

Safety Data Sheet

Safety Data Sheet (conforms to with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 9 August 2004
Document Number: 203
Date Revised: 15 April 2019
Revision Number: 9

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

1.1 Product Identifier:

Trade Name (as labeled): PermaSoft® Liquid
Part/Item Number: N811000, N811100, N811500, N812000, N812100, N812500, N814002, N814005

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

Recommended Use: Denture Liner
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17401
Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics_MSDS@Dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-243-1942

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|---|---------------------------------|------------------------------------|
| Health | Environmental | Physical |
| Eye Irritant Category 2 (H319) Reproductive Toxicity Category 1B (H360d) | Aquatic Acute Category 1 (H400) | Flammable Liquid Category 3 (H226) |

2.2 Label Elements:



Signal Word: Danger

Contains: Dibutyl Phthalate

| Hazard Phrases | Precautionary Phrases |
|--|--|
| <p>H226 Flammable Liquid and vapor. H319 Causes serious eye irritation. H360df May damage the unborn child. Suspected of damaging fertility. H400 Very toxic to aquatic life.</p> | <p>P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood P210 Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment P241 Use explosion-proof electrical, ventilating and lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P264 Wash thoroughly after handling. P280 Wear protective gloves, eye protection and face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P308 + P313 IF exposed or concerned: Get medical attention. P370 + P378 In case of fire: Use carbon dioxide, alcohol foam or dry chemical to extinguish. P273 Avoid release to the environment. P391 Collect spillage P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.</p> |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # / REACH Registration # | Classification | WT % |
|----------------------|----------|---------------------------------------|---|-------|
| Dibutyl Phthalate | 84-74-2 | 201-557-4 / | Repro. 1B, H360df, Aquatic Acute 1, H400 | 60-90 |

| | | | | |
|-------------------------|----------|-------------|---|------|
| Ethyl Acetate | 141-78-6 | 205-500-4 / | Flam. Liq., 2 H225, Eye Irrit. 2A, H319 STOT SE 3, H336 | 5-15 |
| Ethanol (Ethyl Alcohol) | 64-17-5 | 200-578-6 / | Flam. Liq. 2, H225 | 1-10 |

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|--|
| Eye | Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists. |
| Skin | Wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes). |
| Inhalation | Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention. |
| Ingestion | Get medical attention. Call poison control center or go to a hospital emergency room. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person. |

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

Causes eye irritation. May cause skin irritation. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged or repeated overexposure may cause anemia, kidney and liver damage. May cause adverse reproductive effects based on studies with laboratory animals.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use carbon dioxide, alcohol foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

This product is flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.

5.3 Advice for Fire-Fighters:

| | |
|--|---|
| Fire Fighting Procedures/Precautions for Fire Fighters: | Use water to cool exposed containers and structures and disperse flammable vapors. Do not allow run-off from firefighting to enter drains or water courses. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. |
|--|---|

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion

proof equipment. Wear appropriate protective clothing as described in Section 8. Avoid contact with eyes, skin, and clothing. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

6.2 Environmental Precautions:

Do not flush into sewer! Do not allow spills to enter sewers, waterways or the environment. Report releases as required by local, state and federal authorities.

6.3 Methods and Material for Containment and Cleaning up:

Eliminate all ignition sources. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment.

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, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

| | |
|---------|------------------------------------|
| Ethanol | 1000 ppm STEL ACGIH TLV |
| | 1000 ppm TWA OSHA PEL |
| | 500 ppm TWA, 1000 ppm STEL DFG MAK |
| | 1000 ppm TWA UK WEL |
| | Belgium: 1000 ppm TWA |

