



Safety Data Sheet

Revision Date: 04/07/25

This safety data sheet is intended to act as a guide. As a medical device, this product has no legal requirement for an SDS, and the product is not classified according to the Globally Harmonized System (GHS). The SDS has been compiled for convenience, providing information compliant with the GHS according to the format of the regulations indicated. (Ref: Regulation 1907/2006/EC Article 2 (6), Regulation 1272/2008 EC Article 1.5(a)), & OSHA HCS)

Section 1: Product and Company Identification

Product Name: Hygenic Latex Dental Dam

Chemical Family: Latex

Recommended Use: 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. The dental dam is a single use, non-invasive, non-sterile device that is designed to be used only by qualified dental professionals for the described purpose. It is not a measuring device.

Restrictions on Use: 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 to natural rubber latex or other clinical considerations indicate that it should not be used.

Canadian supplier identifier:

Company: Hygenic Company, LLC
1245 Home Avenue
Akron, OH 44310

Telephone: (330) 633-8460 (Only available during normal business hours.)

Emergency Telephone: (800) 321-2135 CHEMTREC (Transportation): (800) 424-9300
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Section 2: Hazards Identification

Natural rubber is considered non-hazardous under normal temperature conditions. At temperatures in excess of 100°C, degradation with the accompanying release of hazardous fumes may occur. Proteins in Natural Rubber Latex may cause Type I allergic reactions. Additionally, traces of processing additives may give rise to Type IV allergic reactions or contact irritant dermatitis. Product should not be used on broken skin.

Emergency Overview:

NFPA: Health = 1, Flammability = 1, Reactivity = 0

GHS Classification: None as defined under 29CFR 1910.1200

GHS Label Elements: None

Pictograms: Not applicable

Signal Word: Not applicable

Hazard Statements: None

Precautionary Statements: None

Classification According to Directive 1999/45/EC: Not applicable

European Economic Community Information: This product meets the definition of the following hazard class as defined by the European Economic Community Guidelines.

EU Classification: Not applicable

EU Risk Phrases: Not applicable

EU Safety Phrases: Not applicable

Other Hazards which do not result in classification: This product contains natural rubber latex which may cause allergic reactions, in some people, when in contact with the skin, eye, or mucosal membranes.

Section 3: Composition/Information on Ingredients

Natural Rubber Sheeting plus essential processing additives and pigments

Chemical Name	Common name and Synonyms	CAS Number and unique identifiers	Percentage concentration
Natural Rubber Latex	Rubber, Latex	9006-04-6	>97%

Section 4: First Aid Measures

Inhalation: Not applicable under normal temperature conditions. Remove from exposure in the event of inhalation of fumes/vapors at elevated temperatures and seek medical advice.

Skin Contact: Not considered hazardous for short term exposure. Product may cause type IV allergic reactions on contact within susceptible individuals. Remove from exposure, perform first aid if necessary and seek medical advice in the event of type IV allergic reaction to the product.

Eye Contact: If product contacts eye, rinse with sterile eye wash.

Ingestion: If product is ingested, perform first-aid measures and seek medical advice.

Section 5: Fire Fighting Measures

Will ignite if in contact with a naked flame. Observe non-smoking regulations in storage areas.

Suitable Extinguishing Media: Water, CO2, Foam

Unsuitable Extinguishing Media: None known

Specific Hazards in Case of Fire: None known

Special Protective Equipment for Fire-Fighters: Wear protective equipment and self-contained breathing apparatus (SCBA).

Section 6: Accidental Release Measures: Not applicable.

Personal Precautions: None

Environmental Precautions: None

Methods for Containment/Cleaning Up: None

Section 7: Handling and Storage

Handling: Observe correct manual handling procedures for bulk volumes.

Storage:

- Ideally, store below 26°C and away from heaters.
- If stored below 15°C, Rubber may become brittle and lose elasticity.
- Avoid damp storage conditions, store below 70% relative humidity.
- 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 UV light
- Avoid exposure to ionizing radiation sources
- Store away from sources of ozone such as mercury vapor 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 natural rubber.
- Store away from heat and open flames.
- Keep out of the reach of children.

Section 8: Exposure Controls/Personal Protection

US Exposure Limits:

Name	CAS Number	TWA (NIOSH)
Not Applicable	Not Applicable	Not Applicable

Engineering Controls: The product is intended to be used with gloves by the practitioner. The product should not be used on broken skin.

Personal Protective Equipment:

Eye Protection: Safety glasses or goggles

Hand Protection: Impermeable gloves

Skin and Body Protection: Overall work wear may be used

Respiratory Protection: None

Hygiene Measures: Do not eat, drink, or smoke while using the product

Section 9: Physical and Chemical Properties

Physical State: Rubber sheeting in cut squares

Color: Various

Odor: Characteristic 'rubber' odor

Odor Threshold: None

pH: Not applicable

Melting/Freezing Point: Not available

Initial Boiling Point: Not available

Flash Point: >250°C

Evaporation Rate: Not applicable

Flammability (solid, gas): Not available

Lower Explosive Limit: Not applicable

Upper Explosive Limit: Not applicable

Lower Flammability Limit: Not applicable

Upper Flammability Limit: Not applicable

Vapor Pressure: Not applicable

Vapor Density: Not applicable

Relative Density: Not available

Water Solubility: Insoluble
Partition Coefficient – n-octanol/water: Not applicable
Auto-ignition Temperature: Not available
Decomposition Temperature: >250°C
Kinematic Viscosity: Not applicable

Section 10: Stability and Reactivity

Stability: Stable under normal conditions of use.
Conditions to Avoid: Decomposes at extreme temperatures, greater than 250°C
Incompatible Materials: Strong oxidizers
Hazardous Decomposition Products: Will decompose into carbon dioxide, carbon monoxide and hydrocarbons at extremely high temperatures.
Hazardous Polymerization: Will not occur

