Acc. to 91/155/EEC adjustment acc. to Directive 2001/58/EC Hoffmann Dental Manufaktur GmbH

Reviewed on: 16 December 2009

1. Identification of substance and manufacturer's name

Product details/Trade name:

Hoffmann's

Manufacturer/Supplier:

Wangenheimstr. 37/39, D-14193 Berlin Telephone: ++49 (0) 30 / 85 10 27 3 Fax: ++49 (0) 30 / 82 70 45 40

Information department/Emergency information:

Quality assurance department, telephone: ++49 (0) 30 / 85 10 27 52

e-mail: sicherheit@hoffmann-dental.com

2. Composition/Data on ingredients

Chemical characterization:

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

Hazardous ingredients:			
CAS: 1314-13-2	Zinc Oxide	N; R 51/53	80 – 90 %
EINECS: 215-222-5			
CAS: 1309-48-4	Magnesium Oxide		5 – 10 %
EINECS: 215-171-9			

3. Hazards identification

Hazard description:

N Hazardous to the environment

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

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

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

Classification system:

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

4. First aid measures

- After inhaling: Fresh air.

- **After skin contact:** Remove by washing under the running water.

- After eye contact: Flush opened eye with running water for several minutes. Consult an eye

specialist.

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

immediately.

5. Fire fighting measures

Suitable extinguishing

agents: Not applicable.

Special protective equipment: No special measures required.

6. Accidental release measures

Person-related safety

precautions: Avoid inhaling of powder.

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

Methods of cleaning up: Pick up dry powder and dispose of as usual. Clean subsequently and

prevent the development of dust.

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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 dry and tightly closed in original container.

- Information about storage in

one common storage facility: Not required.

- Requirements for storage

rooms: No special requirements.

8. Exposure controls and personal protection

Data on limiting values that require monitoring at the workplace:

Ingredients w	vith limiting values that i	equire monitoring at the workplace	
1314-13-2	Zinc Oxide	(EU-No.: 215-222-5)	
TLV	1 A mg/m ³	smoke; DFG	
1309-48-4	Magnesium Oxide	(EU-No.: 215-171-9)	
TLV	6 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: Not required necessarily; 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.

For the permanent contact in application areas without increased risk of injury (e.g. lab) gloves made of the following material are suitable: Natural rubber (Latex).

For the permanent contact of a maximum of 15 minutes gloves made of the following material are suitable:

Natural rubber (Latex).

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

Form:	Powder	
Colour:	Whitish	
Odour:	Odourless	
Change in state		
Boiling point/boiling range:	Not applicable	
Melting point/melting range:	> 1.200 °C	
Flashpoint:	Not applicable	
pH-value:	Not applicable	
Autoflammability	Product does not self ignite	
Danger of explosion:	Product is not explosive	
Bulk density:	500 kg/cm ³	
Solubility in water:	Insoluble	

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Organic solvents: 0,0 %

10. Stability and reactivity

Conditions to be avoided: No decomposition when used according to regulations.

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 according to the literature provided

to us the product does not cause any noxious effects when used and handled according to regulations.

12. Ecological information

Referring to main substance:

Biological decomposition: Is 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.

European Waste Catalogue

18 01 06 Chemicals containing or consisting of hazardous substances

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: III
Hazard label: 9

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

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N.O.S. (ZINC OXIDE)

Maritime transport IMDG sea:



 IMDG/GGV sea class:
 9

 UN-Number:
 3077

 Label:
 9

 Packaging group:
 III

 EMS-Number:
 F-A, S-F

 MARINE POLLUTANT:
 YES

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (ZINC OXIDE)

Air transport ICAO-TI and IATA-DGR:



ICAO / IATA class: 9
UN/ID number: 3077
Label: 9
Packaging group: III

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (ZINC OXIDE)

15. Regulations

Labelling according to EU guideline:

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

Safety phrases: 57 Use appropriate container to avoid environmental contamination.

National regulations:

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

16. Other information

This information is based on our present 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

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Hoffmann Dental Manufaktur GmbH