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

Ultradent® Citric Acid Solution

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

1.1. Product identifier

Product code : CT/66008, CU/15072
Product name : Ultradent® Citric Acid Solution
Product description : Root canal cleanser, conditioner, and mild chelating agent

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

Relevant identified uses : Professional Dental Root Canal Cleansing & Conditioning 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 : Xi
R phrases : R36

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

Health : Eye Irritation, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi

R&S statement(s) : R36: Irritating to eyes.

Classification according to Regulation (EC) No 1272/2008 [CLP]
Ultradent® Citric Acid Solution

Hazard pictogram(s) : Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H319: Causes serious eye irritation.

Precautionary statement(s)


Storage : P273: Avoid release to the environment.


2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Directive 67/548/EEC</th>
<th>Classification according to Regulation (EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>10 - 20</td>
<td>Xi; R36/37/38</td>
<td>Eye Irr., Cat. 2; H319</td>
</tr>
</tbody>
</table>

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 : Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes.

Following skin : Wash with soap and water.
Ultradent® Citric Acid Solution

Following ingestion: Give large volumes of water. Do not induce vomiting. Consult a physician if ingested in large amounts.

Following inhalation: Good general ventilation should be sufficient to control airborne levels.

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

Eyes: Mildly irritating to eyes.

Skin: Substance does not generally irritate and is only mildly irritating to the skin.

Ingestion: May cause mild irritation.

Inhalation: May cause mild irritation to the lungs.

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

Hazardous combustion products: Carbon Dioxide

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: General: Evacuate all personnel; use protective equipment for firefighting. Use self-contained breathing apparatus when the product is involved in fire.

Fire fighting equipment: Foam, dry chemical, carbon dioxide (CO₂).

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: Not Applicable

6.3. Methods and material for containment and cleaning up

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

Large spill: Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections: Not Applicable
SAFETY DATA SHEET
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Dental Use

Date Issued : 03/01/2006
SDS No : 31-001.7
Date Revised : 05/05/2015
Revision No : 8

Ultradent® Citric Acid Solution

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Handling : Stable when stored and handled under recommended conditions.
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 Root Canal Cleansing & Conditioning Agent

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 : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state : Liquid
Colour : Orange

9.2. Other information
Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity
Reactivity : Stable

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 : Heat, flames, and ignition sources

10.5. Incompatible materials
Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products
Hazardous decomposition products: Carbon Dioxide

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)
- 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: Not Available

SECTION 13: Disposal considerations

13.1. Waste treatment methods


SECTION 14: Transport information

14.1. UN number

UN number: N/A

14.2. UN proper shipping name

UN proper shipping name: Not Dangerous Goods

14.3. Transport hazard class(es)
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Ultradent® Citric Acid Solution

Hazard classification : N/A

14.4. Packing group
Packing group : N/A

14.5. Environmental hazards
Marine pollutant #1 : N/A

14.6. Special precautions for user
ADR - road : Not Dangerous Goods
RID - rail : Not Dangerous Goods
IMDG - sea : Not Dangerous Goods
IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Transport in bulk : Not Dangerous Goods

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) : R36/37/38: Irritating to eyes, respiratory system and skin.
Eye Irr., Cat. 2: Eye Irritation, Category 2
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/11/2014 SDS. Revised: Section 1:
Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. Section 8: PERSONAL PROTECTIVE EQUIPMENT - SKIN. Section 10: HAZARDOUS POLYMERIZATION, STABLE. Section 11: ACUTE ( ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. Section 14: AIR (ICAO/IATA) - SPECIAL PROVISIONS VESSEL (IMO/IMDG) ( SPECIAL PROVISIONS ), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. Section 15: SECTION 15: Regulatory information.

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
Ultradent® Citric Acid Solution

determine whether they are appropriate.