| | |
|--|--|
| Dibutyl Phthalate | 5 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL |
| | 0.05 ppm TWA DFG MAK (Inhalable fraction and vapor) 0.1 ppm STEL DFG MAK (Inhalable fraction and vapor) |
| | 5 mg/m ³ TWA UK OEL 10 mg/m ³ STEL UK OEL |
| Ethyl Acetate | 400 ppm TWA ACGIH TLV 400 ppm TWA OSHA PEL |
| | 400 ppm TWA DFG MAK 800 ppm STEL DFG MAK |
| | 200 ppm TWA UK OEL 400 ppm STEL UK OEL |
| Biological Exposure Limits: None | |
| 8.2 Exposure Controls: | |
| Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits. Use explosion-proof equipment where required | |
| Individual Protection Measures (PPE): <p>Specific Eye/face Protection: Chemical safety glasses or chemical splash goggles recommended.</p> <p>Specific Skin Protection: Wear impervious gloves such as 4H™. Clothing with long sleeves may be needed when working with large quantities.</p> <p>Specific Respiratory Protection: None should be needed for normal use. 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.</p> <p>Specific Thermal Hazards: None required</p> | |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|---|----------------------|--|---|
| Appearance: | Light colored liquid | Explosive limits: | LEL: 2.0% (as ethyl acetate) UEL: 19% (as ethyl alcohol) |
| Odor: | Slight odor | Vapor pressure (mmHg): | Not available |
| Odor threshold: | Not available | Vapor density: | 9.6 @ 20°C |
| pH: | Not available | Relative density: | 1.02 |
| Melting/freezing point: | Not available | Solubility(ies): | Partially |
| Initial boiling point and boiling range: | 171° F (77°C) | Partition coefficient: n-octanol/water: | Not available |
| Flash point: | 74°F (23°C) | Auto-ignition temperature: | Not available |
| Evaporation rate: | Not available | Decomposition temperature: | Not available |

| | | | |
|-----------------------------------|--|------------------------------|---------------|
| Flammability (solid, gas): | Not applicable | Viscosity: | Not available |
| Explosive Properties: | Vapors may be explosive in confined areas. | Oxidizing Properties: | None |

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

| |
|---|
| 10.1 Reactivity: None known. |
| 10.2 Chemical Stability: Stable under normal conditions. |
| 10.3 Possibility of Hazardous Reactions: None know. |
| 10.4 Conditions to Avoid: Keep away from heat, sparks and all ignition sources. |
| 10.5 Incompatible materials: Avoid oxidizing agents and inorganic acids. |
| 10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide and carbon dioxide. |

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

| |
|--|
| <p><u>Potential Health Effects:</u></p> <p><u>Eyes:</u> Contact may cause irritation with redness, tearing and stinging.</p> <p><u>Skin:</u> May cause skin irritation with redness and itching. Repeated or prolonged contact may cause drying, defatting of the skin and dermatitis.</p> <p><u>Ingestion:</u> Ingestion may cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.</p> <p><u>Inhalation:</u> Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness. High vapor concentrations may cause burning sensation of the nose and throat and watering of the eyes.</p> <p><u>Chronic Health Effects:</u> Repeated skin contact may cause dermatitis. Prolonged overexposure to ethyl acetate may cause anemia with leukocytes and damage to the kidney and liver.</p> <p><u>Irritation:</u> Ethanol: Not irritating to rabbit skin, Irritating to rabbit eyes.</p> <p><u>Corrosivity:</u> No data available. This product is not expected to be corrosive.</p> <p><u>Sensitization:</u> No data available. This product is not expected to cause sensitization. Dibutyl was not sensitizing in a guinea pig maximization test.</p> <p><u>Carcinogenicity:</u> Ethanol: Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.</p> <p><u>Mutagenicity:</u> Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay. Dibutyl was negative in an in vitro bacterial gene mutation assay.</p> <p><u>Aspiration Hazard:</u> Not an aspiration hazard.</p> |
|--|

Acute Toxicity Data:

Ethanol: LD50 oral rat 7060 mg/kg; LC50: inhalation rat 117-125 mg/L/4 hr.
 Dibutyl Phthalate: LD50 oral rat 6279 mg/kg; LD50 skin rabbit 4200 mg/kg; LC50 inhalation mouse 15.68 mg/L/4 hr
 Ethyl Acetate: LD50 oral rat 5620 mg/kg; LC50 inhalation rat 200 gm/m³; LD50 skin rabbit > 20000 mg/kg

Reproductive Toxicity Data: Ethanol: Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, resulting in fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioral disorders and small head size. Dibutyl phthalate has been shown to cause adverse reproductive effects and birth defects in studies with laboratory animals.

