

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.05.2019

Revision: 26.03.2019

## 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** DermaDam™ Synthetic
- **Article number:** 299
- **CAS Number:**  
9003-31-0
- **Index number:** SDS 163-001.04
- **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Dam
- **Application of the substance / the mixture** Professional Dental Dam
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Isaksson Gumindustri/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
- 
- EC Responsible Person  
Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne Germany  
Email: InfoDE@ultradent.com  
Emergency Phone : +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*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 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.*  
*The substance is not classified, according to the CLP regulation.*
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.*
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.  
9003-31-0 Polyisoprene Rubber

### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** None
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**  
Avoid heat, sparks, and flames  
Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:** Protect from heat.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Store in dry conditions.  
See product labelling.  
Store in a cool place.
- **Specific end use(s)** Professional Dental Dam

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Solid
<b>Colour:</b>	Light blue
<b>Odour:</b>	Not determined
<b>Odour threshold:</b>	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

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· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Product is not flammable. Not determined. Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Not determined.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	0.00 %
· <b>Solids content:</b>	100.0 %
· <b>Other information</b>	Partly soluble in organic solvents. Tensile Strength: 12.0 MPa Modulus at 500% Extension: 1.3 MPa Elongation at Break: 1100% Tear Strength: 24 N/mm

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
  - Ignition sources
  - Sparks
  - Heat
  - Flames
- **Incompatible materials:**
  - Copper & Copper containing alloys
  - Fats & Oils
  - Solvents
- **Hazardous decomposition products:** No dangerous decomposition products known.

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- **Additional information:**  
The behavioural properties of polyisoprene rubber with respect to its performances when exposed to chemicals are comparable to that of natural rubber.

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- **UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated

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· <b>UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	<i>not regulated</i>
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	<i>not regulated</i>
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	<i>not regulated</i>
· <b>Environmental hazards:</b>	<i>Not applicable.</i>
· <b>Special precautions for user</b>	<i>Not applicable.</i>
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	<i>Not applicable.</i>
· <b>UN "Model Regulation":</b>	<i>not regulated</i>

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Chemical safety assessment:** A chemical safety assessment has not been carried out.

### 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Department issuing SDS:** Regulatory Affairs
- **Contact:** Customer Service
- **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*