

## 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): **Hydro-Cast® Tissue Treatment Material, Powder**  
 Part/Item Number: **73020**

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

Recommended Use: Impression material  
 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](mailto: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 SDS Classification:** Not hazardous

| Health        | Environmental | Physical      |
|---------------|---------------|---------------|
| Not Hazardous | Not Hazardous | Not Hazardous |

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

**2.2 Labeling Elements:** None Required

**2.3 Other Hazards:** None Known

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

#### 3.2 Mixture

| Hazardous Components           | C.A.S. #<br>EC# | IUPAC Name | CLP/GHS / EU<br>Classification<br>(1272/2008) (1999/45/EC) | WT % |
|--------------------------------|-----------------|------------|--|------|
| Polyethyl Methacrylate Polymer | Proprietary     |            | Not classified as hazardous                                | 100  |

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               | 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.  |

#### 4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Dust may cause mild eye irritation. Inhalation of dust may cause irritation of the nose and throat, coughing and sneezing.

#### 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





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.

#### 5.2 Special Hazards Arising from the Substance or Mixture:



High concentrations of dust in air may be explosive

#### 5.3 Advice for Fire-Fighters:

|                                       |   |
|---------------------------------------|---|
| <b>Fire Fighting Procedures:</b>      | Cool fire exposed containers and structures with water.   |
| <b>Precautions for Fire Fighters:</b> | 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 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:  |
|--|
| 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. |

| 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 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.. |
| 7.2 Conditions for Safe Storage, Including Any Incompatibilities:  |
| Store away from extreme heat. Keep container closed when not in use  |
| 7.3 Specific End Use (s):  |
| For professional use only.   |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control Parameters:

#### Occupational Exposure Limits:

|                                   |                |                  |
|-----------------------------------|----------------|------------------|
| Polyethyl Methacrylate<br>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

### 8.2 Exposure Controls:

**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 |
|---|------|-------------|---------|
|  |      |             |         |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

|                    |                           |                          |                |
|--------------------|---------------------------|--------------------------|----------------|
| <b>Appearance:</b> | Fine, free flowing powder | <b>Explosive limits:</b> | Not applicable |
|--------------------|---------------------------|--------------------------|----------------|

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

**9.2 Other Information:** None available

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** Will not polymerize or react dangerously.

**10.2 Chemical Stability:** Stable.

**10.3 Possibility of Hazardous Reactions:** None known

**10.4 Conditions to Avoid:** Avoid temperatures above 300°C

**10.5 Incompatible materials:** Avoid oxidizing agents.

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

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

**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

**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:**

|                          |    |                           |    |
|--------------------------|----|---------------------------|----|
| <b>Immediate Hazard:</b> | No | <b>Pressure Hazard:</b>   | No |
| <b>Delayed Hazard:</b>   | No | <b>Reactivity Hazard:</b> | No |
| <b>Fire Hazard:</b>      | 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 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:

None

Supersedes: 26 August 2011

Revision Summary: Comprehensive review, new format

Date of SDS Preparation/Revision: 05 August 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.