

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Endo-Eze™ MTAFlow™, Endo-Eze™ MTAFlow™ White (Powder & Gel)

Manufacturer: Ultradent

SDS Expiry: 11 November 2024

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: Non-Hazardous

HSNO Group Standard: Non-Hazardous

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared on 27 November 2020

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/06/2020

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)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

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

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

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **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.

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

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- **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
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· **PAC-2:**

1314-61-0	Tantalite	260 mg/m ³
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· **PAC-3:**

1314-61-0	Tantalite	1,600 mg/m ³
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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.

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

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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

PEL	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

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Be sure to clean skin thoroughly after work and before breaks.
- **Breathing equipment:**
 - Respirator
 - Dust mask
- **Protection of hands:**
 - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Material of gloves**
 - Nitrile rubber, NBR
 - Latex
- **Penetration time of glove material**
 - The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Face protection
- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· 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.

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

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· 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/water):	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.

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

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· **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

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

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

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

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- **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

US

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1 Identification

- **Product identifier**
- **Trade name:** *Endo-Eze™ MTAFlow™, Endo-Eze™ MTAFlow™ White (Gel)*
- **Article number:** 14083
- **Index number:** SDS 437-001.01
- **Application of the substance / the mixture** *Professional Dental Repair Cement, Part 2 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*

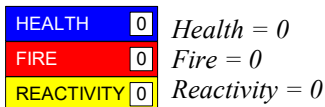
2 Hazard(s) identification

- **Classification of the substance or mixture**
*Emergency Overview: Endo-Eze MTAFlow Gel is slightly caustic water-based gel. Endo-Eze MTAFlow White(Gel) is slightly acidic water-based gel.
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.*

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Trade name: Endo-Eze™ MTAFlow™, Endo-Eze™ MTAFlow™ White (Gel)

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.
- **Dangerous components:** Void

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** May irritate mucosal tissues.
- **Indication of any immediate medical attention and special treatment needed**
Seek medical advice after large-scale exposure.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Foam, dry chemical, carbon dioxide
Water spray
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.
Carbon Oxides
Nitrogen oxides (NOx)
- **Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:** Wipe up and discard in a suitable container.
- **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.

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· **Protective Action Criteria for Chemicals**

· **PAC-1:**

None of the ingredients is listed.

· **PAC-2:**

None of the ingredients is listed.

· **PAC-3:**

None of the ingredients is listed.

7 Handling and storage

· **Handling:**

· **Precautions for safe handling**

Endo-Eze MTAFlow Gel is slightly caustic. Endo-Eze MTAFlow White Gel is slightly acidic. Wear suitable gloves and protective glasses during use. Keep out of eyes or contact with mucosal tissues. After initial contact, wash and rinse with water. Endo-Eze MTAFlow and Endo-Eze MTAFlow White Gel must be kept well-sealed, and free of contamination by pyrogens.

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:** *Provide ventilation for receptacles.*

· **Information about storage in one common storage facility:** *Not required.*

· **Further information about storage conditions:**

Keep receptacle tightly sealed.

Store in a cool place.

Protect from exposure to the light.

Protect from contamination.

See product labelling.

· **Specific end use(s)** *Professional Dental Repair Cement, Part 2 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 product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** *The lists that were valid during the creation were used as basis.*

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:** *Do not eat or drink while working.*

· **Breathing equipment:**

Suitable respiratory protective device recommended.

Dust mask

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· **Material of gloves**

Nitrile rubber, NBR

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Latex

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Face protection

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Liquid
Color:	Light yellow

- **Odor:** Odorless

- **Odor threshold:** Not determined.

- **pH-value at 20 °C:** 3-8

- **Change in condition**

Melting point/Melting range:	0 °C
Boiling point/Boiling range:	~100 °C

- **Flash point:** Not applicable

- **Flammability (solid, gaseous):** Not applicable.

- **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 determined.

- **Density at 20 °C:** ~1.1 g/cm³

- **Relative density** Not determined

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

Water:	Fully miscible.
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- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined

- **Solvent content:**

VOC content:	0.00 %
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	0.0 g/l / 0.00 lb/gal
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VOC (EC)	0.00 %
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 Heat**
- **Incompatible materials:** Do not mix with anything other than MTA Powder
- **Hazardous decomposition products:**
 - Nitrogen oxides
 - Silicon dioxide
 - Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
 - **on the skin:** May irritate skin.
 - **on the eye:** May irritate eyes.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
 - 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** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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Trade name: Endo-Eze™ MTAFlow™, Endo-Eze™ MTAFlow™ White (Gel)

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- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | |
| · DOT, IMDG, IATA | not regulated |
| · 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 II of MARPOL 73/78 and the IBC Code | 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):**

None of the ingredients is listed.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 02/06/2020

Reviewed on 11/11/2019

Trade name: Endo-Eze™ MTAFlow™, Endo-Eze™ MTAFlow™ White (Gel)

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· **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

· **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)

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