Specific Target Organ Toxicity Single Exposure (STOT-SE): May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Ethanol: Ethanol when consumed as a beverage has been found to cause damage to the liver, nervous system and reproductive system. Prolonged overexposure to ethyl acetate may cause damage to the kidney and liver.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Dibutyl Phtalate: LC50 Pimephales promelas (Fathead minnow) 0.92 mg/L/96 hr; EC50 daphnia magna 4.8 mg/L/48 hr; EC50 Pseudokirchnerella subcapitata 0.75 mg/L/ 96 hr
 Ethanol: LC50 rainbow trout 13000 mg/L/96 hr; LC50 daphnia magna 9268-14221 mg/L/48 hr; EC50 Chlorella pyrenoidosa (Green algae; growth inhibition) 9310 mg/L/48 hr
 Ethyl Acetate: LC50 Pimephales promelas (fathead minnow) 230 mg/l/96 hr.

12.2 Persistence and Degradability: Ethanol and dibutyl phthalate are readily biodegradable in screening tests.

12.3 Bio-accumulative Potential: Ethanol has an estimated BCF of 3. Ethyl acetate has an estimated BCF of 3.2.

12.4 Mobility in Soil: Dibutyl phthalate is expected to have a low mobility in soil. Ethyl acetate is expected to have high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

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 | UN1993 | Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate) | 3 | III | No |

| | | | | | |
|------------------|--------|---|---|-----|----|
| ADR/RID | UN1993 | Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate) | 3 | III | No |
| IMDG | UN1993 | Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate) | 3 | III | No |
| IATA/ICAO | UN1993 | Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate) | 3 | III | 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 has a Reportable Quantity (RQ) of 11 lbs. based on the RQ for Dibutyl Phthalate of 10 lbs. Releases above the RQ 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.

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: Acute Health, Chronic Health and Fire Hazard.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

| Components | C.A.S. # | WT % |
|-------------------|----------|-------|
| Dibutyl Phthalate | 84-74-2 | 60-90 |

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: Dibutyl Phthalate (60-90 %).

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2* Flammability – 3 Physical Hazard– 0

*Chronic health hazard.

Full text of Classification abbreviations used in Section 2 and 3:

Flam. Liq. 2 Flammable Liquid Category 2

Eye Irrit. 2A Eye Irritant Category 2A

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

Repro 1B Toxic to Reproduction Category 1B

Aquatic Acute 1 Aquatic Acute Toxicity Category 1

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H360df May damage the unborn child. Suspected of damaging fertility.

H400 Very toxic to aquatic life.

Supersedes: 10 November 2016

Date Updated: 15 April 2019

Revision Summary: Changes to Sections 1 and 2.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.

DENTSPLY International

Prosthetics

Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006,
Regulation (EC) 1272/2008 and Regulation (EC) 2015/830,
US 29CFR1910.1200, Canada Hazardous Products
Regulation

Date Issued: 09 August 2004
Document Number: 202
Date Revised: 15 March 2019
Revision Number:8

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

1.1 Product Identifier:

Trade Name (as labeled): PermaSoft® Soft Denture Liner Powder
Part/Item Number: N811000, N811100, N811500, N812000, N812100,
N812500, N815103, N815003, N815101, N815005,
N815102, N815002, N815105

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

Recommended Use: Denture liner.
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17401
Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics_MSDS@dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-243-1942

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|---------------------|---------------|---------------|
| Health | Environmental | Physical |
| Not Hazardous | Not Hazardous | Not Hazardous |

2.2 Label Elements:

None Required

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # / REACH Registration # | Classification | WT % |
|-------------------------------|-------------|---------------------------------------|----------------|----------|
| Non-hazardous Acrylic Polymer | Proprietary | Proprietary | Not applicable | 90 - 100 |

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|--|
| Eye | Flush eyes with water, holding the eyelids apart. Get medical attention if irritation persists. |
| Skin | Wash skin with soap and water. Get medical attention if irritation develops. Launder clothing before re-use. |
| Inhalation | Remove victim to fresh air. Get medical attention if irritation develops. |
| Ingestion | If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If irritation or discomfort occurs, get immediate medical attention. |

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

Dust may cause mild eye and respiratory irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use water spray, carbon dioxide, foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

High concentrations of dust in air may be explosive.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:: Cool exposed intact containers with water spray. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Wear appropriate protective clothing as described in Section 8. Remove all sources of ignition. Avoid contact with skin, eyes or clothing.

6.2 Environmental Precautions:

Do not allow spills or contaminated water to enter sewers, waterways, lakes, streams, ponds, groundwater, or soil. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Carefully collect and place into a container for disposal. Do not generate airborne dust.

