

# Hygenic® Latex Dental-Dam Coltène/Whaledent GmbH & Co. KG

Version No: 1.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Issue Date: 21/04/2022 Print Date: 18/07/2022

L.GHS.USA.EN

### **SECTION 1 Identification**

### **Product Identifier**

Product name	Hygenic® Latex Dental-Dam
Chemical Name	natural rubber latex
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

### Recommended use of the chemical and restrictions on use

Medical device, for dental use only

### Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	Coltène/Whaledent GmbH & Co. KG	Coltène/Whaledent Inc.
Address	Raiffeisenstrasse 30 89129 Germany	235 Ascot Parkway Cuyahoga Falls, Ohio 44223 United States
Telephone	+49 (7345) 805 0	+1 330 916 8800
Fax	+49 (7345) 805 201	+1 330 916 7077
Website	www.coltene.com	www.coltene.com
Email	msds@coltene.com	info.us@coltene.com

### **Emergency phone number**

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE	
Emergency telephone numbers	+1 855-237-5573	
Other emergency telephone numbers	+61 3 9573 3188	

Once connected and if the message is not in your prefered language then please dial 01

Una vez conectado y si el mensaje no está en su idioma preferido, por favor marque 02

### SECTION 2 Hazard(s) identification

### Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification | Combustible Dust

Label elements

Version No: 1.1 Page 2 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

Hazard pictogram(s) Not Applicable Signal word Warning

### Hazard statement(s)

May form combustible dust concentrations in air

### Hazard(s) not otherwise classified

Not Applicable

### Precautionary statement(s) Prevention

Not Applicable

### Precautionary statement(s) Response

Not Applicable

### Precautionary statement(s) Storage

Not Applicable

### Precautionary statement(s) Disposal

Not Applicable Not Applicable

### **SECTION 3 Composition / information on ingredients**

### Substances

See section below for composition of Mixtures

### **Mixtures**

CAS No	%[weight]	Name
9006-04-6	>99	natural rubber latex

### **SECTION 4 First-aid measures**

### **Description of first aid measures**

Eye Contact	If this product comes in contact with eyes:  • Wash out immediately with water.  • If irritation continues, seek medical attention.  • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs:  Flush skin and hair with running water (and soap if available).  Seek medical attention in event of irritation.
Inhalation	<ul> <li>If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>Other measures are usually unnecessary.</li> </ul>
Ingestion	<ul> <li>Immediately give a glass of water.</li> <li>First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

### Most important symptoms and effects, both acute and delayed

See Section 11

### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

For acute or short term repeated exposures to ammonia and its solutions:

- Mild to moderate inhalation exposures produce headache, cough, bronchospasm, nausea, vomiting, pharyngeal and retrosternal pain and conjunctivitis. Severe inhalation produces laryngospasm, signs of upper airway obstruction (stridor, hoarseness, difficulty in speaking) and, in excessively, high doses, pulmonary oedema.
- Warm humidified air may soothe bronchial irritation.
- ▶ Test all patients with conjunctival irritation for corneal abrasion (fluorescein stain, slit lamp exam)
- Dyspneic patients should receive a chest X-ray and arterial blood gases to detect pulmonary oedema.

Version No: 1.1 Page 3 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### **Hygenic® Latex Dental-Dam**

**SECTION 5 Fire-fighting measures** 

### **Extinguishing media**

- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog Large fires only.

### Special hazards arising from the substrate or mixture

Fire Incompatibility

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may

Special protective equipr	nent and precautions for fire-fighters
Fire Fighting	<ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul>
Fire/Explosion Hazard	Combustion products include: carbon monoxide (CO) carbon dioxide (CO2) hydrogen cyanide nitrogen oxides (NOx) other pyrolysis products typical of burning organic material.

### **SECTION 6 Accidental release measures**

### Personal precautions, protective equipment and emergency procedures

See section 8

### **Environmental precautions**

See section 12

### Methods and material for containment and cleaning up

Minor Spills	<ul> <li>Clean up all spills immediately.</li> <li>Avoid contact with skin and eyes.</li> <li>Wear impervious gloves and safety glasses.</li> <li>Use dry clean up procedures and avoid generating dust.</li> <li>Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>Do NOT use air hoses for cleaning</li> <li>Place spilled material in clean, dry, sealable, labelled container.</li> </ul>
Major Spills	<ul> <li>Clear area of personnel and move upwind.</li> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Control personal contact with the substance, by using protective equipment and dust respirator.</li> <li>Prevent spillage from entering drains, sewers or water courses.</li> <li>Avoid generating dust.</li> <li>Sweep, shovel up. Recover product wherever possible.</li> <li>Put residues in labelled plastic bags or other containers for disposal.</li> <li>If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

Personal Protective Equipment advice is contained in Section 8 of the SDS.

### **SECTION 7 Handling and storage**

### Precautions for safe handling

Safe handling

Limit all unnecessary personal contact.

Version No: 1.1 Page **4** of **12** Issue Date: 21/04/2022 Print Date: 18/07/2022

### **Hygenic® Latex Dental-Dam**

Wear protective clothing when risk of exposure occurs.

- Use in a well-ventilated area.
- ▶ Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- ▶ Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Use good occupational work practice.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are

### Store in original containers.

- Keep containers securely sealed.
- ▶ Store in a cool, dry area protected from environmental extremes.
- ▶ Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS

### Conditions for safe storage, including any incompatibilities

### Suitable container

Other information

- ▶ Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- ▶ Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.
- ► DO NOT use aluminium or galvanised containers

Storage incompatibility

Avoid contamination of water, foodstuffs, feed or seed.

Avoid reaction with oxidising agents

### **SECTION 8 Exposure controls / personal protection**

### **Control parameters**

### Occupational Exposure Limits (OEL)

### **INGREDIENT DATA**

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-3	natural rubber latex	Inert or Nuisance Dust: Respirable fraction	5 mg/m3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	natural rubber latex	Inert or Nuisance Dust: Total Dust	15 mg/m3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	natural rubber latex	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	natural rubber latex	Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	natural rubber latex	Particulates not otherwise regulated	Not Available	Not Available	Not Available	See Appendix D

### **Emergency Limits**

Ingredient	TEEL-1	TEEL-2	TEEL-3
Hygenic® Latex Dental-Dam	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
natural rubber latex	Not Available	Not Available

### MATERIAL DATA

These "dusts" have little adverse effect on the lungs and do not produce toxic effects or organic disease. Although there is no dust which does not evoke some cellular response at sufficiently high concentrations, the cellular response caused by P.N.O.C.s has the following characteristics:

- · the architecture of the air spaces remain intact,
- · scar tissue (collagen) is not synthesised to any degree,

 Version No: 1.1
 Page 5 of 12
 Issue Date: 21/04/2022

 Print Date: 18/07/2022
 Print Date: 18/07/2022

### **Hygenic® Latex Dental-Dam**

· tissue reaction is potentially reversible.

Extensive concentrations of P.N.O.C.s may:

- · seriously reduce visibility
- · cause unpleasant deposits in the eyes, ears and nasal passages,
- · contribute to skin or mucous membrane injury by chemical or mechanical action, per se, or by the rigorous skin cleansing procedures necessary for their removal. [ACGIH]

This limit does not apply:

- · to brief exposures to higher concentrations
- · nor does it apply to those substances that may cause physiological impairment at lower concentrations but for which a TLV has as yet to be determined. This exposure standard applies to particles which
- $\cdot$  are insoluble or *poorly soluble\** in water or, preferably, in aqueous lung fluid (if data is available) and
- · have a low toxicity (i.e.. are not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, and do not emit ionizing radiation, cause immune sensitization, or cause toxic effects other than by inflammation or by a mechanism of lung overload)

### **Exposure controls**

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- F Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:
- (a): particle dust respirators, if necessary, combined with an absorption cartridge;
- (b): filter respirators with absorption cartridge or canister of the right type;
- (c): fresh-air hoods or masks
- ▶ Build-up of electrostatic charge on the dust particle, may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to efficiently remove the contaminant.

# Appropriate engineering controls

Type of Contaminant:	Air Speed:
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 ft/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 ft/min)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 ft/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

### Personal protection









- ► Safety glasses with side shields
- Chemical goggles.

# Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should

### Eye and face protection

Version No: 1.1 Page 6 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers

### Skin protection

See Hand protection below

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact.
- · chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- · Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- · Excellent when breakthrough time > 480 min
- · Good when breakthrough time > 20 min
- · Fair when breakthrough time < 20 min
- · Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene.
- nitrile rubber.
- butyl rubber.
- ▶ fluorocaoutchouc.
- ▶ polyvinyl chloride.

Gloves should be examined for wear and/ or degradation constantly.

### **Body protection**

Hands/feet protection

See Other protection below

### Other protection

No special equipment needed when handling small quantities.

- OTHERWISE: Overalls
- Barrier cream.
- ► Evewash unit

### Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

<sup>\* -</sup> Negative pressure demand \*\* - Continuous flow

### Hygenic® Latex Dental-Dam

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- · Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- · The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- · Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- · Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- · Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- · Use approved positive flow mask if significant quantities of dust becomes airborne.
- $\cdot$  Try to avoid creating dust conditions.

