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

Printing date 15.11.2022 Version number 3 Revision: 15.11.2022

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

- · 1.1 Product identifier
 - Trade name: Heraform, Heraform RS (components A + B)
- · 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 GB 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 -
 - Results of PBT and vPvB assessment

results of FBF and VFVB assessment		
· PB	T:	
	Dodecamethylcyclohexasiloxane	
541-02-6	Decamethylcyclopentasiloxane	
· <i>vP</i>	· vPvB:	
	Dodecamethylcyclohexasiloxane	
541-02-6	Decamethylcyclopentasiloxane	

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Dangerous components: Void
 - ·SVHC

540-97-6 Dodecamethylcyclohexasiloxane

541-02-6 Decamethylcyclopentasiloxane

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - General information No special measures required.
 - · After inhalation Supply fresh air; consult doctor in case of symptoms.
 - After skin contact Instantly wash with water and soap and rinse thoroughly.
 - 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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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. Use fire fighting measures that suit the environment.

· 5.2 Special hazards arising from the substance or mixture

Can be released in case of fire

Carbon dioxide (CO2)

Carbon monoxide (CO2)

- · 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:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

6.4 Reference to other sections

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

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:

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

Not required.

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• 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 item 7.
- Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

- · 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 not absolutely neccessary
- · 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: Different according to colour

· Smell: Odourless

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

· Boiling point or initial boiling point and

boiling range Not determined Not applicable.

· Flammability

Lower and upper explosion limit Lower: Not determined. Upper: Not determined.

>200 °C · Flash point: 400 °C Ignition temperature:

Decomposition temperature: Not determined.

SADT

pН Not determined.

Viscosity:

· Kinematic viscosity at 40 °C 3,700 mm²/s · dynamic: Not determined.

Solubility

Water: Not miscible or difficult to mix

· Partition coefficient n-octanol/water (log

Not determined. value)

Steam pressure at 20 °C: <0.1 hPa

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Density and/or relative de	ensitv
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· Density at 20 °C 1.1 g/cm3 Relative density Not determined. · Vapour density Not determined.

· 9.2 Other information No further relevant information available.

Appearance:

·Form: Viscous

· Important information on protection of health and environment, and on safety.

· Self-inflammability: Product is not selfigniting. · Explosive properties: Product is not explosive.

· Change in condition

· Evaporation rate Not determined.

· Information with regard to physical hazard classes

103363	
· Explosives	Void
· Flammable gases	Void
Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
Self-heating substances and mixtures	Void
· Substances and mixtures, which emit	
flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· 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

Contact with alkali releases flammable gases

Contact with acids releases flammable gases React when heated with acids and alkalis releasing hydrogen

- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials:

Strong oxidizers

Strong bases

Strong acids

10.6 Hazardous decomposition products:

In case of fire the following can be released:

Carbon monoxide and carbon dioxide

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· Additional information: -

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.
 - · Skin corrosion/irritation Based on available data, the classification criteria are not met.
 - · Serious eve 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.
- · 12.5 Results of PBT and vPvB assessment

P	R	T

540-97-6 Dodecamethylcyclohexasiloxane

541-02-6 Decamethylcyclopentasiloxane

· vPvB:

540-97-6 Dodecamethylcyclohexasiloxane

541-02-6 Decamethylcyclopentasiloxane

12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

· 12.7 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - · Recommendation Smaller quantities can be disposed with household garbage.
 - · Uncleaned packagings:
 - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, ADN, IMDG, IATA

Void

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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 to IMO instruments Not applicable.		
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - · LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)
 - Water hazard class: Generally not hazardous for water.
- 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.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations RID: Reglement International concernant le transport des marchandises danigereuses par chemin de les (Regulationis Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
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

GIDS GIDBAILY HARMONISED SYSTEM OF CHASSIFICATION AND LABEILING OF CHEMICAL 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) PBT: Persistent, Bioaccumulative and Toxic VPVB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.