VME	
	Spain	5 mg/m3 TWA VLA-ED	
	Italy	None Established	
	European Union	None Established	
Biological Exposure Limits: None Established			
Appropriate Engineering Controls: No special controls required.			
Individual Protection Measures (PPE) Specific Eye/face Protection: Chemical safety glasses or goggles recommended for handling unreacted product. Specific Skin Protection: Wear impervious gloves to prevent skin contact with unreacted product. Recommended glove: Nitrile 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
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with the eyes, skin and clothing. Wash thoroughly with soap and water after handling.			

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Yellowish colored paste	Explosive limits:	Not applicable
Odor:	Slight, ester like odor	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	>1
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	<1%
Initial boiling point and range:	>482°F / >250°C	Partition coefficient: n-octanol/water:	Not available
Flash point:	>302°F / >150°C	Auto-ignition temperature:	Not available
Evaporation rate:	> 1 (water =1)	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: No unusual reactivity.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

Conditions to Avoid: Avoid heat and UV light.

Incompatible materials: Avoid oxidizing agents, metal powders, peroxides, radical imitators.

Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides, water and acrylic decomposition products.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

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

Skin: Prolonged contact may cause dryness or irritation. May cause allergic skin reaction (sensitization).

Ingestion: No adverse effects are expected from swallowing small amounts. Large amounts may cause gastric upset with nausea.

Inhalation: None expected from normal use.

Chronic Health Effects: None known.

Carcinogenicity: 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:

Product toxicity: LD50 oral rat >5000 mg/kg

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

Toxicity: No adverse effects are expected on aquatic organisms.

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

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

Mobility in Soil: No data is available.

Other Adverse Effects: None known.

Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

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

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

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

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:

E Explosive

O Oxidizer

Xi Irritant

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

R7 May cause fire.

R36 Irritating to eyes.

R43 May cause sensitization by skin contact.

Skin Sens. 1 Skin Sensitizer Category 1

Org. Perox. B Organic Peroxide Type B

Eye Irrit. 2 Eye Irritation Category 2

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Date of SDS Preparation/Revision: 8 July 2013

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