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1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: Endo-EzeTMMTAFlowTM Grey Powder

· Article number: SDS 488-001.01R01, 14084, 3980-US

· Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Manufactured by NuSmile Ltd for:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@ultradent.com

EC Responsible Person Ultradent Products GmbH

Am Westhover Berg 30

51149 Cologne Germany

 ${\it Email: infoDE@ultradent.com}$

Emergency Phone: +49(0)2203-35-92-0

· Further information obtainable from: Customer Service

· Emergency telephone number:

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

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



Skin Corr. 1A H314 Causes severe skin burns and eye damage.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

- · Hazard pictograms GHS05
- · Signal word Danger
- · Hazard statements

H314 Causes severe skin burns and eye damage.

· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P260 Do not breathe dusts or mists.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

P310 Immediately call a POISON CENTER/

P321 Specific treatment (see on this label).

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Safety data sheet according to 1907/2006/EC, Article 31

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P405 Store locked up.

Dispose of contents/container in accordance with local/regional/national/international

regulations.

3 Composition/information on ingredients

· Mixtures

P501

- · **Description:** Mixture of substances listed below with nonhazardous additions.
- · Dangerous components:

12042-78-3 Tricalcium Aluminate

! Eye Irrit. 2, H319

<5%

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · Description of first aid measures
- · 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.

Get medical attention.

· After skin contact:

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

· After eye contact:

Immediately flush eyes with plenty of water for 15 minutes, while holding eyelids apart. Remove contact lenses. Do not use eye ointments.

Get medical attention immediately, even if no symptoms.

· After swallowing:

If ingestion occurs, flush mouth with water, and drink water or milk. Do not induce vomiting. If vomiting occurs, keep head low.

Get medical attention.

· Most important symptoms and effects, both acute and delayed

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

Indication of any immediate medical attention and special treatment needed

Seek medical advice after large-scale (>100 gm) exposure.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Water spray, foam, carbon dioxide, or dry chemical.
- · Special hazards arising from the substance or mixture

Irritating fumes may be released by thermal decomposition. Fumes of Silicon dioxide may be evolved from material in a fire.

· Advice for firefighters: Usual. Avoid inhalation of smoke; use a respirator and protective suit.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Spill/Leak Clean-Up Procedures and Equipment: Wipe up spills with moist rags or vacuum to prevent dust from being dispersed. Discard in trash. Avoid skin contact and inhalation. Dispose of container and unused contents in accordance with federal, state, and local requirements.

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· Environmental precautions:

Dispose of container and unused contents in accordance with federal, state, and local requirements.

- · Methods and material for containment and cleaning up: Discard in trash.
- · 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.

7 Handling and storage

· Precautions for safe handling:

· Handling:

Powder is caustic. Keep out of eyes, lungs, or contact with mucosal tissues. After incidental contact, wash and rinse with water. Wear suitable gloves and protective glasses during use. Endo-Eze MTAFlow powder must be kept well sealed and free of contamination by pyrogens. Protect the powder from humidity. Be careful not to contaminate the powder with a contaminated instrument. Trained personnel use this product exclusively for dental purposes.

- · Conditions for safe storage, including any incompatibilities Not applicable
- Storage:
- Requirements to be met by storerooms and receptacles:

Store at temperatures at room temperature (25C/77F), not refrigerated. Keep bottle tightly closed; material is hydrophilic. Inadequate storage conditions will shorten the shelf life.

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- · Ingredients 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.

- · Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Wear gloves as per universal precautions in dentistry. Wash your hands after use. No eating, drinking, or smoking while handling this product. Wash clothing with spills of material on clothing.

Use liquid to remove dust. Use vinegar to dissolve set material.

· Respiratory protection:

Avoid inhalation

Dust mask

Respirator

- · Hand protection Wear latex or nitrile gloves and avoid skin contact.
- · Eye/face protection Wear safety glasses or face shield.

CD.

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9 Physical and chemical properties	
Information on basic physical and chemical propertie	s
· General Information	~
· Physical state	Solid
· Colour:	Light grey
· Odour:	None
· Odour threshold:	Not determined.
Melting point/freezing point:	>700 °C
Boiling point or initial boiling point and boiling range	
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
Decomposition temperature:	Not determined.
· pH at 20 °C	12
· Viscosity:	
Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
Solubility	
· water:	Soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
Density and/or relative density	
Density at 20 °C:	3.7 g/cm^3
· Relative density	Not determined.
· Vapour density	Not applicable.
· Other information	
· Appearance:	
· Form:	Powder
Important information on protection of health and	d
environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
Information with regard to physical hazard classes	
Explosives	Void
· Flammable gases	Void
· Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gase	s
in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
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· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under recommended conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: May release silica fumes in a fire.
- · Conditions to avoid: Moisture will react with powder.
- · *Incompatible materials:* Keep dry to avoid reaction with water and setting.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation

None.

Causes severe skin burns and eye damage.

- · Additional toxicological information: Toxicity is secondary to effect of caustic powder on moist tissues.
- · Information on other hazards
- · Endocrine disrupting properties

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.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Dispose of contents/container in accordance with international, federal, state, and local regulations.

Do not spread dust. When mixed with water, a solid, non-biodegradable mass will form.

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· Uncleaned packaging: · Recommendation: None.

14 Transport information	
· UN number or ID number · ADR, IMDG, IATA	not regulated
· UN proper shipping name · ADR, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group · ADR, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not Applicable
· Maritime transport in bulk according instruments	to IMO Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Regulations: Hazard code: Xn (irritant): Components are considered to be hazardous material under the
Hazardous Products Act as defined by the Controlled Products Regulations (Class D2A, E-Corrosive Material)
and subject to the requirement of WHMIS.

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

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A chemical safety assessment has not been carried out.

16 Other information

This information is based on our present knowledge; however, this shall not constitute a guarantee for a specific product features. No toxicity data are available for this specific formulation. This health hazard assessment is based on information that is available for its components.

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.

- · Relevant phrases from Section 3 H319 Causes serious eye irritation.
- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service

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· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals 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)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety Skin Corr. 1A: Skin corrosion/irritation – Category 1A Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

* * Data compared to the previous version altered.

GB