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 eyes and skin. Avoid breathing dust or fumes. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Use good housekeeping to minimize accumulation of dust on equipment and surfaces. Keep away from sources of heat or ignition sources.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use. Store away from oxidizers.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

| | |
|---|--|
| Non-hazardous Acrylic Polymer (as Particulates Not Otherwise Specified) | 15 mg/m ³ TWA OSHA PEL (Total Dust) |
| | 5 mg/m ³ TWA OSHA PEL (Respirable) |
| | 4 mg/m ³ TWA DFG MAK (Inhalable) |
| | 1.5 mg/m ³ TWA DFG MAK (Respirable) |
| | 10 mg/m ³ TWA UK OEL (Inhalable) |
| | 4 mg/m ³ TWA UK OEL (Respirable) |

Biological Exposure Limits: None established.

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where needed.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety glasses with side shields or chemical goggles.

Specific Skin Protection: Wear impervious gloves if needed to avoid skin contact. Recommended glove: Rubber. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None needed for normal use. If the exposure limits are exceeded an approved dust/mist respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with all applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|--|--|--|--|
| Appearance: | Pink or clear powder. | Explosive limits: | LEL: Not applicable UEL: Not applicable |
| Odor: | Slight odor. | Vapor pressure: | Not applicable |
| Odor threshold: | Not determined | Vapor density: (Air = 1) | Not applicable |
| pH: | Not applicable | Relative density: | 1.16 |
| Melting/freezing point: | Not applicable | Solubility: | Insoluble |
| Initial boiling point and range: | Not applicable | Partition coefficient: n-octanol/water: | Not applicable |
| Flash point: | >482°F (>250°C) | Auto-ignition temperature: | >752°F (>400°C) |
| Evaporation rate: (n-BuAc = 1) | Not applicable | Decomposition temperature: | 482°F (250°C) |
| Flammability: | Non flammable | Viscosity: | Not applicable |
| Explosive Properties: | High concentrations of dust in air may be explosive. | Oxidizing Properties: | None |

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: None known

10.4 Conditions to Avoid: Product will begin to depolymerization at 482°F (250°C). Keep product away from heat and ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide and

ethyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Dust may cause mechanical irritation.

Skin: May cause mechanical irritation. May cause skin sensitization in some individuals.

Ingestion: No adverse effects expected under normal use conditions.

Inhalation: Inhalation of dust may cause irritation of the eyes, nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.

Chronic Health Effects: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals

Irritation: May cause slight irritation.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: No data available. This product is not expected to cause sensitization.

Carcinogenicity: None of the components of this product listed at >0.1% are carcinogens by OSHA, IARC or NTP or the EU CLP.

Mutagenicity: No data available. This product is not expected to cause mutagenic activity.

Aspiration Hazard: Not an aspiration hazard

Acute Toxicity Data:

Non-hazardous Acrylic Polymer: No data available

Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No data available

12.2 Persistence and Degradability: No data available

12.3 Bio-accumulative Potential: No data available

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

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 | Not applicable |
| ADR/RID | None | Not Regulated | None | None | Not applicable |
| IMDG | None | Not Regulated | None | None | Not applicable |
| IATA/ICAO | None | Not Regulated | None | None | Not applicable |

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.

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): 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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

State Regulations

California:



WARNING: This product can expose you to chemicals including titanium dioxide (at 0.05%), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

International Regulations

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL).

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 0 Flammability – 1 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3:

None.

Supersedes: 9 February 2018

Date Updated: 15 March 2019

Revision Summary: Change to Section 1. Revised California Prop. 65 statement.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.

Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006,
Regulation (EC) 1272/2008 and Regulation (EC) 2015/830,
US 29CFR1910.1200, Canada Hazardous Products
Regulation

Date Issued: 5 September 2002
Document Number: 204
Date Revised: 15 April 2019
Revision Number: 8

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

1.1 Product Identifier:

Trade Name (as labeled): PermaSoft® Denture Liner Sealer
Part/Item Number: N811000, N811100, N811500, N812000, N812100,
N812500, N816002, N816005

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

Recommended Use: Denture Liner Sealant
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17401
Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics_MSDS@dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-243-1942

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|--|---------------|------------------------------------|
| Health | Environmental | Physical |
| Eye Irritant Category 2 (H319) Specific Target Organ Toxicity- Single Exposure Category 3 (H336) | Not Hazardous | Flammable Liquid Category 2 (H225) |

