

EC Safety Data Sheet 1907/2006/EC Provis®

1. Commercial product name and supplier

Commercial product name: Provis®
Application: Temporary dental filling material
Manufacturer: Favodent Karl Huber GmbH
 Greschbachstr.17
 D-76229 Karlsruhe, Germany
 Tel.: +49 (0)721 / 62686-0 Fax: +49 (0)721 / 62686-66
 E-Mail: info@favodent.com
Emergency phone number: Ms Apoth. Wolf, phone number: +49 (0)179 / 5146888

2. Hazard identification

N Dangerous for the environment
 The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU"
Risk phrases:
 R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Classification system:
 This product requires classification according to the criteria of the EC and extended by company and literature data.

3. Composition

Chemical characterisation: Alkali- and Earth alkali-sulphate with a polymer binder and a softening agent
Hazardous components:

| <u>Declaration:</u> | <u>CAS-No.</u> | <u>EINECS-No.</u> | <u>Label</u> | <u>R-Phrases</u> | <u>Weight %</u> |
|---------------------------------|----------------|-------------------|--------------|------------------|-----------------|
| Zinc oxide | 1314-13-2 | 215-222-5 | N | 50/53 | 30-40 |
| Zinc sulphate | 7446-19-7 | 231-793-3 | N, Xn | 22-41-50/53 | 5-15 |
| 2-ethylhexyl-diphenyl Phosphate | 1241-94-7 | 214-987-2 | N | 50/53 | 10-15 |
| Tri phenyl phosphate | 115-86-6 | 204-112-2 | N | 50/53 | <1 |

4. First aid measures

Eye contact:
 Void.
Skin contact:
 Void
Ingestion:
 After Ingestion wash mouth out with water, call a physician immediately and show packaging or label.
Inhalation:
 Void
Further information:
 None

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9. Physical and Chemical Properties

| | |
|------------------------------|---|
| <u>Appearance:</u> | Solid pasty |
| <u>Colour:</u> | white |
| <u>Odour:</u> | odourless |
| <u>Boiling point:</u> | undetermined |
| <u>Melting range:</u> | - |
| <u>Ignition temperature:</u> | Product is not self igniting |
| <u>Flashpoint:</u> | not applicable |
| <u>Explosion limits:</u> | not explosive |
| <u>Vapour pressure:</u> | not applicable |
| <u>Density:</u> | 2,42 g/cm ³ at 25°C |
| <u>pH-Value:</u> | not applicable |
| <u>Solubility in water:</u> | not soluble |
| <u>Viscosity:</u> | 55.000 Pa*s at 20 °C , Rate 0,01/s (Rotation rheometer MCR 300, Fa. Physica) |

10. Stability and reactivity

| | |
|---------------------------------|---|
| <u>Thermal decomposition:</u> | No decomposition if used according to the specifications. Do not heat about 80 °C |
| <u>Hazardous decomposition:</u> | No dangerous decomposition products known. |
| <u>Hazardous reactions:</u> | No dangerous reaction known. |
| <u>Further information:</u> | - |

11. Toxicological information

| | |
|--------------------------------|---|
| <u>Acute toxicity:</u> | No acute toxic effect. |
| <u>After eye contact:</u> | Not irritant. |
| <u>After skin contact:</u> | Not irritant. |
| <u>After inhalation:</u> | - |
| <u>Sensitization:</u> | Not sensitizing. |
| <u>Additional information:</u> | When used and handled according to specification, the product does not have any harmful effects to our experience and the information provided to us. According to our present knowledge, physiologically compatible. In more than 40 years of use no side effects have become known. The components of the preparation are widely used as dental filling material. |

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12. Ecological information

Information about elimination (persistence and degradation)

No degradation data available.

Aquatic toxicity:

Very toxic to fish

Very toxic for aquatic organism, hazardous for water, also poisonous for fish plankton in water bodies

Further ecological information:

Do not allow to enter drains/surface water / groundwater.

German „Wassergefährdungsklasse“ WGK 2.

13. Disposal considerations

Waste (product): Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Not cleaned packaging: Disposal must be according to official regulations.

14. Transport information

Transport at land (GGVS/GGVE)

GGVS/E Class: 9 Miscellaneous dangerous substances and goods

Kemler:

UN-No: 3077

Packing group: III

Overland statement:

Hazard label: 9

Technical Name: Environmentally Hazardous Substance, Solid, n.o.s.,
(Zinc oxide, Zinc sulphate)

Transport at sea (IMDG/GGVSee):

IMDG/GGVSee-Class: 9

Label: 9

IMDG-Code page:

UN-No: 3077

EMS-Number: F-A, S-F

Packing group: III

Marine pollutant: yes

Technical Name: Environmentally Hazardous Substance, Solid, n.o.s.,
(Zinc oxide, Zinc sulphate)

Air transport (ICAO-TI and IATA-DGR):

ICAO/IATA-Class: 9

UN/ID-No: 3077

Label: 9

Packing group: III

Technical Name: Environmentally Hazardous Substance, Solid, n.o.s.,
Zinc oxide, zinc sulphate)

**EC Safety Data Sheet 1907/2006/EC
Provis®****15. Regulatory information**

This product requires classification according to the criteria of the EC and the „Gefahrstoffverordnung“

Hazard designation:

N Dangerous for the environment

Risk phrases:

R 36 Irritant for Eyes

R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Safety phrases:

S 29 Do not allow escaping into sewer system.

S 60-61 This material and its container must be disposed of as hazardous waste

Water hazard class: Water hazard class 2 (self assessment)

16. Other information

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications have not the meaning of guarantees on properties