

Overview

The adhesives are intended for retention of prostheses to skin for day-to-day use.

These products are water based acrylic adhesives and are milky in colour.

User Instructions

Ensure surfaces to be bonded are clean and free from grease/loose particles (makeup, etc).

Apply a thin coating to the back of the prosthesis and allow to dry - the milky adhesive will become clear in colour.

The prosthesis can now be adhered to the skin.

Removal

Wash off residue from skin and prosthesis with soap and warm water

1. Identification of Substance & Company:

Product Name(s)	Ancillary Adhesives
Product Code(s)	G609
Medical Device Class	Class I (according to Annex IX of EC Directive 93/42/EEC)
Product Category/Classification	G5 (according to Annex IX of EC Directive 93/42/EEC)
Main Use	Retention of custom prostheses
Company	MBI (Wales) Limited Unit 5 Kingsway Buildings Bridgend, South Wales, UK. CF31 3YH
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2. Composition / Information on ingredients:

Chemical Nature	Aqueous dispersion of polymer based on: acrylic ester, methacrylic ester, vinyl ester
Hazardous Components	No particular hazards known - may cause skin irritation / contact dermatitis in susceptible persons with long term repeat use if product is allowed to dry on skin

3. Hazards Identification:

Label Elements	Does not require a hazard warning label in accordance with GHS criteria or EC Directives
Classification	No particular hazards known

4. First Aid Measures:

Eye Contact	Remove before dispersion dries. May cause temporary irritation of the eye Irrigate with water for 15 mins, holding eyelid open, seek medical advise if irritation persists
Skin Contact	Remove excess and wash with soap and water. Remove contaminated clothing
Inhalation of Vapour	N/a
Ingestion	May result in gastric disturbances

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Rinse mouth immediately, drink plenty of water – seek medical advice

5. Fire Fighting Measures:

Hazards during firefighting

Aqueous dispersion will not burn. Dried film is combustible

Water, foam, carbon dioxide or dry powder extinguishers are suitable

No particular special hazards known to arise from substance

6. Accidental Release Measures:

Personal Protection

Refer to Section 8

Environmental Precautions

Do not wash away into any drain unless it drains into a suitable effluent treatment process

Methods for clean-up

Soak up with a suitable inert absorbent (eg, sand) and dispose as Section 13, rinse away residues with water

7. Handling & Storage:

Handling

No special precautions necessary provided product is used correctly

Observe good housekeeping / hygienic practises

Storage

Store between 5 deg C and 25 deg C – protect against freezing

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8. Exposure Controls / Personal Protection:

General Protective Measures	Ventilation may be required if product is to be sprayed
Components with workplace parameters	None
Respiratory Protection	Mask if spraying
Hand Protection	Not deemed necessary for normal use, gloves recommended for handling bulk
Eye Protection	Not deemed necessary for normal use, eye glasses recommended when handling bulk
Skin Protection	Not deemed necessary for normal use, suitable clothing for handling bulk
Hygiene Measures	Do not eat, drink or smoke when handling product, wash hands after handling, before eating

9. Physical & Chemical Properties:

Physical Form	Milky liquid
Colour	White
Odour	faint odour
Flash Point	Not applicable
Vapour pressure	23.4 hPa (20 deg C)
Relative Density	No data available
pH	Approx 5.0 (3.0 – 6.0)
Viscosity	800–1600 mPa.s (23 deg C, 250 1/s)
Solids Content	67–70%

10. Stability & Reactivity:

The product is stable under normal storage conditions (refer to Section 7)	
Thermal Decomposition	No decomposition if used correctly
Hazardous Reactions	None when stored and handled according to instructions. Avoid extreme conditions.

11. Toxicological Information:

Long term experience of this product indicates no danger to health when used correctly	
LD50 Rat (oral)	>2000 – 10000 mg/kg
Irritation	Irritation may occur if wet product is allowed to dry on skin in repeated application over time
	Skin corrosiom/irritant (Rabbit) – non irritant
	Serious eye damage/irritant (Rabbit) – non irritant

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Respiratory/Skin Sensitisation	SKIN sensitizing effects were not observed in animals. The product has not been tested -
Germ Cell Mutagenicity	The substance was not mutagenic in bacteria. The product has not been tested - statement derived from products of a similar structure or composition
Carcinogenicity	The whole of the information available provides no indication of a carcinogenic effect
Reproductive Toxicity	Not expected to cause reproductive toxicity (based on composition)
Repeated Dose Toxicity	No adverse effects observed after repeated inhalative exposure on animal studies. The product has not been tested - statement derived from products of a similar structure or composition

Based on our experience and the information available, no adverse health effects are expected if handled and used as recommended with suitable precautions for designated use. The statement was derived from products of similar composition.

12. Ecological Information:

Degradation/elimination	This product can be virtually eliminated from water by adiabatic processes (adsorption onto activated sludge). Inhibition of degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.
Bioaccumulation	No evidence for bioaccumulation
Ecotoxic effects	Do not release untreated into natural waterways. At this present state of knowledge no negative ecological effects are expected. Ecological data are determined by analogy.

13. Disposal Considerations:

Waste product should not be discharged directly into drains or waterways.	
Disposal of product and packaging should always comply with local and national regulations	
EU waste code number	No Waste Code Number available

14. Transport Information:

This product is not classified as Dangerous for Carriage

15. Regulatory Information:

Symbol	The product does not require a hazard warning label in accordance with EC Directives
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This information fulfils the requirements of Directive 1999/45/EC concerning preparations and the associated requirements for 'safety data sheets'

16. Other Information:

Full text of hazard symbols and R-Phrases: None applicable

Refer to product IFU (Instructions for Use) for correct method of using product.

All information given in this Health & Safety Data Sheet is to the best of our knowledge true and accurate and is provided solely for making safety assessments. It is not a sales specification or an indication of suitability for a particular use nor does it replace the need for your own risk assessment.

All information presented in accordance with EC Directive 2001/58/EC and is correct at date of publication and is given in good faith but without warranty.

We cannot accept liability for any loss, damage or patent infringement resulting from the use of this information.

As with all materials, care should be exercised when handling.
