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Revision: 29.05.2024

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
 - · Trade name: Heravest L
- · 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** Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

- · Informing department: E-Mail: msds@kulzer-dental.com
- · 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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, 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
 - · Additional information:

Safety data sheet available on request.

- 2.3 Other hazards -
 - · Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Description: -
 - · Dangerous components:

14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)

substance with a Community workplace exposure limit

· Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - General information No special measures required.
 - · After skin contact The product is not skin irritating.
 - After eye contact Rinse opened eye for several minutes under running water.
 - After swallowing

Rinse out mouth and then drink plenty of water.

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≥10-≤25%



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In case of persistent symptoms consult doctor.

- 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, extinguishing powder or water jet. Fight larger fires with water jet 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.
 - · Additional information -

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: Collect mechanically.
- · 6.4 Reference to other sections

No dangerous materials are released.

See Section 8 for information on personal protection equipment.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
 - Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
 - · Storage
 - Requirements to be met by storerooms and containers: No special requirements.
 - Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with critical values that require monitoring at the workplace:

7727-43-7 barium sulfate

OEL (Ireland) Long-term value: 5 mg/m³

7778-18-9 calcium sulphate, natural

OEL (Ireland) Long-term value: 10 mg/m³

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14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)

OEL (Ireland)

AGW (European Union)

BOELV (European Union)

Long-term value: 0.1 mg/m³

Long-term value: 0.1 mg/m³

Long-term value: 0.1* mg/m³

*respirable fraction

· Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- · Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures
 Keep away from foodstuffs, beverages and food.
 Week hands during brooks and at the and of the we

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not required.
- · Hand protection

Check protective gloves prior to each use for their proper condition. recommended

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR Nitrile rubber, NBR

- Eye/face protection Safety glasses
- · Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
 - · General Information

Physical state
Colour:
Smell:
Solid.
Brown
Odourless

· Odour threshold: Not determined. · Melting point/freezing point: Not determined

Boiling point or initial boiling point and

boiling range Not determined Not determined.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: Not applicable

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Decomposition temperature:	Not determined.
·SADT	
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Kinematic viscosity	
dynamic:	Not applicable.
· Solubility	
· Water:	Insoluble
· Partition coefficient n-octanol/water (log	g
value)	Not determined.
· Steam pressure:	Not applicable.
· Vapour pressure:	,,
Density and/or relative density	
Density at 20 °C	3.070 g/cm³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	See section 3.
9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Powder
Important information on protection of hea	olth
and environment, and on safety.	
Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive.
	Not determined.
· Solvent content:	
· Solids content:	100.0 %
· Change in condition	
· Evaporation rate	Not applicable.
Information with regard to physical haza	
classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
	¥ 0/0
· Flammahle liquide	Void
Flammable liquids	Void Void
· Flammable liquids · Flammable solids	Void
· Flammable liquids · Flammable solids · Self-reactive substances and mixtures	Void Void
· Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids	Void Void Void
 Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids 	Void Void Void Void
Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures	Void Void Void
Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit	Void Void Void Void Void
Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water	Void Void Void Void Void
Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids	Void Void Void Void Void Void
Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water	Void Void Void Void Void

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· Corrosive to metals	Void
 Desensitised explosives 	Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
 - Conditions to be avoided: No decomposition if used and stored according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
 - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:				
7727-43-7 ba	rium sulfate			
Oral	LD50	307,000 mg/kg (rat) (OECD 401)		
Sensitisation	sensitization	(not defined)		
7778-18-9 calcium sulphate, natural				
Oral	LD0	>2,000 mg/kg (rat) (OECD 420)		
Inhalative	LC0/4h	≥3.26 mg/L (rat) (OECD 403)		

- · 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.
- · 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.
- · 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.

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.

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- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
 - · Additional ecological information:
 - · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

- · Uncleaned packagings:
 - Recommendation:

Packaging can be reused or recycled after cleaning.

Non contaminated packagings can be used for recycling.

14.1 UN number or ID 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 Maritime transport in bulk according instruments	t o IMO Not applicable.	

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UN "Model Regulation":

Void

SECTION 15: Regulatory information

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

No further relevant information available.

·DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
 - Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

no information available

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

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

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Date of previous version: 23.11.2020
- Version number of previous version: 3 Abbreviations and acronyms:

Abbreviations and activities.

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.