Material Safety Data Sheet

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Commercial Name: ORTHOJEL PUTTY

1 Identification of the substance/preparation and of the company/undertaking

<u>Commercial Name and synonym:</u> ORTHOJEL PUTTY

Vendor/Supplier:

RMO Europe BP 20334 Rue Geiler de Kaysersberg 67411 ILLKIRCH Cedex France Tel. 03 88 40 67 30 Fax 03 88 67 86 96

2 Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: void

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: void

Information concerning particular hazards for human and environment:

The product does not have to be labeled due to the calculation procedure of the "General classification guideline for preparations of the EU" in the latest valid version.

Label elements:

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of dangerous substance Directive 1999/45/EWG.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable **vPvB:** not applicable

3 Composition/information on ingredients

Chemical characterization:

Description: mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen

siloxane and silica

Hazardous components: none

4 First aid measures

General information: No special measures required

After skin contact: Wash with plenty of water and soap

After eye contact: Rinse with plenty of water and consult a doctor

After swallowing: If symptoms persist consult a doctor

5 Fire-fighting measures

Extinguishing media: CO2, water

Protective equipment: no special measures required

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6 Accidentel releasemeasures

Personal precautions: not required

Environmental precautions: no special measures required

Methods for cleaning up: pick up mechanically

Additional information: none.

7 Handling and storage

Handling:

Information for safe handling: For dental use only. No special measures required.

Recommendation for fire and explosion protection: No special measures required Storage:

Requirements at storerooms and containers: No special measures required

Requirements for storage with other products: not required

Further information on storage conditions: none

8 Exposure controls / personal protection

Components with limits of values to be supervised at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information: The lists valid during the making were used as basis.

Personal protective equipment:

General measures of protection and hygiene: normal hygienic measures

Respiratory protection: not required **Protection of hands:** not required **Eye protection:** not absolute required

9 Physical and chemical properties

Appearance:

Form: paste Color:different Odor:odorless

	Value	Unit	Method
Information on change in the physical state			
Melting point/melting range:	n.a.	$^{\circ}\mathrm{C}$	
Boiling point/boiling range:	n.a.	$^{\circ}\mathrm{C}$	
Flash point:	n.a.	$^{\circ}\mathrm{C}$	
Autoignition temperature:	n.a.		
Danger of explosion:	none		
Density:	$1,50 (20^{\circ}\text{C})$	g/cm ³	
Vapor pressure:	n.a.	mbar	
Viscosity:	paste		
pH:	neutral		
Solubility in/miscibility with:	Partially soluble in tolu	ene, petrol ethe	r
Water:	insoluble		
Content of solvents:	none		
Organic solvents:			
Water:			
Content of solids:	n.a.		

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Commercial Name: Multi-T, Multi-TB, Multi-S, Multi-P

10 Stability and reactivity

Conditions to avoid: No decomposition if used according to specification

Hazardous decomposition products: None under normal conditions of storage and use

11 Toxicological information

Acute toxicity: Primary irritation:

Skin: no irritating effect Eye: no irritating effect

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

General information: Avoid transfer into environment

Classification of water endangerment: WGK 1 (German regulation) slightly hazardous for water.

13 Disposal considerations

Product:

Recommendation: Small quantities can be disposed of with household waste.

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14 Transport information

Land transport ADR, RID: -

Maritime transport: IMDG-Code :-Air transport ICAO-TI/IATA-DGR: -

15 Regulatory information

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31 The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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