

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION



Great Lakes Orthodontics
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CHEMTREC: 800-424-9300

Product Name: Variflex Monomer Kit
Product Number: 046-003, 046-005 046-001, 046-002

Effective Date: 12/13/12

SECTION 2. HAZARDOUS IDENTIFICATION

- **Physical Hazards (Monomer)** – Unstable / reactive upon depletion of inhibitor. Check inhibitor levels periodically.

Potential Health Effects:

Primary Routes of Entry

- Inhalation
- Skin Contact
- Eye Contact

Human Effects and Symptoms of Overexposure:

Skin

Acute – Material may be irritating to the skin. Prolonged exposure may cause more serious effects. Excessive exposure with skin absorption may be harmful. The irritancy of this material varies from person to person and may be the result of the substances skin sensitization and defatting potential. The material may be skin sensitizer and may cause allergic reactions and contact dermatitis in susceptible individuals, resulting in severe irritation, dryness, and cracking of the skin. Irritation or allergic reactions may not necessarily be immediately apparent – effects may be delayed.

Ingestions

May be irritating or toxic if product is swallowed. Symptoms may include nausea, headache, vomiting, and diarrhea, central nervous system effects, burning sensation of the mouth, throat, and respiratory tract, abdominal pain and perhaps unconsciousness. Can also cause liver and kidney injury.

Eyes

Acute – Material (including vapors) may be irritating to the eyes. Eye contact may cause irritation with discomfort, tearing, or blurring of vision. More serious effects, including corneal damage and permanent injury, may result if exposure is not treated.

Inhalation

Vapors may be irritating to the upper respiratory tract, including nasal tissues. High concentrations irritate the respiratory tract and may cause dizziness, headache, and anesthetic effects. Prolonged (hours) exposure may be harmful and cause adverse effects including labored breathing, drowsiness, headaches, nausea, staggering gait, confusion, central nervous system, depression, narcosis, convulsions, and unconsciousness, as well as damage to the upper respiratory tract.

Chronic Effects or Exposure

None listed.

Carcinogenicity

2-Hydroxyethyl Methacrylate contains trace amounts of Ethylene Oxide, a substance known to the state of California to cause cancer and/or reproductive toxicity. Trimethylolpropane Trimethacrylate may contain trace quantities of substances known to the state of California to cause cancer and/or reproductive toxicity. ACGIH lists Acetone as not classifiable as a human carcinogen. All carcinogen studies for all types of cancers were negative. None of the other components of this material are listed by IARC, NTP, OSHA, or ACGIH as carcinogens.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Hazardous Components</u>	<u>CAS #</u>	<u>WT / WT%</u>
EOEMA	2370-63-0	10.0 – 50.0
Ethyl Methacrylate Monomer	97-63-2	10.0 – 50.0
Dioctyl Maleate	142-16-5	10.0 – 50.0
2-Hydroxyethyl Methacrylate	868-77-9	0.0 – 10.0
Trimethylolpropane Trimethacrylate	3290-92-4	0.0 – 10.0
Acetone	67-64-1	0.0 – 10.0

ACGIH	TLV-TWA	TLV-STEL
EOEMA	NOT ESTABLISHED	
Ethyl Methacrylate Monomer	↓	
Dioctyl Maleate	↓	
2-Hydroxyethyl Methacrylate	↓	
Trimethylolpropane Trimethacrylate	↓	
Acetone	500ppm	750ppm

OSHA	PEL TWA	PEL CEILING
EOEMA	NOT ESTABLISHED	
Ethyl Methacrylate Monomer	↓	
Dioctyl Maleate	↓	
2-Hydroxyethyl Methacrylate	↓	
Trimethylolpropane Trimethacrylate	↓	
Acetone	1000PPM	Not Established

	Company Recommendation	Skin
EOEMA	10ppm	Not Established
Ethyl Methacrylate Monomer	100ppm	↓
Dioctyl Maleate	Not Established	
2-Hydroxyethyl Methacrylate	Not Established	
Trimethylolpropane Trimethacrylate	Not Established	
Acetone	500ppm	

*NOTE: this material contains an inhibitor (HQ, MEHQ, etc.) at <1%. The type and amount meet product specifications. Contact manufacturer for exact concentration and details on inhibitor level maintenance.

