Printing date 02/06/2020

ILTRADENT RODUCTS, INC.

Reviewed on 11/11/2019

1 Identification

- · Product identifier
- · Trade name: Endo-Eze[™] MTAFlow[™], Endo-Eze[™] MTAFlow[™] White (Powder)
- Article number: 14084
- Index number: SDS 438-001.01
- · Application of the substance / the mixture Professional Dental Repair Cement, Part 1 of 2
- Details of the supplier of the safety data sheet
 Manufacturer/Supplier: Ultradent Products Inc.
 505 W. Ultradent Drive (10200 S)
 South Jordan, UT 84095-3942
 USA
 onlineordersupport@ultradent.com
- Information department: Customer Service
 Emergency telephone number: CHEMTREC (NORTH AMERICA) :(800) 424-9300 (INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

· Classification of the substance or mixture

Emergency Overview: Dust may irritate throat and respiratory system and cause coughing. Frequent inhalation of dust over a long period of time increase the risk of developing lung diseases. Dust or splashes from the mixture may cause permanent eye damage. Dust has an irritating effect on moist skin. Prolonged contact may cause burns.

The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



· HMIS-ratings (scale 0 - 4)



- · Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 2)

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze^m MTAFlow^m, Endo-Eze^m MTAFlow^m White (Powder)

(Contd. of page 1)

3 Composition/information on ingredients

· Chemical characterization: Mixtures

 $\cdot \textit{Description: Mixture of the substances listed below with nonhazardous additions.}$

· Dangerous components:			
12168-85-3	Tricalcium Silicon Pentaoxide	<50%	
1314-61-0	Tantalite	<50%	
10034-77-2	Dicalcium Silicate	<20%	
7778-18-9	Calcium Sulfate	<5%	

4 First-aid measures

- · Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- After inhalation:

Move individual away from exposure into fresh air. If not breathing give artificial respiration. If breathing is difficult, administer oxygen. Keep patient warm.

- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing:

Do not induce vomiting; immediately call for medical help.

Rinse out mouth and then drink plenty of water.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

• Indication of any immediate medical attention and special treatment needed Treat symptomatically.

Seek medical advice after large-scale (>25 gm) exposure.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:
- Water spray
- Foam, dry chemical, carbon dioxide
- Use fire fighting measures that suit the environment.
- Special hazards arising from the substance or mixture During heating or in case of fire poisonous gases are produced.
- Silicon Dioxide
- Advice for firefighters
- *Protective equipment: Wear self-contained respiratory protective device. Wear fully protective suit.*

6 Accidental release measures

- *Personal precautions, protective equipment and emergency procedures Wear protective clothing. Avoid formation of dust.*
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.

(Contd. on page 3)

US

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze[™] MTAFlow[™], Endo-Eze[™] MTAFlow[™] White (Powder)

	(Contd. of page 2)
Reference to other sections	
See Section 7 for information on safe handling.	
See Section 8 for information on personal protection equipment.	
See Section 13 for disposal information.	
Protective Action Criteria for Chemicals	
• PAC-1:	
1314-61-0 Tantalite	12 mg/m ³
• PAC-2:	
1314-61-0 Tantalite	260 mg/m ³
• PAC-3:	
1314-61-0 Tantalite	1,600 mg/m ³

7 Handling and storage

· Handling:

· Precautions for safe handling

Powder is caustic. Keep out of eyes, lungs, or contact with mucosal tissues. After initial contact, wash and rinse with water. Wear suitable gloves and protective glasses during use. Endo-Eze MTAFlow & Endo-Eze MTAFlow White (powder) must be kept well sealed and free of contamination by pyrogens. Protect powder from humidity. Be careful not to contaminate the powder with a contaminated instrument. Keep receptacles tightly sealed.

· Information about protection against explosions and fires: No special measures required.

- · Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: Material is hydrophilic. Provide ventilation for receptacles.
 Information about storage in one common storage facility: Store away from water.
 Further information about storage conditions: Material is hydrophilic Protect from exposure to the light. See product labelling. Store in dry conditions. Store receptacle in a well ventilated area. Protect from heat

Protect from contamination. • Specific end use(s) Professional Dental Repair Cement, Part 1 of 2

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

· Control parameters

· Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

(Contd. on page 4)

US –

US

Safety Data Sheet acc. to OSHA HCS

Printing date 02/06/2020

Reviewed on 11/11/2019

*Trade name: Endo-EzeTM MTAFlow*TM, *Endo-EzeTM MTAFlow*TM *White (Powder)*

	(Contd. of page 3)
1314	-61-0 Tantalite
PEL	Long-term value: 5 mg/m ³ dusts, as Ta
REL	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ dusts
TLV	dusts; TLV withdrawn due to insufficient data
7778	-18-9 Calcium Sulfate
	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10* mg/m ³ *as inhalable fraction
· Addi	tional information: The lists that were valid during the creation were used as basis.
· Perso · Gene · Brea	sure controls onal protective equipment: ral protective and hygienic measures: Be sure to clean skin thoroughly after work and before breaks. thing equipment:
Dust	irator mask e ction of hands:
The g	glove material has to be impermeable and resistant to the product/ the substance/ the preparation. rial of gloves
Lates	
The observ	
	protection: Face protection protection: Protective work clothing

Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Powder	
Color:	White	
Odor:	Odorless	
Odor threshold:	Not determined.	
pH-value at 20 °C:	~12	
Change in condition		
Melting point/Melting range:	>700 °C	
Boiling point/Boiling range:	>1,800 °C	
Flash point:	Not applicable	
Flammability (solid, gaseous):	Not determined.	

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze[™] MTAFlow[™], Endo-Eze[™] MTAFlow[™] White (Powder)

	(Contd. of page	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
Density at 20 °C:	$3.7 g/cm^3$	
Relative density	Not determined	
Vapor density Not applicable.		
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water at 20 °C:	<3 g/l	
Partition coefficient (n-octanol/wo	ater): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solvent content:		
VOC content:	0.00 %	
Solids content:	100.0 %	
Other information	No further relevant information available.	

10 Stability and reactivity

· Reactivity Stable

· Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid

Moisture

Heat

· Incompatible materials: No further relevant information available.

· Hazardous decomposition products: Silicon dioxide

11 Toxicological information

· Information on toxicological effects

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

1314-61-0 Tantalite

Oral LD50 8,000 mg/kg (rat)

Primary irritant effect:

• on the skin: May irritate skin.

• on the eye: May irritate eyes.

• Sensitization: No sensitizing effects known.

(Contd. on page 6)

US

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze[™] MTAFlow[™], Endo-Eze[™] MTAFlow[™] White (Powder)

(Contd. of page 5)

• Additional toxicological information:

Harmful if swallowed.

Inhalation : Mild irritant

Target Organ(s) Lung

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability Not biodegradable
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- *Mobility in soil* No further relevant information available.
- Additional ecological information:

· General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- **vPvB:** Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- *Recommendation:* Do not allow product to reach sewage system.
- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information

- · UN-Number
- · DOT, IMDG, IATA

not regulated

(Contd. on page 7)

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze[™] MTAFlow[™], Endo-Eze[™] MTAFlow[™] White (Powder)

		(Contd. of page 6
· UN proper shipping name · DOT, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· DOT, ADN, IMDG, IATA · Class	not regulated	
· Packing group · DOT, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
• Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture · Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

• **TSCA (Toxic Substances Control Act):** All components have the value ACTIVE.

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

·NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

• GHS label elements Void

(Contd. on page 8)

US

Printing date 02/06/2020

Reviewed on 11/11/2019

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(Contd. of page 7)

· Hazard pictograms Void

- · Signal word Void
- · Hazard statements Void
- · Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Regulatory Affairs
- Contact: Customer Service
- · Date of preparation / last revision 02/06/2020 / -

• Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit