

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 05/21/2015
SDS No : 363-001.3
Date Revised : 05/10/2017
Revision No : 2

Endo-Eze™ MTAFLOW™ Powder

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

1.1. Product identifier

Product code : 1003624
Product name : Endo-Eze™ MTAFLOW™ Powder
Product description : Powder for mixture with Endo - Eze MTAFLOW Gel

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 1 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]

: Classification according to Regulation (EC) No 1272/2008 [CLP/GHS]
Substance/mixture hazardous properties : Causes serious eye irritation. In case of contact with eyes, moist skin and mucous membranes, the product may cause (Caustic) chemical burns.

Health : Eye Irritation, Category 2

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : WARNING

Hazard statement(s) : H319: Causes serious eye irritation.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.
P261: Avoid breathing vapors.

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Response : 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 advice/attention.

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 : Health effect : Contact with moisture gives the powder alkaline properties and can cause chemical burns to skin and eyes.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Tricalcium Silicate	12168-85-3	235-336-9	< 50	Not classified
Dicalcium silicate	10034-77-2	NAP	< 20	Not classified
Calcium sulfate	7778-18-9	231-900-3	< 3	Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; H315; H318
Silica	14464-46-1	238-455-4	< 0.1	Carc.,Cat. 1A; H350
Bismuth trioxide	1304-76-3	215-134-7	< 30	Not classified

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Promptly rinse eyes with plenty of water (tempered at 20-30 C) for at least 15 minutes. Remove any contact lenses. Hold the eyelids apart. Obtain medical attention and bring these instructions. Continue rinsing during transportation to a physician.

Following skin : Immediately flush skin with plenty of cool soapy water. Remove contaminated clothing and wash contact areas thoroughly.

Following ingestion : Immediately rinse mouth and drink plenty of water (200-300 ml). Do not induce vomiting. Immediately call a POISON CENTER or doctor/physician.

Following inhalation : Fresh air and rest. Get medical attention if any discomfort continues.

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

Eyes : Risk of serious damage to eyes. Symptoms such as strong burning, tearing/watering, redness and blurred vision may occur.

Skin : May cause slight irritation. The powder is corrosive if damp. Contact with moisture gives the powder alkaline properties and can cause chemical burns to skin.

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Ingestion : Irritating. May cause chemical burns in mouth and throat.
Inhalation : Dust may cause irritation symptoms such as coughing and a sore throat. Irritating or corrosive to the mucous membranes in the respiratory tract depending on the humidity.

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. Calcium oxide.
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 of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Ensure adequate ventilation. Avoid generation and spreading of dust. 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

General procedures : Advice on general occupational hygiene: Wash hands after contact with the chemical. Change contaminated clothing and take off protective equipment

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before the meal. Do not smoke, drink or eat in the workplace.

- 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. Improper storage will shorten the shelf life. Advice on storage compatibility: Keep away from : Water/moisture. Food and feed.

7.2. Conditions for safe storage, including any incompatibilities

- Shelf life** : See product labeling. Improper storage will shorten the shelf life.

7.3. Specific end use(s)

- Specific end use(s)** : Professional Dental Mineral Trioxide Aggregate Repair Cement, Part 1 of 2

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

- Control parameters** : Silica, crystalline (cristobalite) CAS no. : 14464-46-1 EC no. : 238-455-4 8-hour TWA: 0.1 mg/m³ respirable
Dust, inorganic, respirable fraction : 8-hour TWA: 4 mg/m³ TWA Year : 2007
- Other information about threshold 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) may lead to other control measures. The protection equipments suitability and durability will depend on application.
- Eye/face protection** : Wear dust resistant safety goggles where there is danger of eye contact. Reference to relevant standard EN 166 (Personal eye-protection. Specifications).
- Skin protection** : The chemical is solid and cannot penetrate normal glove materials. Use protective gloves that are suitable for the application. 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.
In case of inadequate ventilation: Use mask with filter P3 in case of dust formation.

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Reference to relevant standard: EN 143 (Respiratory protective devices. Particle filters. Requirements, testing, marking.)

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	: Powder
Colour	: Yellowish
Odour	: Odorless
Odour threshold	: Not relevant
pH	: ~ 12 (aqueous solution)
Melting temperature	: 700°C to 800°C
Boiling temperature	: > 1800°C
Flash point	: Not relevant
Evaporation rate	: Not relevant.
Vapor pressure	: Not relevant
Vapor density	: Not relevant
Specific gravity	: ~ 3.7
Notes	: (water=1)
Solubility in water	: Slightly soluble in water. Solubility in water: < 1%
Partition coefficient: n-octanol/water	: Not determined
Viscosity	: Not relevant.
Explosive properties	: Not explosive
Oxidising properties	: Not oxidising

9.2. Other information

Additional information : Comments, Spontaneous Combustibility: Not spontaneously flammable

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Alkaline reaction in damp condition.

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

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Conditions to avoid : Protect from moisture.

10.5. Incompatible materials

Incompatible materials : Do not mix with any other material than Endo-Eze MTAFLOW Gel.

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

Skin corrosion/irritation : Causes serious eye irritation.

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

Germ cell mutagenicity : Based on available data, the classification criteria are not met

Carcinogenicity : Contains very small quantities of a substance which may cause cancer. Based on available data, the classification criteria are not met.

Reproductive toxicity : Based on available data, the classification criteria are not met

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

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

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. Contact with water gives a high pH value, which can be harmful to aquatic organisms.

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.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: 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 : Do not allow to enter into sewer, water system or soil

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal method : Do not empty into drains. Disposed of as hazardous waste by approved contractor. The waste code (EWC-Code) is intended as a guide. The code must be chosen by the user, if the use differs from the one mentioned below.
Product classified as hazardous waste: Yes
EWC waste code: EWC: 18 01 06 chemicals consisting of or containing dangerous substances

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

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.

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- Relevant H-statements (number and full text)** : Carc., Cat. 1A: Carcinogenicity, Category 1A
EYE DMG., Cat. 1: Eye Damage, Category 1
Skin Irr., Cat. 2: Skin Irritation, Category 2
H315: Causes skin irritation.
H318: Causes serious eye damage.
H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).
- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 12/22/2015 SDS. Revised: **Section 1:** GENERAL USE, MSDS No. **Section 2:** CANCER STATEMENT, EMERGENCY OVERVIEW - IMMEDIATE CONCERNS MEDICAL CONDITIONS AGGRAVATED, POTENTIAL HEALTH EFFECTS (SKIN, INHALATION, INGESTION), TARGET ORGAN STATEMENT, 2.3. Other hazards. **Section 4:** 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, FLAME PROPAGATION OR BURNING RATE OF SOLIDS, FLAMMABLE CLASS, HAZARDOUS COMBUSTION PRODUCTS, OTHER CONSIDERATIONS. **Section 6:** GENERAL PROCEDURES, LARGE SPILL, SMALL SPILL, WATER SPILL, . **Section 7:** GENERAL PROCEDURES, HANDLING, SHELF LIFE, STORAGE, . **Section 8:** ENGINEERING CONTROLS, OTHER USE PRECAUTIONS, PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE, RESPIRATORY), . **Section 9:** APPEARANCE, BOILING POINT, COEFF. OIL/WATER, COLOR, COMMENTS, EVAPORATION RATE, 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:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE, GENERAL COMMENTS, IARC, NTP, 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) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 13:** DISPOSAL METHOD. **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** : NAP = Not Applicable

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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.