



**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 SP 99**

· CAS Number:

1303-96-4

· EC number:

215-540-4

· Index number:

005-011-01-1

· Registration number 01-2119490790-32-XXXX

· **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**

Eye Irrit. 2 H319 Causes serious eye irritation.

Repr. 1B H360FD May damage fertility. May damage the unborn child.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

disodium tetraborate decahydrate

· **Hazard statements**

H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn child.

· **Precautionary statements**

P281 Use personal protective equipment as required.

P202

Do not handle until all safety precautions have been read and understood.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 2)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

P308+P313
P501

*IF exposed or concerned: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/
international regulations.*

(Contd. of page 1)

- **Additional information:**
Restricted to professional users.
- **2.3 Other hazards -**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Designation:**
1303-96-4 disodium tetraborate decahydrate
1303-96-4
- **Identification number(s): -**
 - **EC number:** 215-540-4
 - **Index number:** 005-011-01-1
- **Dangerous components:** Void

· **SVHC**

1303-96-4 disodium tetraborate decahydrate

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information** Instantly remove any clothing soiled by the product.
 - **After inhalation** Supply fresh air and call for doctor for safety reasons.
 - **After skin contact** Instantly wash with water and soap and rinse thoroughly.
 - **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **4.2 Most important symptoms and effects, both acute and delayed** Gastric or intestinal trouble
- **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** No further relevant information available.

(Contd. on page 3)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 2)

- **5.3 Advice for firefighters**
 - **Protective equipment:**
 - Wear self-contained breathing apparatus.
 - Wear full protective suit.
 - **Additional information -**

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
 - Ensure adequate ventilation
 - Avoid causing dust.
 - Wear protective equipment. Keep unprotected persons away.
 - Use breathing protection against the effects of fumes/dust/aerosol.
 - Avoid contact with eyes and skin.
- **6.2 Environmental precautions:**
 - Damp down dust with water spray jet.
 - Do not allow to enter drainage system, surface or ground water.
 - Inform respective authorities in case product reaches water or sewage system.
- **6.3 Methods and material for containment and cleaning up:**
 - Ensure adequate ventilation.
 - Collect mechanically.
 - Send for recovery or disposal in suitable containers.
 - Dispose of the material collected according to regulations.
- **6.4 Reference to other sections**
 - 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**
 - Wear protective equipment. Keep unprotected persons away.
 - Avoid contact with eyes and skin.
 - Ensure good ventilation/exhaustion at the workplace.
 - Extractor required on object.
 - Prevent formation of dust.
 - Any deposit of dust which cannot be avoided must be removed regularly.
 - **Information about protection against explosions and fires:** The product is not flammable
- **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:**
 - Store away from foodstuffs.
 - Store away from reducing agents.
 - **Further information about storage conditions:**
 - Store container in a well ventilated position.
 - Store in cool, dry conditions in well sealed containers.
 - Protect from humidity and keep away from water.
 - This product is hygroscopic.

(Contd. on page 4)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 3)

Store in a locked cabinet or with access restricted to technical experts or their assistants.
· **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.

· **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.

· **DNELs**

Oral	worker profess., acute, syst.	1.51 mg/Kg (nd)
	worker profess., l.te., syst.	1.51 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	599.6 mg/Kg/d (nd)
	worker profess., l.te., syst.	303.5 mg/Kg/d (nd)
Inhalative	worker industr., acute, local	22.3 mg/m3 (nd)
	worker profess., acute, local	22.3 mg/m3 (nd)
	worker industr., l.te., syst.	12.76 mg/m3 (nd)
	worker industr., l.te., local	22.3 mg/m3 (nd)
	worker profess., l.te., syst.	6.50 mg/m3 (nd)
	worker profess., l.te., local	22.3 mg/m3 (nd)

