

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

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

1.1. Product identifier

Product code : BC/10310
Product name : Astringedent Clear
Product description : Hemostatic Solution

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

Relevant identified uses : Professional Dental Hemostatic Solution

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 Westhoven 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 : C,Xi

R phrases : R36/37/38,R34

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

Health : Skin Corrosion, Category 1B

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) :  C  Xi

Corrosive Irritant

R&S statement(s) : R36/37/38: Irritating to eyes, respiratory system and skin.
 R34: Causes burns.

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

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



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

Hazard pictogram(s)



Corrosive Exclamation mark

Signal Word

: WARNING

Hazard statement(s)

: H314: Causes severe skin burns and eye damage.

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.
 P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
 P301: IF SWALLOWED:
 P315: Get immediate medical advice/attention.
 P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : Corrosive

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	Classification according to Regulation (EC) No 1272/2008 [CLP]
Aluminum Chloride Hexahydrate	7784-13-6	N/A	< 25	Xi; R36/37/38; R22	Skin Corr., Cat. 1B; H314

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

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



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Flush eye with water for 15 minutes. Get medical attention.
Following skin	: Wash with soap and water. Get medical attention if irritation develops or persists.
Following ingestion	: Get medical attention immediately.
Following inhalation	: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Eyes	: Irritating to eyes.
Skin	: Irritating to skin.
Ingestion	: May be harmful if swallowed.
Inhalation	: May cause irritation.

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

Notes to physician	: Not Applicable
---------------------------	------------------

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

General hazard	: Not Determined
Hazardous combustion products	: None known.
Explosion hazards	: None known.
Fire explosion	: Not Determined
Sensitive to static discharge	: Not Determined
Sensitivity to impact	: Not Determined

5.3. Advice for firefighters

Fire fighting procedures	: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
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	: Use only in a well ventilated area.
---------------------------	---------------------------------------

6.2. Environmental precautions

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

6.3. Methods and material for containment and cleaning up

Small spill : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large spill : After removal, flush contaminated area thoroughly with water.

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 Solution

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

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 : Liquid

Appearance : Clear

Colour : Colorless to slight yellow

Odour : Odorless or no characteristic odor

Specific gravity : 1.135

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

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 : None known.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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.

SECTION 12: Ecological information

12.1. Toxicity

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

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

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 : R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13: Disposal considerations

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



Date Issued : 03/09/2006
 SDS No : 42-001.6
 Date Revised : 05/13/2015
 Revision No : 5

Astringedent Clear

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 : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, N.O.S (Aluminum Chloride mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : III

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

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.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 H314: Causes severe skin burns and eye damage.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/24/2014 SDS. Revised: **Section 1:**
Section 2: . **Section 4:** NOTES TO PHYSICIAN. **Section 6:**
Section 7: SHELF LIFE, STORAGE, STORAGE TEMPERATURE,

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



Date Issued : 03/09/2006
SDS No : 42-001.6
Date Revised : 05/13/2015
Revision No : 5

Astringedent Clear

Section 8: PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 9:** SPECIFIC GRAVITY. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 15:** SECTION 15: Regulatory information.

: N/A= Not Applicable

: 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.

General statements

Manufacturer disclaimer