

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use



Date Issued : 05/21/2015
SDS No : 362-001.3
Date Revised : 05/10/2017
Revision No : 2

Endo-Eze™ MTAFLOW™ Gel

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 1003625
Product name : Endo-Eze™ MTAFLOW™ Gel
Product description : Water-Based Liquid Used For Mixing With Endo - Eze™ MTAFLOW™ Powder

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Mineral Trioxide Aggregate Repair Cement, Part 2 of 2

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
505 W. Ultradent Drive (10200 South)
South Jordan, UT 84095

EC Responsible Person

Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300
(INTERNATIONAL) :+1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

Health : Not Classified

2.2. Label elements

NOT CLASSIFIED according to health- fire- and environmental hazard.

Classification according to Regulation(EC) No 1272/2008 [CLP]

Precautionary statement(s)

Disposal : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

Immediate concerns : May be slightly irritating to skin and eyes.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Water soluble silicone-based gel	NAP	NAP	100	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

- General information** : Emergency telephone number: see section 1.4. In case of unconsciousness or severe accidents, call Emergency Contact Number or Chemtrec.
- Following eyes** : Immediately rinse with water for several minutes. Hold eyelids apart. Remove any contact lenses. Get medical attention if any discomfort continues.
- Following skin** : Wash skin thoroughly with soap and water. Remove contaminated clothing immediately. Get medical attention if any discomfort continues.
- Following ingestion** : Immediately rinse mouth and drink plenty of water (200-300 ml). Do not induce vomiting. Call a POISON CENTER or doctor/physician.
- Following inhalation** : Gel is unlikely to be inhaled.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : May be slightly irritating after eye contact.
- Skin** : May be slightly irritating after skin contact.
- Ingestion** : May be slightly irritating after ingestion
- Inhalation** : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

- Additional information** : Other information : Treat symptomatically.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Dry-powder, carbon dioxide (CO₂), water mist, foam.
All common fire extinguishing agents may be used. Use fire-extinguishing media appropriate for surrounding materials.
Improper extinguishing media : Do not use water jet.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : May include, but is not limited to: Carbon monoxide (CO). Carbon dioxide (CO₂). Oxides of silicon.
- Explosion hazards** : This product is not flammable.

5.3. Advice for firefighters

- Fire fighting procedures** : Self-contained breathing apparatus may be required by rescue workers. In case of evacuation, use escape mask where possible.
- Additional information** : Containers close to fire should be removed immediately or cooled with water. Extinguishing water must not be discharged into drains. Extinguishing water must be disposed or in accordance with local regulations.

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General procedures : Ensure adequate ventilation. Use protective equipment as referred to in section 8.

6.2. Environmental precautions

Water spill : Do not allow to enter, water system or soil.

6.3. Methods and material for containment and cleaning up

Small Spill : Wipe up small amounts with a chemical resistant, damp cloth. After cleaning, wipe the surface with water. Collect in suitable containers and deliver as waste according to section 13.

6.4. Reference to other sections

Reference to other sections : See also sections 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Handling : May only be handled by people with relevant training. Only for dental use, follow the instructions of the manufacturer. Avoid contamination by other substances. Do not mix with any other material than Endo-Eze MTAFLOW Gel. Provide good ventilation. Avoid contact with skin and eyes. Use protective equipment as referred to in Section 8.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature : Store in original container at room temperature. Keep containers tightly closed and dry. Improper storage will shorten the shelf life.

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Mineral Trioxide Aggregate Repair Cement, Part 2 Of 2

Additional information : Conditions for safe storage: Keep away from: Food and feed.

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

Control parameters : Contains no substances with occupational exposure limit values. References (laws/regulations): EH40/2005 Workplace exposure limits, with later amendments.

8.2. Exposure controls

Engineering controls : Provide adequate ventilation. The personal protective equipment must be CE-marked and the latest version of the standards shall be used. The protective equipment and the specified standards recommended below are only suggestions, and should be selected on advice from the supplier of such equipment. A risk assessment of the work place/work activities (the actual risk)

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may lead to other control measures. The protection equipments suitability and durability will depend on application.

Eye/face protection

: Wear approved safety goggles.
Reference to relevant standard : EN 166 (Personal eye-protection).
Specifications).

Skin protection

: Hand protection: Use chemical resistant gloves. Glove thickness must be chosen in consultation with the glove supplier, who can inform about the breakthrough time for the glove.
Suitable gloves type: Nitrile Rubber (natural latex).
Reference to relevant standard: BS-EN 420 (Protective gloves. General requirements and test methods).
BS-EN 374 (Protective gloves against chemicals and micro-organisms).
Skin protection (except hands) : Ordinary workwear. Long sleeved clothing.

Respiratory protection

: Normally not required.

Other precautions

: Appropriate environmental exposure control: Environmental exposure controls: Do not allow to enter into sewer, water system or soil.
Other information: Eye wash facilities should be available when handling this chemical.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Viscous liquid.
Colour	: Transparent./Slightly cloudy.
Odour	: Odorless
Odour threshold	: Not relevant
pH	: (as supplied) Value: 7-8
Melting temperature	: 0° C
Freezing temperature	: 0°C
Boiling temperature	: ~ 100°C
Flash point	: Not relevant. Not flammable.
Evaporation rate	: Not determined
Flammability (solid, gas)	: Not relevant
Flammable limits	: Comments, Spontaneous combustability : Not spontaneously flammable.
Vapor pressure	: Not determined
Vapor density	: Not determined
Density	: Not determined
Specific gravity	: ~ 1.1
Notes	: (water=1)
Solubility in water	: Soluble

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Partition coefficient: n-octanol/water : n-octanol/water: Not determined
Viscosity : Not determined
Explosive properties : Not determined
Oxidising properties : Not oxidising

9.2. Other information

Additional information : No further information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : No test data available. Mildly alkaline reaction.

10.2. Chemical stability

Chemical stability : Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Hazardous polymerization : Polymerization will not occur.

10.4. Conditions to avoid

Conditions to avoid : Heat

10.5. Incompatible materials

Incompatible materials : Do not mix with anything other than Endo-Eze MTAFLOW Powder.

10.6. Hazardous decomposition products

Hazardous decomposition products : None under normal conditions. See also section 5.2.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Oral LD₅₀ : > 155 gm/kg (guinea pig)

Inhalation LC₅₀ : Rat, 4H: 109 g/m³

Notes : Acute toxicity:
Acute oral toxicity: No adverse effect observed.
Acute dermal toxicity: No adverse effect observed.
Acute inhalation toxicity : No adverse effect observed.

Skin corrosion/irritation : Based on available data, the classification criteria are not met.

Serious eye damage/irritation : Mildly irritant to rabbit eye:1.25 g/24 h

Respiratory or skin sensitisation : Based on available data, the classification criteria are not met.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None known

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

STOT-single exposure : Based on available data, the classification criteria are not met

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STOT-repeated exposure : Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

Aspiration Hazard : Based on available data, the classification criteria are not met

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : The chemical is not classified as harmful to the environment.

12.2. Persistence and degradability

Persistence and degradability : The chemical consists of mainly of inorganic materials. The criteria for biodegradability is not applicable.

12.3. Bioaccumulative potential

Bioaccumulative potential : Data not available.

12.4. Mobility in soil

Mobility in soil : No data available. The product is water soluble and may spread in water systems.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : PBT assessment results: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : Other adverse effects/Remarks: Do not allow to enter into sewer, water system or soil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product disposal : Do not empty into drains. Confirm disposal procedures with environmental engineer and local regulations. Empty and cleaned packages may be disposed of or recycled as household waste.
 Product classified as hazardous waste : No
 EWC waste code : EWC: 18 01 07 chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information

14.1. UN number

UN number : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

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Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

Additional information : Not considered as dangerous goods under UN, IMO, ADR/RID or IATA/ICAO regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : References (laws/regulations) : Regulation (EC) No 1907/2006 on the registration, evaluation, authorization and restriction of chemicals (REACH Regulation), with later amendments. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP-regulation) with later amendments. The European Waste Catalogue (EWC) Dangerous Goods regulations European Community Medical Devices Directive 93/42/EEC (MDD).

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : This product is not considered dangerous for transportation.

SECTION 16: Other information

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/22/2015 SDS. Revised: **Section 1:** GENERAL USE, MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** COMMENTS. **Section 4:** ADDITIONAL INFORMATION, COMMENTS, EYES, INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN), SKIN. **Section 5:** COMMENTS, EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT, FIRE FIGHTING PROCEDURES, HAZARDOUS COMBUSTION PRODUCTS. **Section 6:** GENERAL PROCEDURES, LARGE SPILL, SMALL SPILL, WATER SPILL, . **Section 7:** COMMENTS, HANDLING, STORAGE TEMPERATURE, . **Section 8:** ENGINEERING CONTROLS, OTHER USE PRECAUTIONS, PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE, RESPIRATORY), . **Section 9:** BOILING POINT, COEFF. OIL/WATER, COLOR, COMMENTS, DENSITY, EVAPORATION RATE, FLAMMABLE

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LIMITS, FLASHPOINT AND METHOD, MELTING POINT, ODOR, ODOR THRESHOLD, OXIDIZING PROPERTIES, PERCENT VOLATILE, pH, PHYSICAL STATE, SOLUBILITY IN WATER, SPECIFIC GRAVITY, VAPOR DENSITY, VAPOR PRESSURE, VISCOSITY, . **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:** ACUTE (INHALATION LC₅₀ (rat) ACUTE, GENERAL COMMENTS, ASPIRATION HAZARD, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY, , STOT-REPEATED EXPOSURE, STOT-SINGLE EXPOSURE, , SKIN CORROSION/IRRITATION. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), SECTION 12: Ecological information. **Section 13:** DISPOSAL METHOD, PRODUCT DISPOSAL. **Section 14:** COMMENTS, ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** RoHS. **Section 16:** Revision Summary, GENERAL STATEMENTS.

General statements

: Abbreviations used in section 11:
 LD50: Lethal dose, is the amount of a substance given to a group of test animals, which causes the death of 50%.
 LCLo: Lowest published lethal concentration.
 LDLo: Lowest published lethal dose.
 Abbreviations used in section 12:
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.