### **SECTION 9 Physical and chemical properties**

### Information on basic physical and chemical properties

Appearance	Coloured		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	>267
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (Not Available%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

### **SECTION 10 Stability and reactivity**

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

### **SECTION 11 Toxicological information**

### Information on toxicological effects

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives

Version No: 1.1 Page 8 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

The highly irritant properties of ammonia vapour result as the gas dissolves in mucous fluids and forms irritant, even corrosive solutions

Inhalation of the ammonia fumes causes coughing, vomiting, reddening of lips, mouth, nose, throat and conjunctiva while higher concentrations can cause temporary blindness, restlessness, tightness in the chest, pulmonary oedema (lung damage), weak pulse and cyanosis.

Inhalation of high concentrations of vapour may cause breathing difficulty, tightness in chest, pulmonary oedema and lung damage. Brief exposure to high concentrations > 5000 ppm may cause death due to asphyxiation (suffocation) or fluid in the lungs

Prolonged or regular minor exposure to the vapour may cause persistent irritation of the eyes, nose and upper respiratory tract. Massive ammonia exposures may produce chronic airway hyperactivity and asthma with associated pulmonary function changes. The average nasal retention of ammonia by human subjects was found to be 83%.

### Ingestion

The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

### Skin Contact

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Open cuts, abraded or irritated skin should not be exposed to this material

### Eve

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

The vapour when concentrated has pronounced eye irritation effects and this gives some warning of high vapour concentrations. If eye irritation occurs seek to reduce exposure with available control measures, or evacuate area.

Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

There is a possibility that unintended contact with this product (such as through a cut, needle stick, eye or mucous membrane, or inhalation) could result in allergic or hypersensitivity reactions. Such reactions are more likely following repeated exposures or in persons with a pre-existing allergy to certain proteins.

### Chronic

Dusts produced by proteins are capable, under certain conditions, of sensitising workers by virtue of the bodies reaction to foreign proteins. Typical allergic asthma may be rapidly produced after exposure, with symptoms may include chronic cough, sputum production, fever, myalgia, fatigue, airway obstruction; chest radiographs may show a generalised reticulonodular pattern, or basal or apical fibrosis. In addition there may be retrosternal discomfort, headache, stomach-ache and general severe dyspnoea may develop giving a clinical picture similar to that of farmer's lung and allied conditions of extrinsic allergic alveolitis. No irritation is likely after brief skin contact, but prolonged contact in the presence of moisture may result in soreness, redness, inflammation and possible ulceration of the skin. Repeated attacks may lead to permanent impairment of lung function due to fibrotic change.

Hygenic® Latex	TOXICITY	IRRITATION
Dental-Dam	Not Available	Not Available
	TOXICITY	IRRITATION
natural rubber latex	Not Available	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS.	

Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Occupational exposures in the rubber-manufacturing industry are carcinogenic to humans (Group 1), IARC Working Groups There is sufficient evidence in humans for the carcinogenicity of occupational exposures in the rubber-manufacturing industry. Occupational exposures in the rubber-manufacturing industry cause leukaemia, lymphoma, and cancers of the urinary bladder, lung, and stomach.

Also, a positive association has been observed between occupational exposures in the rubber-manufacturing industry and cancers of the prostate, oesophagus, and larynx.IARC Working Group.

### Hygenic® Latex **Dental-Dam**

The multiple genetic and cytogenetic effects observed among workers employed in the rubber-manufacturing industry provide strong evidence to support genotoxicity as one mechanism for the observed increase in cancer risks. However, due to the complexity and changing nature of the exposure mixture and the potential interactions between exposures in the rubbermanufacturing industry, other mechanisms are also likely to play a role. While it is clear that exposure to some agents in the rubber-manufacturing industry has been reduced over time, the results of recent cytogenetic studies continue to raise concerns about cancer risks.

The rubber-manufacturing industry has used and still uses a wide variety of substances that belong to many different chemical categories, e.g. carbon black, aromatic amines, PAH, N-nitrosamines, mineral oils, other volatile organic compounds from curing fumes, trace amounts of monomers from synthetic rubber like 1,3-butadiene, acetonitrile, styrene, vinyl chloride, ethylene oxide, etc.. For this reason, it has been difficult to relate the observed cancer hazards in the rubber-manufacturing industry to exposure

 Version No: 1.1
 Page 9 of 12
 Issue Date: 21/04/2022

 Print Date: 18/07/2022
 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

to specific chemicals.

