

According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

• Trade name: Prosthetics Skin – Part A

· Utilization of the substance of the formulation: Moulding & Casting.

• 1.2 Relevant identified uses of the substance or mixture and uses advised against:

• Application for the substance / the preparation: Products with prolonged contact with the human body.

• Uses advised against: Not suitable for use with food.

• 1.3 Details of the supplier of the safety data sheet: • Supplier: DWR plastics Broadway Newport Shropshire TF10 7TP Tel: +44 (0) 1630 659739 Email: info@dwrplastics.com

• 1.4 Emergency telephone number: + 44 (0) 1630 659739

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture:

• Classification according to Regulation (EC) No 1272/2008 The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

· 2.2 Label elements:

• Labelling according to Regulation (EC) No 1272/2008 Not a hazardous substance or mixture.

SECTION 3: Composition/information on ingredients

• 3.2 Chemical characterization: Mixture

· Description: Silicone elastomer

Chemical Composition	CAS No.	EC No.	Weight (%)
Poly(Vinylmethoxysiloxane)	68037-87-6		50-70
Silica	14464-46-1	238-878-4	20-30
Poly(Dimethylsiloxane)	9006-65-9		0-30
Platinum Based Catalyst Trace	68478-92-2	270-844-4	≤ 0.01



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

SECTION 4: First Aid Measures

- 4.1 Description of first aid measures:
- General Information: Normal use does not require special measures.
- *Eye Contact:* Flush eyes with plenty of water. If irritation persists, seek medical attention.
- Skin Contact: If irritation occurs remove contaminated clothing and shoes. Immediately wash with water and soap and rinse thoroughly. If irritation persists, seek medical attention.
- · If Inhaled: Remove to fresh air. Get medical attention.
- *Ingestion:* Rinse mouth thoroughly with water. Do not induce vomiting unless instructed by a physician. Never give anything by mouth to an unconscious person.
- 4.2 Most important symptoms and effects, both acute and delayed: No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed: No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media:
- Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · Unsuitable extinguishing agents: None known.
- 5.2 Special hazards arising from the substance or mixture:
- · Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
- *Hazardous combustion products:* In case of fire, the following can be released: Carbon oxide and silicone oxides.
- 5.3 Advice for firefighters:
- Protective equipment: Wear self-contained respiratory protective device. Wear fully protective impervious suit.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
- 6.2 Environmental precautions: Discharge into the environment must be avoided. Do not allow to enter sewers/ surface or ground water. Prevent further leakage or spillage if safe to do so.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.

(Contd. on page 3)



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

6.4 Reference to other sections:

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling:

- Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- · Local/Total ventilation: Use only with adequate ventilation.
- Advice on safe handling: Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes and prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Take care to prevent spills, waste and minimize release to the environment.
- *Hygiene measures:* Ensure that eye flushing systems. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
- 7.2 Conditions for safe storage, including any incompatibilities:
- *Requirements to be met by storerooms and receptacles: Keep container tightly closed and dry and storage in a good ventilated room. Storage temperature: 15 25 °C.*
- · Information about storage in one common storage facility: Do not store together with oxidising and acidic materials.
- Further information about storage conditions: Store in dry conditions. Protect from frost.
- 7.3 Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters: Contains no substances with occupational exposure limit values.
- *Additional information:* The lists valid during the making were used as basis.
- · 8.2 Exposure controls:
- · Personal protective equipment:
- General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.
- Eye protection: Safety glasses.
- · Skin & Body protection: Skin should be washed after contact.
- · Respiratory protection: Not necessary.

(Contd. on page 4)



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and chemical properties:

· General Information	
· Appearance:	
Form:	Liquid
Colour:	Translucent
· Odour:	None
• Odour threshold:	Not determined
· pH-value:	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Not determined
· Flash point:	100°C (Closed cup)
· Flammability (solid, gaseous):	Non-flammable
· Ignition temperature:	Not determined
• Decomposition temperature:	Not determined
· Self-igniting:	Not determined
• Danger of explosion:	Not determined
· Explosion limits:	
Lower:	Not determined
Upper:	Not determined
· Vapour pressure:	Not determined
· Density at 20 °C:	Not determined
· Relative density	Not determined
· Vapour density	Not determined
· Evaporation rate	Not determined
· Solubility in / Miscibility with water:	Hardly soluble in water
· Viscosity:	Not determined
· Solvent content:	
Organic solvents:	None
VOC (EC)	None

• 9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity: Not classifies as a reactivity hazard.

10.2 Chemical stability: Stable.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: Flames, sparks and other sources of ignition, incompatible materials.

10.5 Incompatible materials: Strong oxidizing agents.

10.6 Hazardous decomposition products: Carbon dioxide and silicone oxide.

(Contd. on page 5)



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects:

- · Information on likely routes of exposure: Inhalation, skin contact, ingestion, eye contact.
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction): Based on available data, the classification criteria are not met.
- Germ cell mutagenicity: Based on available data, the classification criteria are not met.
- · Carcinogenicity: Based on available data, the classification criteria are not met.
- Reproductive toxicity: Based on available data, the classification criteria are not met.
- · STOT-single exposure: Based on available data, the classification criteria are not met.
- STOT-repeated exposure: Based on available data, the classification criteria are not met.
- · Aspiration hazard: Based on available data, the classification criteria are not met.
- Potential health effects:
- · Inhalation: None.
- · Ingestion: None.
- Skin: None.
- · Eyes: None.

SECTION 12: Ecological information

- · 12.1 Toxicity:
- · 12.2 Persistence and degradability: No further relevant information available.
- 12.3 Bio accumulative potential: No further relevant information available.
- · 12.4 Mobility in soil: No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment:
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- 12.6 Other adverse effects: No further relevant information available.

(Contd. on page 6)



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

SECTION 13: Disposal considerations

• 13.1 Waste treatment methods:

• *Recommendation:* Dispose of in accordance to local to the regulations pertaining to the disposal of waste.

· Uncleaned packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information				
· 14.1 UN-Number				
· ADR, ADN, IMDG, IATA	Void			
· 14.2 UN proper shipping name				
· ADR, ADN, IMDG, IATA	Void			
· 14.3 Transport hazard class(es)				
· ADR, ADN, IMDG, IATA				
· Class	Void			
· 14.4 Packing group · ADR, IMDG, IATA	Void			
14.5 Environmental hazards:				
Marine pollutant:	No			
14.6 Special precautions for user	Not applicable.			
14.7 Transport in bulk according to Annex II of				
Marpol and the IBC Code	Not applicable.			
· UN "Model Regulation":	Void			

SECTION 15: Regulatory information

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

• Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

· Hazard pictograms: Not applicable.

· Signal word: Not applicable.

- · Hazard statements: Not applicable.
- · Precautionary statements Not applicable.

(Contd. on page 7)



According to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 4

Revision: 15.09.2023

PROSTHETICS SKIN - PART A

- **Response Precautions:** P305 + P351 +P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention.
- Storage Precautions: P233 Keep container tightly closed.
- · 2.3 Other hazards:
- · Results of PBT and vPvB assessment:
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Directive 2012/18/EU:
- · Water hazard class: None

This material safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

Chemical Composition	CAS No.	TSCA	EC No.	EINECS
Poly(Vinylmethoxysiloxane)	68037-87-6	Listed		Not Listed
Silica	14464-46-1	Listed	238-878-4	Listed
Poly(Dimethylsiloxane)	9006-65-9	Listed		Not Listed
Platinum Based Catalyst Trace	68478-92-2	Listed	270-844-4	Listed

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing MSDS: Environment protection department

• Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods IATA:

International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of

Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU)