

SAFETY DATA SHEETS

This SDS packet was issued with item:

072760783

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070425462 070441162 072760775 072760858 072760882 072760890

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070469593 070639989 072759116 072759124 072759132 072759140 072759900 072759934 072760189 072760759
072760767 072760791 072760866 072760874 072760924 072760932 072760940 072760957 072760965 072760999
072761005 072761013 078562617 273044119 273044121 273045762

DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Date Issued: 5/28/04
Document Number: 151
Date Revised: 09/09/2011
Revision Number: 4

1. PRODUCT IDENTIFICATION

| | |
|---|--|
| Trade Name (as labeled): | Lucitone Liquid |
| Product Identifier (Part/Item Number): | 684309, 684315 |
| U.N. Number: | UN1247 |
| U.N. Dangerous Goods Classification: | 3, PG II |
| Recommended Use: | Fabrication of Dentures |
| Restrictions on Use: | For Professional Use Only |
| Manufacturer/Supplier Name: | Dentsply Prosthetics |
| Manufacturer/Supplier Address: | 570 West College Ave. York, PA 17405-0872 |
| Manufacturer/Supplier Telephone Number: | 717-845-7511 (Product Information) |
| Emergency Contact Telephone Number: | 800-424-9300 Chemtrec |
| Email address: | Prosthetics_MSDS@Dentsply.com |

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC): Highly Flammable (F), Irritant (Xi) R11, R37/38, R43

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

Labeling in accordance with 1999/45/EC



Highly Flammable



Irritant

Contains: Methyl Methacrylate
R11 Highly flammable.
R37/38 Irritating to respiratory system and skin
R43 May cause sensitization by skin contact.
S24/25 Avoid contact with skin and eyes.
S36/37 Wear suitable protective clothing and gloves.

US Hazard Classification: Hazardous.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components | C.A.S. # | EINECS # | Substance Classification | WT % |
|--------------------------------|----------|-----------|--------------------------|---------|
| Methyl Methacrylate | 80-62-6 | 201-297-1 | F, Xi, R11, R37/38, R43 | 90 - 99 |
| Ethylene Glycol Dimethacrylate | 97-90-5 | 202-617-2 | Xi R36/37 | 1-10 |

Refer to Section 16 for the full text of the GHS and H phrases and 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 immediate medical attention. |
| Skin | Wash skin with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use. |
| Inhalation | Remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen, and obtain immediate medical attention. |
| 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. Get immediate medical attention. |
| Most important symptoms of exposure | May cause respiratory tract, eye and skin irritation. Prolonged or repeated contact may cause allergic skin reaction (skin rash). Inhalation of vapors may cause dizziness, headache, and other central nervous system effects. |
| Note to Physicians (Treatment, Testing, and Monitoring) | |
| Treat symptomatically. | |

5. FIRE-FIGHTING MEASURES

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|---|--|
| Suitable Extinguishing Media: | Use carbon dioxide, foam, water spray or water fog. |
| Fire Fighting Procedures: | Fight fire from a safe distance of protected location. Water may be ineffective unless used as a fine spray or fog. 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. Heat of fire may cause an exothermic auto polymerization reaction. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat. |
| Precautions for Fire Fighters: | Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus. |

Recommended Protective Equipment for Fire Fighters:

| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|---|---|--|---|
|  |  |  |  |




6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Provide explosion-proof ventilation. Wear appropriate protective clothing.

Environmental Precautions: Do not allow spills to enter sewers, waterways or the environment.

Methods and Materials for Containment and Clean-up: Eliminate all ignition sources. Contain and absorb spills with inert material and transfer to a suitable container for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:

| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|---|---|--|---------|
|  |  |  | |

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with eyes, skin, and clothing. Avoid breathing vapors or mist. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Keep away from heat, sparks and flames. Ground container when pouring. Do not expose to direct sunlight.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a cool, dry, well ventilated area. Keep container tightly closed when not in use. Do not store in direct sunlight. Prevent moisture contact. Protect from physical damage. Keep away from oxidizers and other incompatible materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Methyl Methacrylate

