

SAFETY DATA SHEET

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

Date Issued : 3/3/2008
SDS No : 163-001.2
Date Revised : 5/12/2014
Revision No : 3

Non-Latex DermaDam

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

1.1. Product identifier

Product name : Non-Latex DermaDam
Product description : Non-Latex Rubber Dam

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

Relevant identified uses : Professional Dental Barrier

1.3. Details of the supplier of the safety data sheet

Manufacturer

Isaksson Gummiindustri/Profimed AB
 Box 6074
 129 97 Hägersten
Emergency Contact : Peter Ahren
Emergency Phone : 08-646-1911

Distributor

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095
Emergency Phone : 801-553-4539

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

2.2. Label elements

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

Hazard statement(s) : 9502HLMN: This Material is not considered to be hazardous for the health.

2.3. Other hazards

Immediate concerns : May cause sensitization.

Additional information : Polyisoprene is generally considered non-hazardous and is safe for use by persons who know they are susceptible to natural latex allergies. However, the product contains higher levels of dithiodicarbamate than natural rubber latex and the nitrosamine by-products may cause sensitization by skin contact and give rise to Type IV Allergies. Persons who know they are susceptible to nitrosamines should avoid contact with DermaDam non-latex.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC
Polyisoprene rubber	9003-31-0	N/A	~ 100	Not Applicable

Additional information : Polyisoprene rubber is not considered to be 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.

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 spray, fog, or mist, foam, dry chemical, carbon dioxide.

SECTION 6: Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

General procedures : None Expected.

6.2. Environmental precautions

Water spill : Not Applicable

6.3. Methods and material for containment and cleaning up

Large spill : Sweep up and place in a container for disposal. Avoid raising dust.
Ventilate area and wash spill site after material pickup is complete.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Minimize direct contact with eyes or skin and prevent inhalation of dust.

Handling : Keep away from high temperature

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 Barrier

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Not needed for normal use.

Skin protection : S36/37: Wear suitable protective clothing and gloves.

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

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 : Characteristic odor

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

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10.1. Reactivity

Stable : Yes

10.2. Chemical stability

Chemical stability : Exposure to light triggers decomposition

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

10.4. Conditions to avoid

Conditions to avoid : Strong oxidizing agents

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon Monoxide and Carbon Dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

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

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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 classified

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 : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

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 : Not Determined

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) : R36: Irritating to eyes.

Revision summary : This SDS replaces the 3/3/2008 SDS.

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General statements

: NA = Not Applicable

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.