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

Reviewed on: 16 December 2009

Identification of substance and manufacturer's name

Product details/Trade name:



HOFFMANN'S CEMENT NORMAL SETTING, POWDER

Manufacturer/Supplier:

Wangenheimstr. 37/39, D-14193 Berlin Telephone: ++49 (0) 30 / 85 10 27 3 ++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 50/53 | 80 - 90 % |
| EINECS: 215-222-5 | | | |
| CAS: 1309-48-4 | Magnesium Oxide | | 5 - 10 % |
| EINECS: 215-171-9 | | | |
| CAS: 7789-75-5 | Calcium Fluoride | | 0 – 5 % |
| EINECS: 232-188-7 | | | |

3. Hazards identification

Hazard designation:

Hazardous to the environment.

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 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.

4. First aid measures

- After inhaling: Fresh air.

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

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

eye specialist.

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

physician immediately.

Fire fighting measures 5.

Suitable extinguishing

Not applicable

Special protective equipment: No special measures are required.

6. Accidental release measures

Person-related safety

precautions: Avoid inhaling of powder.

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

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

prevent the development of dust.

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 r | 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 |
| 7789-75-5 | Calcium Fluoride | (EU-No.: 232-188-7) | |
| TLV | 2,5 E mg/m ³ | | DFG |
| | as F | | |

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 materials 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

| General information: | |
|------------------------------|----------------|
| Form: | Powder |
| Colour: | Whitish |
| Odour: | Odourless |
| Change in state | |
| Boiling point/boiling range: | Not applicable |
| Melting point/melting range: | > 1.200 °C |
| Flash point: | Not applicable |

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| pH-value: | Not applicable The product does not self ignite. | |
|----------------------|--|--|
| Autoflammability: | | |
| Danger of explosion: | Product is not explosive | |
| Bulk density: | 500 kg/cm ³ | |
| Solubility in water: | Insoluble | |
| Solvent content: | | |
| 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

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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:

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: Ш Packaging group: **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: **UN/ID Number:** 3077 Label: 9 Ш Packaging group:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name:

N.O.S. (ZINC OXIDE)

15. 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: 50/53 Very toxic to aquatic organisms, may cause long-term harmful effects in 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

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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