50 ppm TWA TLV

100 ppm STEL TLV

100 ppm PEL



50 ppm TWA DFG MAK

50 ppm TWA UK WEL

100 ppm STEL UK WEL

Ethylene Glycol Dimethacrylate:

None established

| | | | |
|---|--|--------------------|-------------|
| Biological Exposure Limits: None | | | |
| 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) Specific Eye/face Protection: Wear safety glasses when the possibility exists for eye contact due to splashing or spraying material. Specific Skin Protection: Wear nitrile rubber or other impervious gloves to prevent skin contact. Wear impervious clothing if needed to prevent any contact with this product, such as gloves, apron, boots, or whole body suit. Specific Respiratory Protection: None required with adequate ventilation. An approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain limited circumstances where airborne concentrations are expected to exceed exposure limits. Protection provided by air purifying respirators is limited. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection. Selection and use of respiratory equipment must be in accordance with appropriate regulations and good industrial hygiene practice. Specific Thermal Hazards: None required. | | | |
| Recommended Personal Protective Equipment | | | |
| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|  |  | | |
| Environmental Exposure Controls: Do not allow spills to enter sewers or waterways. | | | |
| General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Avoid breathing vapors or mist. Wash thoroughly after handling. | | | |
| Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment. | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|--------------------------------|--------------------------------|--------------------------|----------------|
| Appearance: | Clear liquid | Explosive limits: | Not available |
| Odor: | Acrylic odor. | Vapor pressure: | 29 mmHg @ 68°F |
| Odor threshold: | 0.21 ppm (methyl methacrylate) | Vapor density: | 3.45 |
| pH: | Not available | Relative density: | 0.94 |
| Melting/freezing point: | -54°F (-48°C)/Not available | Solubility: | 1.5% |

| | | | |
|---|------------------------------------|--|---------------|
| Initial boiling point and range: | Not available | Partition coefficient: n-octanol/water: | Not available |
| Flash point: | 55°F (13°C) TOC | Auto-ignition temperature: | 815°F (435°C) |
| Evaporation rate: | 3.1 (Bac = 1) | Decomposition temperature: | Not available |
| Flammability: | LEL: 2.1% UEL: 12.5% | Viscosity: | Not available |
| Explosive Properties: | Vapors are explosive above the LEL | Oxidizing Properties: | None |

10. STABILITY AND REACTIVITY

Reactivity: May auto polymerize.

Chemical Stability: Unstable if heated.

Possibility of Hazardous Reactions: Polymerization can occur. Reaction with oxidizers may cause fire.

Conditions to Avoid: Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.

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

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, methyl methacrylate, and irritating smoke and fumes.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Liquid and vapors can cause moderate irritation (tears, blurred vision and redness).

Skin: May cause skin irritation with allergic skin reaction (skin sensitization).

Ingestion: Causes irritation, a burning sensation of the mouth, throat and gastrointestinal tract and abdominal pain.

Inhalation: May cause respiratory tract irritation with coughing, mucous production and shortness of breath. High concentration is irritating to the respiratory tract and may cause dizziness, headache and anesthetic effects.

Chronic Health Effects: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals, as well as kidney, lung, liver, and heart damage.

Carcinogenicity: The results of a 2-year inhalation studies conducted for NTP showed no evidence of carcinogenicity of methyl methacrylate for male rats exposed at 500 or 1,000 ppm and female rats exposed at 250, 500 or 1,000 ppm. In another study, no increase was seen in the number or type of tumors in either rats or hamsters from a chronic inhalation study. No carcinogenic activity was also reported in a chronic oral study. However, acute oral exposure studies and structure-activity relationship comparisons with other acrylates suggest that the introduction of a methyl group to the acrylate moiety (e.g., EC to MMA) negates carcinogenic activity. None of the components of this product are listed as

