

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™ Acrylic Resin Powder + Intrinsic Modifier Powder

Chemical Name/Classification: Proprietary polymer

Product Identifier (Part/Item Number): 71015, 71020, 71025, 71030, 71035

U.N. Number: None

U.N. Dangerous Goods Classification: None

Recommended Use: Impression material

Restrictions on Use: Use only as directed

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

EU Classification (1999/45/EC as amended): Not a dangerous preparation

EU Labeling: None Required

US Hazard Classification: Not Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components | C.A.S. # EC# | IUPAC Name | Substance Classification | WT % |
|--------------------------------|-----------------|---------------|-----------------------------|------|
| Polyethyl Methacrylate Polymer | Proprietary | | Not classified as hazardous | 100 |





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 | Wash skin with soap and water. |
| Inhalation | Remove to fresh air. If irritation develops, get medical attention. |
| Ingestion | Rinse mouth with water. If large amounts are swallowed, get medical attention. |
| Most important symptoms of exposure | Dust may cause mild eye irritation. Inhalation of dust may cause irritation of the nose and throat, coughing and sneezing. |
| 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: | Water fog, carbon dioxide dry chemical. Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source. |
| Fire Fighting Procedures: | Cool fire exposed containers and structures with water. |
| Specific Hazards Arising from the Chemical: | High concentrations of dust in air may be explosive. |
| 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 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: Carefully collect and place into a container for disposal. Remove all sources of ignition. Do not generate airborne dust. Spilled powder can be a slip hazard.

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. Do not breathe dust. Wash thoroughly after handling. Use with adequate ventilation. Use good housekeeping to minimize accumulation of dust on equipment and surfaces. Keep away from sources of heat or ignition sources. Use in accordance with package instructions.

Conditions for Safe Storage: Store away from extreme heat. Keep container closed when not in use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

| | | |
|--------------------------------|----------------|------------------|
| Polyethyl Methacrylate Polymer | 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: No special controls required.


Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses with side shields should be worn when handling the material.

Specific Skin Protection: None normally required.

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: | Fine, free flowing powder | Explosive limits: | Not applicable |
| Odor: | Very slight fruity acrylic odor. | Vapor pressure: | Not applicable |
| Odor threshold: | Not available | Vapor density: | Not applicable |
| pH: | Not available | Relative density: | Not available |
| Melting/freezing point: | Not available | Solubility: | Nil |
| Initial boiling point and range: | Not applicable | Partition coefficient: n-octanol/water: | Not available |
| Flash point: | None | Auto-ignition temperature: | Not available |
| Evaporation rate: | Not applicable | Decomposition temperature: | Not available |
| Flammability: | Not flammable | Viscosity: | Not available |
| Explosive Properties: | None | Oxidizing Properties: | None |

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize or react dangerously.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known

Conditions to Avoid: Avoid temperatures above 300°C

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon monoxide, carbon dioxide, ethyl methacrylate, methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

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

Skin: No adverse effects are expected under normal use conditions. Skin sensitization may occur in sensitive individuals.

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

Inhalation: Inhalation of dust may cause irritation to the nose and throat with coughing and sneezing.

Chronic Health Effects: None known.

Carcinogenicity: None of the other 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: 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

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: None | DOT: None |

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.

OSHA Hazard Classification: Not Hazardous

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: | No | 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 |
|--|
| <p>Full text of Classification abbreviations used in Section 2 and 3: None</p> <p>Date of SDS Preparation/Revision: 26 August 2011</p> <p>Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.</p> |