



Safety Data Sheet according to WHS Regulations

Date of issue: 07.03.2025

Revision: 07.03.2025

1 Identification

· **Other means of identification**

· **Trade name:** DermaDam™ Synthetic

· **Article number:** SDS 163-001.05R01, 299, 330, S299

· **CAS Number:**
9003-31-0

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the mixture**

Non-latex rubber dams are manufactured from synthetic polyisoprene polymer which has physical properties similar to those of natural rubber latex, but without the proteins that occur in natural rubber latex that may cause allergic reactions. The dental dam is used as a protective oral barrier during endodontic procedures to reduce the risk of infection, to isolate the working area, to prevent particles or small objects making their way into the patient's airways and to improve patient comfort.

· **Uses advised against**

It is the responsibility of the dental practitioner to determine if the use of dental dam is appropriate for each individual patient. The dental dam should not be used in situations where the skin in the relevant area is broken, the patient has known sensitivity or other clinical considerations indicate that it should not be used.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Manufactured by Four D Rubber Company Ltd for:

*Ultradent Products, Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com*

Ultradent Australia Pty Ltd.

Level 22/2 Market Street

Sydney NSW 2000

Australia

Email: info.anz@ultradent.com

Toll Free: 1-800-290929

· **Further information obtainable from:** *Customer Service*

· **Emergency telephone number:**

CHEMTREC (NORTH AMERICA) : (800) 424-9300

(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**

The substance is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** *Void*

· **Hazard pictograms** *Void*

· **Signal word** *Void*

· **Hazard statements** *Void*

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3 Composition and Information on Ingredients

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

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:**
Not applicable under normal temperature conditions. Remove from exposure in the event of inhalation of fumes/vapours at elevated temperatures and seek medical advice.
- **After skin contact:**
Not considered hazardous for short term exposure. Product may cause type IV allergic reactions on contact within susceptible individuals. Remove exposure, perform first aid if necessary and seek medical advice in the event of type IV allergic reaction to the product.
- **After eye contact:** If product contacts eye, rinse with sterile eye wash.
- **After swallowing:** If product is ingested, perform first-aid measures, and seek medical advice.
- **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 Fire Fighting Measures

- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
Carbon dioxide
Water
Foam
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.
- **Additional information**
Will ignite if in contact with a naked flame. Observe non smoking regulations in storage areas.

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:**
No special measures required.

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See product labeling.

- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
Ideally store below 26C and away from heaters. If stored below 15C, rubber may become brittle and lose elasticity. Avoid damp storage conditions, store below 70% relative humidity. Avoid exposure to ionising radiation sources. Store away from sources of ozone such as mercury vapour lamps and high voltage electrical equipment. Avoid contact with copper, manganese and associated alloys containing either metal which will cause staining. Avoid contact with oils, solvents and greases, which will destroy synthetic rubber.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Product should be stored flat in supplied container with lid closed when not in use. Protect from prolonged exposure to light, especially bright sunlight or strong U.V. light.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Appropriate engineering controls** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **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.
The product is intended to be used with latex or non-latex gloves by the operator. The product should not be used on broken skin.
- **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

- **General Information**
- **Appearance:**
- **Form:** Rubber Sheetting, either as a roll or cut squares
- **Colour:** Not determined.
- **Odour:** Characteristic 'rubber' odour
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.

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- **Change in condition**
 - **Melting point/freezing point:** Undetermined.
 - **Initial boiling point and boiling range:** Undetermined.
 - **Flash point:** Not applicable.
 - **Flammability** Product is not flammable.
 - **Decomposition temperature:** Not determined.
 - **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.
 - **Kinematic:** Not applicable.
-
- **Other information**
 - **Particle characteristics** Not determined.
 - **Physical state** Solid

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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**
Not thought to cause skin irritation. Traces of the processing additives within synthetic rubber latex can cause contact irritant dermatitis in some cases, leading to redness, soreness, dryness or cracking of the skin.
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.
- **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**
No known significant effects or critical hazards.
Based on available data, the classification criteria are not met.

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- **STOT-single exposure**
No information available
Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
Not known.
Based on available data, the classification criteria are not met.
- **Aspiration hazard**
Product is intended to be placed in the mouth, improper use could cause an aspiration hazard. Product is intended to be used by professionals, and the patient should be continually supervised when the product is in use.
Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
Allergies: Traces of the processing additives within the synthetic rubber latex can give rise to type IV allergic reactions, leading to redness, soreness, dryness or cracking of the skin.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability**
Synthetic rubber does biodegrade over time, however the time taken to fully degrade the rubber varies with the composition of the rubber and the conditions it experiences. Certain conditions are more favourable to rubber degradation. The degradation products are not known to be harmful to the environment to the best of our knowledge.
- **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**
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|----------------------------------|---------------|
| · UN-Number | |
| · ADG, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADG, IMDG, IATA | not regulated |

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· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, 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**

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

Substance is not listed.

· **Australian Inventory of Industrial Chemicals**

Substance is listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

Substance is not listed.

· **Australia: Priority Existing Chemicals**

Substance is not listed.

· **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:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety