



Safety data sheet according to UK REACH

Printing date 07.03.2025

Version number 1

Revision: 07.03.2025

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

· **Product identifier**

· **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

EC Responsible Person

Ultradent Products GmbH

Am Westhoyer 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**

The substance is not classified, according to the GB CLP regulation.

· **Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** *Void*

· **Hazard pictograms** *Void*

· **Signal word** *Void*

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· **Hazard statements** Void

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3 Composition/information on ingredients

- **Substances**
- **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:**
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.
- **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.
Carbon dioxide
Water
Foam
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **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.

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7 Handling and storage

- **Precautions for safe handling:**

No special measures required.

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/personal protection

- **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**

- **Appropriate engineering controls** No further data; see section 7.

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not required.

- **Hand protection**

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/face protection** Not required.

- **Body protection:** Protective work clothing

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· Physical state	<i>Solid</i>
· Colour:	<i>Not determined.</i>
· Odour:	<i>Characteristic 'rubber' odour</i>
· Odour threshold:	<i>Not determined.</i>
· Melting point/freezing point:	<i>Undetermined.</i>
· Boiling point or initial boiling point and boiling range	<i>Undetermined.</i>
· Flammability	<i>Product is not flammable.</i>
· Lower and upper explosion limit	
· Lower:	<i>Not determined.</i>
· Upper:	<i>Not determined.</i>
· Flash point:	<i>Not applicable.</i>
· Decomposition temperature:	<i>Not determined.</i>
· pH	<i>Not applicable.</i>
· Viscosity:	
· Kinematic viscosity	<i>Not applicable.</i>
· Dynamic:	<i>Not applicable.</i>
· Solubility	
· water:	<i>Insoluble.</i>
· Partition coefficient n-octanol/water (log value)	<i>Not determined.</i>
· Vapour pressure:	<i>Not applicable.</i>
· Density and/or relative density	
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>

· **Other information**

· Appearance:	
· Form:	<i>Rubber Sheeting, either as a roll or cut squares</i>
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	<i>Not determined.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Change in condition	
· Evaporation rate	<i>Not applicable.</i>

· **Information with regard to physical hazard classes**

· Explosives	<i>Void</i>
· Flammable gases	<i>Void</i>
· Aerosols	<i>Void</i>
· Oxidising gases	<i>Void</i>
· Gases under pressure	<i>Void</i>
· Flammable liquids	<i>Void</i>
· Flammable solids	<i>Void</i>
· Self-reactive substances and mixtures	<i>Void</i>
· Pyrophoric liquids	<i>Void</i>
· Pyrophoric solids	<i>Void</i>
· Self-heating substances and mixtures	<i>Void</i>
· Substances and mixtures, which emit flammable gases in contact with water	<i>Void</i>
· Oxidising liquids	<i>Void</i>
· Oxidising solids	<i>Void</i>

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· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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:** 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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **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.
- **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.
- **Information on other hazards**

- **Endocrine disrupting properties**

Substance is not listed.

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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.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **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.

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

<ul style="list-style-type: none"> · UN number or ID number · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · UN proper shipping name · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class 	<i>not regulated</i>
<ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · Environmental hazards: 	<i>Not applicable.</i>
<ul style="list-style-type: none"> · Special precautions for user 	<i>Not Applicable</i>
<ul style="list-style-type: none"> · Maritime transport in bulk according to IMO instruments 	<i>Not applicable.</i>

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· **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.

· **Poisons Act**

· **Regulated explosives precursors**

Substance is not listed.

· **Regulated poisons**

Substance is not listed.

· **Reportable explosives precursors**

Substance is not listed.

· **Reportable poisons**

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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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