

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 14.05.2020

Revision: 28.03.2019

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

- **Product identifier**
- **Trade name:** DermaDam™
- **Article number:** 311, 314
- **CAS Number:**
9006-04-6
- **EC number:**
232-689-0
- **Index number:** SDS 181-001.05
- **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Latex Barrier
- **Application of the substance / the mixture** Professional Dental Latex Barrier
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **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**



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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** GHS07
- **Signal word** Warning
- **Hazard statements**
H317 May cause an allergic skin reaction.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 14.05.2020

Revision: 28.03.2019

Trade name: **DermaDam™**

(Contd. of page 1)

- **Precautionary statements**

- P101 *If medical advice is needed, have product container or label at hand.*
- P102 *Keep out of reach of children.*
- P103 *Read label before use.*
- P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
- P272 *Contaminated work clothing should not be allowed out of the workplace.*
- P280 *Wear protective gloves.*
- P302+P352 *IF ON SKIN: Wash with plenty of water.*
- P362+P364 *Take off contaminated clothing and wash it before reuse.*
- P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
- P321 *Specific treatment (see on this label).*
- P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **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.**

9006-04-6 Natural rubber latex

- **Identification number(s)**

· **EC number:** 232-689-0

4 First aid measures

- **Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** If symptoms persist consult doctor.

- **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:**

Wear fully protective suit.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 14.05.2020

Revision: 28.03.2019

Trade name: **DermaDam™**

(Contd. of page 2)

Wear self-contained respiratory protective device.

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:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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:** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
See product labelling.
Store in a cool place.
- **Specific end use(s)** Professional Dental Latex Barrier

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:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

(Contd. on page 4)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 14.05.2020

Revision: 28.03.2019

Trade name: DermaDam™

(Contd. of page 3)

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 determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

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:**

Form:	Solid
Colour:	Blue
Odour:	Latex
Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Product is not flammable.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Not determined.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not applicable.

Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

- **Solubility in / Miscibility with water:**

Insoluble.

- **Partition coefficient: n-octanol/water:** Not determined.

- **Viscosity:**

Dynamic: Not applicable.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 14.05.2020

Revision: 28.03.2019

Trade name: **DermaDam™**

(Contd. of page 4)

Kinematic:	Not applicable.
Solids content:	100.0 %
Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** Decomposes with exposure to light
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
Light
Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

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**
May cause an allergic skin reaction.
- **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.

(Contd. on page 6)

GB2

Safety data sheet
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(Contd. of page 5)

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

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

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:**
Medical grade latex has a known toxicological profile and a long history of safe use in persons who are not latex-sensitive.

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

(Contd. on page 7)

Safety data sheet
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(Contd. of page 6)

*IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Skin Sens. 1: Skin sensitisation – Category 1*

GB2