

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):	TempART™ Self-Cure Liquid
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	71010, 71040, 71041
U.N. Number:	UN 1247
U.N. Dangerous Goods Classification:	3, PG II
Recommended Use:	Temporary Crown and bridging material
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9 th 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

EU Classification (1999/45/EC as amended): Highly Flammable (F), Harmful (Xn) Irritant (Xi) R11, R20/21/22, R33, R37/38, R43

EU Labeling:

<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Highly Flammable</p> </div> <div style="text-align: center;">  <p>Harmful</p> </div> </div>	<p>Contains: Methyl Methacrylate, N,N-dimethyl-p-toluidine R20/21/22 Harmful by inhalation, in contact with the skin and if swallowed. R33 Danger of cumulative effects R37/38 Irritating to respiratory system and skin R43 May cause sensitization by skin contact. S16 Keep away from sources of ignition – No smoking. S24/25 Avoid contact with skin and eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention S36/37 Wear suitable protective clothing and gloves. S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p>
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US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Methyl Methacrylate	80-62-6 / 201-297-1	methyl methacrylate	F, Xi, R11, R37/38, R43	>99
N,N-dimethyl-p-toluidine	99-97-8 / 202-805-4	N,N,4-trimethylaniline	T R23/24/25, R33, R52/53	0 - 1





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 water for at least 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation or other symptoms develop, get medical attention. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Get immediate attention. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person.
Most important symptoms of exposure	May cause eye, skin and respiratory tract irritation. Prolonged or repeated contact may cause allergic skin reaction (skin rash). Inhalation of vapors may cause dizziness, headache, weakness, confusion, palpitations, chest pain, discoloration of the skin and blood, seizures and other central nervous system effects.
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 carbon dioxide, foam, water spray or water fog.
Fire Fighting Procedures:	Water may be ineffective unless used as a fine spray or fog. Use water to cool fire-exposed containers.
Specific Hazards Arising from the Chemical:	Vapors are heavier than air and may travel to ignition source and flash back. Heat of fire may cause an exothermic auto polymerization reaction. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.





Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Provide explosion-proof ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8. Eliminate all sources of ignition.

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: Contain and absorb spills with inert material and transfer to a suitable container for disposal.

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 eyes, skin, and clothing. Avoid breathing vapors or mist. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Ground container when pouring. Keep away from heat, sparks, flames and all sources of ignition. Do not expose to direct sunlight. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a cool, dry, well ventilated area. Keep container tightly closed when not in use. Do not store in direct sunlight. Prevent moisture contact. Protect from physical damage. Keep away from oxidizers and other incompatible materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Methyl Methacrylate	United States	50 ppm TWA ACGIH TLV, 100 ppm STEL 100 ppm TWA OSHA PEL
	Germany	50 ppm TWA DFG MAK
	United Kingdom	50 ppm TWA UK OEL, 100 ppm STEL
	France	100 ppm INRS VME, 200 ppm VLCT
	Spain	50 ppm TWA VLA-ED, 100 ppm VAL-EC
	Italy	None Established
	European Union	50 ppm TWA EU IOEL, 100 ppm STEL
,N-dimethyl-p-toluidine	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

Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits. Use explosion-proof equipment where required.



Individual Protection Measures (PPE)

Specific Eye/face Protection: Wear safety chemical goggles when the possibility exists for eye contact due to splashing or spraying material.

Specific Skin Protection: Wear nitrile rubber or other impervious gloves to prevent skin contact. Wear impervious clothing if needed to prevent any contact with this product, such as gloves, apron, boots, or whole body suit. Recommended glove: Nitrile rubber. Contact glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required with adequate ventilation. An approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain limited circumstances where airborne concentrations are expected to exceed exposure limits. Protection provided by air purifying respirators is limited. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known or any other circumstances where air purifying respirators may not provide adequate protection. Selection and use of respiratory equipment must be in accordance with appropriate regulations and good industrial hygiene practice.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			
Environmental Exposure Controls: Do not allow spills to enter sewers or waterways			
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: Wear appropriate protective clothing and equipment.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colorless liquid	Explosive limits:	LEL: 1.7% UEL: 8.2% (methyl methacrylate)
Odor:	Acrid acrylic odor	Vapor pressure:	38.5 mm Hg at 25 deg C (As methyl methacrylate)
Odor threshold:	Not available	Vapor density:	3.46 (Air = 1)
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	1.6% by wt.
Initial boiling point and range:	214°F / 101°C	Partition coefficient: n-octanol/water:	Not available
Flash point:	50°F (10°C) TCC	Auto-ignition temperature:	Not available
Evaporation rate:	> 1 (Butyl acetate = 1)	Decomposition temperature:	Not available
Flammability:	Flammable	Viscosity:	Not available
Explosive Properties:	Vapors may be explosive in confined areas	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: Polymerization can occur.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Polymerization can occur. Conditions leading to polymerization are excessive heat, oxygen-free atmosphere, inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.

Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, direct sunlight.

Incompatible materials: Avoid contact with oxidizing agents, reducing agents, acids, and bases.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, methyl methacrylate, and irritating smoke and fumes.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Liquid and vapors can cause irritation with redness, tearing and blurred vision. Corneal damage can occur.

Skin: May cause skin irritation with allergic skin reaction (skin sensitization). May be harmful if absorbed through the skin causing effects similar to inhalation.