SECTION 4. FIRST AID MEASURES

Eye Contact

If product gets in the eyes, flush with copious amounts of lukewarm water for at least 15 minutes. If irritation occurs, contact a physician.

Skin Contact

If irritation occurs and product is on the skin, rinse thoroughly with lukewarm water, followed by a thorough washing of the affected area with soap and water. If irritation, redness, or swelling persists, contact a physician immediately.

Inhalation

Remove to fresh air. See immediate medical attention.

Ingestion

If ingested, do not induce vomiting. If product has been swallowed, drink plenty of water or milk IMMEDIATELY. If the patient is vomiting, continue to offer water or milk. Never give anything by mouth to an unconscious person. Provide an estimate of the time at which the material was ingested and the amount of the substance that was swallowed. Get medical attention immediately.

Clothing

Remove contaminated clothing, was thoroughly before reuse. Treat symptoms conventionally, after thorough decontamination.

Treatment

Treat symptoms conventionally, after thorough decontamination.

SECTION 5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media

Chemical foam, Dry chemical, Carbon Dioxide (CO₂). For large fires alcohol resistant foams are preferred.

Special Fire Fighting Procedures

This product is a flammable liquid. When involved in a fire, this product may ignite readily and decompose to produce carbon oxides. Vapors of this product are heavier than air and may travel to a source of ignition and flash back to a leaking or open container. Do not enter fire area without proper protection. Fight fire from a safe location. Heat / impurities may cause pressure to build and/or rupture closed containers, spreading fire, increasing risk of burns/injuries. Structural firefighters must wear SCBAs and full protective equipment.

Unusual Fire / Explosion Hazards

High temperatures, inhibitor depletion, accidental impurities, or exposure to radiation or oxidizers may cause spontaneous polymerizing reaction generating heat / pressure. Closed containers may rupture or explode during a runaway polymerization. Use a water spray or fog to reduce or direct vapors. Water may not be effective in actually extinguishing a fire involving this product.

- **Sensitive to mechanical impact:** NO
- **Sensitive to static discharge:** YES

SECTION 6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Procedures

Before cleaning any spill or leak, individuals involved must wear appropriate personal protective equipment (e.g.: goggles, gloves). Deny entry to all unprotected individuals. Dike and contain spill with inert material (e.g.: sand and earth). Use ONLY non-sparking tools for recovery and cleanup. Maximize ventilation (open doors and windows) and secure all sources of ignition. Place into appropriate closed container(s) for disposal in accordance with local, state, and federal regulations. Wash all affected areas with plenty of warm water and soap. Remove any contaminated clothing and wash thoroughly before reuse. Keep spills and cleaning runoffs out of municipal sewers and open bodies of water.

SECTION 7. HANDLING & STORAGE

Handling Precautions

Use local explosion-proof ventilation with a minimum capture velocity of 100 ft. /min (30 m/min) at point of material release. Refer to industrial ventilation: A Manual of Recommended Practice published by the American Conference of Governmental Hygienist. Observe precautions found on label. Use explosion-proof equipment. During some processing and use conditions of this monomer or its downstream products (especially at high temperatures or very low or high PH conditions), it is possible that 2-ethoxy ethanol may evolve.

Storage Precautions

Store containers in a cool, dry location, away from direct sunlight, heat, sparks, flame, other light sources, or sources of intense heat. Keep container closed after each use. Ground and bond all containers when transferring. Check inhibitor levels periodically, add to the bulk material if needed. Maintain at a minimum, the original headspace in the product container. Do not blanket or mix with oxygen-free gas as it renders the inhibitor ineffective.

Industrial Hygiene

Avoid contact with skin, eyes, clothing, and prolonged contact with the product. Use good personal hygiene and housekeeping. After use, wash hands and exposed skin with soap and water. Do not eat, drink, or smoke while handling product.

Ventilation Measures

Refer to section #7 regarding ventilation requirements for working with this product. Use explosion-proof local exhaust at processing equipment, including buffers, sanders, grinders, and polishers. High temperature processing equipment should be well ventilated.

Respiratory Protection

Respirator equipped with organic vapor cartridges are anticipated to provide adequate respiratory protection during short-term exposures to low concentrations of the material. Workers should wear air-supplied respirator or self-contained breathing apparatus any time exposure is above low levels or during extended periods of exposure periods. If necessary, use only respiratory protection authorized per U.S. OSHA's requirement in 29 CFR 1910.134 or other appropriate governing standard.

