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DETAX

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

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

Classification (67/548/EEC, 1999/45/EC):

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

2.2 Labelling

Labelling (67/548/EEC, 1999/45/EC):

Y	N	Environmentally hazardous		
R-Phrases		Indication		
R 50/53		Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.		
S-Phrases		Indication		
S 60		This material and its container must be disposed of as hazardous waste.		
S 61		Avoid release to the environment. Refer to special instructions / Safety data sheets.		

Hazardous ingredients (Labelling according to EC): Contains Zinc oxide.

3 Composition / information on ingredients

3.1 Chemical characterisation (preparation):

Description: Dental temporary filling cement.

3.2 Hazardous ingredients

Ingredient	CAS-No.	EC-No.	Index-No.	Concentration	Hazard symbols	R-Phrases
Zinc oxide	1314-13-2	215-222-5	030-013- 00-7	20 - 40%	* N	50/53

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Ingredient	CAS-No.	EG-No.	Index-No.	Concentration	Hazard symbols	R-Phrases
Zinc sulphate	7446-19-7	231-793-3	030-006- 00-9	< 10%	Xn Y	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").

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 regula-

tions (for disposal see section 13).

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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

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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:

Storage class (Germany): 13 (Non-flammable solid substances).

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-

ted. When using to not eat, drink or smoke. Take off all contami-

nated 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 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.

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Vapour pressure n.a.

Density = approx. 2.44 g/cm³ 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, -com-

plexes.

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.

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).

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Containers may be recycled or re-used.

Uncleaned containers must be disposed of as hazardous waste.

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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 + Label ENVIRONMENTAL POLLUTANT Warning board - Hazard No.: 90 Substance No.: 3077 PG: III Nomenclature...... Environmentally hazardous substance, solid, n.o.s.

Further information.....: Contains zinc oxide

Tunnel restriction code: E

Limited Quantities: 5 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 + Label MARINE POLLUTANT 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 + Label ENVIRONMENTAL POLLUTANT UN-No.: 3077

PG: IIIPage: 320 (52 edition)

Proper shipping name..: Environmentally hazardous substance, solid, n.o.s.

Technical name.....: Contains zinc oxide

Packing regulations.....: PAC: 956 Max. net.: 400 kg CAO: 956 Max. net.: 400 kg

EQ E1.....: 30 g / 1 kg

LTD.QTY..... 30 kg gross weight (Y956)

15 Regulatory information

15.1 National regulations (Germany):

Observe local/national byelaws.

Information for labelling is given in section 2 of this document.

Occupational restrictions: Observe the restrictions on juvenile employment as defined in the

"Jugendarbeitsschutzgesetz".

Observe the restrictions on the employment of expectant and nur-

sing 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

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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

ADR 2011, Verkehrsverlag Fischer Düsseldorf

IMDG-Code 2011, Amendment 35-10, Verkehrsverlag Fischer Düsseldorf

IATA Gefahrgutvorschriften, 52. Ausgabe, International Air Transport Association Montreal

16.4 Product:

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.

This Safety Data Sheet has been adjusted to the Directive (EC) 453/2010.