Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 *Version number 1* *Revision: 11.11.2022*

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

· **Product identifier**

· **Trade name: ViscoStat™ Clear**

· **Article number:** SDS 66-001.13, 73203
· **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**

corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **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.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 Version number 1 Revision: 11.11.2022

Trade name: ViscoStat™ Clear

(Contd. of page 1)

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.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
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:**

CAS: 7784-13-6 EC number: 616-520-1	Aluminum Chloride Hexahydrate Acute Tox. 4, H302	>35-<55%
CAS: 1303-96-4 EINECS: 215-540-4	Sodium Borate Repr. 1B, H360FD Specific concentration limit: Repr. 1B; H360: C ≥ 8.5 %	≤1%
	Dimethicone Repr. 2, H361f; STOT RE 2, H373	≤1%

· **SVHC**

1303-96-4	Sodium Borate

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

4 First aid measures

· **Description of first aid measures**
· **General information:** Immediately remove any clothing soiled by the product.
· **After inhalation:**
This product is a viscous gel, therefore chance of inhalation is extremely low.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
If swallowed in large quantities seek medical attention.
Drink plenty of water and provide fresh air. Call for a doctor 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**
No further relevant information available.

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.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 Version number 1 Revision: 11.11.2022

Trade name: ViscoStat™ Clear

(Contd. of page 2)

· **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:**
Dilute with plenty of water.
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

· **Precautions for safe handling:**
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.
· **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

· **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 item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 Version number 1 Revision: 11.11.2022

Trade name: ViscoStat™ Clear

(Contd. of page 3)

Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
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.

· **Hand protection**

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/face protection**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Fluid
· **Colour:**	Whitish
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **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**	<1
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Fully miscible.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

(Contd. of page 4)

· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density at 20 °C:**	1.284 g/cm³
· **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**
· **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.
· **Hazardous decomposition products:** No dangerous decomposition products known.

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

(Contd. of page 5)

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	4,403 mg/kg

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)

· **Skin corrosion/irritation** Causes severe skin burns and eye damage.
· **Serious eye damage/irritation** Causes serious eye damage.
· **Germ cell mutagenicity** Does not meet the classification criteria for this hazard class.
· **Carcinogenicity** Does not meet the classification criteria for this hazard class.
· **Reproductive toxicity** Does not meet the classification criteria for this hazard class.
· **STOT-single exposure** Does not meet the classification criteria for this hazard class.
· **STOT-repeated exposure** Does not meet the classification criteria for this hazard class.
· **Aspiration hazard** Does not meet the classification criteria for this hazard class.
· **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**
· **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.
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.

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 *Version number 1* *Revision: 11.11.2022*

Trade name: ViscoStat™ Clear

(Contd. of page 6)

13 Disposal considerations

· ***Waste treatment methods***
· ***Recommendation***
Dispose of contents/container in accordance with international, federal, state, and local regulations.

· ***Uncleaned packaging:***
· ***Recommendation:*** *Disposal must be made according to official regulations.*
· ***Recommended cleansing agents:*** *Water, if necessary together with cleansing agents.*

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 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***

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *None of the ingredients is listed.*

· ***National regulations:***

· ***Substances of very high concern (SVHC) according to UK REACH***	
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 from Section 3***
H302 Harmful if swallowed.
H360FD May damage fertility. May damage the unborn child.

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.11.2022 *Version number 1* *Revision: 11.11.2022*

Trade name: ViscoStat™ Clear

(Contd. of page 7)

H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.

· ***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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye 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
· **** Data compared to the previous version altered.***