

MATERIAL SAFETY DATA SHEET

SECTION I - PRODUCT IDENTIFICATION

PRODUCT NAME: Cobalt™ MV and Cobalt™ MV with gentamicin Bone Cements

DOT/UN SHIPPING NAME: Methyl Methacrylate monomer inhibited
Class 3, UN 1247, Packing Group II

USE RESTRICTED TO LICENSED PHYSICIAN ONLY

MANUFACTURER: BIOMET MANUFACTURING, INC.
ADDRESS: P.O.BOX 587
WARSAW, IN 46581-0587

FOR INFORMATION CALL: 574 267-6639 During Business Hours
574 267-8850 At All Other Times

REVISION DATE: 7/7/09

UPDATED BY: IKM.

SECTION II - INGREDIENTS OF MIXTURE

| COMPONENT | CAS NO | % | TLV (UNITS) | PEL (UNITS) |
|---------------------------|------------|--------|----------------------------|----------------------|
| Liquid Component | | | | |
| Methyl Methacrylate | 80-62-6 | 98 | 100 ppm | 100 ppm |
| N,N-Dimethyl-P-Toluidine | 99-97-8 | 2 | NE | NE |
| Hydroquinone | 123-31-9 | 0.006 | 2 mg/m ³ | 2 mg/m ³ |
| Powder Component | | | | |
| Copolymer | 25034-86-0 | 65-75 | 10 mg/m ³ | 15 mg/m ³ |
| Polymethyl methacrylate ~ | 9011-14-7 | 10-25 | 10 mg/m ³ | 15 mg/m ³ |
| Zirconium Dioxide | 1314-23-4 | 10 | 5 mg/m ³ | 5 mg/m ³ |
| Benzoyl Peroxide | 94-36-0 | < 2 | 5 mg/m ³ | 5 mg/m ³ |
| FD&C Blue #2 Alum. Lake | 16521-38-3 | < 0.15 | (not defined as hazardous) | |

In Cobalt MV with Gentamicin Bone Cement:

Gentamicin sulfate 1405-41-0 2 (not defined as hazardous)

This product contains Methyl Methacrylate Monomer and Hydroquinone, which are subject to the reporting requirements of the Emergency Planning and Community Right-to Know Act of 1986 (SARA 313) and 40 CFR 372. OSHA defines these materials as hazardous under 29 CFR 1910.1200.

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SECTION III – PHYSICAL DATA

LIQUID COMPONENT

BOILING POINT: 101 °C, 214 °F **SPECIFIC GRAVITY:** (H₂O=1): 0.94

VAPOR PRESSURE: 29 mm Hg @ 20 °C **PERCENT VOLATILE W/W%:** 99+
68 °F

VAPOR DENSITY (AIR=1): 3.5 @ 16 °C **EVAPORATION RATE:** (BuAc=1): 3.0
60 °F

SOLUBILITY IN WATER: Moderate 1.6 gm/100 gm @ 20 °C, 68 °F

APPEARANCE AND ODOR: Clear, acrid fruity odor (Odor threshold 0.21 ppm).

POWDER COMPONENT

BOILING POINT: NA **SPECIFIC GRAVITY:** (H₂O=1): 1.2

VAPOR PRESSURE: NE **PERCENT VOLATILE W/W%:** NE

VAPOR DENSITY: NA **EVAPORATION RATE:** NA

SOLUBILITY IN WATER: Insoluble.

APPEARANCE AND ODOR: Fine, light blue powder. Faint odor in bulk.

SECTION IV – FIRE AND EXPLOSION HAZARD DATA

LIQUID COMPONENT

FLASH POINT: 10 °C, 51 °F **FLAMMABLE LIMIT, AIR VOL% LOWER:** 2.12
UPPER: 12.5

AUTOIGNITION TEMPERATURE: 435 °C, 815 °F

EXTINGUISHER METHOD: Chemical Foam, Carbon Dioxide, Dry Chemical.

SPECIAL FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus, and full protective gear.

EXPLOSION HAZARD: Fight fire from protected location.

