

SAFETY DATA SHEETS

This SDS packet was issued with item:

076661201

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

076661219 076661227 076661235

Safety Data Sheet

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

Date Issued: 6 June 2009
 Document Number: 79010MS
 Date Revised: 26 August 2011
 Revision Number: 3

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Silgimix® Alginate Replacement Material

Chemical Name/Classification: Mixture

Product Identifier (Part/Item Number): 79010, 79015, 79020, 79025

U.N. Number: None

U.N. Dangerous Goods Classification: None

Recommended Use: Impression models

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

US Hazard Classification: Not Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Non-hazardous Ingredients	Mixture		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	Wipe off excess. 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 with soap and water.
Inhalation	None needed under normal use conditions
Ingestion	Rinse mouth with water. If large amounts are swallowed, get medical attention.
Most important symptoms of exposure	May cause mild eye irritation.
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: For large spills, wear eye protection. Small spills do not require special precautions.

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 scrape 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. Use in accordance with package instructions.

Conditions for Safe Storage: Store away from extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Non-hazardous Ingredients	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 should be worn if contact is likely.

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: Routine hand washing after use recommended.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Various colored pastes	Explosive limits:	Not applicable
Odor:	Faint berry 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:	Insoluble
Initial boiling point and range:	>392°F / >200°C	Partition coefficient: n-octanol/water:	Not available
Flash point:	>415°F / >212°C	Auto-ignition temperature:	Not available
Evaporation rate:	< 1	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: Extreme heat.

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides, silica and formaldehyde.

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.

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 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:

Product toxicity based on component data: LD50 oral rat >2,000 mg/kg

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

Specific Target Organ Toxicity (STOT):

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

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.

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

Full text of Classification abbreviations used in Section 2 and 3:
None

Date of SDS Preparation/Revision: 26 August 2011

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

Safety Data Sheet

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

Date Issued: 6 June 2009
 Document Number: 0079010MS
 Date Revised: 14 August 2014
 Revision Number: 4

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

1.1 Product Identifier:

Trade Name (as labeled):	Silgimix® Alginate Replacement Material
Part/Item Number:	79010, 79015, 79020, 79025

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

Recommended Use:	Impression models
Restrictions on Use:	Use only as directed

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

1.4 Emergency Telephone Number:

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

2.1 Classification of the Substance or Mixture: Not hazardous

GHS SDS Classification:

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

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Non-hazardous Ingredients	Mixture		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	Wipe off excess. 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 with soap and water.
Inhalation	None needed under normal use conditions
Ingestion	Rinse mouth with water. If large amounts are swallowed, get medical attention.

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

May cause mild eye irritation.

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





Use media appropriate for surrounding fire.

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:			
For large spills, wear eye protection. Small spills do not require special precautions.			
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 scrape 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. Use in accordance with package instructions.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store away from extreme heat.
7.3 Specific End Use (s):
For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits

Non-hazardous Ingredients	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 should be worn if contact is likely.

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:

Appearance:	Various colored pastes	Explosive limits:	Not applicable
Odor:	Faint berry 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:	Insoluble
Initial boiling point and range:	>392°F / >200°C	Partition coefficient: n-octanol/water:	Not available
Flash point:	>415°F / >212°C	Auto-ignition temperature:	Not available
Evaporation rate:	< 1	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: Will not polymerize or react dangerously

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None Known.

10.4 Conditions to Avoid: Extreme heat.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides, silica and formaldehyde.

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.

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 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:

Product toxicity based on component data: LD50 oral rat >2,000 mg/kg

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

Specific Target Organ Toxicity (STOT):

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

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: 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.

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:

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

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: 14 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.