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 Art. -No., product name: **02054 / 02311 Fermin**

DETAX**1 Identification of the substance or preparation and of the company**

- 1.1 Identification of the substance/the preparation:
 Commercial Product Name: Fermin
- 1.2 Use of the substance/the preparation: Professional.
 Provisional filling material for use in dentistry.
- 1.3 Company / undertaking identification:
 Manufacturer / distributor: DETAX GmbH & Co. KG
 Street / POB-No.: Carl-Zeiss-Str. 4
 State / postal code / city: D-76275 Ettlingen
 Telephone: +49 7243/510-0 Telefax: +49 7243/510-100
 E-Mail: post@detax.de
- 1.4 Emergency number: +49 7243/510-0
 This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.).

2 Hazards identification

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

3 Composition / information on ingredients

- 3.1 Chemical characterisation (preparation):
 Description: Dental temporary filling cement.
- 3.2 Hazardous ingredients:
- | | | |
|------------------------|-------------------|----------------------|
| Name: | <u>Zinc oxide</u> | <u>Zinc sulphate</u> |
| CAS-No.: | 1314-13-2 | 7446-19-7 |
| EG-No.: | 215-222-5 | 231-793-3 |
| Index-No.: | 030-013-00-7 | 030-006-00-9 |
| Concentration: | 20 – 40% | < 10% |
| Identification letter: | N | Xn N |
| EC/R: | 50/53 | 22-41-50/53 |
- 3.3 Further information: The identification letters and the R-Phrases are described in section 16.

4 First aid measures

- 4.1 General information: In case of persistent complaints, seek medical advice (if possible, show the label or this MSDS). Take off all contaminated clothing.
- 4.2 After inhalation: Move to fresh air. In case of persistent irritation, seek medical advice.
- 4.3 After contact with the skin: Remove the product mechanically by means of a cloth or paper. Wash with plenty of water and soap. In case of visible skin reaction or complaints, seek medical advice (if possible, show the label or this MSDS).
- 4.4 After contact with the eyes: Rinse the open eyes immediately with plenty of water for at least 15 minutes, seek immediately medical advice.
- 4.5 After swallowing: Immediately rinse mouth well with water and drink plenty of water. If you feel unwell, seek medical advice.
- 4.6 Autoprotection of the first assistant: Take care of a sufficient autoprotection (hand protection, foil mask "Life key").

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DETAX**5 Fire fighting measures**

- 5.1 Suitable extinguishing media: The product itself is not combustible. Extinguishing media depend on environmental fire.
- 5.2 Extinguishing media which must not be used for safety reasons: Depending on the combustible materials in the surrounding area.
- 5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: ZnO-fumes and sulphur oxides may occur. Do not breathe combustion gases.
- 5.4 Special protective equipment for fire fighting: Use respiratory protection independent of recirculated air.
- 5.5 Further information: Collect contaminated extinguishing water separately. Prevent it running into in-shore waters, ground water and earth.

6 Accidental release measures

- 6.1 Personal precautions: If material is accidentally spilled, refer to the possible danger of skidding. Do not pass through the spilled material.
- 6.2 Environmental precautions: Keep away from sewage treatment plants, in-shore waters and earth. Observe local byelaws.
- 6.3 Methods for cleaning up: Pick up the product mechanically by means of a cloth or paper and collect it in a suitable container, labelled according to regulations (for disposal see section 13).

7 Handling and storage

- 7.1 Handling:
 Precautions for safe handling: The usual precautions in handling with chemicals are to be observed. When using to not eat, drink or smoke. Avoid contact with eyes.
- Precautions against fire and explosion: Remove all containers not yet affected by fire. Cool endangered containers with water mist or cover them with foam.
- 7.2 Storage:
 Conditions for storage rooms and vessels: Keep the product in the original container in a cool and dry place, away from foodstuffs.
- Advice for storage of incompatible materials: Keep away from acids and lyes.
- Further information for storage: Keep at temperature not exceeding 25 °C / 77 °F.
 Keep away from humidity.
- 7.3 Definite use: Dental provisional filling cement for use by trained specialist staff.

8 Exposure controls and personal protection

- 8.1 Exposition limit values:
 Associate substances with specific control parameters such as limit values
 Recommendations of the MAK-Commission:
 Zinc oxide fume
 1 mg/m³
 with reference to the alveolar fraction.
 Peak limitation: Excursion factor 1; duration 15 min, mean; 4 times per shift; interval 1 hour.
- 8.2 Limitation and control of the exposition
- 8.2.1 Limitation and control of the exposition at the place of work: Exposition limit values must be supervised by means of appropriate analytical equipment.

General protection and hygiene measures: The usual precautions in handling with chemicals must be respec-

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DETAX

ted. When using to not eat, drink or smoke. Take off all contaminated clothing.

Personal protection equipment:
 Respiratory protection: Under the usual working conditions not necessary.
 Hand protection: Protective gloves are recommended, e.g. such as gloves of nitrile rubber.
 Eye protection: To avoid mechanical injuring of the eyes, wear protective glasses.
 Body protection: Wear working clothing.

8.2.2 Limitation and control of the environmental exposition: Prevent the material getting into in-shore waters, ground water and earth.

9 Physical and chemical properties

9.1 Appearance

Form: paste
 Colour: white
 Odour: almost odourless

9.2 Important information on health and environmental protection and on safety Method (67/ 548/EEC)

pH-value	n.a.	
Boiling point	n.a.	DIN 51356
Flash point	n.a.	DIN 51755
Ignition temperature	n.a.	DIN 51794
Vapour pressure	n.a.	
Density	= approx. 2.44 g/cm ³ at 20 °C / 68 °F	DIN 51757
Solubility in water	= virtually insoluble	
Distribution coefficient octanol / water:	n.a.	
Viscosity, dynamic	= > 15 Mio. mPa.s at 23 °C / 73 °F	Brookfield
Explosion limits	n.a.	

9.3 Further information:

Thermal decomposition: not tested

10 Stability and reactivity

10.1 Conditions to avoid: Moisture uptake causes a quality defect of the paste.

10.2 Materials to avoid: Reacts with acids and lyes forming the corresponding salts, -complexes.

10.3 Hazardous decomposition products: No decomposition, if stored and handled in accordance with standard industrial practices. In case of fire, ZnO-fumes and sulphur oxides may occur.

11 Toxicological information

11.0 General information: According to present experience, the material shows no health risk if handled appropriately, observing the usual hygiene at place of work.

11.1 Toxicological tests

Acute toxicity
 Acute oral toxicity (LD₅₀): species rat > 15 000 mg/kg
 origin: literature
 these data refer to the ingredient zinc oxide.

Acute inhalative toxicity (LC₅₀): species rat 5.7 mg/l 4 hours
 origin: literature
 these data refer to the ingredient zinc oxide.

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12 Ecological information

- 12.1 Ecological toxicity:
 Effects in sewage treatment plants (bacteria toxicity: respiration-/reproduction inhibition):
 Do not introduce into purification plants.
- 12.2 Mobility: No data available.
- 12.3 Persistence and degradability
 Biodegradation / further information: May cause long-term adverse effects in the aquatic environment.
- 12.4 Potential of biological accumulation: No data available.
- 12.5 Other harmful effects: Very toxic to aquatic organisms.
- 12.6 Further ecotoxicological effects: Avoid escape into water, drainage, sewer, or the ground. Do not dispose of to a public disposal site.

13 Disposal considerations

- 13.1 Waste management (product): Recommendation: Dispose of according to regulations by handing over to a special waste disposal company. Observe the local byelaws.
 European Waste Catalogue Ref.No.: Please ask your local waste disposal company about the correct Ref.No. according to the European Waste Catalogue.
- 13.2 Contaminated packaging: Recommendation: Fully empty containers (scraped carefully). Containers may be recycled or re-used. Uncleaned containers must be disposed of as hazardous waste. Observe local/national byelaws.

