

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

Printing date 10.04.2019

Revision: 05.10.2018

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

- **Product identifier**
- **Trade name:** Astringedent™, Astringedent™ X, & ViscoStat™
- **Article number:** 10308, 10309, 64500
- **Index number:** SDS 8-001.14
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Hemostatic Agent
- **Application of the substance / the mixture** Professional Dental Hemostatic Agent
- **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 Westhoyer 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. 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**
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
- **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.

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- P103 Read label before use.
 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/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).
 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.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 10028-22-5 EINECS: 233-072-9	Iron (III) Sulfate	⚠ Eye Irrit. 2, H319	>50-≤100%
CAS: 57-55-6 EINECS: 200-338-0	Propylene Glycol	substance with a Community workplace exposure limit	>10-≤25%

- **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.
 Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
 Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
 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:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **Information for doctor:**
 · **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.

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- **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:**
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:** No special requirements.
- **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 Agent

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:**

10028-22-5 Iron (III) Sulfate

WEL (Great Britain)	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³ as Fe
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57-55-6 Propylene Glycol

WEL (Great Britain)	Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates
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- **Additional information:** The lists valid during the making were used as basis.

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· **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.**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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:****Form:***Liquid***Colour:***According to product specification*· **Odour:***Slight iron odor*· **Odour threshold:***Not determined.*· **pH-value at 20 °C:***<2*· **Change in condition****Melting point/freezing point:***Undetermined.***Initial boiling point and boiling range:** *Undetermined.*· **Flash point:***Not applicable.*

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· 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 at 25 °C:	0.2 hPa
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Partly miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	<30 %
Water:	<80 %
VOC (EC)	<30 %
Solids content:	<90.0 %
· 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:**
Reacts with peroxides.
These products will react violently with peroxides so mixing with peroxides should be avoided.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Inhalative	LC50/4 h	4.04 mg/l (rat)

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57-55-6 Propylene Glycol

Oral	LD50	18,000 mg/kg (rabbit)
	LC50 Fish	>5,000 mg/l (Fish)
Dermal	LD50	20,800 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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:**

57-55-6 Propylene Glycol		
EC50	18,100 mg/l (Algae)	
	>100,000 mg/l (daphnia)	

- **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.
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**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP 4	Irritant - skin irritation and eye damage
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	UN3264
· ADR, IMDG, IATA	
· UN proper shipping name	3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Iron (III) Sulfate)
· ADR	
· IMDG, IATA	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Iron (III) Sulfate)
· Transport hazard class(es)	
· ADR, IMDG, IATA	
	
· Class	8 Corrosive substances.
· Label	8
· Packing group	II
· ADR, IMDG, IATA	
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Corrosive substances.
· Danger code (Kemler):	60
· EMS Number:	F-A,S-B
· Segregation groups	Acids
· Stowage Category	A
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

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· **UN "Model Regulation":** *UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Iron (III) Sulfate), 8, II*

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
- **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**
H319 Causes serious eye irritation.
- **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
vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

GB2