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Version number 1

Revision: 04.04.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: PMMA Disc · CAS Number: 9011-14-7 · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. · Application of the substance / the mixture PMMA disc for the CAD/CAM technology · 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Manufacturer: Sagemax Bioceramics, Inc. 34210 9th Avenue South, Suite 118 Federal Way, WA 98003 USA Tel. +1 253-214-0389 / +1 877-386-0389 Fax +1 888-856-2615 EC Representative: AB Ardent Generatorgatan 8 SE-19560 Arlandastad / Sweden Tel. +46 8594 412 57 Fax +46 8591 161 83 • Further information obtainable from: Quality Assurance / Regulatory Affairs USA: support@sagemax.com EU: info@sagemax.com · 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008 The substance is not classified, according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void · 2.3 Other hazards Avoid breathing sanding dust /swarf. · Results of PBT and vPvB assessment · **PBT:** Not applicable. · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

• 3.1 Chemical characterisation: Substances • CAS No. Description 9011-14-7 polymethylmethacrylate

(Contd. on page 2)

Printing date 11.08.2020

Version number 1

Revision: 04.04.2019

Trade name: **PMMA Disc**

(Contd. of page 1)

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: No special measures required.

• After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.

• After skin contact: Generally the product does not irritate the skin.

• After eye contact:

Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

• After swallowing: Grinding dust: Rinse out mouth and then drink plenty of water.

• 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.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.

- · 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- 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

Only adequately trained personnel should handle this product. For use in dentistry only.

· Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.

· Information about storage in one common storage facility: Not required.

• Further information about storage conditions: Protect from heat and direct sunlight.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

(Contd. on page 3)

GB

Printing date 11.08.2020

Version number 1

Revision: 04.04.2019

Trade name: **PMMA Disc**

(Contd. of page 2) · 8.1 Control parameters · Ingredients with limit values that require monitoring at the workplace: Not required. · 8.2 Exposure controls · Personal protective equipment: • General protective and hygienic measures: Usual hygienic measures for dental practice and dental laboratories. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. • **Respiratory protection:** Use respiratory protective device against the effects of dust. • Recommended filter device for short term use: Filter P1 Protection of hands: Protective gloves should always be worn during mechanical and thermal processing. After use of gloves apply skin-cleaning agents and skin cosmetics. · Material of gloves Mechanical processing: Leather gloves Strong material gloves · Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. • Eye protection: Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9.1 Information on basic physical and c General Information	hemical properties	
Appearance:		
Form:	Solid	
Colour:	Different according to colouring	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
-	Not determined.	
Change in condition		
Melting point/freezing point:	~150 °C	
Initial boiling point and boiling range	e: Undetermined.	
Flash point:	~250 °C	
Flammability (solid, gas):	Product is not flammable.	
Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Not determined.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not applicable.	
Density at 20 °C:	~1.2 g/cm ³	
Relative density	Not determined.	

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Version number 1

Revision: 04.04.2019

Trade name: **PMMA Disc**

		(Contd. of page 2
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solids content:	100.0 %	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- · 10.2 Chemical stability Stable under normal handling and storage conditions.
- · Thermal decomposition / conditions to be avoided:
- Can decompose slowly with localised heating above 150°C.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- \cdot 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- 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.
- \cdot Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- $\cdot \textit{Reproductive toxicity Based on available data, the classification criteria are not met.}$
- \cdot **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.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 5)

GB

Printing date 11.08.2020

Version number 1

Trade name: **PMMA Disc**

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

• 13.1 Waste treatment methods • Recommendation Smaller quantities can be disposed of with household waste.

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

• Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information	on
· 14.1 UN-Number · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex Marpol and the IBC Code	x II of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

SECTION 15: Regulatory information

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I Substance is not listed.

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

• 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.

(Contd. on page 6)

GB

(Contd. of page 4)

Printing date 11.08.2020

Version number 1

Revision: 04.04.2019

Trade name: PMMA Disc

(Contd. of page 5)

GB

• Abbreviations and acronyms:

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 CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative