

Safety Data Sheet

according to Regulation (EC) No. 1907/2006

Fermin

Revision date: 07.11.2022

Product code: 10787

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Fermin

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Provisional filling material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	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.)	

1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1907/2006

Eye Dam. 1; H318
 Aquatic Acute 1; H400
 Aquatic Chronic 1; H410

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No. 1907/2006

Hazard components for labelling

Zinc sulfate monohydrate

Signal word: Danger

Pictograms:



Hazard statements

H318 Causes serious eye damage.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 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/doctor.
 P391 Collect spillage.
 P501 Dispose of contents/container to according to local and applicable legislation of dispose of waste.

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Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Dental temporary filling cement.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No. 1907/2006)			
1314-13-2	zinc oxide			20 - < 40 %
	215-222-5	030-013-00-7		
	Aquatic Acute 1, Aquatic Chronic 1; H400 H410			
7446-19-7	Zinc sulfate monohydrate			5 - < 20 %
	231-793-3	030-006-00-9		
	Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H302 H318 H400 H410			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
1314-13-2	215-222-5	zinc oxide	20 - < 40 %
	oral: LD50 = > 5000 mg/kg		
7446-19-7	231-793-3	Zinc sulfate monohydrate	5 - < 20 %
	oral: LD50 = 2949 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink 1 glass of water.

Do not induce vomiting. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

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5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Keep away from strong acids and bases.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

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Dental provisional filling cement.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste	
Colour:	white	
Odour:	odourless	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		>200 °C
Flammability		
Solid/liquid:		not determined
Gas:		not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		>200 °C
Auto-ignition temperature:		not determined
Decomposition temperature:		not determined
pH-Value:		not determined
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.	
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		<0,5 hPa
(at 20 °C)		
Vapour pressure:		>2,00 hPa
Density (at 20 °C):		2,52 g/cm ³

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Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic:

>15000000 mPa·s

(at 23 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : acids and lyes forming the corresponding zinc salts, -complexes.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

In case of fire ZnO-fumes and sulphur oxides may occur.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No. 1907/2006

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) 7434,9 mg/kg; ATE (inhalation vapour) 53,53 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1314-13-2	zinc oxide				
	oral	LD50 > 5000 mg/kg	Rat	IUCLID	
7446-19-7	Zinc sulfate monohydrate				
	oral	LD50 2949 mg/kg	Rat		

Irritation and corrosivity

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Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Based on a Bovine Corneal Permeability Study conducted in accordance with OECD Guideline No. 437 (July 2013), H318 is not shown.

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Very toxic to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
1314-13-2	zinc oxide					
	Acute fish toxicity	LC50 mg/l	1120	96 h		GESTIS
	Acute algae toxicity	ErC50 mg/l	0,21	72 h	Selenastrum capricornutum	CSR
	Acute crustacea toxicity	EC50 mg/l	0,67	48 h	Ceriodaphnia spec	CSR

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

Not identified as PBT/ vPvB substances

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

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Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M7
Special Provisions:	274 335 375 601
Limited quantity:	5 kg
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

Contains: zinc oxide

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M7
Special Provisions:	274 335 375 601
Limited quantity:	5 kg
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number or ID number:	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Special Provisions:	274, 335, 966, 967, 969
Limited quantity:	5 kg
Excepted quantity:	E1
EmS:	F-A, S-F

Other applicable information (marine transport)

Contains zinc oxide

Air transport (ICAO-TI/IATA-DGR)

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14.1. UN number or ID number:	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Special Provisions:	A97 A158 A179 A197 A215
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y956
Excepted quantity:	E1
IATA-packing instructions - Passenger:	956
IATA-max. quantity - Passenger:	400 kg
IATA-packing instructions - Cargo:	956
IATA-max. quantity - Cargo:	400 kg

Other applicable information (air transport)

Contains zinc oxide

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): E1 Hazardous to the Aquatic Environment

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

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GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
 UN: United Nations
 DNEL: Derived No Effect Level
 DMEL: Derived Minimal Effect Level
 PNEC: Predicted No Effect Concentration
 ATE: Acute toxicity estimate
 LL50: Lethal loading, 50%
 EL50: Effect loading, 50%
 EC50: Effective Concentration 50%
 ErC50: Effective Concentration 50%, growth rate
 NOEC: No Observed Effect Concentration
 BCF: Bio-concentration factor
 PBT: persistent, bioaccumulative, toxic
 vPvB: very persistent, very bioaccumulative
 RID: Regulations concerning the international carriage of dangerous goods by rail
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
 EmS: Emergency Schedules
 MFAG: Medical First Aid Guide
 ICAO: International Civil Aviation Organization
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships
 IBC: Intermediate Bulk Container
 SVHC: Substance of Very High Concern
 For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1907/2006

Classification	Classification procedure
Eye Dam. 1; H318	Calculation method
Aquatic Acute 1; H400	Calculation method
Aquatic Chronic 1; H410	Calculation method

Relevant H and EUH statements (number and full text)

H302 Harmful if swallowed.
 H318 Causes serious eye damage.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

SU: Sectors of use

PC: Product categories

PROC: Process categories

ERC: Environmental release categories

AC: Article categories

TF: Technical functions

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)