

SAFETY DATA SHEET

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

Date Issued : 03/03/2008
SDS No : 163-001.3
Date Revised : 02/08/2016
Revision No : 4

DermaDam® Synthetic

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

1.1. Product identifier

Product code : 299
Product name : DermaDam® Synthetic
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 Dam

1.3. Details of the supplier of the safety data sheet

Manufacturer

Isaksson Gummiindustri/Profimed AB
Box 17163
104 62 Stockholm
Sweden

Emergency Contact : Peter Ahren
Emergency Phone : +46-08-646-1911
Alternate Emergency Phone : +46-07-0914-5060

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 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. This material is not considered hazardous to health.

Health : Not Classified

2.2. Label elements

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

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 : P103: Read label before use.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : Health hazard: Polyisoprene is generally considered non-hazardous and is safe

SAFETY DATA SHEET

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

Date Issued : 03/03/2008
SDS No : 163-001.3
Date Revised : 02/08/2016
Revision No : 4

DermaDam® Synthetic

for use by persons who know they are susceptible to natural latex allergies. However, the product contains higher levels of dithiocarbamate than natural latex rubber and consequently may cause sensitization by skin contact and give rise to Type IV Allergies. Persons who know they are susceptible to dithiocarbamates should avoid contact with polyisoprene. N-Nitrosamine by-products of dithiocarbamate are below BSEN12868 limits.

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]
Polyisoprene rubber	9003-31-0	N/A	~ 100	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : N/A
Following skin : Wash with soap and water. Seek medical attention if irritation develops.
Following ingestion : N/A
Following inhalation : N/A

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

Eyes : N/A
Skin : N/A
Ingestion : N/A
Inhalation : N/A

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

Notes to physician : N/A

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

5.2. Special hazards arising from the substance or mixture

General hazard : Fire hazard: Sheetting should be protected during handling and storage should be away from naked flames as rubber is flammable. In storage areas it is advisable to observe no-smoking restrictions.

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.

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

Date Issued : 03/03/2008
SDS No : 163-001.3
Date Revised : 02/08/2016
Revision No : 4

DermaDam® Synthetic

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : No special equipment/procedures required

6.2. Environmental precautions

Water spill : N/A

6.3. Methods and material for containment and cleaning up

Small Spill : N/A

Large Spill : N/A

6.4. Reference to other sections

Reference to other sections : N/A

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from flame.

Storage : Avoid damp storage conditions.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature : Store below 26°C and away from heaters.

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Dam

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : N/A

Skin protection : N/A

Respiratory protection : N/A

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Rubber sheeting

Colour : Light Blue.

Solubility in water : Partly soluble in organic solvents.

9.2. Other information

Percent volatile : Not Volatile

Additional information : Tensile strength: 12.0 MPa
Modulus at 500% Extension: 1.3MPa
Elongation at Break: 1100%

SAFETY DATA SHEET

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

Date Issued : 03/03/2008
SDS No : 163-001.3
Date Revised : 02/08/2016
Revision No : 4

DermaDam® Synthetic

Tear Strength: 24 N/mm

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Light: Protect from prolonged exposure to light, in particular UV and bright sunlight which will degrade light coloured sheets.
Metals: Avoid contact with copper and copper containing alloys which stain light coloured sheets brown.
Oils and solvents: Avoid contact with oils, solvents and greases, which will destroy polyisoprene rubber.

The behavioural properties of polyisoprene rubber with respect to its performance when exposed to chemicals are comparable to that of natural rubber.

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 : Prolonged exposure to light, in particular UV and bright sunlight

10.5. Incompatible materials

Incompatible materials : Copper, copper containing alloys, oils, solvents and greases.

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

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

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

Date Issued : 03/03/2008
 SDS No : 163-001.3
 Date Revised : 02/08/2016
 Revision No : 4

DermaDam® Synthetic

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

Environmental data : Not Applicable

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.

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

Chemical safety assessment : Not Determined

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

Date Issued : 03/03/2008
SDS No : 163-001.3
Date Revised : 02/08/2016
Revision No : 4

DermaDam® Synthetic

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

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.