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.


2.3. Other hazards
Immediate concerns : Health hazard: 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 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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyisoprene rubber</td>
<td>9003-31-0</td>
<td>N/A</td>
<td>~ 100</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

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: Sheeting 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.
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### 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% |
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
DermaDam® Synthetic

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
### Additional information

This product is not considered dangerous for transportation

### SECTION 16: Other information

<table>
<thead>
<tr>
<th>Prepared by</th>
<th>Anu Kattoju</th>
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</thead>
<tbody>
<tr>
<td>Revision summary</td>
<td>This SDS replaces the 05/12/2014 SDS. Revised: <strong>Section 1</strong>: Date-Revised.</td>
</tr>
<tr>
<td>General statements</td>
<td>N/A= Not Applicable</td>
</tr>
<tr>
<td>Manufacturer disclaimer</td>
<td>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.</td>
</tr>
</tbody>
</table>