

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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Explosion hazards	: Not Determined
Fire explosion	: Not Determined
Sensitive to static discharge	: Not Determined
Sensitivity to impact	: Not Determined

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.
Fire fighting equipment	: Water spray, alcohol - resistant foam, dry chemical or carbon dioxide

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

Water spill	: 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

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	: Not Applicable
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	: Use suitable protective equipment.
Storage	: See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life	: See product labeling
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7.3. Specific end use(s)

Specific end use(s)	: Professional Dental Hemostatic Solution
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters	: Not Determined
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8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

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9.1. Information on basic physical and chemical properties

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

9.2. Other information

Percent volatile	: Not Determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	: Stable
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10.2. Chemical stability

Chemical stability	: Sensitive to light.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: None known.
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10.5. Incompatible materials

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

Notes	: 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

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

12.2. Persistence and degradability

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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.