

Safety Data Sheet

IMPORTANT

Read this SDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	Latex dam
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: (SU20) Health services;
Restricted Use	(SU21) Consumer Uses: Private households (=general public = consumers);
Description	Dental Product for professional use only

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number

Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Not hazardous at 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.
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2.2 Label Elements

Hazard Pictograms	None
Signal Word	None
Hazard Statement	None
Precautionary Statement: Prevention	None
Precautionary Statement: Response	None

2.3 Other hazards

Other hazards	PBT. vPvB. Not applicable.
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Further information

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).

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Natural Rubber						

4. FIRST AID MEASURES

4.2 Indication of any immediate medical attention and special treatment needed

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.
Eye Contact	If product contacts eye, rinse with sterile eye wash.
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.
Ingestion	If product is ingested, perform assisted first-aid measures and seek medical advice.

General information

	If you feel unwell, seek medical advice (show the label where possible).
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	In the event of fire use water, carbon dioxide, foam.
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5.2 Special hazards arising from the substance or mixture

	Not determined
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5.3 Advice for firefighters

	Evacuate all personnel, use protective equipment for firefighting. Use self-contained breathing apparatus when product is involved in fire.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	Not applicable
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6.2 Environmental precautions

	Not applicable
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6.3 Methods and material for containment and cleaning up

	Not applicable
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6.4 Reference to other sections

	Not applicable
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	Will ignite if in contact with naked flame. Observe non-smoking regulations in storage areas.
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7.2 Conditions for safe storage, including any incompatibilities

	Store ideally 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.
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7.3 Specific end use(S)

	See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.2 Exposure controls

	
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8.2.1 Appropriate engineering controls

	The product is intended to be used with latex or non-latex gloves by the operator.
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8.2.2 Individual protection measures

Eye/face protection	Not applicable
Skin protection – Hand protection	The product should not be used on broken skin.
Respiratory protection	Not applicable.

8.2.3 Environmental exposure controls

	Not applicable.
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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Square rubber sheet	Flash point	>250°C
Colour	Green	Solubility in water	Insoluble
Odour	Characteristic	Ignition temperature	>200°C

9.2 Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

	Stable under normal conditions of use
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10.2 Chemical stability

	N/a
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10.3 Possibility of hazardous reactions

	N/a
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10.4 Conditions to avoid

	N/a
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10.5 Incompatible materials

	N/a
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10.6 Hazardous decomposition products

	N/a
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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	Not thought to be toxic
Primary effects to skin	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.
Primary effect to eyes	Not known
Primary effects to respiratory system	Not known with normal use (see allergies)

Reproductive toxicity	Not known
Carcinogenicity	Not known
Reproductive toxicity	Not known
STOT – single exposure	Not known
STOT – 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 continuously supervised when product is in use.
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.
Additional toxicological info.	N/a

11. ECOLOGICAL INFORMATION

11.1 Toxicity

Toxicity	No data available
Aquatic toxicity (acute)	No data available

11.2 Persistence and degradability

	No data available
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11.3 Bio accumulative potential

	No data available
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11.4 Mobility in soil

	No data available
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11.5 Results of PBT and vPvB assessment

	No data available
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11.6 Other adverse effects

	None known
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Natural rubber is considered to be biodegradable.

12. DISPOSAL CONSIDERATIONS

12.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.
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13. TRANSPORT INFORMATION

13.1 UN number

	No specific transport considerations.
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13.2 UN proper shipping name

	N/a
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13.3 Transport hazard class(es)

	N/a
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13.4 Packing group

	N/a
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13.5 Environmental hazards

Environmental hazards	N/a
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13.6 Special precautions for user

ADR/RID

	N/a
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IMDG

	N/a
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IATA

	N/a
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13.7 Transportation in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	N/a
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14. REGULATORY INFORMATION
14.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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

	Chemical safety assessment: See section 8
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15. OTHER INFORMATION
Other information

Text of Hazard Statements in Section 3	N/a
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Further information

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.