Latex contains low-molecular-weight soluble proteins, which are the cause of IgE-mediated allergic reactions. At least 10 different proteins have been implicated. Added accelerators and antioxidants may also be significant mediators of type IV or allergic contact dermatitis, and may cause or exacerbate irritant contact dermatitis Latex is known to cause 2 of the 4 (or 5) types of hypersensitivity. The most serious and rare form, type I is an immediate and potentially life-threatening reaction, not unlike the severe reaction some people have to bee stings. Such reactions account for a significant proportion of perioperative anaphylactic reaction, especially in children with myelomeningocele Type IV reactions are caused by the chemicals used to process the rubber. Also known as allergic contact dermatitis. This involves a delayed skin rash that is similar to poison ivv with blistering and oozing of the skin. This type is caused by a naturally occurring latex protein. Latex can also cause irritant contact dermatitis: The most common type of reaction. This causes dry, itchy, irritated areas on the skin, most often on the hands. It can be caused by the irritation of using gloves, or it can also be caused by exposure to other workplace products. Frequent washing of the hands. incomplete drying, exposure to hand sanitizers, and the talc-like powder coatings (zinc oxide, etc) used with gloves can aggravate symptoms. Irritant contact dermatitis is not a true allergy Some people who have latex allergy may also have an allergic response to any of a number of plant products, usually fruits. This is known as the latex-fruit syndrome. Fruits (and seeds) involved in this syndrome include banana, pineapple, avocado, chestnut, kiwi fruit, mango, passionfruit, strawberry, and soy. Some but not all of these fruits contain a form of latex. Some individuals who are highly allergic to latex have had allergic reactions to foods that were handled or prepared by people wearing latex gloves

### **NATURAL RUBBER LATEX**

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens). Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis.

Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. No significant acute toxicological data identified in literature search.

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	×
Serious Eye Damage/Irritation	×	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×

**Legend: X** − Data either not available or does not fill the criteria for classification

✓ – Data available to make classification

### **SECTION 12 Ecological information**

### **Toxicity**

Uharania (h. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	Endpoint	Test Duration (hr)	Species	Value	Source
Hygenic® Latex Dental-Dam	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source

### Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

### For Ammonia

Atmospheric Fate: Ammonia reacts rapidly with available acids (mainly sulfuric, nitric, and sometimes hydrochloric acid) to form the corresponding salts. Ammonia is persistent in the air.

Aquatic Fate: Biodegrades rapidly to nitrate, producing a high oxygen demand. Non-persistent in water (half-life 2 days).

Version No: 1.1 Page 10 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

Ecotoxicity: Moderately toxic to fish under normal temperature and pH conditions and harmful to aquatic life at low concentrations. Does not concentrate in food chain.

Proteins are generally easily biodegradable.

### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

### Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

### Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

### **SECTION 13 Disposal considerations**

### Waste treatment methods

### **Product / Packaging** disposal

Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.

### **SECTION 14 Transport information**

### **Labels Required**

Marine Pollutant	NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

### Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
natural rubber latex	Not Available

### Transport in bulk in accordance with the ICG Code

Product name	Ship Type
natural rubber latex	Not Available

### **SECTION 15 Regulatory information**

Safety, health and environmental regulations / legislation specific for the substance or mixture

natural rubber latex is found on the following regulatory lists

Version No: 1.1 Page 11 of 12 Issue Date: 21/04/2022 Print Date: 18/07/2022

### **Hygenic® Latex Dental-Dam**

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5

US NIOSH Recommended Exposure Limits (RELs)

US OSHA Permissible Exposure Limits (PELs) Table Z-1 US OSHA Permissible Exposure Limits (PELs) Table Z-3

### **Federal Regulations**

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

## Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No	
Gas under pressure		
Explosive	No	
Self-heating	No	
Pyrophoric (Liquid or Solid)	No	
Pyrophoric Gas	No	
Corrosive to metal	No	
Oxidizer (Liquid, Solid or Gas)	No	
Organic Peroxide	No	
Self-reactive	No	
In contact with water emits flammable gas	No	
Combustible Dust	Yes	
Carcinogenicity	No	
Acute toxicity (any route of exposure)	No	
Reproductive toxicity	No	
Skin Corrosion or Irritation	No	
Respiratory or Skin Sensitization	No	
Serious eye damage or eye irritation		
Specific target organ toxicity (single or repeated exposure)		
Aspiration Hazard		
Germ cell mutagenicity		
Simple Asphyxiant		
Hazards Not Otherwise Classified		
	·	

### US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported

### **State Regulations**

### US. California Proposition 65

None Reported

### **National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (natural rubber latex)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (natural rubber latex)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (natural rubber latex)

 Version No: 1.1
 Page 12 of 12
 Issue Date: 21/04/2022

 Print Date: 18/07/2022
 Print Date: 18/07/2022

### Hygenic® Latex Dental-Dam

National Inventory	Status
Taiwan - TCSI	Yes
Mexico - INSQ	No (natural rubber latex)
Vietnam - NCI	Yes
Russia - FBEPH	Yes
	Yes = All CAS declared ingredients are on the inventory
Legend:	No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

### **SECTION 16 Other information**

Revision Date	21/04/2022
Initial Date	11/02/2022

### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

### **Definitions and abbreviations**

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit。

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List
NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

**ENCS: Existing and New Chemical Substances Inventory** 

KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act

TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Powered by AuthorITe, from Chemwatch.