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

Printing date 03.06.2017 Version number 3 Revision: 03.06.2017

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

- · 1.1 Product identifier
 - · Trade name: Hera SWE 2000
- · 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

- · 2.2 Label elements
 - Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. P210

Keep container tightly closed. P233

P370+P378 In case of fire: Use for extinction: CO2, sand, extinguishing powder.

Store in a well-ventilated place.

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

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

Description: -

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· Dangerous components:		
CAS: 64-17-5	ethanol	> 90%
EINECS: 200-578-6 Reg.nr.: 2119457610-43-xxxx	Flam. Liq. 2, H225	
CAS: 67-64-1	acetone	0-5%
EINECS: 200-662-2	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	
· Additional information Fo	or the wording of the listed hazard phrases refer to section 16.	

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · 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. Then consult doctor.
 - · After swallowing

Rinse out mouth and then drink plenty of water.

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 fire with alcohol-resistant foam.

- · For safety reasons unsuitable extinguishing agents Water with a full water jet.
- · 5.2 Special hazards arising from the substance or mixture

In case of fire the following can be released:

Carbon monoxide (CO)

Carbon dioxide (CO2)

Danger of toxic fluorine based pyrolysis products

- · 5.3 Ădvice for firefighters
 - · Protective equipment: No special measures required.
 - · Additional information -

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures
 - Wear protective equipment. Keep unprotected persons away.
- · 6.2 Environmental precautions:

Dilute with much water.

Prevent material from reaching sewage system, holes and cellars.

6.3 Methods and material for containment and cleaning up:

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

Do not flush with water or aqueous cleansing agents

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· 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 Keep containers tightly sealed.
 - Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
 - Storage
 - · Requirements to be met by storerooms and containers: Store in cool location.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions:
 - Store in cool, dry conditions in well sealed containers.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

	ol parameters	hat require monitoring at the workplace:
64-17-5 et		nat require monitoring at the workplace.
	000 mg/m³, 1000 ppm	
67-64-1 a		
OEL () 12 IO	110 mg/m³, 500 ppm ELV	
· [DNELs	
64-17-5 et	thanol	
Oral	ge.pop., l.te, syst.	87 mg/Kg (nd)
Dermal	worker profess., l.te., syst.	343 mg/Kg/d (nd)
	ge.pop., acu., local	950 mg/Kg/d (nd)
	ge.pop., l.te, syst.	206 mg/Kg/d (nd)
Inhalative	worker profess., acute, local	1900 mg/m3 (nd)
	worker profess., I.te., syst.	1900 mg/m3 (nd)
	ge.pop., acu., local	950 mg/m3 (nd)
	ge.pop., l.te, syst.	114 mg/m3 (nd)

67-64-1 acetone

Oral ge.pop., l.te, syst. 62 mg/Kg (nd)

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Dermal w	orker pro	fess., acute, syst.	
W	orker pro	fess., l.te., syst.	186 mg/Kg/d (nd)
ge	e.pop., I.t	e, syst.	62 mg/Kg/d (nd)
Inhalative w	orker pro	fess., l.te., syst.	1210 mg/m3 (nd)
ge	e.pop., I.t	e, syst.	200 mg/m3 (nd)
· PN	EC s		
64-17-5 etha	anol		
freshwater		0.96 mg/l (nd)	
marine water	r	0.79 mg/l (nd)	
STP		580 mg/l (nd)	
sedim., dw, f	re.wat.	3.6 mg/Kg (nd)	
soil,dw		0.63 mg/Kg (nd)	
67-64-1 acet	tone		
freshwater		10.6 mg/l (nd)	
marine water	r	1.06 mg/l (rabbit)	
STP		19.5 mg/l (nd)	
sedim., dw, f	re.wat.	30.4 mg/Kg (nd)	
sedim., dw, r	mar.wat.	3.04 mg/Kg (nd)	
soil,dw		0.112 mg/Kg (nd)	

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

· 8.2 Exposure controls

- · Personal protective equipment
 - General protective and hygienic measures

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

- · Breathing equipment: Not necessary if room is well-ventilated.
- 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

Value for the permeation: Level ≤ 2

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 protection: Protective goggles are recommended.

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· Body protection: Light weight protective clothing

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SECTION 9: Physical and chem	nical properties
9.1 Information on basic physical and General Information Appearance: Form:	d chemical properties Fluid
· Colour:	Colourless
· Smell:	Alcohol-like
· Odour threshold:	Not determined.
· pH-value:	Not determined.
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Not determined 78 °C
· Flash point:	16 °C
· Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	425 ℃
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
Critical values for explosion: Lower: Upper:	3.5 Vol % 15.0 Vol %
· Steam pressure at 20 °C:	57 hPa
 Density at 20 °C Relative density Vapour density Evaporation rate 	0.79 g/cm³ Not determined. Not determined. Not determined.
· Solubility in / Miscibility with · Water:	Fully miscible
· Partition coefficient (n-octanol/wa	ater): Not determined.
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 10.2 Chemical stability
 - · Conditions to be avoided: No decomposition if used and stored according to specifications.
- · 10.3 Possibility of hazardous reactions No decomposition if used according to specifications.
- · 10.4 Conditions to avoid Heat, flames and sparks.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products:

In case of fire the following can be released:

Carbon monooxide

Carbon dioxide

Danger of toxic pyrolysis products

· Additional information: -

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/	· LD/LC50 values that are relevant for classification:		
64-17-5 et	thanol		
Oral	LD50	6200 mg/kg (rat)	
Inhalative	LC50/4 h	95.6 mg/l (rat)	
67-64-1 a	cetone		
Oral	LD50	5800 mg/kg (rat)	
Dermal	LD50	20000 mg/kg (rabbit)	

- · Primary irritant effect:
 - · 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.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 - 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
 - · Aquatic toxicity:

67-64-1 acetone

EC50/48h 6100 mg/l (daphnia)

LC50/96h | 5540 mg/l (fish)

- 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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- · Additional ecological information:
 - · General notes:

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

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

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.

- · Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.
 - · Recommended cleaning agent: Water, if necessary with cleaning agent.

SECTION	14: Transport	information
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- · 14.1 UN-Number
 - · ADR, IMDG, IATA

UN1170

- · 14.2 UN proper shipping name
 - · ADR
 - · IMDG
 - · IATA

1170 ETHANOL (ETHYL ALCOHOL), solution ETHANOL (ETHYL ALCOHOL), solution

ETHANOL, solution

- · 14.3 Transport hazard class(es)
 - · ADR



- · Class
- · Label

- 3 (F1) Flammable liquids.
- 3

· IMDG, IATA



- · Class
- · Label

3 Flammable liquids.

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14.4 Packing group ADR, IMDG, IATA	II .
· 14.5 Environmental hazards: · Marine pollutant:	No
 14.6 Special precautions for user Kemler Number: EMS Number: 	Warning: Flammable liquids. 33 F-E,S- <u>D</u>
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	nex II of Not applicable.
· Transport/Additional information:	-
· ADR · Limited quantities (LQ) · Transport category · Tunnel restriction code	1 L 2 D/E
· UN "Model Regulation":	UN1170, ETHANOL (ETHYL ALCOHOL) solution, 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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.

Relevant phrases

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport 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)

DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH) LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

Flam. Liq. 2: Flammable liquids - Category 2

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Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 • * Data compared to the previous version altered.

IRL