

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 1/19/2006

SDS No : 8-001.10

Date Revised : 6/24/2014

Revision No : 13

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

UP Dental GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: info@updental.de
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**

Danger symbols : Xn
R phrases : R22

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

Hazard pictogram(s) : Xn



Harmful

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

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

Hazard pictogram(s) :



Exclamation mark

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Signal Word : WARNING
Hazard statement(s) : H302: Harmful if swallowed.

2.3. Other hazards

Immediate concerns : R36/38: Irritating to eyes and skin.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

| Chemical Name | CAS | EINECS No. | Wt. % | Classification according to Directive 67/548/EEC |
|-----------------------------------|------------|------------|-------|--|
| Iron Anion-Sulfate and Subsulfate | 10028-22-5 | 233-072-9 | < 70 | Xn; R22; R36/38 |

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 : Wash with soap and water.

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 : Prolonged or exposure may cause skin irritation

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 : Not Applicable

SECTION 5: Fire fighting measures

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Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

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.

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 : Not Applicable

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

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Hemostatic Agent

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

Control parameters : Not Determined

8.2. Exposure controls

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Eye/face protection : Wear eye protection
Skin protection : S36/37: Wear suitable protective clothing and gloves.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Gel
Colour : Brown
Odour : Slight iron odor, Product Code VU/73202- has mint odor.
Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

Stable : Yes

10.2. Chemical stability

Chemical stability : Sensitive to light.

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

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.

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**

Dermal LD₅₀ : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

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.

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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

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Transport in bulk : N/A

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

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.
R36: Irritating to eyes.

Prepared by : Anu Kattoju**Revision summary** : This SDS replaces the 3/4/2014 SDS. Revised: **Section 1:** . **Section 2:** . **Section 4:** NOTES TO PHYSICIAN. **Section 7:** STORAGE.**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 MSDS(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.