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| carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive. |
| Mutagenicity: Methyl Methacrylate: Negative in AMES test, positive and negative in in-vitro studies. Negative in vivo studies. |
| Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin conditions may be at increased risk from exposure. |
| Acute Toxicity Data: Methyl Methacrylate: Oral rat LD50 7800 mg/kg; Inhalation rat LC50 7093 ppm/4 hr. Ethylene Glycol Methacrylate: Oral rat LD50: 3300 mg/kg; Oral mouse LD50: 2 g/kg |
| Reproductive Toxicity Data: In a study in rats, there were no developmental effects, although there were decreases in maternal body weight following inhalation of concentrations up to 8,315 mg/m ³ . There was no reduction in fertility in a dominant lethal assay in mice exposed to this compound at concentrations up to 36,900 mg/m ³ and no adverse effects on reproductive organs in repeated dose studies conducted to date. |
| Specific Target Organ Toxicity (STOT): Single Exposure: In an inhalation study with dogs, a 2000 ppm dose showed a drop in arterial blood pressure and GI motor activities. The lethal oral dose for methyl methacrylate is 6 to 9 g/kg in lab animals. Poisoned animals exhibit respiratory depression, and coma; also irritation of skin, eyes and respiratory tract. Repeated Exposure: Methyl Methacrylate: Impairment of locomotor activity and learning and behavioral effects on the brain were observed in rats exposed orally to 500 mg/kg bw/day for 21 days. |

12. ECOLOGICAL INFORMATION

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| Toxicity: Methyl Methacrylate: Fathead minnow LC50 96h: 130 mg/L Algae EC50 48h: 170 mg/L Ethylene Glycol Dimethacrylate: No data available. |
| Persistence and Degradability: Methyl methacrylate is readily biodegradable - 88% after 28 days. |
| Bio-accumulative Potential: The potential for bioaccumulate is expected to be low for methyl methacrylate. |
| Mobility in Soil: Methyl methacrylate is expected to have very high to high mobility in soil. |
| Other Adverse Effects: None known |
| Results of PBT/vPvB Assessment: Not required. |

13. DISPOSAL CONSIDERATIONS

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|---|
| Regulations: Dispose in accordance with all national and local regulations. |
| Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers. |
| Waste Treatment Recommendations: No discharge to wastewater anticipated. |

14. TRANSPORT INFORMATION

UN Identification Number: UN1247

UN Proper Shipping Name: Methyl Methacrylate Monomer, Inhibited

Transport hazard class(es): 3

Packing Group: PG II

Special precautions for user: Take appropriate precautions to avoid release

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Flammable Liquid, Irritant, Sensitizer , Target organ effects.

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Releases above the RQ of 1,000 lbs (based on the RQ for methyl methacrylate of 1,000 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

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: | Yes |
| 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 % |
|---------------------|----------|--------|
| Methyl Methacrylate | 80-62-6 | 80-95% |

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None.

| Components | C.A.S. # | WT % |
|------------|----------------|----------------|
| None. | Not applicable | Not applicable |

International Regulations

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

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not covered by WHMIS.

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.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability– 3 Physical Hazard– 2

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

F Flammable
Xi Irritant
R11 Highly flammable.
R36/37 Irritating to eyes and respiratory tract.
R37/38 Irritating to respiratory system and skin
R43 May cause sensitization by skin contact.

Supersedes: September 21, 2007

Revision Summary: Change in format. Comprehensive review. Changes to all sections.

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

DENTSPLY International

DENTSPLY PROSTHETICS

Safety Data Sheet

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

Date Issued: 20 November 1985

Document Number: 150

Date Revised: 14 January 2014

Revision Number: 3

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

1.1 Product Identifier:

Trade Name (as labeled):

Lucitone 199® Denture Base Powder

Part/Item Number:

688103, 688203, 688303, 688403, 688105, 688205, 688305, 688405, 688106, 688206, 688306, 688406, 688111, 688211, 688311, 688411, 688102, 688107, 688120, 688220, 688320, 688420

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

Recommended Use:

Resin used in removable dental appliances.