1303-96-4 disodium tetraborate decahydrate

Oral	ge.pop., acu., syst.	1.51 mg/Kg (nd)
	ge.pop., l.te, syst.	1.51 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	599.6 mg/Kg/d (nd)
	ge.pop., l.te, syst.	303.5 mg/Kg/d (nd)
Inhalative	worker industr., acute, local	22.3 mg/m3 (nd)
	worker industr., l.te., syst.	12.76 mg/m3 (nd)
	worker industr., l.te., local	22.3 mg/m3 (nd)
	ge.pop., acu., local	22.3 mg/m3 (nd)
	ge.pop., l.te, syst.	6.5 mg/m3 (nd)
	ge.pop., l.te, local	22.3 mg/m3 (nd)

· **PNECs**

STP	10 mg/l (nd)
soil,dw	5.4 mg/Kg (nd)

1303-96-4 disodium tetraborate decahydrate

freshwater	2.02 mg/l (nd)
marine water	2.02 mg/l (nd)
STP	10 mg/l (nd)
soil,dw	5.4 mg/Kg (nd)

(Contd. on page 5)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 4)

· **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**

Avoid contact with the eyes.

Ensure that washing facilities are available in the work place.

Do not eat, drink or smoke while working.

Pregnant women must strictly avoid inhalation or contact with the skin.

Avoid close or long term contact with the skin.

Use skin protection cream for preventive skin protection.

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

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

Store protective clothing separately.

Avoid contact with the eyes and skin.

· **Breathing equipment:** *Filter P3.*

· **Protection of hands:**

Impervious gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Check the permeability prior to each renewed use of the glove.

To avoid skin problems reduce the wearing of gloves to the required minimum.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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

· **Material of gloves**

Natural rubber, NR

Chloroprene rubber, CR

Nitrile rubber, NBR

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Recommended thickness of the material: ≥ 0.5 mm

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.

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 ≤ 8 h

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:** *not absolutely necessary*

(Contd. on page 6)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

· **Body protection:** Protective work clothing.

(Contd. of page 5)

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**

Solid in various forms

Powder

Granulate

White

· **Colour:**

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value at 20 °C:** 9.2

· **Change in condition**

· **Melting point/Melting range:**

62 °C

· **Boiling point/Boiling range:**

1575 °C

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Product is not inflammable.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Not determined.

· **Danger of explosion:** Product is not explosive.

· **Critical values for explosion:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Steam pressure at 20 °C:** 0 hPa

· **Density at 20 °C** 1.71 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

· **Evaporation rate**

Not applicable.

· **Solubility in / Miscibility with**

· **Water at 20 °C:**

~47 g/l

· **Partition coefficient (n-octanol/water) at 25 °C:** -0.757 log POW

· **Viscosity:**

· **dynamic:**

Not applicable.

· **kinematic:**

Not applicable.

· **Solids content:** 100.0 %

(Contd. on page 7)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 6)

· **9.2 Other information** No further relevant information available.

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.
 - Loss of constitutional water on heating
- **10.3 Possibility of hazardous reactions**
 - Reacts with reducing agents
 - Reacts with light alloys to form hydrogen
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Reacts with reducing agents

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values that are relevant for classification:**

1303-96-4 disodium tetraborate decahydrate		
Oral	LD50	4500-5000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
 - Causes serious eye irritation.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** May impair fertility.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Repr. 1B
 - **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**
 - May damage fertility. May damage the unborn child.
 - **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:**

1303-96-4 disodium tetraborate decahydrate	
EC50/48h	1085-1402 mg/l (daphnia)

(Contd. on page 8)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 7)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential**
Due to the distribution coefficient n-octanol/water an accumulation in organisms is not expected.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **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** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR
· ADN, IMDG, IATA | Void
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 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

GB
(Contd. on page 9)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Hera SP 99

(Contd. of page 8)

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: 30

· **National regulations**

· **Information about limitation of use:**

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning pregnant and lactating women must be observed.

Employment restrictions concerning women of child-bearing age must be observed.

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

1303-96-4 disodium tetraborate decahydrate

· **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:**

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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

· *** Data compared to the previous version altered.**