Safety Data Sheet
acc. to OSHA HCS

Printing date 09/27/2023 Reviewed on 09/27/2023

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1 Identification

· **Product identifier**

· **Trade name: Astringedent™ - Astringedent™ X - ViscoStat™**

· **Article number:** SDS 8-001.15R01, 10309, 64500, 10308
· **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

· **Information department:** Customer Service
· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS05 Corrosion

Skin Corrosion 1A	H314 Causes severe skin burns and eye damage.
Eye Damage 1	H318 Causes serious eye damage.

GHS07

Acute Toxicity - Inhalation 4 H332 Harmful if inhaled.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS05, GHS07
· **Signal word** Danger

· **Health Hazard-determining components of labeling:**
Iron (III) Sulfate
· **Hazard statements**
H332 Harmful if inhaled.
H314 Causes severe skin burns and eye damage.
· **Precautionary statements**

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.
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.

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

· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 3
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *3
Fire = 0
Reactivity = 0

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3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
10028-22-5	Iron (III) Sulfate	>14-<50%
25322-68-3	Polyethylene Glycol	>10-<30%
57-55-6	Propylene Glycol	>5-<25%
	Trade Secret	>1-<10%

· **Additional information:**
The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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 copious amounts of water and provide fresh air. Immediately call a doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
· **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 neutralizing 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 protection against explosions and fires:** 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 receptacle tightly sealed.
· **Specific end use(s)** Professional dental hemostatic agent

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
10028-22-5 Iron (III) Sulfate	
REL	Long-term value: 1 mg/m³ as Fe
TLV	Long-term value: 1 mg/m³ as Fe
25322-68-3 Polyethylene Glycol	
WEEL	Long-term value: 10 mg/m³ (H); MW>200
57-55-6 Propylene Glycol	
WEEL	Long-term value: 10 mg/m³
Trade Secret	
TWA	Short-term value: 0.8 mg/m³

· **Additional information:** The lists that were valid during the creation 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.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **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 is based 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

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· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	According to product specification
· **Odor:**	Slight iron odor
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C:**	1.23-1.27
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure at 25 °C:**	0.2 hPa
· **Density:**	Not determined
· **Relative density**	Not determined
· **Vapor 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
· **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.

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· **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:**

· **LD/LC50 values that are relevant for classification:**		
25322-68-3 Polyethylene Glycol		
Oral	LD50	19,600 mg/kg (Guinea pig)
		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>20,000 mg/kg (rabbit)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)
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)
Trade Secret		
Oral	LD50	>15,000 mg/kg (mouse)
		>3,300 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.139 mg/l (rat)

· **Primary irritant effect:**
· **on the skin:** Strong caustic effect on skin and mucous membranes.
· **on the eye:**
Strong caustic effect.
Strong irritant with the danger of severe eye injury.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful
Corrosive
Irritant
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

57-55-6 Propylene Glycol	
EC50	18,100 mg/kg (Algae)
Trade Secret	
EC50	>1,000 mg/kg (daphnia)

· **Persistence and degradability** No further relevant information available.
· **Behavior 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 (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 bodies of water or drainage ditch undiluted or unneutralized.
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:**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**	
· **DOT, IMDG, IATA**	UN3264
· **UN proper shipping name**	
· **DOT**	Corrosive liquid, acidic, inorganic, n.o.s.
· **IMDG, IATA**	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

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· **Transport hazard class(es)**

· **DOT**

· **Class**	8 Corrosive substances
· **Label**	6.1

· **IMDG, IATA**

· **Class**	8 Corrosive substances
· **Label**	8
· **Packing group**	
· **DOT, IMDG, IATA**	II
· **Environmental hazards:**	Not Applicable.
· **Special precautions for user**	Warning: Corrosive substances
· **Hazard identification number (Kemler code):**	60
· **EMS Number:**	F-A,S-B
· **Segregation groups**	(SGG1) Acids
· **Stowage Category**	A
· **Stowage Code**	SW2 Clear of living quarters.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not Applicable.
· **Transport/Additional information:**	
· **DOT**	
· **Quantity limitations**	On passenger aircraft/rail: 60 L On cargo aircraft only: 220 L
· **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
· **UN "Model Regulation":**	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. 8, II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

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· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

10028-22-5	Iron (III) Sulfate	ACTIVE
25322-68-3	Polyethylene Glycol	ACTIVE
57-55-6	Propylene Glycol	ACTIVE

· **Hazardous Air Pollutants**
None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **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.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Date of preparation / last revision** 09/27/2023
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value

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PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Toxicity - Inhalation 4: Acute toxicity – Category 4
Skin Corrosion 1A: Skin corrosion/irritation – Category 1A
Eye Damage 1: Serious eye damage/eye irritation – Category 1
· **** Data compared to the previous version altered.***