

according to Regulation (EC) No 1907/2006

Fermin

Revision date: 03.03.2017

Product code: 10787

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

1.1. Product identifier

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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 & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	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.)

1.4. Emergency telephone

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 - 4.00 p.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Serious eye damage/eye irritation: Eye Irrit. 2

Hazardous to the aquatic environment: Aquatic Acute 1

Hazardous to the aquatic environment: Aquatic Chronic 1

Hazard Statements:

Causes serious eye irritation.

Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects.

2.2. Label elements

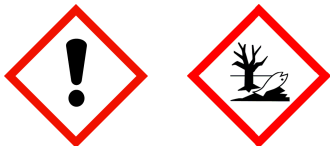
Regulation (EC) No. 1272/2008

Hazard components for labelling

zinc oxide, zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)

Signal word: Danger

Pictograms:



Hazard statements

H319 Causes serious eye irritation.

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.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

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P310 present and easy to do. Continue rinsing.
P391 Immediately call a POISON CENTER/doctor.
P501 Collect spillage.
Dispose of contents/container to according to local and applicable legislation of dispose of waste.

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 according to Regulation (EC) No. 1272/2008 [CLP]			
1314-13-2	zinc oxide			30 - < 35 %
	215-222-5	030-013-00-7		
	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1; H400 H410			
7446-19-7	zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)			5 - < 10 %
	231-793-3	030-006-00-9		
	Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H302 H318 H400 H410			
115-86-6	triphenylphosphate			< 1 %
	204-112-2			
	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1; H400 H410			

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

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 plenty 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.

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SECTION 5: Firefighting measures**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**

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

Absorb with liquid-binding material (e.g. 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. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Advice on storage compatibility

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)

Dental provisional filling cement.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
115-86-6	Triphenyl phosphate	-	3		TWA (8 h)	WEL
		-	6		STEL (15 min)	WEL

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.

Protective and hygiene measures

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.

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

Wear suitable 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

Test method

pH-Value:	not determined
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Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	not determined

Flammability

Solid:	not applicable
Gas:	not applicable

Lower explosion limits:	not determined
Upper explosion limits:	not determined

Auto-ignition temperature

Solid:	not applicable
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Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidizing.

Vapour pressure: not determined

Density (at 20 °C): 2,43 g/cm³

Water solubility: insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic:
(at 23 °C) >15000000 mPa·s

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

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 toxicological effects

Acute toxicity

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

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CAS No	Chemical name			
	Exposure route	Dose	Species	Source
1314-13-2	zinc oxide			
	oral	LD50 > 5000 mg/kg	Rat	IUCLID
7446-19-7	zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)			
	oral	LD50 2949 mg/kg	Rat	
115-86-6	triphenylphosphate			
	oral	LD50 3500 mg/kg	Rat	GESTIS
	dermal	LD50 >7900 mg/kg	Rabbit	GESTIS

Irritation and corrosivity

Causes serious eye irritation.

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.

Additional information on tests

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

SECTION 12: Ecological information

12.1. Toxicity

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h] [d]	Species	Source
1314-13-2	zinc oxide				
	Acute fish toxicity	LC50 1120 mg/l	96 h		GESTIS
	Acute algae toxicity	ErC50 0,21 mg/l	72 h	Selenastrum capricornutum	CSR
	Acute crustacea toxicity	EC50 0,67 mg/l	48 h	Ceriodaphnia spec	CSR
115-86-6	triphenylphosphate				
	Acute fish toxicity	LC50 0,7 mg/l	96 h		GESTIS
	Acute algae toxicity	ErC50 2 mg/l	96 h		GESTIS
	Acute crustacea toxicity	EC50 1 mg/l	48 h		GESTIS

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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

Not identified as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

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

Advice on disposal

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)

<u>14.1. UN number:</u>	UN 3077
<u>14.2. UN proper shipping name:</u>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Contains: zinc oxide
<u>14.3. Transport hazard class(es):</u>	9
<u>14.4. Packing group:</u>	III
Hazard label:	9
Classification code:	M7
Limited quantity:	5 kg/ 30 kg
Transport category:	3
Hazard No:	90

Other applicable information (land transport)

Contains: zinc oxide

Marine transport (IMDG)

<u>14.1. UN number:</u>	UN 3077
<u>14.2. UN proper shipping name:</u>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Contains zinc oxide
<u>14.3. Transport hazard class(es):</u>	9
<u>14.4. Packing group:</u>	III
Hazard label:	9
Marine pollutant:	P
Limited quantity:	5 kg/ 30 kg
EmS:	F-A, S-F

Other applicable information (marine transport)

Contains zinc oxide

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Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Contains zinc oxide
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
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. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

National regulatory information

Employment restrictions:	Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).
Water contaminating class (D):	3 - highly water contaminating

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%

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

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H410 Very toxic to aquatic life with long lasting effects.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Identified uses

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

SU main: Main user groups

PC: Product categories

ERC: Environmental release categories

SU: Sectors of use

PROC: Process categories

AC: Article categories

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