

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 03/01/2006
SDS No : 31-001.8
Date Revised : 12/07/2016
Revision No : 9

Ultradent® Citric Acid Solution

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

1.1. Product identifier

Product code : 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

EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

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

Health : Eye Irritation, Category 2A

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : WARNING

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

Precautionary statement(s)

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

Response : P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313: If eye irritation persists: Get medical advice/attention.

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

Storage : P273: Avoid release to the environment.
Disposal : P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Citric Acid	5949-29-1	201-069-1	< 25	Eye Irr.,Cat. 2A; STOT SE,Cat 3; H319; H335
Siloxane	NAP	NAP	< 1	STOT SE,Cat. 2; Rep. Tox.,Cat. 2; H361f; H373

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes. : Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

Following skin : Wash with soap and water.

Following ingestion : No special measures required.

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

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

Eyes : May cause eye irritation.

Skin : May cause mild skin irritation.

Ingestion : None expected for this product.

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 : Foam, dry chemical, CO₂

5.2. Special hazards arising from the substance or mixture

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Hazardous combustion products : Carbon Dioxide

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.

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 empty into drains or the aquatic environment.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Avoid contact with eyes, skin, and clothing.

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 : Siloxane
REL: 5ppm

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 : Low viscosity liquid

Colour : Orange

pH : 1.7

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Specific gravity : 1.1 - 1.2

9.2. Other information

Additional information : No further relevant information available.

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

Dermal LD₅₀ : Not able to calculate ATE mix(dermal) due to lack of data on the components.

Oral LD₅₀ : > 13000 mg/kg Rat/Mouse

Inhalation LC₅₀ : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

Reproductive toxicity : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm. Siloxane

Other information : 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.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information 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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm. Siloxane.

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This product is not considered dangerous for transportation.

SECTION 16: Other information

- Relevant H-statements (number and full text)** : Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Rep. Tox., Cat. 2: Reproductive Toxicity, Category 2
STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3
STOT SE, Cat. 2: Target Organ Toxicity (Single exposure), Category 2
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H361f: Suspected of damaging fertility.
H373: May cause damage to organs (lungs) through prolonged or repeated exposure.
- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 05/05/2015 SDS. Revised: **Section 1:** MSDS No, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 4:** EYES, INGESTION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** WATER SPILL. **Section 7:** HANDLING. **Section 8:** . **Section 9:** COMMENTS, PERCENT VOLATILE, pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 11:** ACUTE (INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.
- General statements** : NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
AMU = Atomic Mass Unit
- 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,

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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.