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):	**Genie® VPS Tray Adhesive**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	77100
U.N. Number:	UN 1173
U.N. Dangerous Goods Classification:	3, PG II
Recommended Use:	Impression Material
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA 17404
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): Highly Flammable (F), Irritant (Xi) R11, R36, R66, R67

EU Labeling

Highly Flammable

Irritant

R36 Irritating to eyes.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapors may cause drowsiness and dizziness.
S16 Keep away from sources of ignition - No smoking.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S33 Take precautionary measures against static discharges.
S51 Use only in well-ventilated areas.

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Ethyl Acetate	141-78-6 / 205-500-4	ethyl ethanoate	F, Xi, R11, R36, R66, R67	>60

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 water for at least 15 minutes, holding the eyelids apart. Get medical attention.
Skin	Wash skin thoroughly with soap and water. If irritation or other symptoms develop, get medical attention.
Inhalation	Remove to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention**.**
Ingestion	If conscious, rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.
Most important symptoms of exposure	May cause eye irritation. Prolonged skin contact may cause irritation. Vapors or mists may cause mucous membrane and respiratory tract 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 carbon dioxide, foam, water spray or water fog.
Fire Fighting Procedures:	Use water to cool fire-exposed containers.
Specific Hazards Arising from the Chemical:	Vapors are heavier than air and may travel to ignition source and flash back. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Provide explosion-proof ventilation. Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8. Eliminate all ignition sources.

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: Contain and absorb spills with inert material and place into a suitable container for disposal.

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 eyes. Avoid prolonged skin contact. Avoid breathing vapors or mist. Wash thoroughly after handling. Use with adequate ventilation. Do not expose to direct sunlight.

Conditions for Safe Storage: Store in a cool, dry, well ventilated area. Keep container tightly closed when not in use. Keep away from heat, spark, flames and other sources of ignition.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Ethyl Acetate	United States	400 ppm TWA ACGIH TLV 400 ppm TWA OSHA PEL
	Germany	400 ppm TWA DFG MAK
	United Kingdom	200 ppm TWA UK OEL, 400 ppm STEL
	France	400 ppm INRS VME
	Spain	400 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Wear safety chemical goggles if contact is possible.

Specific Skin Protection: Wear butyl rubber gloves for prolonged contact. Recommended glove: Butyl rubber. Contact glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required with adequate ventilation. If the exposure limits are exceeded an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

Environmental Exposure Controls: Do not allow spills to enter sewers or waterways

General Hygiene Considerations and Work Practices: Avoid contact with the eyes. Avoid prolonged contact with skin. Wash with soap and water after handling.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Viscous purple liquid	**Explosive limits:**	LEL: 2.2% (ethyl acetate) UEL: 9.0% (ethyl acetate)
Odor:	Sweet solvent odor.	**Vapor pressure:**	94 mm Hg at 25 deg C
Odor threshold:	Not available	**Vapor density:**	3.04 (ethyl acetate)
pH:	Not available	**Relative density:**	Not available
Melting/freezing point:	Not available	**Solubility:**	Not available
Initial boiling point and range:	63°C (145°F)	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	<23°F (<-5°C) PMCC	**Auto-ignition temperature:**	Not available
Evaporation rate:	9 (butyl acetate = 1)	**Decomposition temperature:**	Not available

Flammability:	Flammable	**Viscosity:**	Not available
Explosive Properties:	Vapors may be explosive in confined areas	**Oxidizing Properties:**	None

10. STABILITY AND REACTIVITY

Reactivity: May react with incompatible materials.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, direct sunlight.

Incompatible materials: Avoid contact with strong oxidizing agents, strong acids, strong bases and nitrates.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, silicone dioxide and formaldehyde.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause irritation with redness, tearing and blurred vision.

Skin: Prolonged skin contact may cause irritation.

Ingestion: May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Inhalation: Vapors or mists may cause mucous membrane and respiratory irritation. High concentration may cause headache, dizziness, drowsiness, incoordination, narcosis, nausea and vomiting. May cause kidney and liver effects.

Chronic Health Effects: Prolonged overexposure to ethyl acetate may cause anemia and damage to the kidneys and liver.

Carcinogenicity: None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: Ethyl Acetate: Negative in AMES test, CHO chromosomes aberrations assay and CHO sister chromatid exchange assay.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing eye conditions may be at increased risk from exposure.

Acute Toxicity Data:

Ethyl Acetate: Oral rat LD50 5.6 g/kg; Inhalation rat LC50 2,500 ppm/4 hr

Reproductive Toxicity Data: In a 13 -week inhalation reproductive study, rats were exposed to 1,500 ppm ethyl acetate. No effects were seen on sperm number, motility or morphology; and there were no test substance-related pathology finding in reproductive tissues examined microscopically.

Specific Target Organ Toxicity (STOT):

Single Exposure: In a human skin patch study, no sensitization was observed after 48 hours. In a sensitization study with human volunteers, no sensitization was observed. In a study with rabbits, ethyl acetate had a narcotic effect in concentrations

>5,000 ppm.

Repeated Exposure: Ethyl Acetate: In a study with rabbits, repeated exposures of 4,450 ppm of ethyl acetate for 1 hr/day/40 days resulted in anemia with leukocytosis, and damage to liver and kidneys.

12. ECOLOGICAL INFORMATION

Toxicity: Ethyl Acetate: 96 hr LC50 Pimephales promelas (fathead minnow) 220 mg/L

Persistence and Degradability: Ethyl acetate is readily biodegradable - 77% after 28 days.

Bio-accumulative Potential: The potential for bioaccumulate is expected to be low for ethyl acetate.

Mobility in Soil: Ethyl acetate is expected to have high mobility in soil.

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.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN1173	IMDG: UN1173	IATA: UN1173	DOT: UN1173
UN proper shipping name:	ADR/RID: Ethyl Acetate Solution IMDG: Ethyl Acetate Solution IATA: Ethyl Acetate Solution DOT: Ethyl Acetate Solution			
Transport hazard class(es):	ADR/RID: 3	IMDG: 3	IATA: 3	DOT: 3
Packaging group:	ADR/RID: PG II	IMDG: PG II	IATA: PG II	DOT: PG II
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No

Special precautions for user: Flammable Liquid

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Releases above the RQ of 8,333 lbs (based on the RQ for ethyl acetate of 5,000 lbs present at 60% max) must be reported to the National Response Center. 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: Flammable Liquid, Irritant, Target organ effects.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	**Yes**	**Pressure Hazard:**	**No**
Delayed Hazard:	**Yes**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

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:

F Highly Flammable
Xi Irritant
R11 Highly flammable.
R36 Irritating to eyes.
R66 Repeated exposure may cause skin dryness or cracking
R67 Vapors may cause drowsiness and dizziness.

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