

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 23.02.2024

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

- **Product identifier**
- **Trade name:** Endo-Eze™ MTAFlow™ Gel (Gray and White)
- **Article number:** 490-001.01R01, 4980, 13866
- **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
-
- 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
- **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**



corrosion

- Skin Corr. 1A H314 Causes severe skin burns and eye damage.
- **Additional information:** Emergency Overview: Slightly acidic water-based gel solution

- **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.

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<p>P310</p> <p>P321</p> <p>P405</p> <p>P501</p>	<p>Immediately call a POISON CENTER/doctor.</p> <p>Specific treatment (see on this label).</p> <p>Store locked up.</p> <p>Dispose of contents/container in accordance with local/regional/national/international regulations.</p>
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3 Composition/information on ingredients

- **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.

4 First aid measures

- **Description of first aid measures**
- **After inhalation:**
Move to fresh air. If breathing is difficult, give oxygen. Perform artificial respiration if breathing has stopped. Get medical attention immediately.
Keep patient warm
- **After skin contact:** Immediately flush skin with plenty of cool soapy water. Get medical attention
- **After eye 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.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
Seek medical advice after large-scale exposure.

5 Firefighting measures

- **Extinguishing media** Water spray, foam, carbon dioxide, or dry chemical.
- **Suitable extinguishing agents:** None.
- **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.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** None.
- **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 contents 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.

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7 Handling and storage

· **Precautions for safe handling:**

· **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.

· **Conditions for safe storage, including any incompatibilities**

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

· **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/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**

· **Individual protection measures, such as 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

Dust mask

Respirator

· **Hand protection** *Wear latex or nitrile gloves*

· **Eye/face protection** *Wear safety glasses or face shield.*

9 Physical and chemical properties

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

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Pale Yellow

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

0 °C

· **Boiling point or initial boiling point and boiling range**

100 °C

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

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· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH at 20 °C	3-4
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· Other information	
· Appearance:	
· Form:	Gel
· Important information on protection of health and 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 determined.

· 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 gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· 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.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Heat
- **Incompatible materials:** Do not mix with material other than MTA Flow Powders.

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· **Hazardous decomposition products:**

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

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.
- **Serious eye damage/irritation** None.
- **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.
- **Additional toxicological information:** None.
- **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** For information on endocrine disrupting properties see section 11.
- **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.

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14 Transport information

· UN number or ID number · ADR, IMDG, IATA	not regulated
· UN proper shipping name · ADR, ADN, 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 to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

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.
· 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
 - 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
- *** Data compared to the previous version altered.**