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

· Product identifier

· Trade name: MTApexTM Sealer Gel

· Article number: SDS 491-001.01R01, 13868, 4900

· 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

Email: infoDE@ultradent.com

Email: injoDE@uiiradeni.com
Emergency Phone: +49(0)2203-35-92-0

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· 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/o

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.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

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 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.

Get medical attention.

· 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 the head lower than chest to avoid aspiration into the lungs. Never give anything by mouth to an unconscious or convulsing person.

Get medical attention.

- · 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.

Treat symptomatically.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Water spray, foam, carbon dioxide, or dry chemical.
- · 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: 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:

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

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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

- · 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
- · Storage:
- Requirements to be met by storerooms and receptacles:

Store at room temperature (25 C/77 F). Keep bottle tightly closed. Inappropriate storage 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
- · 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 and avoid skin contact.
- · Eve/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

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(Contd. of page 3) Pale Yellow · Colour: · Odour: **Odourless** · Odour threshold: Not determined. · Melting point/freezing point: $0 \, {}^{\circ}C$ · 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. · pH at 20 °C 11 · Viscosity: · Kinematic viscosity Not determined. · Dynamic: Not determined. Solubility · water: Soluble. · 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/cm³ · Relative density Not determined. · Vapour density Not determined. · Other information · Appearance: · Form: Liquid · 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

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· Desensitised explosives

Void

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal temperatures and pressures.
- Possibility of hazardous reactions:

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

- · Conditions to avoid: Heat.
- · Incompatible materials: Do not mix with material other than MTApex powders.
- · 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

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

Causes severe skin burns and eye damage.

- · 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

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.

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	t o IMO 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