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SECTION IV – FIRE AND EXPLOSION HAZARD DATA CONTINUED

UNUSUAL FIRE AND EXPLOSION HAZARDS: When above the flashpoint, flammable vapors emitted can mix with air and burn, or be explosive. Vapors are heavier than air and may travel to the source of ignition and flash back. Heat can cause polymerization with rapid release of energy. (Spontaneous polymerization may occur on prolonged storage).

POWDER COMPONENT

FLASH POINT: 304 °C, 580 °F **FLAMMABLE LIMIT, AIR VOL% LOWER:** NA

AUTOIGNITION TEMPERATURE: NA **UPPER:** NA

EXTINGUISHER METHOD: Water, Carbon Dioxide, Dry Chemical.

SPECIAL FIRE FIGHTING PROCEDURES: Avoid extinguishing methods that may generate dust clouds. Water stream can disperse dust into air, producing a fire hazard and possible explosion hazards if exposed to ignition source.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Polymer dust is combustible. The explosive limits of the polymer particles suspended in air are approximately those of coal dust. Firefighters should wear self-contained breathing apparatus.

SECTION V – HEALTH HAZARD DATA

PRIMARY ROUTES OF ENTRY: Inhalation, skin and eyes.

CARCINOGENICITY: Hydroquinone is listed as a suspect carcinogen by NTP. IARC lists Benzoyl Peroxide as unclassifiable as to carcinogenicity to humans. None of the other components of this material are listed by IARC, NTP, OSHA, or AClGH as carcinogens.

TARGET ORGANS: For Methyl Methacrylate: Nose, liver and kidneys. For Hydroquinone: Kidneys and eyes. For Zirconium Dioxide: Lungs.

THRESHOLD LIMIT VALUE (TLV): For Methyl Methacrylate monomer: 100 ppm. For Zirconium Oxide: 5 mg/m³. For Benzoyl Peroxide: 5 mg/m³. For Hydroquinone: 2 mg/m³.

PERMISSIBLE EXPOSURE LIMIT (PEL): For Methyl Methacrylate monomer: 100 ppm. For Zirconium Oxide: 5 mg/m³. For Benzoyl Peroxide: 5 mg/m³. For Hydroquinone: 2 mg/m³.

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SECTION V – HEALTH HAZARD DATA CONTINUED

TOXICITY INFORMATION: For Methyl Methacrylate Monomer: LD₅₀ Acute Oral Rat: 7990 mg/kg. LD₅₀ Acute Dermal Rabbit: 35,500 mg/kg. LC₅₀ Acute Inhalation Rat: >12,500 to 16,500 ppm for 0.5 hours. TC_{LO} Inhalation Human: 60 mg/m³. Human patch test: Approximately one-third of subjects developed mild redness at the site of application. Twenty percent showed sensitivity when tested 10 days later. Reproductive Effects: TC_{LO} Inhalation Rat: 109 gm/m³/54 minutes, 6-15 days of pregnancy. TC_{LO} Inhalation Rat: 54 mg/m³/24 hours, 8 weeks of pregnancy. TC_{LO} Inhalation Rat: 4480 mg/m³/2 hours, 6-18 days of pregnancy. RTECS: OZ50750000. TSCA: 1986. EINECS: Listed.

For Substituted Toluidine: LD₅₀ Intraperitoneal Mouse: 212 mg/kg. RTECS: XU5805000. TSCA: 1986. EINECS: Listed.

For Hydroquinone: LD human, adult: 70-170 mg/kg. LD human, child: 2.4-4.0 mg/kg. LD₅₀ Acute oral rat: 400 mg/kg. LD₅₀ Acute oral, mouse: 100-200 mg/kg. LD₅₀ Dermal, guinea pig: >1000 mg/kg. Eye irritation, rabbit: Moderate erythema clearing by day 14. RTECS: MX3500000. TSCA: 1986. EINECS: Listed.

For Benzoyl Peroxide: LD_{LO} Intraperitoneal Mouse: 250 mg/kg. LD₅₀ Oral Rat: 7710 mg/kg. RTECS: DM8575000. TSCA: 1986. EINECS: Listed.

EFFECTS OF OVER EXPOSURE: For Methyl Methacrylate Monomer: Liquid or high vapor concentration can irritate eyes, respiratory system and cause skin rashes. Prolonged exposure can lead to headaches, nausea, staggering gait, confusion, drowsiness and unconsciousness. Repeated and prolonged over exposure may cause permanent brain and nervous system damage, allergic skin rashes, eye corrosion and permanent injury, as well as changes in liver and kidney function or damage.

For Substituted Toluidine: Liquid is rapidly absorbed through skin. Absorption of this product into the body causes the formation of methemoglobin, which in sufficient concentration causes cyanosis; symptoms include headache, dizziness, nausea and abdominal pain. In case of blue discoloration (cyanosis) of skin, lips or fingernails, give oxygen to breathe. No alcohol or physical exertion. Contact a physician.

For Hydroquinone: May irritate eyes, may cause contact dermatitis and may cause cases of poisoning, however, 300-500 mg/day/5 months caused no abnormalities in studies of blood and urine.

For Polymer: OSHA classifies this material as Particulates, Not Otherwise Classified. Eyes, Skin and Respiratory Tract may be irritated by gross overexposure to particulates, no matter how they were generated. Avoid inhalation of dust. Keep dust out of eyes to prevent possible irritation.

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SECTION V – HEALTH HAZARD DATA CONTINUED

For Zirconium Dioxide: May be harmful if inhaled. May cause eye irritation. Chronic over exposure may do damage to the lungs. Prolonged inhalation may cause benign pneumoconiosis.

For Benzoyl Peroxide: Prolonged skin contact may cause skin irritation. May cause eye irritation or damage. Dust may cause irritation of the nose, throat and lungs. May produce muscular weakness upon ingestion.

EMERGENCY AND FIRST AID PROCEDURES:

LIQUID COMPONENT

| | |
|-------------|--|
| INHALATION: | Remove to fresh air. If breathing has stopped give oxygen. Get medical help if discomfort persists. |
| EYES: | Flush with water for 15 minutes, including under eyelids. Contact a physician. |
| SKIN: | Wash thoroughly with soap and water. Remove contaminated clothing. Contact a physician. |
| INGESTION: | Do not induce vomiting. Dilute with 2 glasses of water. Never give anything to an unconscious person. Contact a physician. |
| CLOTHING: | Wash thoroughly before reuse. |
| TREATMENT: | Treat symptoms conventionally after decontamination. |

EMERGENCY AND FIRST AID PROCEDURES:

POWDER COMPONENT

| | |
|-------------|--|
| INHALATION: | Remove to fresh air. Get medical help if discomfort persists. |
| EYES: | Flush with water for 15 minutes, including under eyelids. Get medical help if discomfort persists. |
| SKIN: | Wash with soap and water. Get medical help if discomfort persists. |
| INGESTION: | Rinse mouth out with water. Call doctor if amount was large. |
| CLOTHING: | Wash before reuse. |
| TREATMENT: | Treat symptoms after thorough decontamination. |

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SECTION V – HEALTH HAZARD DATA CONTINUED

HAZARDOUS MATERIAL IDENTIFICATION SYSTEMS (HMIS) RATING:

LIQUID COMPONENT

| | |
|--------------------------------|--|
| HEALTH: | 2 |
| FLAMMABILITY: | 3 |
| REACTIVITY: | 2 |
| PERSONAL PROTECTIVE EQUIPMENT: | Gloves and Chemical Splash Goggles or Safety Glasses |

POWDER COMPONENT

| | |
|--------------------------------|--|
| HEALTH: | 1 |
| FLAMMABILITY: | 1 |
| REACTIVITY: | 0 |
| PERSONAL PROTECTIVE EQUIPMENT: | Gloves and Chemical Splash Goggles or Safety Glasses |

SECTION VI – REACTIVITY DATA

LIQUID COMPONENT

STABILITY: UNSTABLE: X STABLE:

CONDITIONS TO AVOID: Heat above 77 °F (23 °C), sources of ignition, aging and contamination.

INCOMPATIBILITY (MATERIALS TO AVOID): Reducing agents, oxidizing agents and UV light. Material has strong solvent properties and can soften paint and rubber.

HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of Carbon when burned.