Ingestion: Causes irritation, a burning sensation of the mouth, throat and gastrointestinal tract and abdominal pain. Large doses may cause effects similar to inhalation.

Inhalation: May cause respiratory tract irritation with coughing, mucous production and shortness of breath. High concentration is irritating to the respiratory tract and may cause dizziness, headache and anesthetic effects. Absorption may cause effects on the red blood cells resulting in methemoglobinemia (reduction in the oxygen carrying capacity of the blood). Symptoms, which may be delayed, include headache, weakness, confusion, palpitations, chest pain, discoloration of the skin and blood and seizures.

Chronic Health Effects: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals, as well as kidney, lung, liver, and heart damage.

Carcinogenicity: The results of a 2-year inhalation study conducted for NTP showed no evidence of carcinogenicity of methyl methacrylate for male rats exposed at 500 or 1,000 ppm and female rats exposed at 250, 500 or 1,000 ppm. In another study, no increase was seen in the number or type of tumors in either rats or hamsters from a chronic inhalation study. No carcinogenic activity was also reported in a chronic oral study. However, acute oral exposure studies and structure-activity relationship comparisons with other acrylates suggest that the introduction of a methyl group to the acrylate moiety (e.g., EA to MMA) negates carcinogenic activity. None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive.

Mutagenicity: Methyl Methacrylate: Negative in AMES test, positive and negative in in-vitro studies. Negative in-vivo studies. N,N-dimethyl-p-toluidine: Negative in AMES test, positive in in-vitro chromosome aberration assay, ambiguous in in-vivo assays with mice and rats.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin conditions may be at increased risk from exposure.

Acute Toxicity Data:

Methyl Methacrylate: Oral rat LD50 7,800 mg/kg; Inhalation rat LC50 7,093 ppm/4 hr.

N,N-dimethyl-p-toluidine: Oral rat LD50: 1,650 mg/kg; Inhalation rat LC50 4 hr: 1,400 mg/m³; LD50 dermal rabbit >2,000

mg/kg.
Reproductive Toxicity Data: Methyl Methacrylate: In a study in rats, there were no developmental effects, although there were decreases in maternal body weight following inhalation of concentrations up to 8,315 mg/m ³ . There was no reduction in fertility in a dominant lethal assay in mice exposed to this compound at concentrations up to 36,900 mg/m ³ and no adverse effects on reproductive organs in repeated dose studies conducted to date.
Specific Target Organ Toxicity (STOT): Single Exposure: Methyl methacrylate: In an inhalation study with dogs, a 2,000 ppm dose showed a drop in arterial blood pressure and GI motor activities. The lethal oral dose for methyl methacrylate is 6 to 9 g/kg in lab animals. Poisoned animals exhibit respiratory depression, and coma; also irritation of skin, eyes and respiratory tract. Repeated Exposure: Methyl Methacrylate: Impairment of locomotor activity and learning and behavioral effects on the brain were observed in rats exposed orally to 500 mg/kg bw/day for 21 days.

12. ECOLOGICAL INFORMATION

Toxicity: Methyl Methacrylate: 96 hr LC50 fathead minnow 130 mg/L; 48 hr EC50 algae 170 mg/L N,N-dimethyl-p-toluidine: 96 hr LC50 fathead minnow 16-52 mg/L; 48 hr EC50 daphnia magna 24 mg/L; 96 hr EC50 algae 16 mg/L
Persistence and Degradability: Methyl methacrylate is readily biodegradable - 88% after 28 days. N,N-dimethyl-p-toluidine: expected to be rapidly biodegradable based on similar compounds.
Bio-accumulative Potential: The potential for bioaccumulate is expected to be low for methyl methacrylate.
Mobility in Soil: Methyl methacrylate is expected to have very high to high mobility in soil.
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: This product will polymerize when exposed to sunlight. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.
Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN1247	IMDG: UN1247	IATA: UN1247	DOT: UN1247
UN proper shipping name:	ADR/RID: Methyl Methacrylate Monomer, Stabilized Solution IMDG: Methyl Methacrylate Monomer, Stabilized Solution IATA: Methyl Methacrylate Monomer, Stabilized Solution DOT: Methyl Methacrylate Monomer, Stabilized Solution			

Transport hazard class(es):	ADR/RID: 3	IMDG: 3	IATA: 3	DOT: 3
Packaging group:	ADR/RID: PG II	IMDG: PG II	IATA: PG II	DOT: PG II
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Flammable Liquid				

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Releases above the RQ of 1,010 lbs (based on the RQ for methyl methacrylate of 1,000 lbs present at 99% max) must be reported to the National Response Center. 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.

OSHA Hazard Classification: Flammable Liquid, Irritant, Sensitizer, Target organ effects.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act

Clean Air Act (CAA): Methyl methacrylate is regulated under the Clean Air Act.

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:	Yes	Reactivity Hazard:	Yes
Fire Hazard:	Yes		

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

Components	C.A.S. #	WT %
Methyl Methacrylate	80-62-6	>99

State Regulations

California: This product contains the following chemical(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:

Date of SDS Preparation/Revision: 15 October 2012

F Highly Flammable

Xi Irritant

Xn Harmful

T Toxic

R11 Highly flammable.

R20/21/22 Harmful by inhalation, in contact with the skin and if swallowed.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R33 Danger of cumulative effects

R37/38 Irritating to respiratory system and skin

R43 May cause sensitization by skin contact.

R52/53 Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment.

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