according to 1907/2006/EC, Article 31
Hoffmann Dental Manufaktur GmbH

Reviewed on 11 June 2012

. Identification of substance and manufacturer's name

Product details/Trade name:



HOFFMANN'S GUTTAPERCHA

Manufacturer/Supplier:

Wangenheimstr. 37/39, D-14193 Berlin
Telephone +49 (0) 30 / 82 00 99 0
Fax +49 (0) 30 / 82 28 145
Information department / Emergency information:

Quality assurance department

e-mail: sicherheit@hoffmann-dental.com

2. Composition / Data on ingredients

Chemical characterization:

Description: Mixture of below-mentioned substance with innocuous additions.

Hazardous ingredients:			
CAS: 1314-13-2	Zinc Oxide	Warning; H410	80 – 90 %
EINECS: 215-222-5		N; R 50/53	

3. Hazard identification

Hazard designation:

N Hazardous to environment.

$\label{thm:continuous} \textbf{Special danger warning for human and environment:}$

This product has to be labelled do to the calculation procedure of the "EU-Directive of the General Classification of the Preparations" in the latest valid version.

H410: Very toxic to aquatic life with long lasting effects.

R 50/53: Very toxic to aquatic organisms may cause long-term harmful effects in the waters.

Classification system:

The classification is in compliance with the current EU-lists, but is also completed with details given by technical literature and company.

First aid measures

- After inhaling: Not applicable, because of solid material.

- After skin contact: Not applicable.- After eye contact: Not applicable.

- After swallowing: (A plenty of substance) In case of feeling unwell consult a physician.

5. Fire fighting measures

Suitable extinguishing agents: Adapt to the environment.

Special protective equipment:Staying in dangerous area only with a self-contained breathing apparatus. **Other information:**Prevent any spillage of water for fire-fighting from entering surface or ground

waters. No special measures are required.

6. Accidental release measures

Person related safety precautions: Not required.

Environmental precautions: Prevent any spillage from entering the sewage system.

Methods of cleaning up: Pick up mechanically.

according to 1907/2006/EC, Article 31 Hoffmann Dental Manufaktur GmbH

7. Handling and storage

Handling: The product is only for dental use.
- Information about safe handling: No special measures are required.

- Information about protection against explosion and fire:

No special measures are required.

Storage:

- **Information about storage**: Store tightly closed and dry in original container.

- Information about storage in one common storage facility:

one common storage facility:
 Requirements for storage rooms:
 No special requirements.

8. Exposure control and personal protection

Data on limiting values that require monitoring at the workplace:

Ingredients with limiting values that require monitoring at the workplace:				
1314-13	-2 Zinc Oxide	(EU-No.: 215-222-5)		
TLV	1 A mg/m ³ smoke; DFG			

Technical protective measures: Not required.

Notice:

When used according to regulations, no smoke containing zinc is released.

Personal protective equipment

Respiratory protection: Not required

Skin protection: Wear suitable protective gloves. The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to absent tests no recommendations about the glove material can be given for the product/the preparation/the chemical mixture. The selection of the glove material should be in consideration of the breakthrough time, kinds of permeation and the degradation.

Material of gloves: The selection of the suitable gloves does not only depend on material but also on further quality characteristics 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 to be checked prior to the application.

Penetration time of glove material: The exact breakthrough time is to be obtained from the manufacturer of the protective gloves and has to be observed.

Eye protection: Recommended: Protective goggles with side protection.

Body protection: Lightweight protective clothing.

General protective and hygienic measures: The usual precautionary measures for contact with chemicals are to observe.

9. Physical and chemical properties

General information:		
Form:	Solid	
Colour:	Whitish	
Odour:	Odourless	
Change in state		
Softening point:	Approximately at 65 °C	
Boiling point/boiling range:	Not determined	
Flashpoint:	Not applicable	
pH-value:	Not determined	
Autoflammability:	Product does not self-ignite	
Danger of explosion:	Product is not explosive	
Bulk density:	Not applicable	
Solubility in Water:	Insoluble	

according to 1907/2006/EC, Article 31 Hoffmann Dental Manufaktur GmbH

10. Stability and reactivity

Conditions to be avoided:No decomposition when used according to the regulation.

Do not heat above 80 °C.

Hazardous reactions: No hazardous reactions are known.

Hazardous decomposition products: No hazardous decomposition products are known.

11. Toxicological information

Values given below refer to basic substance Zinc Oxide.

From subacute to chronic toxicity:

Sensitisation: Research on human: No sensitising effect. Mutagenicity Test: Ames-Test: Negative; no mutagenic effect

Additional toxicological information:

In our experience and relating to the available information the product does not cause any noxious effects when used and handled according to regulations.

12. Ecological information

Referring to main substance:

Biological decomposition: Not determined.

Ecotoxicological information Quantitative data about ecological effects are not available for this product.

Biological effects: Very toxic to aquatic organisms. May cause long-term harmful effects in the waters.

General information: Prevent releasing into waters, sewage system and soil.

Water hazard class 2 (self-assessment): Hazardous to waters.

13. Disposal details



Product

Do not dispose of together with domestic waste.

Prevent releasing into sewage system.

Uncleaned packaging:

Dispose of in accordance with official regulations.

according to 1907/2006/EC, Article 31 Hoffmann Dental Manufaktur GmbH

14. Transport information

Land transport ADR/RID and GGVS/GGVE (cross-border / national):



ADR/RID-GGVS/E class: 9 (M7) Miscellaneous hazardous substances and items

Kemler-Number:

UN-Number: 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE

Packaging group: Ш Hazard label:

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE)

Maritime transport IMDG/GGV sea:



IMDG/GGV sea class: **UN-Number:** 3077 Label: 9 Packaging group: Ш EMS-Number: F-A, S-F MARINE POLLUTANT: YES

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE) Proper shipping name:

Air transport ICAO-TI and IATA-DGR:



ICAO / IATA class: **UN/ID Number:** 3077 Label: 9 Packaging group:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE) Proper shipping name:

according to 1907/2006/EC, Article 31 Hoffmann Dental Manufaktur GmbH

15. Regulations according to GHS

Signal word: WARNING **Hazard pictogram:**



Hazard Statements: H410: Very toxic to aquatic life with long lasting effects

Precautionary Statements: P273: Avoid release to the environment

16. Regulations

Labelling according to EU-Directive:

The product has been classified and labelled in accordance with EU-Directives / Ordinance on Hazardous Materials (GefStoffV).

Labels:



N Hazardous to the environment

Risk phrases: Safety phrases: 50/53 Very toxic to aquatic organisms, may cause long-term harmful effects in waters.

57 Use appropriate container to avoid environmental contamination.

60-61 This material and its container are to dispose of as hazardous waste; prevent releasing into the environment.

National regulations: Water hazard class: 2 (hazardous to waters), self-assessment.

17. Other information

This information is based on our present level of knowledge. However, they do not represent a guarantee for any product features and do not establish a contractual relationship. It is to emphasize that there are no warnings at all about human health risks by Zinc Oxide as far as the product is used according to regulations.

Department issuing MSDS: Quality assurance department