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Safety Data Sheet acc. to OSHA HCS

Printing date 05/29/2024

Reviewed on 05/29/2024

Tel.: +49 (0)800 4372522

1 Identification

· Product identifier

· Trade name: Heravest L

Application of the substance / the mixture Auxiliary for manufacture of dental prothesis

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Information department:

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com

· Emergency telephone number:

Emergency CONTACT (24-Hour-Number)
ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
 - GHS label elements Void
 - · Hazard pictograms Void
 - · Signal word Void
 - · Hazard statements Void
- Classification system
 - · NFPA ratings for USA (scale 0-4)



Health = 0Fire = 0Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = 0Fire = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
 - · Description: -
 - Dangerous components:

7727-43-7 barium sulfate

≥25-≤50%

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7778-18-9 calcium sulphate, natural	≥10-≤25%
14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)	≥10-≤25%
Additional information For the wording of the listed hazard phrases refer to section	on 16.

- · Description of first aid measures
 - · General information No special measures required.
 - After skin contact Generally the product does not irritate the skin.
 - After eye contact Rinse opened eye for several minutes under running water.
 - · After swallowing

4 First-aid measures

Rinse out mouth and then drink plenty of water.

- If symptoms persist consult doctor.
- Information for doctor
 - · Most important symptoms and effects, both acute and delayed
 - No further relevant information available.
 - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
 - · Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- Reference to other sections

No dangerous substances are released.

See Section 8 for information on personal protection equipment.

· Protective Action Criteria for Chemicals

· PAC-1:	
7727-43-7 barium sulfate	15 mg/m³
14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)	0.075 mg/m³
· PAC-2:	
7727-43-7 barium sulfate	170 mg/m³
14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)	33 mg/m³
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· PAC-3:	
7727-43-7 barium sulfate	990 mg/m³
14808-60-7 Silicon dioxide, < 1 % quartz (not respirable)	200 mg/m³

7 Handling and storage

- · Handling
 - Precautions for safe handling No special measures required.
 - Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
 - Storage
 - Requirements to be met by storerooms and receptacles: No special requirements. Information about storage in one common storage facility: Not required.

 - · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.

	rol parameters omponents with limit values that require monitoring at the workplace:
	-43-7 barium sulfate
PEL	Long-term value: 15* 5** mg/m³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m³ *total dust **respirable fraction
TLV	Long-term value: 5* mg/m³ *inhalable fraction; E
7778	-18-9 calcium sulphate, natural
PEL	Long-term value: 15* 5** mg/m³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m³ *total dust **respirable fraction
TLV	Long-term value: 10* mg/m³ *as inhalable fraction
1480	8-60-7 Silicon dioxide, < 1 % quartz (not respirable)
PEL	Long-term value: 0.05* mg/m³ *resp. dust; 30mg/m3/%SiO2+2
REL	Long-term value: 0.05* mg/m³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m³ *respirable particulate matter, A2

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

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- · Exposure controls
 - Personal protective equipment
 - General protective and hygienic measures
 Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- · Breathing equipment: Not required.
- Protection of hands:

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 through 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 protection: Safety glasses
- · Body protection: Light weight protective clothing

9 Physical and chemical properties · Information on basic physical and chemical properties General Information Appearance: Form: Powder Color: Brown · Odor: Odorless · Odor threshold: Not determined. · pH-value: Not applicable. · Change in condition Melting point/Melting range: undetermined Boiling point/Boiling range: undetermined · Flash point: Not applicable · Flammability (solid, gaseous) Not determined. · Decomposition temperature: Not determined. · Ignition temperature: Product is not selfigniting. Danger of explosion: Product does not present an explosion hazard.

Not determined.

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Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapor pressure:	Not applicable.	
· Density at 20 °C (68 °F): · Relative density · Vapor density · Evaporation rate	3.070 g/cm³ (25.61915 lbs/gal) Not determined. Not applicable. Not applicable.	
· Solubility in / Miscibility with · Water:	Insoluble	
· Partition coefficient (n-octanol/	water): Not determined.	
· Viscosity: · dynamic: · kinematic:	Not applicable. Not applicable.	
· Solvent content:		
· Solids content:	100.0 %	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none

11 Toxicological information

- · Information on toxicological effects
 - Acute toxicity:

· LD/LC	50 values tha	nt are relevant for classification:
7727-43-7 ba	arium sulfate	
Oral	LD50	307,000 mg/kg (rat) (OECD 401)
Sensitization	sensitization	(not defined)
7778-18-9 ca	alcium sulpha	nte, natural
Oral	LD0	>2,000 mg/kg (rat) (OECD 420)
Inhalative	LC0/4h	≥3.26 mg/L (rat) (OECD 403)

- · Primary irritant effect:
 - on the skin: No irritant effect.
 on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.

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· Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

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

· Carcinogenic categories

	RC (International Agency for Research on Cancer)
14808-60-7	Silicon dioxide, < 1 % quartz (not respirable)

1

NTP (National Toxicology Program)

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

K

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Reproductive toxicity Based on available data, the classification criteria are not met.

12 Ecological information

- · Toxicity
 - · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · Mobility in soil No further relevant information available.
- · Additional ecological information:
 - · General notes:

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

- · Results of PBT and vPvB assessment
 - · **PBT:** Not applicable.
 - · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

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UN-Number		
DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA Class	Void	
Packing group · DOT, ADR, IMDG, IATA	Void	
Environmental hazards: Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.	
Transport/Additional information:	-	
UN "Model Regulation":	Void	

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

· Sara

SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· SARA Section 313 (specific toxic chemical listings)

7727-43-7 barium sulfate

· Hazardous Air Pollutants

None of the ingredients is listed.

Proposition 65

Prop 65 - Chemicals known to cause cancer

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

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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· Cancerogenity categories

· EPA (Environmental Protection Agency)

7727-43-7 barium sulfate

D, CBD(inh), NL(oral)

· TLV (Threshold Limit Value)

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

A2

NIOSH-Ca (National Institute for Occupational Safety and Health)

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

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

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 preparation / last revision 05/29/2024

Abbreviations and acronyms:

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

DOT: US Department of Transportation

IATA: International Air Transport Association
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)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

* Data compared to the previous version altered.