

Safety data sheet according to UK REACH

Printing date 21.05.2025

Version number 1

Revision: 21.05.2025

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

- **Product identifier**
- **Trade name:** Endo-Eze™ MTAFlow™ 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
- **EC Responsible Person**
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **Additional information:** Emergency Overview: Slightly acidic water-based gel solution
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

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.

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4 First aid measures

- **Description of 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 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**
Treat symptomatically.
Seek medical advice after large-scale exposure.

5 Firefighting 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.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **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.

7 Handling and storage

- **Precautions for safe handling:** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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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/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.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **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
Respirator
Dust mask
- **Hand protection** 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/face protection** Wear safety glasses or face shield.
- **Body protection:** Protective work clothing

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.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.

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· 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.	
· 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.
- **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.

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· **Hazardous decomposition products:**

Decomposition products of the minor components of gel include carbon dioxide, nitrogen oxides, 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.

· **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.

· **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** The product does not contain substances with endocrine disrupting properties.

· **Other adverse effects**

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

· **Additional ecological information:**

· **General notes:** Not known to be hazardous to water.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

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

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

14 Transport information

- | | |
|--|------------------------|
| · UN number or ID number | |
| · ADR, IMDG, IATA | <i>not regulated</i> |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | <i>not regulated</i> |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | <i>not regulated</i> |
| · Packing group | |
| · ADR, IMDG, IATA | <i>not regulated</i> |
| · Environmental hazards: | <i>Not applicable.</i> |
| · Special precautions for user | <i>Not Applicable</i> |
| · Maritime transport in bulk according to IMO instruments | <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**

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

None of the ingredients is listed.

- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

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.*

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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

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

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