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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Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled):	**Genie® VPS Impression Material**
Part/Item Number:	77600, 77605, 77610, 77615, 77620, 77625, 77630, 77635, 77640, 77645, 77650, 77651, 77655, 77700, 77705, 77710, 77715, 77720, 77725

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

Recommended Use:	Impression models
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

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

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	Substance Classification	WT %
Base Components				
Silicone Polymer	Proprietary	None	Not classified as hazardous	30-60
Crystalline Silica, Quartz *	14808-60-7 /	dioxosilane	Carc 1 H350 STOT RE 1 H372 Xn 48/20	40-60
Catalyst Components				
Silicone Polymer	Proprietary	None	Not classified as hazardous	30-60
Crystalline Silica, Quartz *	14808-60-7 /	dioxosilane	Carc 1 H350 STOT RE 1 H372 Xn 48/20	40-60
Titanium Dioxide *	13463-67-7 / 236-675-5	dioxotitanium	Carc 2 H351	0.1-1

* The titanium dioxide and crystalline silica in this product are inextricably bound in a manner that no exposure occurs during normal use and handling. Therefore this product is not classified as a carcinogen.

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 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.

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 Handing:
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:

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

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:**	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

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 and silica.

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: 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

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	Maine 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 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.

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:

Xn Harmful
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
Carc 1 Carcinogen Category 1
Carc 2 Carcinogen Category 2
STOT RE 1 Single Target Organ Toxicity Repeated Exposure 1

H350 May cause cancer by inhalation
H351 Suspected of causing cancer.
H372 Causes damage to organs through prolonged exposure.

Supersedes: 20 March 2012

Revision Summary: Comprehensive review, new format

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