

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 05/09/2008

SDS No : 216-001.3

Date Revised : 10/19/2015

Revision No : 2

Ultrapro™ Tx Handpiece Lubricant

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

1.1. Product identifier

Product code : 8316
Product name : Ultrapro™ Tx Handpiece Lubricant
Product description : Hand Piece Lubricant

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

Relevant identified uses : Dental Handpiece Lubricant

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
 This material is not considered hazardous to health.

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

Health : Not Classified

2.2. Label elements

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

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.
 P337+P313: If eye irritation persists: Get medical advice/attention.
 P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P313: Get medical advice/attention.

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P301: IF SWALLOWED:
P330: Rinse mouth.
P309+P311: IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

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 : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

No Hazardous Components To Report

SECTION 4: First aid measures

4.1. Description of first aid measures

General notes : No recommendations given.
Following eyes : Flush eyes with water. Get medical attention if irritation develops or persists.
Following skin : Remove contaminated clothing. Wash with soap and water.
Following ingestion : Rinse mouth out with water. Seek medical attention if irritation develops or persists.
Following inhalation : Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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

Eyes : May cause mild irritation.
Skin : May cause slight irritation.
Ingestion : Not a likely route of exposure.
Inhalation : May cause irritation.

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

Notes to physician : NO recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY!

SECTION 5: Fire fighting measures

5.1. Extinguishing media

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

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5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Oxides of carbon

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 : Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media
Water.

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

6.4. Reference to other sections

Reference to other sections : For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : No specific usage precautions noted.

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) : Dental Handpiece Lubricant

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.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Clear
Odour	: No characteristic odor
Flash point	: > 150°C (338°F) COC (Cleveland Open Cup)
Flammable limits	: Not available
Density	: 0.85 at 25°C
Solubility in water	: Insoluble
Auto-ignition temperature	: Not Available
Viscosity	: 30 cSt at 40°C

9.2. Other information

(VOC)	: Non-Volatile
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	: No specific reactivity hazards associated with this product. Reaction with: Oxidizing materials.
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10.2. Chemical stability

Chemical stability	: Stable under normal temperature conditions and recommended use.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: Avoid exposing to heat and contact with strong oxidizing substances.
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10.5. Incompatible materials

Incompatible materials	: Strong oxidizing agents
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10.6. Hazardous decomposition products

Hazardous decomposition products	: During fire, toxic gases (CO, CO ₂) are formed.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute	
Oral LD ₅₀	: 20000 mg/kg
Irritation	: Serious eye damage/irritation: not irritating
Corrosivity	: Skin Corrosion/Skin Irritation: not irritating/ not irritating
Sensitisation	: Respiratory or skin sensitization: Toxicological studies are not yet

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available. Not sensitizing.

Mutagenicity

: Germ cell mutagenicity: Negative.

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.

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : The product is expected to be biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential : No data available on bioaccumulation.

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : This product does not contain any PBT or vPvB Substances.

12.6. Other adverse effects

Environmental data : Biodegradable

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 : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

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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
 Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 10/23/2014 SDS. Revised: **Section 1:** PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** ADDITIONAL INFORMATION, INGESTION, NOTES TO PHYSICIAN, SKIN. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** COMMENTS, . **Section 7:** HANDLING. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 9:** AUTOIGNITION TEMPERATURE, DENSITY, FLAMMABLE LIMITS, FLASHPOINT AND METHOD, PERCENT VOLATILE, SOLUBILITY IN WATER, VISCOSITY #1, (VOC). **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)), COMMENTS, MUTAGENICITY, SENSITIZATION, IRRITATION, CORROSIVITY. **Section 12:** CHEMICAL FATE INFORMATION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) - Notes SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** COMMENTS, SECTION 15: Regulatory information. **Section 16:** Revision Summary, GENERAL STATEMENTS.

General statements : N/A= Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and

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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.