

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/19/2006

SDS No : 8-001.12

Date Revised : 05/19/2015

Revision No : 15

**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 solution

**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. 10200 S.  
 South Jordan, UT 84095

**Distributor**

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 Directive 1999/45/EC**

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

**Danger symbols** : Xn  
**R phrases** : R22

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

**Health** : Acute Toxicity (Oral), Category 4  
 Skin Corrosion, Category 1B  
**Physical** : Metal Corrosion, Category 1

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xn



Harmful

**R&S statement(s)** : R22: Harmful if swallowed.

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Hazard pictogram(s)

:

Exclamation  
mark

Signal Word

: DANGER

Hazard statement(s)

: H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H290: May be corrosive to metals.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305: IF IN EYES:

P351: Rinse cautiously with water for several minutes.

P313: Get medical advice/attention.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P361: Take off immediately all contaminated clothing.

P315: Get immediate medical advice/attention.

P301: IF SWALLOWED:

P310: Immediately call a POISON CENTER or doctor/physician.

P331: Do NOT induce vomiting.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.  
(EC1975L0442-20/11/2003)**2.3. Other hazards**

Immediate concerns

: Corrosive

**SECTION 3: Composition / information on ingredients****3.1. Substances**

Not Applicable

**3.2. Mixtures**

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Iron Anion-Sulfate and Subsulfate	10028-22-5	233-072-9	< 70	Xn; R22; R36/38	Acute Tox. (O), Cat. 4; Skin Corr., Cat. 1B; Met. Corr., Cat. 1; H290; H302; H314

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

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

- Following eyes** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- 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. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

- Eyes** : Irritating to eyes.
- Skin** : May cause skin burns.
- Ingestion** : Harmful if swallowed.
- Inhalation** : None expected for this product.

**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** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

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<b>Explosion hazards</b>	: Not Determined
<b>Fire explosion</b>	: Not Determined
<b>Sensitive to static discharge</b>	: Not Determined
<b>Sensitivity to impact</b>	: Not Determined

**5.3. Advice for firefighters**

<b>Fire fighting procedures</b>	: As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.
<b>Fire fighting equipment</b>	: Water spray, alcohol - resistant foam, dry chemical or carbon dioxide

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

<b>General procedures</b>	: Refer to Section 8 for Personal Protective Equipment.
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**6.2. Environmental precautions**

<b>Water spill</b>	: Do not allow to enter sewers or drains that may lead to waterways.
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**6.3. Methods and material for containment and cleaning up**

<b>Small spill</b>	: Wipe up with cloth, soap and water.
<b>Large spill</b>	: Collect in tightly closed containers.

**6.4. Reference to other sections**

<b>Reference to other sections</b>	: Not Applicable
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**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

<b>Handling</b>	: Use suitable protective equipment.
<b>Storage</b>	: See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

<b>Shelf life</b>	: See product labeling
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**7.3. Specific end use(s)**

<b>Specific end use(s)</b>	: Professional Dental Hemostatic Solution
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**SECTION 8: Exposure controls / personal protection****8.1. Control parameters**

<b>Control parameters</b>	: Not Determined
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**8.2. Exposure controls**

<b>Eye/face protection</b>	: Wear eye protection
<b>Skin protection</b>	: Wear suitable protective clothing and gloves.

**SECTION 9: Physical and chemical properties**

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**Astringedent®, Astringedent® X, and Viscostat®****9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	: Viscostat is a Gel, Astringedent & Astringedent X are liquids.
<b>Colour</b>	: Brown
<b>Odour</b>	: Slight iron odor
<b>Solubility in water</b>	: Partially Soluble

**9.2. Other information**

<b>Percent volatile</b>	: Not Determined
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**SECTION 10: Stability and reactivity****10.1. Reactivity**

<b>Reactivity</b>	: Stable
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**10.2. Chemical stability**

<b>Chemical stability</b>	: Sensitive to light.
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**10.3. Possibility of hazardous reactions**

<b>Hazardous polymerization</b>	: None
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**10.4. Conditions to avoid**

<b>Conditions to avoid</b>	: None known.
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**10.5. Incompatible materials**

<b>Incompatible materials</b>	: Strong acids, strong bases, and oxidizing agents.
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**10.6. Hazardous decomposition products**

<b>Hazardous decomposition products</b>	: None known.
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**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute**

<b>Notes</b>	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.
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**SECTION 12: Ecological information****12.1. Toxicity**

<b>Toxicity</b>	: Not Determined
<b>Aquatic toxicity (acute)</b>	: Do not allow to enter sewers or drains that may lead to waterways.
<b>96-hour LC<sub>50</sub></b>	: Not Determined
<b>48-hour EC<sub>50</sub></b>	: Not Determined
<b>96-hour EC<sub>50</sub></b>	: Not Determined

**12.2. Persistence and degradability**

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**Astringedent®, Astringedent® X, and Viscostat®****Persistence and degradability** : Not Determined**12.3. Bioaccumulative potential****Bioaccumulative potential** : Not Determined**12.4. Mobility in soil****Mobility in soil** : Not Determined**12.5. Results of PBT and vPvB assessment****Results of PBT and vPvB assessment** : Not Determined**12.6. Other adverse effects****Environmental data** : Not Available**SECTION 13: Disposal considerations****13.1. Waste treatment methods****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** : N/A**14.6. Special precautions for user****ADR - road** : N/A**RID - rail** : N/A**IMDG - sea** : N/A**IATA - air** : N/A**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code****Transport in bulk** : N/A**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

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**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
 R36/38: Irritating to eyes and skin.  
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
 Met. Corr., Cat. 1: Metal Corrosion, Category 1  
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B  
 H290: May be corrosive to metals.  
 H302: Harmful if swallowed.  
 H314: Causes severe skin burns and eye damage.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 02/26/2015 SDS. Revised: **Section 1:**  
 . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN SKIN.

**General statements** : N/A= Not Applicable

**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.