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

- **Product identifier**
  - **Trade name:** ViscoStat™ Clear
  - **Article number:** 73203
  - **Index number:** SDS 66-001.12
- **Relevant identified uses of the substance or mixture and uses advised against**
  - *Professional Dental Hemostatic Solution*
- **Application of the substance / the mixture**
  - *Professional Dental Hemostatic Solution*
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    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**
    - **GHS05 corrosion**
      - Skin Corr. 1 H314 Causes severe skin burns and eye damage.
    - **GHS07**
      - Acute Tox. 4 H332 Harmful if inhaled.
- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
  - **Hazard pictograms** GHS05, GHS07
  - **Signal word** Danger

(Contd. on page 2)
Hazard statements
H332 Harmful if inhaled.
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 label before use.
P260 Do not breathe dusts or mists.
P264 Wash thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water
(or shower).
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international
regulations.

Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

Composition/information on ingredients

Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 7784-13-6  EC number: 616-520-1  Aluminum Chloride Hexahydrate  Acute Tox. 4, H302  <50%
CAS: 1303-96-4  EINECS: 215-540-4  Sodium Borate  Repr. 1B, H360FD  <1%
CAS: 25322-68-3  NLP: 500-038-2  Dimethicone  Repr. 2, H361f; STOT RE 2, H373  <1%
CAS: 25322-68-3  NLP: 500-038-2  Polyethylene Glycol  ≤6%

SVHC
1303-96-4 Sodium Borate

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

First aid measures

Description of first aid measures
General information: Immediately remove any clothing soiled by the product.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: ViscoStat™ Clear

5 Firefighting measures

· Extinguishing media
  · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture
  During heating or in case of fire poisonous gases are produced.

· Advice for firefighters:
  · Protective equipment: Mouth respiratory protective device.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures
  Mount respiratory protective device.
  Wear protective equipment. Keep unprotected persons away.

· Environmental precautions: Do not allow to enter sewers/surface or ground water.

· Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Use neutralising agent.
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.

· 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:

· Precautions for safe handling:
  Use only in well ventilated areas.
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.

· Information about fire - and explosion protection: Keep respiratory protective device available.

· Conditions for safe storage, including any incompatibilities

· Storage:
  · Requirements to be met by storerooms and receptacles:
    Use only receptacles specifically permitted for this substance/product.
  · Information about storage in one common storage facility: Not required.
Trade name: ViscoStat™ Clear

- Further information about storage conditions:
  See product labelling.
  Keep container tightly sealed.
- Specific end use(s) Professional Dental Hemostatic Solution

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 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
  - Personal protective equipment:
    - General protective and hygienic measures:
      Keep away from foodstuffs, beverages and feed.
      Immediately remove all soiled and contaminated clothing.
      Wash hands before breaks and at the end of work.
      Avoid contact with the eyes and skin.
    - Respiratory protection:
      In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
  - Protection of hands:
    - Protective gloves
      The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
      Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
    - 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:
    - Tightly sealed goggles
  - Body protection: Protective work clothing

(Contd. on page 5)
### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Gel
    - **Colour:** Whitish
  - **Odour:** Odourless
  - **Odour threshold:** Not determined.

- **pH-value at 20 °C:** <1

- **Change in condition**
  - **Melting point/freezing point:** Undetermined.
  - **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not applicable.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.284 g/cm³
  - **Relative density:** Not determined.
  - **Vapour density:** Not determined.
  - **Evaporation rate:** Not determined.

- **Solubility in / Miscibility with water:** Not miscible or difficult to mix.

- **Partition coefficient: n-octanol/water:** Not determined.

- **Viscosity:**
  - **Dynamic:** Not determined.
  - **Kinematic:** Not determined.

- **Solvent content:**
  - **Water:** <60 %
  - **VOC (EC):** 0.00 %

- **Other information**
  - No further relevant information available.

### 10 Stability and reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
11 Toxicological information

- Information on toxicological effects
- Acute toxicity
  Harmful if inhaled.

- LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th></th>
<th>Oral</th>
<th>Inhalative</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50</td>
<td>4,403 mg/kg</td>
<td>4.71 mg/l (rat)</td>
</tr>
<tr>
<td>LC50/4 h</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7784-13-6 Aluminum Chloride Hexahydrate

| Oral  | LD50 | 1,990 mg/kg (mouse) |
|       |      | 3,300 mg/kg (rat)   |

1303-96-4 Sodium Borate

| Oral  | LD50 | 5,330 mg/kg (Guinea pig) |
|       |      | 2,000 mg/kg (mouse)     |
|       |      | 396-689 mg/kg (rat)     |
| LC50 Fish | 54 mg/l (Fish) |
| Dermal | LD50 | >2,000 mg/kg (rabbit)   |
| Inhalative | LC50/4 h | >0.002 mg/l (rat) |

- Primary irritant effect:
  - Skin corrosion/irritation
    Causes severe skin burns and eye damage.
  - Serious eye damage/irritation
    Causes severe skin burns and eye damage.
  - Respiratory or skin sensitisation
    Based on available data, the classification criteria are not met.
  - CMR effects
    - 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.

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:
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Trade name: ViscoStat™ Clear

Must not reach sewage water or drainage ditch undiluted or unneutralised. Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
  - Other adverse effects No further relevant information available.

13 Disposal considerations

- Waste treatment methods
  - Recommendation Do not allow product to reach sewage system.

- European waste catalogue
  - HP6 Acute Toxicity
  - HP10 Toxic for reproduction

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - ADR, IMDG, IATA UN2581

- UN proper shipping name
  - ADR 2581 ALUMINIUM CHLORIDE SOLUTION
  - IMDG, IATA ALUMINIUM CHLORIDE SOLUTION

- Transport hazard class(es)
  - ADR, IMDG, IATA

  - Class 8 Corrosive substances.
  - Label 8

- Packing group
  - ADR, IATA III

- Environmental hazards:
  - Not applicable.

- Special precautions for user
  - Warning: Corrosive substances.
  - EMS Number: F-A,S-B
  - Segregation groups Acids
  - Stowage Category A

- Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.
51.0.1 Transport/Additional information:

- ADR
- Limited quantities (LQ) 5L
- Excepted quantities (EQA)
  - Code: E1
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 1000 ml
- UN "Model Regulation":
  - UN 2581 ALUMINIUM CHLORIDE SOLUTION, 8, III

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- National regulations:
- Other regulations, limitations and prohibitive regulations
- Substances of very high concern (SVHC) according to REACH, Article 57
  - 1303-96-4 Sodium Borate
- Chemical safety assessment:
  - Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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.

- Relevant phrases
  - H302 Harmful if swallowed.
  - H360FD May damage fertility. May damage the unborn child.
  - H361f Suspected of damaging fertility.
  - H373 May cause damage to organs through prolonged or repeated exposure.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service
- Abbreviations and acronyms:
  - ADR: Accord européen sur le transport 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)
  - VOC: Volatile Organic Compounds (USA, EU)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - SVHC: Substances of Very High Concern
  - vPvB: very Persistent and very Bioaccumulative
  - Acute Tox. 4: Acute toxicity - oral – Category 4
  - Skin Corr. 1: Skin corrosion/irritation – Category 1
  - Repr. 1B: Reproductive toxicity – Category 1B
  - Repr. 2: Reproductive toxicity – Category 2
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2