

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use



Date Issued : 01/19/2006
SDS No : 8-001.13
Date Revised : 05/08/2017
Revision No : 16

Astringedent®, Astringedent® X, and Viscostat

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : AS/10308, AX/10309, VS/64500
Product name : Astringedent®, Astringedent® X, and Viscostat
Product description : Hemostatic Agent

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Hemostatic Agent

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
505 W. Ultradent Drive (10200 South)
South Jordan, UT 84095

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

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300
(INTERNATIONAL) :+1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health : Acute Toxicity (Oral), Category 4
Skin Corrosion, Category 1
Acute Toxicity (Inhalation), Category 4

Environmental : Acute Hazards to the Aquatic Environment, Category 3
Chronic Hazards to the Aquatic Environment, Category 3

2.2. Label elements

Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s) :



Signal Word : DANGER

Hazard statement(s) : H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H412: Harmful to aquatic life with long lasting effects.

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H335: May cause respiratory irritation.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P260: Do not breathe dust/mist.
P264: Wash hands thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.

Response

: P301: IF SWALLOWED:
P330: Rinse mouth.
P331: Do NOT induce vomiting.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P353: Rinse skin with water [or shower].
P363: Wash contaminated clothing before reuse.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P310: Immediately call a POISON CENTER or doctor/physician.

Storage

: P273: Avoid release to the environment.
P405: Store locked up.

Disposal

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Regulation(EC) No 1272/2008 [CLP]
Iron Anion-Sulfate and Subsulfate	10028-22-5	233-072-9	< 70	Acute Tox. (O),Cat. 4; Eye Irr.,Cat. 2; STOT SE,Cat. 3; Aquatic Acute,Cat 3; Aquatic Chronic,Cat 3; H302; H319; H335

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes

: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

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Following skin : Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.

Following ingestion : IF SWALLOWED: Rinse mouth with water. Do NOT induce vomiting.

Following inhalation : If inhaled, remove victim to fresh air. Seek immediate medical assistance.

4.2. Most important symptoms and effects, both acute and delayed

Eyes : May cause damage.

Skin : May cause skin burns.

Ingestion : Harmful if swallowed.

Inhalation : May be harmful if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician : Corrosive

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.

5.3. Advice for firefighters

Fire fighting procedures : As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small Spill : Wipe up with cloth, soap and water.

Large Spill : Collect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

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Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Hemostatic Solution

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : None Required

8.2. Exposure controls

Eye/face protection : Wear eye protection .

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : AS and AX are clear liquids
 VS is a viscous liquid

Colour : AS & VS: Yellow brown AX: Dark brown

Odour : Metallic

pH : AS & VS: 1.0 - 1.5 AX: Not Determined

Specific gravity : AS: 1.15 AX: 1.35 VS: 1.22

Solubility in water : Partially Soluble

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Sensitive to light.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : None known.

10.5. Incompatible materials

Incompatible materials : Strong acids, strong bases, and oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 9200 mg/kg Rabbit

Notes : ~ 73% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 5900 mg/kg Rat/Rabbit

Notes : ~75% of the mixture consists of components of unknown toxicity (Oral)

Inhalation LC₅₀ : > 0.8 mg/l/4H Rat/Rabbit

Notes : ~73% of the mixture consists of components of unknown toxicity (Inhalation).
As this is a viscous liquid, although there are hazardous substances in the mixture, the form and use of this mixture is extremely unlikely to be inhaled. The form and LC50 Inhalation of some of the raw materials in this product supports classifying the finished with the Health Hazard Acute Toxicity Inhalation Category 4.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : 3264

14.2. UN proper shipping name

UN proper shipping name : Corrosive Liquid, Acidic, Inorganic, N.O.S. (Ferric sulfate mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Aquatic Acute, Cat 3: Acute Hazards to the Aquatic Environment, Category 3
 Aquatic Chronic, Cat 3: Chronic Hazards to the Aquatic Environment, Category 3
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract

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Category 3
H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 05/19/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** EYES, INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** COLOR, COMMENTS, ODOR, PERCENT VOLATILE, pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

General statements

: NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.