Safety Data Sheet according to 1907/2006/EC, Article 31

Date of issue: 21.03.2019 Version: 1

Printing date: 21.03.2019

1. Product identification/preparation/company undertaking

Product details

Trade name: Harvard LiquiCord® Use or preparation: Retraction paste

Manufacturer/supplier:

Harvard Dental International GmbH,

Margaretenstraße 2-4,

15366 Hoppegarten, Germany

info@harvard-dental-international.de

Emergency information:

+ 49 (0) 30 99 28 978-0 (Quality Management)

2. Hazards identification

Classification of the substance or mixture

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

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 Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards

Results of PBT and vPvB assessment

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

3. Composition/Information of Ingredients

Chemical characterization:

Description:

mixture of non-hazardous substances (aluminium salts)

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. Accidental release measures

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 limits of values to be supervised 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: required

Protection of hands: required Eye protection: required

9. Physical and chemical properties

Appearance:

Content of solvents:

Form: paste Color: blue

C0101.	0100			
Odor:	characteristi	racteristic		
	<u>Value</u>	Unit	Method	
Information on change in the physica	ıl state			
Melting point/melting range:	n.a.	°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:	$1,74 (20^{\circ}C) g/cm^{3}$			
Vapor pressure:	n.a.	mbar		
Viscosity:	paste			
pH:	ca. 4			
Solubility in/miscibility with:				
Water:	partially soluble			

none

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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: slightly irritating effect possible 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 consideration

Product:

Recommendation: 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: no subject to transport regulations

Maritime transport: IMDG-Code: no subject to transport regulations Air transport ICAO-TI/IATA-DGR: no subject to transport regulations

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:

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.