Hand Protection

If anticipated that prolonged and repeated skin contact will occur during use of this product, wear chemical resistant gloves for routine industrial use. Gloves made of Butyl Rubber are anticipated to afford adequate hand protection. Gloves made of PVC, nitrile, and neoprene are not expected to provide adequate hand protection. If necessary, refer to U.S. OSHA's requirement in 29 CFR 1910.138 or other appropriate governing standards.

Eye Protection

Depending on the use of this product, splash or safety glasses may be worn. Chemical safety goggles should be worn whenever there is the possibility of contact with the eyes. Spectacle type safety glasses do not provide satisfactory protection. Wear plastic face shield in addition to safety goggles where there is a danger of splashing. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or other appropriate governing standard. Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes.

Additional Protective Measures

Wear protective clothing and boots impervious to the product for the duration of the anticipated exposure if there is a potential for skin contact. If necessary, refer to appropriate governing standards. An eyewash station and a safety shower are recommended.

SECTION 9. PHYSICAL & CHEMICAL PROPERTIES

- **Appearance** – Liquid
- **Color** – Clear colorless
- **Odor** – Ester odor
- **PH** – Not determined
- **Flash Point (Acetone)** – -18 °C (0 °F)
- **Lower Explosion Limit** – 1.8
- **Upper Explosion Limit** – Saturation concentration.
- **Boiling Point** – Not determined
- **Freezing Point** – Not established
- **Viscosity** – Not established
- **Vapor Pressure** – 29 mm Hg @ not established
- **Percent Volatile W/W%** - Not established
- **Vapor Density (AIR=1)** – Not established
- **Evaporation Rate (BuAc=1)** – Not established
- **Solubility in Water** – Negligible
- **Auto-ignition Temperature** - 411 °C (771 °F)

SECTION 10. STABILITY & REACTIVITY

Hazardous Reactions – Hazardous polymerization may occur.

Stability – Unstable / Reactive upon depletion of inhibitor.

Materials to Avoid – Strong oxidizers, strong reducers, free radical initiators, inert gases, oxygen scavengers. Material has strong solvent properties and can soften paint and rubber.

Conditions to Avoid – Temperatures above 21 °C (70 °F), localized heat sources (example drum or band heaters) oxidizing conditions, freezing conditions, direct sunlight, ultraviolet radiation, inert gas blanketing.

Hazardous Decomposition Products – Oxides of Carbon when burned.

SECTION 11. TOXICOLOGICAL INFORMATION

Toxicity Data - This product has not been tested on animals to obtain toxicology data. There is toxicology data for the components of the product, which is found in scientific literature. Some of this data is presented below.

Toxicity Data for EOEMA

Acute oral toxicity

- LD50: > 2,000 mg/kg (Rat)

Acute dermal toxicity

- LD50: > 2,000 mg/kg (Dermal Rabbit)

Toxicity Data for Dioctyl Maleate

Acute oral toxicity

- LD50: 14,000 mg/kg (Rat)

Acute dermal toxicity

- LD50: 14,154 mg/kg (Dermal Rabbit)

Toxicity Data for Ethyl Methacrylate

Acute oral toxicity

- Rat

Acute dermal toxicity

- LD50: > 10,000 mg/kg (Dermal Rabbit)

Inhalation

- LC50: 8,300 ppm/4H (Rat)

Intraperitoneal

- LD50: 1,369 mg/kg (Mouse)
- LD50: 1,223 mg/kg (Rat)

Toxicity Data for 2-Hydroxyethyl Methacrylate

Acute oral toxicity

- LD50: 3,275 mg/kg (Mouse)
- LD50: 5,050 mg/kg (Rat)
- LD50: 4,680 mg/kg (Guinea Pig)

Intraperitoneal

- LD50: 497 mg/kg (Mouse)
- LD50: 1,250 mg/kg (Rat)

Toxicity Data for Trimethylolpropane Trimethacrylate

Intraperitoneal

- LD50: 2,889 mg/kg (Mouse)

Acute dermal toxicity

- LD50: > 2,000 mg/kg (Dermal Rabbit)

Toxicity Data for Acetone

Inhalation

- TCLO: 500 ppm (Human)
- LC50: 50,100 mg/m³ 8H (Rat)