Section 11: Toxicological Information

Allergies: Natural rubber latex proteins can cause type I allergic reactions and in rare cases can result in anaphylactic shock. Clinical reactions can involve the skin, eyes, mucous membranes and respiratory system, including localized or generalized rash (urticaria), inflammation of the mucous membranes in the nose (rhinitis), red and swollen eyes with discharge (conjunctivitis) and asthma. Traces of the processing additives within natural rubber latex can also give rise to type IV allergic reactions leading to redness, soreness, dryness or cracking of the skin.
Acute toxicity: Not thought to be toxic
Inhalation: Not classified
Ingestion: Not classified
Skin Contact: Not thought to cause skin irritation except to allergic individuals. Natural rubber latex can cause contact irritant dermatitis in some cases, leading to redness, soreness, dryness or cracking of the skin.
Eye Contact: Not thought to cause eye irritation except to allergic individuals.
Sensitization: Exposure to natural rubber may cause allergic reactions in some people such as skin rashes, hives, nasal, eye or skin symptoms, asthma or in extreme cases, anaphylactic shock.

Section 12: Ecological Information

Not water soluble. Natural rubber is considered to be biodegradable.

Section 13: Disposal Considerations

Dispose of according to local/national regulations. Use an authorized waste disposal company.

Section 14: Transport Information

Not regulated

Section 15: Regulatory Information

US Regulatory Information:

Product is registered with the Food and Drug Administration

Product complies to both Food Drug and Cosmetic act 1938 and 21 CFR subchapter H

SARA 302: No ingredients listed

SARA 311/312: Not classified

SARA 313: No ingredients listed

TSCA: No ingredients listed

California Proposition 65: No ingredients listed

NTP (National Toxicology Program) Report on Carcinogens: No ingredients listed

Canadian Regulatory Information:

DSL List: Yes

European Economic Community Information for Constituents:

Product registered with European Medicines Agency

Labelling according to Regulation (EC) No 1272/2008 not required

Product complies with EU Medical Device Regulation (MDR) 2017/745

The product contains no CMR substances of category 1A or B

The product contains no substances with endocrine disrupting properties identified in Article 59 of Regulation (EC) No 1907/2006 or Article 5(3) of Regulation (EU) No 528/2012

The product contains no substances listed on the SVHC list

EU Labeling and Classification According to Directive 1999/45/EC: This product meets the definition of the following hazard class as defined by the European Economic Community Guidelines.

EU Classification: not applicable

EU Risk Phrases: not applicable

EU Safety Phrases: not applicable

EU Symbols: None

Japanese Information:

Japanese Minister of International Trade and Industry (MITI) Status: *The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.*

Japanese ENCS Inventory: *The components of this product are on the ENCS Inventory if required.*

Poisonous and Deleterious Substances Control Law: *No component of this product is a listed poisonous, deleterious, or specified poisonous substance under the Poisonous and Deleterious Substances Control Law.*

Other International Chemical Inventories:

China Inventory of Existing Chemical Substances (IECSC): *The components of this product are on the IECSC if required.*

Korean Existing Chemicals List (KECL): *The components of this product are on the KECL if required.*

Philippines Inventory of Chemicals and Chemical Substances (PICCS): *The components of this product are on the PICCS if required.*

Section 16: Other Information

The information contained in this SDS is presented in good faith and believed to be accurate based on the information provided. The SDS does not purport to be all inclusive and shall be used only as a guide. While Performance Health, Inc. believes that the data contained herein comply with 29 CFR 1910.1200, they are not to be taken as a warranty or representation for which Performance Health, Inc. assumes legal responsibility. Performance Health, Inc. shall not be held liable or accountable for any loss or damage associated with the use of this material and information. The recommended industrial hygiene and safe use, handling, storage, and disposal procedures are believed to be generally applicable. However, since the use, handling, storage, and disposal are beyond Performance Health, Inc. control, it is the responsibility

of the user both to determine safe conditions for use of this product and to assume liability of loss, damage, or expense arising out of the material's improper use.

HMIS Classification:

Health Hazard:	1
Flammability:	1
Physical Hazards:	0

Legend:

ACGIH: American Conference of Governmental & Industrial Hygienists
CAS: Chemical Abstract Service
CFR: Code of Federal Regulations
DOT: Department of Transportation
DSL/NDL: Domestic Substances List/Non-Domestic Substances List
EC Number: EINECS Number or ELINCS Number
EINECS: European Inventory of Existing Commercial Chemical Substance
ELINCS: European List of Notified Substance
ENCS: Existing and New Chemical Substances
EU: European Union
GHS: Globally Harmonized System of Chemical Classification and Labelling
HMIS: Hazardous Materials Identification System
IARC: International Agency for the Research of Cancer
IATA: International Air Traffic Association
ICAO: International Civil Aviation Organization
IDLH: Immediately Dangerous to Life or Health
IMDG: International Maritime Dangerous Goods
IMO: International Maritime Organizations
MAK: Maximale Arbeitsplatzkonzentration (Exposure Limit)
NIOSH: National Institute of Occupational Safety and Health
NFPA: National Fire Protection Association
NTP: National Toxicology Program
OSHA: Occupational Safety & Health Administration
PEL: Permissible Exposure Limits
RCRA: Resource Conservation & Recovery Act
REL: Recommended Exposure Limits
RQ: Reportable Quantity
RTK: Right-To-Know
SARA: Superfund Amendments & Reauthorization Act
STEL: Short Term Exposure Limit
TLV: Threshold Limit Value
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average
TCLP: Toxicity Characteristic Leaching Procedure
US: United States
VOC: Volatile Organic Compounds
