SultanHealthcare

Safety Data Sheet

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

Date Issued: 28 July 2009
Document Number: 77600MS
Date Revised: 20 March 2012
Revision Number: 4

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Genie® VPS Impression Material**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	77600, 77605, 77610, 77615, 77620, 77625, 77630, 77635, 77640, 77645, 77650, 77651, 77655, 77700, 77705, 77710, 77715, 77720, 77725
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Impression models
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

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

EU Labeling: None

US Hazard Classification: Non-Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Base Components				
Silicone Polymer	Proprietary	None	Not classified as hazardous	30-60
Crystalline Silica, Quartz (not respirable)	14808-60-7 /	dioxosilane	Not classified as hazardous	40-60
Catalyst Components				
Silicone Polymer	Proprietary	None	Not classified as hazardous	30-60
Crystalline Silica, Quartz (not respirable)	14808-60-7 /	dioxosilane	Not classified as hazardous	40-60
Titanium Dioxide	13463-67-7 / 236-675-5	dioxotitanium	Not classified as hazardous	0.1-1

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	Wipe off excess. Flush eyes with large quantities of water for 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 Handing: 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:

Silicone 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
Crystalline Silica, Quartz	United States	0.025 TWA ACGIH TLV (respirable) 10 mg/m3 TWA US OSHA PEL (respirable dust) % SiO_2 +2
	Germany	None Established
	United Kingdom	0.1 mg/m3 TWA UL OEL
	France	0.1 mg/m3 TWA INRS VME
	Spain	0.1 mg/m3 TWA VLA-ED (respirable fraction)
	Italy	None Established
	European Union	None Established
Titanium Dioxide	United States	15 mg/m3 TWA US OSHA PEL (total dust) 10 mg/m3 TWA ACGIH TLV
	Germany	1.5 mg/m3 (respirable dust) DFG MAK
	United Kingdom	10 mg/m3 (inhalable) 4 mg/m3 (respirable dust) TWA UK OEL
	France	10 mg/m3 INRS VME
	Spain	10 mg/m3 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: 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:**	Nil
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 and silica.

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: Titanium dioxide is listed by IARC as a group 2B carcinogen (possible human carcinogen). Respirable crystalline silica, quartz is listed by IARC as a group 1 carcinogen (carcinogenic to humans) and by NTP as a "known to be a human carcinogen". These components are encapsulated in a polymer matrix so no inhalable exposure occurs during use or disposal. 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 but the product is not expected to be acutely toxic.
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: Inhalation of respirable crystalline silica may cause lung disease, however, no respirable silica is present and the silica is inextricably bound in the polymer matrix so no exposure can occur.

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 as 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: Non-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: 20 March 2012

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