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

Reviewed on: 10 August 2012

1. Identification of substance and manufacturer's name

Product details/Trade name:



HOFFMANN'S Harmonic Shades, Liquid

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 substances with innocuous additions.

Hazardous ingredients:			
CAS: 1314-13-2 EINECS: 215-222-5	Zinc Oxide	Warning; H411 N; R 51/53	10 – 15 %
CAS: 7664-38-2 EINECS: 231-633-2	Ortho-Phosphoric Acid	Danger; H314 C; R 34	> 50 %

3. Hazards identification

Hazard designation:

N Hazardous to the environment

C Corrosive

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.

H314: Causes severe skin burns and eye damage.

H411: Toxic to aquatic life with long lasting effects.

R 34: Causes burns

R 51/53: 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

General warnings: Remove contaminated clothing immediately.

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

- After eye contact: Immediately flush opened eye under running water for several minutes (at least 10 min.),

consult an eye specialist.

- After swallowing: Drink plenty of water, do not induce vomiting (danger of perforation) and consult a

physician immediately.

- After inhaling: Not applicable.

5. Fire fighting measures

Suitable extinguishing agents : Not applicable

Special protective equipment:No special measures required.

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6. Accidental release measures

Person-related safety

precautions: Wear personal protective clothing.

Environmental precautions: Inform responsible authorities in case of spillage into waters or sewage system. Dilute with

plenty of water.

Methods of cleaning up: Absorb with liquid binding material (chemical binders; use cellulose for small

amounts). Use neutralizing agent.

Additional information: See chapter 8 for information about personal protective equipment.

See chapter 13 for disposal information.

7. Handling and storage

Handling: The product is only for dental use.
- Information about safe handling: Keep containers tightly closed.

- 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:

- Requirements for storage rooms:

No special requirements.

Not required.

8. Exposure controls and personal protection

Data on limiting values that require monitoring at the workplace:

Ingredients with limiting values that require monitoring at the workplace		
CAS 7664-38-2	Ortho-Phosphoric Acid	(EU-No.: 231-633-2)
TLV	1 mg/m³ EU	

Technical protective measures: Not required.

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 caracteristics 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. Suitable glove material is e. g. butyl rubber, fluorocarbon rubber (Viton), natural rubber (Latex). For the permanent contact of a maximum of 15 minutes gloves made of PVC or PE are suitable.

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: Protective goggles with side protection are recommended.

Body protection: Lightweight protective clothing. **General protective and hygienic measures**:

The usual precautionary measures for contact with chemicals are to observe.

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

9. Physical and chemical properties

General information:	
Form:	Liquid
Colour:	Colourless
Odour:	Odourless
Change in state	
Boiling point/boiling range:	> 100 °C
Melting point/melting range:	Not determined
Flashpoint:	Not applicable
pH-value:	1 – 2
Autoflammability:	Product does not self ignite.
Danger of explosion:	Product is not explosive
Density at 20 °C:	1,8 g/cm ³
Solubility in water:	fully miscible
Solvent content:	
Organic solvents:	0,0 %
Water:	25 %
VOC EU:	0,0 %
Solid content:	19 %

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 Phosphoric Acid:

Acute toxicity: In our experience the product does not cause any noxious effects when used and handled according to

regulations.

LD50 (dermal rabbit): 2740 mg/kg (referring to pure substance)
LDLo (oral, rat): 1530 mg/kg (referring to pure substance)
LC50/4h (relating to inhalation, rat : > 850 mg/ I (referring to pure substance)

Specific symptoms in animal experiments:

Test for for eye irritation (rabbit): Corrosive effect
Test for for skin irritation (rabbit): Corrosive effect

From subacute to chronic toxicity:

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

Irritation effects on human:

- **Swallowing:** Strong corrosive effect on mouth and throat.

- Skin: Corrosive effect.- Eye: Strong corrosive effect.

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. 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 water.

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

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

06 01 04 Phosphoric acid phosphorous acids

14. Transport information

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



ADR/RID-GGVS/E class: 8 (C1) corrosive substances

Kemler-Number: 80
UN-Number: 1805
Packaging group: III
Hazard Label: 8

Proper shipping name: 1805 PHOSPHORIC ACID, LIQUID

Maritime transport IMDG sea:



 IMDG/GGV sea class:
 8

 UN-Number:
 1805

 Label:
 8

 Packaging group:
 III

 EMS-Number:
 F-A, S-B

 MARINE POLLUTANT:
 NO

Proper shipping name: PHOSPHORIC ACID, SOLUTION

Air transport ICAO-TI and IATA-DGR:



ICAO / IATA class: 8
UN/ID number: 1805
Label: 8
Packaging group: III

Proper shipping name: PHOSPHORIC ACID, SOLUTION

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

15. Regulations according to GHS

Signal word: Danger Hazard pictogram:





Hazard Statements:

H314: Causes severe skin burns and eye damage H411: Toxic to aquatic life with long lasting effects

Precautionary Statements:

P270: Do not eat, drink or smoke when using this product

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

P310: Immediately call a POISON CENTER or doctor/physician.

P363: Wash contaminated clothing before reuse

P391: Collect spillage.

16. Regulations

Labelling according to the 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
- C Corrosive

Risk phrases: 34 Causes burns

51/53 Toxic to aquatic organisms, may cause long-term harmful effects in the waters.

Safety phrases: 20 Do not drink and eat when using.

24 Avoid skin contact.

25 Avoid eye contact.

26-28 In case of eye contact get prompt medical attention; contaminated clothing must be removed immediately; in case of skin contact wash skin with plenty of water

immediately.

36/37/39 Wear suitable protective clothing, gloves and eye/face protection. 45 In case of accident or if you feel unwell consult a physician immediately. 57 Use appropriate container to prevent environmental contamination.

National regulations:

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

17. 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

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

Reviewed on: 10 August 2012

1. Identification of substance and manufacturer's name

Product details/Trade name:



HOFFMANN'S Harmonic Shades, Powder

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 substances with innocuous additions.

Hazardous ingredients:			
CAS: 1314-13-2 EINECS: 215-222-5	Zinc Oxide	Warning; H410 N; R 50/53	80 - 90 %
CAS: 1309-48-4 EINECS: 215-171-9	Magnesium Oxide		5 - 10 %
CAS: 7789-75-5 EINECS: 232-188-7	Calcium Fluoride		0 – 5 %

3. Hazards identification

Hazard designation:

N 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.

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.

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 are 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.

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 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 with limiting values that require monitoring at the workplace			
1314-13-2	Zinc Oxide	(EU-No.: 215-222-5)	
TLV	1 A mg/m³	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.

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

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
pH-value:	Not applicable
Autoflammability:	The product does not self ignite.
Danger of explosion:	Product is not explosive
Bulk density:	500 kg/m 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: <u>Research on human</u>: 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 vv

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

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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

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: III
Hazard label: 9

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (ZINC OXIDE)

Maritime transport IMDG/GGV 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 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

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

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: 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.

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