Safety Data Sheet

Products Covered: UnoDent Latex Dental Dams
Product Thickness: Thin (0.15/0.18 mm), Medium(0.18/0.23 mm), Heavy (0.23/0.28 mm) and X-Heavy (0.28/0.32 mm)

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 Harmonised 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)

1. Chemical Product and Company Identification

Composition:
Natural Rubber Sheeting plus essential processing additives and pigments

General description
Latex rubber dams are manufactured from natural rubber latex. 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.

Indications for Use

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. It is designed for use by the professional in a medical environment for periods of up to 30 minutes.

Contraindications
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.

Manufactured by: Unodent Ltd, 10 PERRY WAY, Witham, Essex, England, CM8 3SX
Tel. 0800585586

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.

3. Composition/Information on Ingredients

Natural Rubber Sheeting plus essential processing additives and pigments

4. First Aid Measures

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.

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.

5. Firefighting Measures

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

Firefighting measures: Water, CO_2, Foam

6. Accidental Release Measures

Not applicable.

7. Handling

Observe correct manual handling procedures for bulk volumes.

Storage Conditions:

- 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 u.v. light
- 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 natural rubber.

8. Exposure Controls and Personal Protection

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.

9. Physical and Chemical Properties

Appearance: Rubber sheeting, either as a roll or cut squares.
Odour: Characteristic 'rubber' odour
Flash Point: >250^{o}C
Water Solubility: Insoluble
Ignition Temperature: >200^{o}C

10. Stability and Reactivity

Stable under normal conditions of use.

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 localised or generalised 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
Skin irritation: Not thought to cause skin irritation. Traces of the processing additives within natural rubber latex can cause contact irritant dermatitis in some cases, leading to redness, soreness, dryness or cracking of the skin.
Eye damage/irritation: Not known
Respiratory or skin sensitisation: Not known with normal use (see allergies)
Reproductive cell mutagenicity: Not known
Carcinogenicity: Not known
Reproductive toxicity: Not known
Specific target organ toxicity -single exposure: Not known
Specific target organ toxicity - repeated exposure: Not known
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 product is in use.

12. Ecological Considerations

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

13. Disposal Considerations

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

14. Transport Information

No specific transport considerations.

15. Regulatory Information

UNITED KINGDOM

Product registered with Medicines and Healthcare Regulatory Authority
Product complies with UK MDR 2002

EUROPE

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

UNITED STATES OF AMERICA

Product is registered with the Food and Drug Administration
Product complies to both Food Drug and Cosmetic act 1938 and 21 CFR subchapter H
TSCA (Toxic Substances Control Act): *No ingredients listed*
California Proposition 65: *No ingredients listed*
NTP (National Toxicology Program) Report on Carcinogens: *No ingredients listed*

Disclaimer

The information on this data sheet is presented in good faith and is accurate to the best of our knowledge at the above date. However, it is issued without guarantee and 4D Rubber Company accept no liability for any incorrect information documented within or any unforeseen hazards that are not mentioned within this data sheet.

References:

This Safety Data Sheet Guide has been prepared as if in accordance with the requirements of the following regulations:

1. ISO 11014:2009 Safety data sheet for chemical products
2. European Regulation 1907/2006/EC as amended by Regulation (EC) 1272/2008 and Regulation (EU) 2015/830
3. For UK: Statutory Instrument 2008 No. 2852 The REACH Enforcement Regulations 2008
4. For US: Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200
5. Globally Harmonized System of Classification and Labelling of Chemicals (United Nations)

Version History

Version	Author	Change	Date
1	L. Williams	Release	9th December 2021