14 Transportation information

- 14.1 Land transportation ADR/RDI and GGVS/GGVE:
 GGVS/GGVE-class..... : 9 cl.-code M7
 ADR/RID-class..... : 9 cl.-code M7
 Transportation emergency card number: 9
 Warning board - Hazard No.: 90 Substance No.: 3077 PG: III
 Nomenclature..... : Environmentally hazardous substance, solid, n.o.s.
 Further information..... : Contains zinc oxide
 Limited Quantities : LQ27 (6 kg / 30 kg)
- 14.2 Inland navigation ADN/ADNR:
 Further information: No data available.
- 14.3 Transportation by sea IMDG/GGVsea:
 IMDG/GGVsea-class .. : 9 Label 9 UN-No.: 3077 PG: III
 EmS-No..... : F-A, S-F
 Marine pollutant : P
 Proper shipping name.. : Environmentally hazardous substance, solid, n.o.s.
 Technical name..... : Contains zinc oxide
 LTD. QTY..... : 5 kg / 30 kg
- 14.4 Air transportation ICAO-TI and IATA-DGR transportation by air:
 ICAO/IATA-class..... : 9 Label 9 UN-No.: 3077 PG: III Page: 281 (49 edition)
 Proper shipping name.. : Environmentally hazardous substance, solid, n.o.s.
 Technical name..... : Contains zinc oxide
 Packing regulations..... : PAC: 911 Max. net.: 400 kg
 CAO: 911 Max. net.: 400 kg
 Excepted Quantities..... : 30 g / 1 kg
 LTD.QTY..... : 30 kg gross weight (Y911)

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DETAX**15 Regulatory information**

15.1 EC regulations

Identification according to EC directives:

Identification letters and hazard indications

Identification letters: **N**

Hazard indications: Environmentally hazardous

Hazardous components for labelling: Contains: Zinc oxide.

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

S-Phrases: 26-60-61 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions / Safety data sheets.

15.2 National regulations (Germany):

Occupational restrictions: Observe the restrictions on juvenile employment as defined in the „Jugendarbeitsschutzgesetz”. Observe the restrictions on the employment of expectant and nursing mothers as defined in the „Mutterschutzverordnung”.

Classification of possible adverse effects in the aquatic environment (Wassergefährdungsklasse):
Class 2 (adverse effects in the aquatic environment).**16 Other information**

16.1 Wording of the R-phrases under section 3:

R-Phrases and identification letters

R-Phrases:

R 22	Harmful if swallowed
R 41	Risk of serious damage to eyes
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Identification letters:

N Environmentally hazardous Xn Harmful

16.2 Further information

Explanation of the abbreviations:

n.a. = not applicable n.s. = not subject to

16.3 Literature register

Richtlinie 1999/45/EG für die Einstufung, Verpackung und Kennzeichnung gefährlicher Zubereitungen

Richtlinie 67/548/EWG für die Einstufung, Verpackung und Kennzeichnung gefährlicher Stoffe, Anhang I

Neue Datenblätter für gefährliche Arbeitsstoffe nach der Gefahrstoffverordnung, WEKA-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Sicherheitstechnische Kenndaten chemischer Stoffe, ecomed-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Handbuch der Abfallentsorgung, ecomed-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Erste Allgemeine Verwaltungsvorschrift zum Bundes-Immissionsschutzgesetz (Technische Anleitung zur Reinhaltung der Luft – TA Luft)

VCI: Leitfaden für die Zusammenlagerung von Chemikalien

DFG Deutsche Forschungsgemeinschaft: MAK- und BAT-Werte – Liste 2007

Allgemeine Verwaltungsvorschrift zur Änderung der Verwaltungsvorschrift wassergefährdender Stoffe - VwVwS vom 27. Juli 2005

Safety data sheets and further information from manufacturers / distributors

BGIA GESTIS-Stoffdatenbank, Online research

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IATA Gefahrgutvorschriften, 49. Ausgabe, International Air Transport Association Montreal

The given information describes exclusively the safety requirements of the product(s) and is based on our present-day knowledge. It does not represent a guarantee for the properties of the product(s) described in terms of the legal warranty regulations.