2.2 Label Elements:



Signal Word: Danger

Contains: Methyl Ethyl Ketone

| Hazard Phrases | Precautionary Phrases |
|--|--|
| <p>H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.</p> | <p>P210 Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment P241 Use explosion-proof electrical, ventilating and lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P261 Avoid breathing mist, vapors, or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves, eye protection and face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P370 + P378 In case of fire: Use carbon dioxide, alcohol foam or dry chemical to extinguish. P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.</p> |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # / REACH Registration # | Classification | WT % |
|----------------------------------|----------|---------------------------------------|---|-------|
| Methyl Ethyl Ketone (2-butanone) | 78-93-3 | 201-159-0 / | Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 | 70-95 |

| | | | | |
|---------|-------------|-------------|----------------|------|
| Polymer | Proprietary | Proprietary | Not Applicable | 5-30 |
|---------|-------------|-------------|----------------|------|

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|---|
| Eye | Immediately flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation persists. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation or symptoms develop, get medical attention. Launder clothing before re-use. |
| Inhalation | Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if breathing is difficult or irritation persists. |
| Ingestion | If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting unless directed to do so by a medical professional. Get medical attention if symptoms develop or if you feel unwell. |

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

Causes eye irritation. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged and/or repeated overexposure may cause nervous system damage.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use water spray, carbon dioxide, alcohol foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

This product is highly flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat. Decomposition may release carbon monoxide, carbon dioxide and unidentified organics.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters: Use water to cool exposed containers and structures and disperse flammable vapors. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Avoid breathing vapors or mists. Ventilate area with explosion proof equipment. Avoid contact with eyes. Avoid prolonged contact with skin and clothing. Wear appropriate protective clothing as described in Section 8. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

6.2 Environmental Precautions:

Do not allow spills to enter sewers, waterways or the environment. Report releases as required by local, state and federal authorities.

6.3 Methods and Material for Containment and Cleaning up:

Eliminate all ignition sources. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment.

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 eyes. Avoid prolonged contact with skin and clothing. Avoid breathing vapors or mists. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

| | |
|---------------------|--|
| Methyl Ethyl Ketone | 200 ppm TWA, 300 ppm STEL ACGIH TLV |
| | 200 ppm TWA OSHA PEL |
| | 200 ppm TWA, 200 ppm STEL DFG MAK (skin) |
| | 200 ppm TWA, 300 ppm STEL UK WEL |
| | 200 ppm TWA, 300 ppm STEL Belgium OEL |
| | 200 ppm TWA, 300 ppm STEL EU OEL |
| Polymer | None Established |

| |
|--|
| <p>Biological Exposure Limits: Methyl Ethyl Ketone: Methyl ethyl ketone in urine, End of shift, 2 mg/L.</p> |
| <p>8.2 Exposure Controls:</p> |
| <p>Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits. Use explosion-proof equipment where required</p> |
| <p>Individual Protection Measures (PPE): <p>Specific Eye/face Protection: Chemical splash goggles recommended. Specific Skin Protection: Wear impervious gloves such as butyl rubber to avoid prolonged skin contact. Clothing with long sleeves may be needed when working with large quantities. Specific Respiratory Protection: None should be needed for normal use. 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: None required</p> </p> |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|---|--|--|---|
| Appearance: | Colorless liquid | Explosive limits: | LEL: 1.4% (Methyl Ethyl Ketone) UEL: 11.4% (Methyl Ethyl Ketone) |
| Odor: | Characteristic sweetish odor | Vapor pressure (mmHg): | 77.5 mmHg @ 68°F (20°C) |
| Odor threshold: | Not available | Vapor density: (Air = 1) | 2.5 |
| pH: | Not available | Relative density: | 0.80 |
| Melting/freezing point: | -123°F (-86°C) | Solubility(ies): | 29 g/100 mL |
| Initial boiling point and boiling range: | 176°F (80°C) | Partition coefficient: n-octanol/water: | Not available |
| Flash point: | 23°F (-5°C) | Auto-ignition temperature: | Not available |
| Evaporation rate: (n-BuAc = 1) | Not available | Decomposition temperature: | Not available |
| Flammability (solid, gas): | Not applicable | Viscosity: | Not available |
| Explosive Properties: | Vapors may be explosive in confined areas. | Oxidizing Properties: | None |

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions. Reacts with strong oxidizing agents.