Restrictions on Use:

For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:

Dentsply Prosthetics

Manufacturer/Supplier Address:

570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number:

717-845-7511 (Product Information)

Email address:

Prosthetics_MSDS@Dentsply.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:

800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|-----------------------------------|---------------|---------------|
| Health | Environmental | Physical |
| Skin Sensitizer Category 1 (H317) | Not Hazardous | Not Hazardous |

EU Classification: Not classified as dangerous

OSHA Specific Classification: Combustible Dust

2.2 Label Elements:



Signal Word: Warning

Contains: Benzoyl Peroxide

| Hazard Phrases | Precautionary Phrases |
|---|---|
| May form combustible dust concentrations in air. H317 May cause an allergic skin reaction. | P210 Keep away from heat, sparks, and open flames. No smoking. P261 Avoid breathing dust. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection or face protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P501 Dispose of contents and container in accordance with local and national regulations. |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # | Classification | WT % |
|------------------------|-------------|-------------|---|--------|
| Polymethylmethacrylate | Proprietary | Proprietary | Not applicable | 90-100 |
| Benzoyl Peroxide | 94-36-0 | 202-327-6 | E, O, Xi, R3, R7, R36, R43 Org. Perox. Type B, H241 Eye Irrit. 2A, H319 Skin Sens. 1, H317 | <0.5% |

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|---|
| Eye | Flush victim's eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation persists. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash occurs. Launder clothing before re-use. |
| Inhalation | Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist. |

| | |
|------------------|--|
| Ingestion | If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention. |
|------------------|--|

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

Dust may cause mild eye and respiratory irritation. May cause skin sensitization. Individuals with sensitivity to methacrylates may also 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.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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





5.2 Special Hazards Arising from the Substance or Mixture:

Dust generated in processing of this material may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust. Thermal decomposition may release carbon oxides, and methyl methacrylate.

5.3 Advice for Fire-Fighters:

| | |
|---------------------------------------|---|
| Fire Fighting Procedures: | Cool fire exposed containers and structures with water. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard. |
| Precautions for Fire Fighters: | Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus. Do not enter fire area without proper protection. |

Recommended Protective Equipment for Fire Fighters:

| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|---|---|--|---|
|  |  |  |  |

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Eliminate all sources of ignition. Avoid contact with skin, eyes or clothing. Do not breathe dust. Wear appropriate protective clothing as described in Section 8. Powders that become wet may cause surfaces to be extremely slippery and present a slip hazard.

| Recommended Personal Protective Equipment for Containment and Clean-up: | | | |
|---|---|-------------|------|
| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|  |  | | |

6.2 Environmental Precautions:

Do not allow spills to enter sewers or waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Scoop or shovel up using methods that minimize the generation of airborne dust. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue.

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. Do not breathe dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding.

Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, sources of ignition and incompatible materials. Keep container tightly closed when not in use. Keep away from oxidizing agents.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

| | | |
|------------------------|----------------|--|
| Polymethylmethacrylate | United States | 5 mg/m ³ (respirable), 15 mg/m ³ (total dust) TWA OSHA PEL (As PNOC) |
| | Germany | 4 mg/m ³ TWA DFG MAK (Inhalable) (As Dust, general threshold limit value) |
| | United Kingdom | None Established |
| | European Union | None Established |
| Benzoyl Peroxide | United States | 5 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL |
| | Germany | 5 mg/m ³ TWA (Inhalable), 5 mg/m ³ STEL (Inhalable) DFG MAK |
| | United Kingdom | 5 mg/m ³ TWA UK WEL |
| | European Union | Belgium: 5 mg/m ³ TWA |

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Provide local exhaust ventilation where product is processed in a manner that generates dust. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use only appropriately classified electrical equipment.

Individual Protection Measures (PPE):



Specific Eye/face Protection: Wear safety glasses or goggles where eye contact is possible.

Specific Skin Protection: Wear impervious gloves such as rubber to avoid skin contact.

Specific Respiratory Protection: If the exposure limits are exceeded, an approved respirator with dust/mist cartridges or supplied air 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.

