

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: 74015MS Date Revised: 26 August 2011 Revision Number: 3

| Trade Name (as labeled): | Versa-Soft [™] Silicone Denture Liner, Catalyst + Base |
|--|---|
| Chemical Name/Classification: | Mixture |
| Product Identifier (Part/Item Number): | 74015 |
| U.N. Number: | None |
| U.N. Dangerous Goods Classification: | None |
| Recommended Use: | Permanent denture relining material |
| Restrictions on Use: | For professional use only |
| Manufacturer/Supplier Name: | Sultan Healthcare |
| Manufacturer/Supplier Address: | 411 Hackensack Avenue, 9 th 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 |
| | |

1. PRODUCT IDENTIFICATION

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 of symptoms and cl | (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control inical 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 | |
| B | | | | |

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.

| Recommende | 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 Lim | <u>.</u> | | | |
|---|--|---|----------------------|--|
| 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) | | |
| | | <u>10 mg/m3</u> TWA US OSHA PEL (resp | birable dust) | |
| | ~ | % SiO ₂ +2 | | |
| | Germany | None Established | | |
| | United Kingdom | 0.1 mg/m3 TWA UK 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 o | dust) | |
| | a | 10 mg/m3 TWA ACGIH TLV | | |
| | Germany | 1.5 mg/m3 (respirable dust) DFG MAK | | |
| | United Kingdom | 10 mg/m3 (inhalable) 4 mg/m3 (respiral | ble dust) TWA UK OEL | |
| | France | 10 mg/m3 INRS VME | | |
| | | | | |
| | Spain | 10 mg/m3 VLA-ED | | |
| | Italy | None Established | | |
| Biological Exposure Limits: | Italy European Union | | | |
| Biological Exposure Limits: Appropriate Engineering Co | Italy European Union None Established. | None Established None Established | | |
| Appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec | Italy European Union None Established. ontrols: No special contr rres (PPE) otection: Avoid eye con tion: None normally req | None Established None Established rols required. ttact. Safety glasses should be worn if con juired. | tact is likely. | |
| appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory | Italy European Union None Established. ontrols: No special contr ures (PPE) otection: Avoid eye con tion: None normally req v Protection: None requ | None Established None Established rols required. | tact is likely. | |
| ppropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory | Italy European Union None Established. ontrols: No special contr rres (PPE) otection: Avoid eye con tion: None normally req | None Established None Established rols required. ttact. Safety glasses should be worn if con juired. | tact is likely. | |
| Appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory | Italy European Union None Established. ontrols: No special contr ares (PPE) otection: Avoid eye con tion: None normally req protection: None requ azards: Not applicable | None Established None Established rols required. ttact. Safety glasses should be worn if con juired. | tact is likely. | |
| Appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory | Italy European Union None Established. ontrols: No special contr ares (PPE) otection: Avoid eye con tion: None normally req protection: None requ azards: Not applicable | None Established None Established rols required. ntact. Safety glasses should be worn if con juired. ired under normal use conditions. | tact is likely. | |
| Appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory Specific Thermal Ha | Italy European Union None Established. ontrols: No special contr res (PPE) otection: Avoid eye con tion: None normally req v Protection: None requ azards: Not applicable Recommended I | None Established None Established rols required. ttact. Safety glasses should be worn if con juired. ired under normal use conditions. Personal Protective Equipment: | | |
| Appropriate Engineering Co ndividual Protection Measu Specific Eye/face Pr Specific Skin Protec Specific Respiratory Specific Thermal Ha | Italy European Union None Established. ontrols: No special contr ures (PPE) otection: Avoid eye con tion: None normally req v Protection: None requ azards: Not applicable Recommended I SKIN | None Established None Established rols required. ntact. Safety glasses should be worn if con juired. ired under normal use conditions. Personal Protective Equipment: RESPIRATORY | | |
| Appropriate Engineering Condividual Protection Measu Specific Eye/face ProSpecific Skin Protect Specific Respiratory Specific Thermal Hat EYES/FACE | Italy European Union None Established. ontrols: No special control otection: No special control otection: Avoid eye control otection: None normally required of Protection: None required for the second second SKIN | None Established None Established rols required. ntact. Safety glasses should be worn if con juired. ired under normal use conditions. Personal Protective Equipment: RESPIRATORY | THERMAL | |

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.

| Appearance: | Various colored pastes | Explosive limits: | Not applicable |
|----------------------------------|------------------------|---|----------------|
| Odor: | Faint berry odor. | Vapor pressure: | Not applicable |
| Odor threshold: | Not available | Vapor density: | Not applicable |
| рН: | 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. PHYSICAL AND CHEMICAL PROPERTIES

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.

<u>Ingestion</u>: 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.

<u>Reproductive Toxicity Data:</u> No reproductive or teratogenic effects are expected.

Specific Target Organ Toxicity (STOT):

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

<u>Repeated Exposure</u>: 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 Reg IMDG: Not Regula IATA: Not Regulat DOT: Not Regulate | ted ed | | |
| 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: 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: 22 June 2009 Document Number: 74010MS Date Revised: 26 August 2011 Revision Number: 3

1. PRODUCT IDENTIFICATION

| Trade Name (as labeled): | Versa-Soft™ Silicone Denture Soft Liner, Primer |
|--|---|
| Chemical Name/Classification: | Mixture |
| Product Identifier (Part/Item Number): | 74010, 74012, 74020 |
| 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: | 411 Hackensack Avenue, 9 th 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): Highly Flammable (F), Irritant (Xi) R11, R36, R66, R67

EU Labeling

| (| × | Contains ethyl acetate 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 |
|------------------|----------|--|
| Highly Flammable | Irritant | 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 | 60-100 |

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 | 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 develops, 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 of symptoms and clin | Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control nical 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-ex | Use water to cool fire-exposed containers. | | |
| Specific Hazards Arising fro the Chemical: | m toxic fumes under fire co | 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 Fighter | 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 | |
| B | | | | |

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.

| Recommen | 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:

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

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: | Colorless liquid | Explosive limits: | LEL: 2.2% (ethyl acetate) UEL: 9.0% (ethyl acetate) |
|----------------------------------|------------------------|---|--|
| Odor: | Acetate-like odor | Vapor pressure: | 93.2 mm Hg at 25 deg C (ethyl acetate) |
| Odor threshold: | Not available | Vapor density: | 3.04 (ethyl acetate) |
| рН: | Not available | Relative density: | 0.95 |
| Melting/freezing point: | Not available | Solubility: | Complete |
| Initial boiling point and range: | 77°C (177°F) | Partition coefficient: n- octanol/water: | Not available |
| Flash point: | 25°F (-4°C) PMCC | Auto-ignition temperature: | 800°F (426.6°C) |
| Evaporation rate: | >1 (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.

<u>Inhalation:</u> 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.

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

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

<u>Mutagenicity</u>: 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 2500 ppm/4 hr

<u>Reproductive Toxicity Data</u>: 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):

<u>Single Exposure</u>: 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.

<u>Repeated Exposure</u>: 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 Ace IMDG: Ethyl Acetate 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 |

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Releases above the RQ of 5,000 lbs (based on the RQ for ethyl acetate of 5,000 lbs present at 100% 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. 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, and Country websites for occupational exposure limits.