

Safety Data Sheet according to WHS Regulations

Printing date 03.08.2023

Revision: 03.08.2023

1 Identification

- **Product identifier**
- **Trade name:** Ultradent™ Citric Acid Solution
- **Article number:** SDS 31-001.09R02, 15072
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Root Canal Cleansing & Conditioning Agent
- **Application of the substance / the mixture** Professional Dental Root Canal Cleansing & Conditioning Agent
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products, Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

- **Classification of the substance or mixture**



Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS05, GHS07
- **Signal word** Danger
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.

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· Precautionary statements

- P101 *If medical advice is needed, have product container or label at hand.*
- P102 *Keep out of reach of children.*
- P103 *Read label before use.*
- P260 *Do not breathe dusts or mists.*
- P303+P361+P353 *IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*
- P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
- P310 *Immediately call a POISON CENTER/doctor.*
- P321 *Specific treatment (see on this label).*
- P405 *Store locked up.*
- P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

3 Composition and Information on Ingredients

· Chemical characterisation: Mixtures**· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

5949-29-1	Citric Acid Monohydrate	≥20-<30%
	 Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
	Dimethicone	<3%
	 Repr. 2, H361f; STOT RE 2, H373	

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- General information:** Immediately remove any clothing soiled by the product.
- After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
- After skin contact:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
- Information for doctor:**
- Most important symptoms and effects, both acute and delayed** No further relevant information available.
- Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- Suitable extinguishing agents:**
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- Protective equipment:**
Wear fully protective suit.

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Mouth respiratory protective device.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

· **Handling:**

· **Precautions for safe handling:**

Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· **Information about fire - and explosion protection:** Keep respiratory protective device available.

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:**

See product labelling.

Keep container tightly sealed.

· **Specific end use(s)** Professional Dental Root Canal Cleansing & Conditioning Agent

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** The lists valid during the making were used as basis.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

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· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· Form:	Liquid
· Colour:	Orange
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value at 20 °C:	1.7

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	100 °C
· Flash point:	Not Determined
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.1-1.2 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

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|--|--|
| · Solubility in / Miscibility with | |
| · water: | Partly soluble. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| · Dynamic: | Not determined. |
| · Kinematic: | Not determined. |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity Stable**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
 - Ignition sources
 - Flames
 - Heat
- **Incompatible materials:** Strong caustics, most metals
- **Hazardous decomposition products:** Carbon dioxide

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:
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5949-29-1 Citric Acid Monohydrate
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Oral LD50	5,790 mg/kg (mouse)
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- **Skin corrosion/irritation** Causes severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
 - Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
 - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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Must not reach sewage water or drainage ditch undiluted or unneutralised.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Dispose of contents/container in accordance with international, federal, state, and local regulations.

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**

· **ADG, ADN, IMDG, IATA** not regulated

· **UN proper shipping name**

· **ADG, ADN, IMDG, IATA** not regulated

· **Transport hazard class(es)**

· **ADG, ADN, IMDG, IATA**

· **Class** not regulated

· **Packing group**

· **ADG, IMDG, IATA** not regulated

· **Environmental hazards:** Not applicable.

· **Special precautions for user** Not Applicable

· **Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **UN "Model Regulation":** not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

7732-18-5	Water
5949-29-1	Citric Acid Monohydrate
11138-66-2	Xanthan Gum
1934-21-0	FD&C Yellow <u>5</u>
25956-17-6	FD&C Red <u>40</u>

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· Standard for the Uniform Scheduling of Medicines and Poisons
None of the ingredients is listed.
· Australia: Priority Existing Chemicals
None of the ingredients is listed.
· Directive 2012/18/EU
· Named dangerous substances - ANNEX I *None of the ingredients is listed.*
· Chemical safety assessment:
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases from Section 3
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
· Department issuing SDS: Environmental, Health, and Safety
· Contact: Customer Service

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

· * Data compared to the previous version altered.

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