

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/10/2007

SDS No : 181-001.3

Date Revised : 05/19/2015

Revision No : 3

DermaDam®

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

1.1. Product identifier

Product code : 298, 311, 314, S313
Product name : DermaDam®
Product description : Latex Rubber Dam

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

Relevant identified uses : Professional Dental Latex Barrier

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.
 This material is not considered hazardous to health.

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

Health : Skin Sensitization, Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC : This material is not considered to be hazardous for the health.

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

Hazard statement(s) : H317: May cause an allergic skin reaction.

Precautionary statement(s)

Prevention : P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Response : P302+P352: IF ON SKIN: Wash with plenty of soap and water
 P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

Storage : P273: Avoid release to the environment.

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Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : May cause sensitization.

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]
Latex	9006-04-6	232-689-0	~ 100	Skin Sens., Cat. 1; H317

Additional information : Latex is not considered hazardous.

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 : No special measures required.

Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : No special measures required.

Following inhalation : No special measures required.

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

Eyes : None expected for this product.

Skin : May cause sensitization to skin.

Ingestion : None expected for this product.

Inhalation : None expected for this product.

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

Additional information : May irritate persons with latex allergies

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

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 fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
Fire fighting equipment	: Water, foam, dry chemical, CO2

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures	: None Expected.
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6.2. Environmental precautions

Water spill	: Not Applicable
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6.3. Methods and material for containment and cleaning up

Large spill	: Shovel or vacuum spill and place in a container for disposal.
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6.4. Reference to other sections

Reference to other sections	: Not Applicable
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	: Keep away from high temperature
Storage	: See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life	: See product labeling
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7.3. Specific end use(s)

Specific end use(s)	: Professional Dental Latex Barrier
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters	: Not Determined
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8.2. Exposure controls

Eye/face protection	: Not needed for normal use.
Skin protection	: Wear suitable protective clothing and gloves.
Respiratory protection	: Good general ventilation should be sufficient to control airborne levels.

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Other precautions : Use caution when using around latex sensitive persons.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Rubber sheeting

Odour : Light latex odor

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Exposure to light triggers decomposition

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Not Determined

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon Monoxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Medical grade latex has a known toxicological profile and a long history of safe use in persons who are not latex-sensitive.

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

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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 defined

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)

Primary hazard class/division : 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

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Chemical safety assessment : See Section 11
Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) :
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H317: May cause an allergic skin reaction.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 05/12/2014 SDS. Revised: **Section 1:** Date-Revised.

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 determine whether they are appropriate.