10.3 Possibility of Hazardous Reactions: Methyl Ethyl Ketone may react violently with strong oxidants and inorganic acids causing fire and explosion hazard. Methyl Ethyl Ketone can attack some plastic.

10.4 Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents, inorganic acids, copper, hydrogen peroxide, chloroform and halogens.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide and unidentified organics.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging.

Skin: Prolonged contact may cause irritation with redness, itching and pain. The liquid may be absorbed through the skin causing effects similar to those described under inhalation and ingestion.

Ingestion: Ingestion may cause mucous membrane and gastrointestinal irritation and nervous system depression with symptoms of headache, dizziness, abdominal pain, nausea, vomiting and unconsciousness.

Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, drowsiness, fatigue, nausea, shortness of breath, confusion, and unconsciousness.

Chronic Health Effects: Prolonged occupational overexposure may cause defatting of the skin, dermatitis and damage to the nervous system. Methyl ethyl ketone has been found to cause adverse reproductive effects and/or birth defects in studies with laboratory animals.

Irritation: Methyl ethyl ketone: Irritating to rabbit eyes. Not irritating to rabbit skin.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: No data available. This product is not expected to cause sensitization.

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

Mutagenicity: Methyl ethyl ketone: Mutagenicity studies on MEK. The test systems comprised the Salmonella/microsome (Ames) assay, the L5178/TK+/- mouse lymphoma (M/L) assay, the BALB/3T3 cell transformation (CT) assay, unscheduled DNA synthesis (UDS) and the micronucleus test. MEK was not found to be genotoxic in these assays.

Aspiration Hazard: Not an aspiration hazard

Acute Toxicity Data:

Methyl ethyl ketone: Oral rat LD50-2193 mg/kg; Dermal rabbit LD50- >8000 mg/kg; Inhalation rat LC50- > 5000 ppm/6 hr.

Reproductive Toxicity Data: Methyl ethyl ketone has been found to cause adverse reproductive effects and/or birth defects in studies with laboratory animals.

Specific Target Organ Toxicity Single Exposure (STOT-SE): Methyl ethyl ketone: CNS depression/ and other nerve dysfunctions. The common symptoms of short term exposure are fatigue, headache, nausea, sleep disturbance, and alteration in memory. Psychomotor performance of adverse effects on intellectual or memory functions are demonstrated with psychological test batteries after long-term occupational exposure to organic solvents.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Methyl ethyl ketone: Male and female Fischer 344 rats were exposed to 0, 1250, 2500, or 5000 ppm methyl ethyl ketone (MEK) vapors 6 hr/day, 5 day/wk. for 90 days. The 90 day exposures had no adverse effect on the clinical health or growth of male or female rats except for a depression of mean body wt. in the 5000 ppm exposure group. The 5000 ppm animals had a slight but significant increase in liver weight, liver weight/body weight ratio, and liver weight/brain weight ratio at necropsy.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Methyl ethyl ketone: 96hr LC50 Fathead minnow- 2993 mg/L; 48hr EC50 Daphnia magna- 308 mg/L

12.2 Persistence and Degradability: Methyl ethyl ketone (MEK) is readily oxidized by microorganisms in activated sludge following selection and/or adaptation, with over 80% being removed in 24 hr.

12.3 Bio-accumulative Potential: Methyl ethyl ketone: An estimated BCF of 3 was calculated in fish for methyl ethyl ketone, using a log Kow of 0.29 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bio concentration in aquatic organisms is low.

12.4 Mobility in Soil: Methyl ethyl ketone is expected to have very high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

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 | UN1193 | Methyl Ethyl Ketone | 3 | II | No |
| ADR/RID | UN1193 | Methyl Ethyl Ketone | 3 | II | No |
| IMDG | UN1193 | Methyl Ethyl Ketone | 3 | II | No |
| IATA/ICAO | UN1193 | Methyl Ethyl Ketone | 3 | II | 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 has a Reportable

Quantity (RQ) of 5,263 lbs. (based on the RQ for Methyl Ethyl Ketone of 5,000 lbs present at 75-95%). Releases above the RQ 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.

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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: Acetaldehyde (<83.6 ppm), Vinyl Chloride (<83.6 ppm).

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 3 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

Flam. Liq. 2 Flammable Liquid Category 2

Eye Irrit. 2A Eye Irritant Category 2A

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Supersedes: 20 November 2017

Date Updated: 15 April 2019

Revision Summary: Changes to Section 2.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.