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1 Identification

- · Other means of identification
- · Trade name: Endo-EzeTM MTAFlowTM Gel (Gray and White)
- · Article number: SDS 490-001.02R01, 13866, 4980
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture Void
- 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

Ultradent Australia Pty Ltd. Level 22/2 Market Street Sydney NSW 2000

Australia

Email: info.anz@ultradent.com Toll Free: 1-800-290929

- · Further information obtainable from: Customer Service
- Emergency telephone number:

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

2 Hazard(s) Identification

· Classification of the substance or mixture

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

- · Additional information: Emergency Overview: Slightly acidic water-based gel solution
- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.
- · Dangerous components: Void
- · Additional information: For the wording of the listed hazard phrases refer to section 16.

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4 First Aid Measures

- · General information: No special measures required.
- · After inhalation:

Supply fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Keep patient warm.

- · After skin contact: Immediately flush skin with plenty of cool soapy water. Get medical attention
- · After eve contact:

Immediately flush eyes with plenty of water for several minutes, while holding eyelids apart. Get medical attention immediately.

- · After swallowing: If ingestion occurs, flush mouth with water, and seek medical attention immediately.
- 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 exposure.

5 Fire Fighting Measures

- · Extinguishing media Water spray, foam, carbon dioxide, or dry chemical.
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · Special hazards arising from the substance or mixture

Fumes of carbon dioxide, nitrogen oxides, and carbon monoxide may be evolved in a fire.

- · Advice for firefighters: Usual. Avoid inhalation of smoke; use a respirator and protective suit.
- · Protective equipment: No special measures required.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Methods and material for containment and cleaning up:

Wipe up spills with rags to prevent material from being dispersed, and discard in trash.

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

· 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

· Handling:

Gel is slightly acidic. Wear suitable gloves and protective glasses during use. Keep out of eyes or contact with mucosal tissues. After incidental contact, wash and rinse with water. Endo-Eze MTAFlow Gel must be kept well-sealed, and free of contamination by pyrogens. Only trained personnel may use this product exclusively for dental purposes.

- · Precautions for safe handling: No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities

Store at room temperature (25C/77F). Keep bottle tightly closed. Inappropriate storage will shorten the shelf life.

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- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · 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 and personal protection

- · Appropriate engineering controls No further data; see section 7.
- 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.

- · Additional information: The lists valid during the making were used as basis.
- Personal protective equipment:
- General protective and hygienic measures:

Use in a well-ventilated area.

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.

· Respiratory protection:

Avoid inhalation

Respirator

Dust mask

- · Protection of hands: Wear latex or nitrile gloves
- · Material of gloves

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: Wear safety glasses or face shield.
- · Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Gel

Pale Yellow · Colour: Odour: **Odourless** · Odour threshold: Not determined. 3-4

· pH-value at 20 °C:

Decomposition temperature:

· Change in condition · Melting point/freezing point: 0 °C

Initial boiling point and boiling range: 100 °C · Flash point: Not applicable. Not applicable. · Flammability

Product is not selfigniting. · Ignition temperature:

Product does not present an explosion hazard. · Explosive properties:

Not determined.

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· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not determined.
Density at 20 °C: 1.1 g/cm³
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.

· Solubility in / Miscibility with

• water: Fully miscible. • Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.Kinematic: Not determined.

· Other information

• Particle characteristics Not applicable.

· Physical state Fluid

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: No dangerous reactions known.
- · Conditions to avoid: Heat
- · Incompatible materials: Do not mix with material other than MTA Flow Powders.
- · Hazardous decomposition products:

Decomposition products of the minor components of gel include carbon dioxide, nitrogen oxiders, and carbon monoxide.

11 Toxicological Information

- Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation

None.

Based on available data, the classification criteria are not met.

· Serious eye damage/irritation

None.

Based on available data, the classification criteria are not met.

- 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 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.

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· Additional toxicological information: None.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- 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

Toxicity, Environmental Fate, Physical/Chemical Data, or Other Data Supporting Environmental Hazard Statements; Discard in Trash

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

- · Uncleaned packaging:
- · Recommendation: None.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

UN-Number		
ADG, IMDG, IATA	not regulated	
UN proper shipping name ADG, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADG, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not Applicable	
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

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15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Australian Inventory of Industrial Chemicals

None of the ingredients is listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

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 any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service
- · 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

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

* Data compared to the previous version altered.

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