HAZARDOUS POLYMERIZATION: MAY OCCUR: X WILL NOT OCCUR:

CONDITIONS TO AVOID: Temperatures above 77 °F (23 °C), oxidizing or reducing agents, peroxides, acids, alkalies and amines.

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SECTION VI – REACTIVITY DATA CONTINUED

POWDER COMPONENT

STABILITY: UNSTABLE: STABLE: X

CONDITIONS TO AVOID: Temperatures above 77 °F (23 °C). Heating above 464 °F (240 °C) may cause decomposition of polymer.

INCOMPATIBILITY (MATERIALS TO AVOID): Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS: Methacrylate and styrene Monomers, and Oxides of Carbon when burned.

HAZARDOUS POLYMERIZATION: MAY OCCUR: WILL NOT OCCUR: X

CONDITIONS TO AVOID: NA

SECTION VII – SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

LIQUID COMPONENT

Eliminate sources of ignition. Use self-contained breathing apparatus if ventilation is inadequate. Dike and absorb with inert material. Transfer to proper containers for disposal in accordance with the regulations of local authorities. Keep spills and cleaning runoffs out of sewers and open bodies of water.

POWDER COMPONENT

Sweep up to avoid slipping hazard. Keep airborne particulate at a minimum when cleaning up spills.

ENVIRONMENTAL EFFECTS:

AQUATIC TOXICITY: For Methylmethacrylate Monomer: Estimate of 96 hours median Threshold limit (TL_{m96}): 100-1000 ppm. Flathead minnows and goldfish TL_{m24}: 420 ppm. Bluegills TL_{m24}: 368 ppm.

For Hydroquinone: 96 hr LC₅₀, flathead minnows: 0.1-0.8 mg/L. 48 hr LC₅₀, goldfish: 0.287 mg/L. 48 hr LC₅₀, golden orfe: 0.16 mg/L. 48 hr LC₅₀, rainbow trout: 0.097 mg/L. 48 hr LC₅₀, water flea: 0.032-0.32 mg/L.

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SECTION VII – SPILL OR LEAK PROCEDURES CONTINUED

WASTE DISPOSAL METHOD:

LIQUID COMPONENT

Incinerate liquid and diking material, in accordance with Federal, State and Local regulations. Do not allow liquid to enter sewers or open bodies of water. Small quantities can be mixed with cement powder component according to instructions for use, and the cured, solid material can be disposed of in landfill or incinerated.

POWDER COMPONENT AND CURED CEMENT

May be disposed of in landfill or incinerated. Follow Federal, State and Local regulations for disposal.

SECTION VIII – SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: Avoid breathing particulate and vapors generated by the liquid component. Use particulate mask if necessary. Use self-contained breathing apparatus when needed or when methyl methacrylate vapor level exceeds 100 ppm.

VENTILATION: Use local good explosion-proof ventilation with a minimum capture velocity of 100 ft/ min (30 m/min) at point of monomer release. Refer to Industrial Ventilation: A Manual of Recommended Practice published by the American Conference of Governmental Industrial Hygienists. Local exhaust ventilation is preferred since it prevents contamination dispersion into the work area by controlling it at its source.

PROTECTIVE GLOVES: Impervious.

EYE PROTECTION: Safety glasses or chemical splash goggles.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Provide eyewash, safety shower and impervious clothing. Protective creams should not be used for protection, but may be used for ease of clean up.

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SECTION IX – SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: Observe precautions found on the label. Store in a dark, dry, ventilated area between 6 and 23°C (43 and 77°F). Use explosion-proof equipment when liquid vapors are generated.

OTHER PRECAUTIONS: Wash face and hands thoroughly with soap and water after handling and before eating, drinking and smoking.

SECTION X – ADDITIONAL INFORMATION

The information on this Material Safety Data Sheet has been assembled by the manufacturer based on its own study and on the work of others. Seller makes no warranty or representation of any kind, express or implied, concerning the product, including **NO IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS OF THE GOODS FOR ANY OTHER PARTICULAR PURPOSE.** No such warranties shall be implied by law and no agent of seller is authorized to alter this warranty in any way except in writing with a specific reference to this warranty.