

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Trade Name: JOSPI®

Product Name: JOSPI® Dental Dam

Product Description: Natural Rubber Latex - Dental DAM

Relevant Product Use: Dental Latex Barrier - for professional dental use only. Intended for isolating a tooth from fluids in the mouth during dental procedures.

CAS-Number: 9006-04-6

EC-Number: 232-689-0

MANUFACTURER:

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SECTION 2: HAZARDS IDENTIFICATION



Classification of the substance or mixture 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.

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.

P280 Wear protective gloves.

P362+364 Take off contaminated clothing and wash it before reuse.

P333+313 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.

P235+410 Keep cool. Protect from sunlight

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Description: Mixture of substances listed below with nonhazardous additions. Please note that Light Dental Rubber Dam does not include pigments.

Name	Chemical Name	CAS	EINECS	Content
Dental Rubber Dam - made from - Natural Rubber Latex	NRL / C5H8	009006-04-6	232-689-0	>99 %
Pigment used in Green Dental Dam	Phtalocyanine Green	1328-53-6	215-524-7	<0,1%

SECTION 4: FIRST AID MEASURES

General information: May cause allergic reaction. If patient exhibits sensitivity to latex proteins, immediately remove any clothing soiled by the product.

After eye contact: Rinse opened eye under running water for at least 15 minutes. Get medical advice/attention if irritation persists.

After ingestion: Get medical advice/attention.

After inhalation: Supply fresh air and get medical advice/attention. In case of unconsciousness place patient in stable side position for transportation.

After skin contact: Immediately wash with water and soap and rinse thoroughly. If a rash or swelling develops, take antihistamine or try a soothing lotion. If skin irritation persists, get medical advice/attention.

Information for doctor: No further relevant information available.

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

SECTION 5: FIRE-FIGHTING MEASURES**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.

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. Wear self-contained respiratory protective device.

SECTION 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: Collect mechanically, dispose contaminated material as waste in accordance with section 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.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Ensure good ventilation/exhaustion at the workplace. When handling latex dental dams do not use oil based hand creams or lotions which can cause deterioration of the dam, unless they have shown to reduce latex related problems and maintain barrier protection.

Information about fire - and explosion protection: No special measures required.

Conditions for safe storage, including any incompatibilities

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: Keep out of reach of children. Protect from exposure to UV-light. Store in a cool place, keep refrigerated when storing long term. See product labelling for more information.

Storage Temperature: 3°C Minimum to 30°C Maximum

Specific end use(s): Dental Latex Barrier - for professional dental use only. Intended for isolating a tooth from fluids in the mouth during dental procedures.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Precautions: Exercise caution when using product near persons with increased risk of latex sensitivity.

Ingredients with limit values that require monitoring at the workplace: Not required.

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: Use of protective gloves is recommended if user has increased risk for allergic reaction to protein found in Natural Rubber Latex.



Material of gloves: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies depending on manufacturer.

Penetration time of glove material: To ensure minimal risk, we recommend a maximum wearing time which corresponds to 50% of the gloves penetration time as determined by EN 374 part III.

Eye protection: Not required.

Body protection: Protective work clothing

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties - General Information****Appearance**

Form: Solid rubber sheeting

Colour: Green / Light

Odour: Light latex odor

Odour threshold: Not determined.

pH-value: Not applicable.

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: >267°C (514°F)

Auto-ignition temperature: Not determined.
Explosive properties: Product does not present an explosion hazard.
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.
Dynamic viscosity: Not applicable.
Kinematic viscosity: Not applicable.
Solvent content VOC (EC): 0.00 %
Solids content: 100.0 %
Other information: Partly soluble in organic solvents. No further relevant information available.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not reactive
Chemical stability: Chemically stable
Possibility of chemical reactions: None known
Thermal decomposition / conditions to be avoided: Decomposes at extreme temperatures, greater than 267°C (514°F). Exposure to UV-light in combination with free oxygen triggers a slow decomposition.
Possibility of hazardous reactions: No dangerous reactions known.
Conditions to avoid: Light, Heat
Incompatible materials: Strong oxidizers
Hazardous decomposition products: Will decompose into carbon dioxide, carbon monoxide and hydrocarbons at extremely high temperatures.