Intraperitoneal

- LDLO: 8 gm/kg (Dog)
- LD50: 1,297 mg/kg (Mouse)
- LD50: 500 mg/kg (Rat)

Intravenous

- LD50: 5,500 mg/kg (Rat)
- LDLO: 1,576 mg/kg (Rabbit)

Oral

- LDLO: 8 gm/kg (Dog)
- TDLO: 2,857 mg/kg (Man)
- LD50: 3,000 mg/kg (Mouse)
- LD50: 5,800 mg/kg (Rat)
- LD50: 5,340 mg/kg (Rabbit)

Subcutaneous

- LDLO: 5gm/kg (Dog)
- LD50: 5,000 mg/kg (Guinea Pig)

Skin

- LD50: 20mL/kg (Rabbit)

Eye Irritation Data (EOEMA)

This compound produced slight eye irritation when tested in rabbits.

Skin Irritation Data (EOEMA)

This compound produced slight skin irritation when tested in rabbits during a 4-hour exposure period. This compound did not produce skin sensitization when tested in Guinea pigs.

Sub-chronic Data (EOEMA)

No sub-chronic data is available for this product. The anticipated pathway for the metabolism of this product in humans may be de-esterification resulting in the metabolite, 2-ethoxy ethanol. The compound 2-ethoxy ethanol may cause blood, bone marrow and organ effects. Contact company for additional information.

Target Organs

- Monomers – None listed.
- Acetone – Liver, kidneys, and central nervous system.

Mutagenicity Data

- **EOEMA** – This compound produced negative results in the vitro Ames test. The acrylate analog, 2-ethoxyethyl acrylate, has been found to be positive in in-vitro mutagenicity assays.
- **Trimethylolpropane Trimethacrylate** – Mouse lymphoma studies indicate that this material may have a mutagenic potential. However the Ames assay for mutagenicity was negative. Therefore, there is reason to believe that the mouse lymphoma assay was a false positive.
- **Acetone** –
 - Fibroblast Hamster – Cytogenetic Analysis = 40 gm/L.
 - S Cerevisitae – Sex Chromosome Loss and Non-disjunction = 47,600ppm.

Reproductive Toxicity Data

- **EOEMA** –
 - Embryo toxicity – This product is not reported to produce embryo toxic effects in humans.
 - Teratogenicity – No teratogenicity data is available for this product. The anticipated pathway for the metabolism of this product in humans may be de-esterification resulting in the metabolite, 2-ethoxy ethanol. The compound 2-ethoxy ethanol has been found to be teratogenic in animal embryotoxicity, reduced fetal body weights, minor skeletal and cardiovascular effects, delayed onset of labor, and increased fetal resorptions. Contact company for additional information.
 - Reproductive Toxicity – No reproductive data is available for this product. The anticipated pathway for the metabolism of this product in humans may be de-esterification resulting in the metabolite, 2-ethoxy ethanol. The compound 2-ethoxy ethanol has been found to be a reproductive toxicant in animals including effects on the testes (and possibly ovaries), reduced sperm counts, and abnormal sperm morphology. Contact company for additional information.
- **Ethyl Methacrylate Monomer** –
 - No information available.
- **Trimethacrylate** –
 - Embryotoxicity – This product is not reported to produce embryo toxic effects in humans.
 - Teratogenicity – This product is not reported to cause teratogenic effects in humans.
 - Reproductive Toxicity – This product is not reported to cause reproductive effects in humans.
- **Acetone** –
 - Inhalation Mammal: TCLO 31,500 – $\mu\text{g}/\text{m}^3$ 24H 1-13 days pregnant.

SECTION 12. ECOLOGICAL INFORMATION (non-mandatory)

There is no specific data available for this product; however, very large releases of this product may be harmful or fatal to overexposed aquatic life. There is ecological data for the components of the product which is found in scientific literature. Some of this data is presented below.

Aquatic Toxicity

EOEMA – slightly toxic to fish, Daphnia, and algae. Low potential to bio-accumulate. Not expected to be readily biodegradable. Short (hours) atmospheric half-life.

- LC50: 27.7 mg/L, 96 H (Fish)
- EC50: 170 mg/L, 48H (Daphnia)
- LC50: 37 mg/L, 72H (Algae)
- Chronic Fish: 0.5 mg/L 32 days

Ethyl Methacrylate Monomer

- EC50: > 66 mg/L, 48 H (Daphnia Magna)
- LC50: 100 mg/L, 96H (Rainbow Trout)
- EC50: > 0.70 mg/L, 72H (Algae)

2-Hydroxyethyl Methacrylate

- LC50: 227 mg/L, 96H (Flathead Minnows)

Acetone

- LC50: >100 mg/L, 96H (Flathead Minnows)

Environmental Fate (Methyl Methacrylate)

EOEMA – This substance was not found to be readily biodegradable. The BCF is predicted to be 2.8.

Ethyl Methacrylate Monomer – Biodegradation: Inherently biodegradable 79% in 28 days.

Acetone –

- Biodegradation (soil) – Readily biodegradable when released to soil. It is expected to leach to the groundwater. It is expected to evaporate quickly.
- Biodegradation (water) – Readily biodegradable when released to water. It is expected to evaporate quickly.

Physical / Chemical Properties

EOEMA

The Log Kow was found to be 1.36. The Henry's Law constant is predicted to be 8.48×10^{-7} atm*m³/mol. Insoluble in water. The Koc is predicted to be 12.7.

SECTION 13. DISPOSAL CONSIDERATIONS (non-mandatory)

Waste Disposal Method

If discarded in its manufactured form, this product may be a characteristic hazardous waste under RCRA. After addition of excess inhibitor, dispose waste material in accordance with Federal, State, and Local regulations.

Disposal of Empty Containers

Reuse of empty drums or containers is not recommended. Employees should be advised of the potential hazards, due to residual flammable material associated with empty containers. Dispose of all empty containers properly in accordance with Federal, State, and Local regulations.

SECTION 14. TRANSPORT INFORMATION (non-mandatory)

- **DOT / UN Shipping Name** – Flammable Liquid, NOS (Acetone, Ethyl Methacrylate, Stabilized)
- **DOT / UN Class** - 3
- **NA/UN Number** - 1993
- **Packing Group** – II
- **Label** – Flammable Liquid
- **IMDG Class** – 3
- **CERCLA RQ** – For Ethyl Methacrylate = 1000lbs
For Acetone = 1000lbs

SECTION 15. REGULATORY INFORMATION (non-mandatory)

SARA Reporting Requirements – YES

SARA Threshold Planning Quantity – There are specific threshold planning quantities for the components of this product. This substance, 2-ethoxyethyl Methacrylate is subject to the reporting requirements of Section 313 of the Emergency Planning and Community Right To Know Act because the substance meets the definition of the glycol ethers category.

TSCA Inventory Status – The components of this product are listed on the TSCA inventory.

Other Federal Requirements – This product complies with the appropriate sections of the Food and Drug Administration’s 21 CFR.

Other Canadian Requirements – This product has been classified according to the hazard criteria of the CPR and the SDS contains all of the information required by the CPR. The components of this product are listed on the DSL/NDSL. None of the components of this product are listed on the Priorities Substances List.

State Regulatory Information – This product may contain components that are covered under specific state criteria. This product contains ethylene glycol monoethyl ether (2-ethoxy ethanol), a substance known to the State of California to cause reproductive toxicity. The maximum amount of ethylene glycol monoethyl ether is 200ppm. This information is provided to assist users of this product that conduct business in California.

RISK STATEMENTS

- R11 – Highly flammable
- R36/37/38 – Irritating to eyes, respiratory system, and skin.
- R43 – May cause sensitization by skin contact.

SAFETY STATEMENTS

- S2 – Keep out of reach of children.
- S9 – Keep container in a well-ventilated place.
- S16 – Keep away from sources of ignition – No smoking.
- S29 – Do not empty into drains.
- S33 – Take precautionary measures against static discharges.

SECTION 16. OTHER INFORMATION (non-mandatory)
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HMIS Rating:

- **Health** – 2
- **Flammability** – 3
- **Reactivity** – 2
- **Personal Protective Equipment** – Gloves and safety glasses or Chemical Splash Goggles.

NFPA Rating:

- **Health** – 2
- **Flammability** – 3
- **Reactivity** - 2

0 = Minimal, 1 = Slight, 2 = Moderate, 3 = Serious, 4 = Severe

* = Chronic Health Hazard