Recommended Personal Protective Equipment

| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|---|---|-------------|------|
|  |  | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|---|---|--|---|
| Appearance: | Pink free flowing powder | Explosive limits: | LEL: 20 g/m3 UEL: Not determined |
| Odor: | Faint methacrylate odor | Vapor pressure (mmHg): | Not applicable |
| Odor threshold: | Not determined | Vapor density: | Not applicable |
| pH: | Not applicable | Relative density: | Not determined |
| Melting/freezing point: | Not applicable | Solubility(ies): | Not soluble |
| Initial boiling point and boiling range: | Not applicable | Partition coefficient: n-octanol/water: | Not applicable |
| Flash point: | 572°F (300°C) | Auto-ignition temperature: | >570°F (>299°C) |
| Evaporation rate: | Not applicable | Decomposition temperature: | 392°F (200°C) |
| Flammability (solid, gas): | Polymer dust is combustible | Viscosity: | Not applicable |
| Explosive Properties: | High concentrations of dust in the presence of an ignition source could result in a dust explosion. | Oxidizing Properties: | None |

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Avoid heat, sparks, flames and all other sources of ignition. Avoid hygroscopic conditions and dust formation. Avoid excessive heat (temperatures greater than 392°F (200°C)).

10.5 Incompatible materials: Oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon oxides and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Dust may cause mechanical irritation with redness and tearing.

Skin: Dust may cause irritation, redness, rash and swelling. May cause skin sensitization in sensitive individuals.

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|--|
| <u>Ingestion:</u> May cause gastrointestinal irritation with nausea, vomiting and diarrhea. |
| <u>Inhalation:</u> Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract. |
| <u>Chronic Health Effects:</u> Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals. |
| <u>Irritation:</u> Benzoyl Peroxide: Not irritating to rabbit skin and was moderately irritating to rabbit eyes after 24 hours. This product is not expected to cause eye or skin irritation. |
| <u>Corrosivity:</u> No data available. This product is not expected to be corrosive. |
| <u>Sensitization:</u> Benzoyl Peroxide: Benzoyl peroxide was found to be sensitizing in a mouse local lymphnode assay (LLNA). Individuals with sensitivity to methacrylates may develop an allergic reaction. |
| <u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive. |
| <u>Mutagenicity:</u> No data available. |
| <u>Medical Conditions Aggravated by Exposure:</u> Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure. |
| <u>Acute Toxicity Data:</u> Polymethylmethacrylate: No toxicity data available. Benzoyl Peroxide: Oral rat LD50 ->5,000 mg/kg; Inhalation rat LD50 ->24.3 mg/L/4hr |
| <u>Reproductive Toxicity Data:</u> No data available |
| <u>Specific Target Organ Toxicity (STOT):</u> <u>Single Exposure:</u> No data available <u>Repeated Exposure:</u> No data available |

12. ECOLOGICAL INFORMATION

| |
|---|
| 12.1 Toxicity: Benzoyl Peroxide: 96 hr LC50 Rainbow Trout – 0.0602 mg/L; 48 hr EC50 Daphnia magna- 0.0602 mg/L |
| 12.2 Persistence and Degradability: Benzoyl Peroxide: Readily biodegradable in screening tests – 68% in 28 days. This product is expected to not be biodegradable. |
| 12.3 Bio-accumulative Potential: No data available |
| 12.4 Mobility in Soil: No data is available |
| 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:

| |
|--|
| <u>Regulations:</u> Dispose in accordance with all national and local regulations. |
| <u>Properties (Physical/Chemical) Affecting Disposal:</u> Empty containers retain product residues and may be hazardous. Follow all SDS precautions when handling empty containers. |

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:

| | | | |
|--------------------------|-----|---------------------------|----|
| Immediate Hazard: | Yes | 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 substances known to the state of California to cause cancer and/or reproductive toxicity:

| Components | C.A.S. # | WT % |
|------------------|------------|-------|
| Titanium Dioxide | 13463-67-7 | <0.1% |

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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 – 2 Physical Hazard – 0

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

E Explosive

O Oxidizing

Xi Irritant

R3 Extreme risk of explosion by shock, friction, fire or others sources of ignition.

R7 May cause fire.

R36 Irritating to the eyes.

R43 May cause sensitization by skin contact.

Eye Irrit. 2A Eye Irritant Category 2A

Org. Perox. Type B Organic Peroxide Category Type B

Skin Sens. 1 Skin Sensitizer Category 1

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Supersedes: 16 March 2011

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.