

# 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 dithiodicarbamate 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(CO<sub>2</sub>)

#### 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 LD<sub>50</sub>** : Not Determined

**Oral LD<sub>50</sub>** : Not Determined

**Inhalation LC<sub>50</sub>** : Not Determined

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Toxicity** : Not Determined

#### Aquatic toxicity (acute)

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : 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.