SECTION 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.

Sensitization: Exposure to natural rubber may cause allergic reactions such as skin rashes, hives, nasal, eye or skin symptoms, asthma or in extreme cases, anaphylactic shock.

SECTION 12: ECOLOGICAL INFORMATION

Aquatic toxicity: No further relevant information available.

Persistence and degradability: No further relevant information available.

Behaviour in environmental systems

Bioaccumulative potential: Material will not bioconcentrate in fish and aquatic organisms nor will it absorb to sediment and suspended organic matter.

Mobility in soil: No further relevant information available.

Other adverse effects: No further relevant information available.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal method: Dispose of in compliance with governmental regulation (EC 1975L0442-20/11/2003) or in accordance with local regulations.

Recommendation: Dispose if shelf-life has been exceeded. Do not allow product to be processed in sewage system.

SECTION 14: TRANSPORT INFORMATION**UN-Number (ADR, ADN, IMDG, IATA):** Not regulated.**UN proper shipping name (ADR, ADN, IMDG, IATA):** Not regulated.**Road and Rail (ADR/RID) Hazard Class:** No classification.**Air (ICAO/IATA) Hazard Class:** No classification.**Vessel (IMO/IMDG) Hazard Class:** No classification.**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.**SECTION 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 latexsensitive.**SECTION 16: OTHER INFORMATION****Prepared By:** Johannes Fengved**Manufacturer Disclaimer:** FOR DENTAL USE ONLY. Use as directed.

This information is based on our present knowledge, and is believed to be accurate; however, Isakssons Gummifabrik AB 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. The information found in this data sheet shall not constitute a guarantee for any specific product features and does not establish a legally valid contractual relationship.

Abbreviations and acronyms**ADN:** European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways**ADR:** European Agreement concerning the International Carriage of Dangerous Goods by Road**C:** Celsius**CAS:** Chemical Abstracts Service (division of the American Chemical Society)**CLP:** Classification, Labelling, and Packaging**DSD:** Dangerous Substance Directive**DSL:** Domestic Substances List**EC:** European Commission**EEC:** European Economic Community**EIN:** European Inventory of (Existing Commercial Chemical Substances)**EINECS:** European Inventory of Existing Commercial Chemical Substances**EPA:** Environmental Protection Agency**EU:** European Union**F:** Fahrenheit**GHS:** Globally Harmonised System of Classification and Labelling of Chemicals**IARC:** International Agency for Research on Cancer**IATA:** International Air Transport Association**ICAO:** International Civil Aviation Organization**IDL:** Ingredient Disclosure List**IDLH:** Immediately Dangerous to Life and Health**IMDG:** International Maritime Code for Dangerous Goods**IMO:** International Maritime Organization**IUCLID:** International Uniform Chemical Information Database**LEL:** Lower Explosive Limit**LLV:** Level Limit Value**MAK:** Maximum Concentration Value in the Workplace**MEL:** Maximum Exposure Limits**Nq:** Non-quantitative**OSHA:** Occupational Safety and Health Administration**PBT:** Persistent, Bioaccumulative and Toxic**PEL:** Permissible Exposure Limit**REACH:** Registration, Evaluation, Authorisation, and restriction of Chemicals**RID:** Regulation concerning the International Carriage of Dangerous Goods by Rail**Sq:** Semi-quantitative**Skin Sens. 1:** Skin sensitisation – Category 1**STEL:** Short-term Exposure Limit**STOT:** Specific target organ toxicity**TDG:** Transportation of Dangerous Goods**TLV:** Threshold Limit Value**TSCA:** Toxic Substances Control Act**TWA:** Time Weighted Average**UEL:** Upper Explosive Limit**UN:** United Nations**VOC:** Volatile Organic Compounds (USA, EU)**vPvB:** very Persistent and very Bioaccumulative