Pulp Canal Sealer Powder

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision date: 6/24/2026 Supersedes version of: 8/2/2018

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

1.1. Product identifier

Product form : Mixture
Trade name : Pulp Canal Sealer Powder

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Dental product: Endodontic Obturation Systems and Fill Products

1.2.2. Uses advised against

Restrictions on use : For professional use only

1.3. Details of the supplier of the safety data sheet

Manufacturer
Kerr Italia, S.r.l.
Via Passanti, 174
Scafati (SA) 84018, Italy
T +39 081 850 3511

1.4. Emergency telephone number

Emergency number : (Chemical Spills, Leaks, Fire, Exposure or Accident only): CHEMTREC 1-800-424-9300 (in the US), 1-703-527-3887 (Outside the US)

Country/Area	Organisation	Emergency number
Germany	Informationszentrale gegen Vergiftungen. Klinik und Poliklinik für Allgemeine Pädiatrie. Zentrum für Kinderheilkunde, Universitätsklinikum Bonn. Gebäude 30, ELKI (Eltern-Kind-Zentrum). Venusberg-Campus 1 53127 Bonn.	+49 (0) 228 19 240
United Kingdom	National Poisons Information Service (Birmingham Centre). City Hospital. Dudley Road B18 7QH.	0344 892 0111 Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, category 1B	H317
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



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GHS07 GHS09

Signal word (CLP) : Warning

Contains : Thymol iodide

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing dust.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P273 - Avoid release to the environment.
P280 - Wear protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zinc oxide	CAS-No.: 1314-13-2 EC-No.: 215-222-5 EC Index-No.: 030-013-00-7	30-60	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Silver substance with national workplace exposure limit(s) (DE, GB); substance with a Community workplace exposure limit	CAS-No.: 7440-22-4 EC-No.: 231-131-3	10-30	Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)
Thymol iodide	CAS-No.: 552-22-7 EC-No.: 209-007-5	0.1-1	Skin Sens. 1B, H317

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Move the affected person to fresh air. Get medical attention if symptoms occur.

First-aid measures after skin contact : Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse eyes with water as a precaution. Get medical attention if irritation develops and persists.

First-aid measures after ingestion : Do NOT induce vomiting. Rinse mouth out with water. Get medical advice/attention if you feel unwell.

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

Inhalation : Dust from this product may cause respiratory irritation.

Skin : May cause an allergic skin reaction. Repeated exposure may cause skin dryness or cracking.

Eyes	:	Dust from this product may cause minor eye irritation.
Ingestion	:	May cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Chronic symptoms	:	None known.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	:	Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	:	Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard	:	This product is not classified as flammable or combustible.
Hazardous decomposition products in case of fire	:	Carbon oxides (CO, CO2). Halogenated compounds. Metal oxides.

5.3. Advice for firefighters

Firefighting instructions	:	Cool down the containers exposed to heat with a water spray. Exercise caution when fighting any chemical fire. Do not allow run-off from firefighting to enter drains or water courses.
Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not touch or walk on the spilled product.

6.1.1. For non-emergency personnel

Protective equipment	:	Wear recommended personal protective equipment.
Emergency procedures	:	Avoid contact with eyes, skin and clothing. Avoid breathing dust.

6.1.2. For emergency responders

Protective equipment	:	Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	:	Stop leak if safe to do so.
Methods for cleaning up	:	Carefully shovel or sweep up spilled material and place in suitable container. Avoid raising powdered materials into airborne dust. Wash contaminated area with large amounts of water.
Other information	:	Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	:	Avoid contact with eyes, skin and clothing. Wear personal protective equipment. Avoid breathing dust. Ensure adequate ventilation.

Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area. Keep away from heat and direct sunlight. Store in original container. Keep container closed when not in use. Store away from incompatible materials.

7.3. Specific end use(s)

Dental applications.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Silver (7440-22-4)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Silver, metallic
IOEL TWA	0.1 mg/m³
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	Silber
AGW (OEL TWA)	0.1 mg/m³ (E)
Peak exposure limitation factor	8(II)
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission); EU - Europäische Union (Von der EU wurde ein Luftgrenzwert festgelegt: Abweichungen bei Wert und Spitzenbegrenzung sind möglich)
Regulatory reference	TRGS900
United Kingdom - Occupational Exposure Limits	
Local name	Silver
WEL TWA (OEL TWA)	0.01 mg/m³ soluble compounds as Ag 0.1 mg/m³ metallic
WEL STEL (OEL STEL)*	0.03 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

*STEL value is calculated based on the TWA limit

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:
Use eye protection according to EN 166.

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing. EN 13034. EN 14605

Hand protection:
Wear suitable gloves tested to EN374. Contact your glove supplier for selection assistance.

8.2.2.3. Respiratory protection

Respiratory protection:
In operations where exposure limits are exceeded or exposure levels are excessive, an approved respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Beige.
Appearance	:	Powder.
Odour	:	Odourless.
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not flammable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Insoluble in water.
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	> 1
Relative vapour density at 20°C	:	Not applicable
Particle characteristics	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Keep away from heat and direct sunlight.

10.5. Incompatible materials

Oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Zinc oxide (1314-13-2)	
LD50 oral rat	> 5000 mg/kg
LD50 oral	5000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LD50 dermal	5000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 5.7 mg/l/4h No mortality

Silver (7440-22-4)	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 5.16 mg/l/4h

Thymol iodide (552-22-7)	
LD50 oral rat	> 2000 mg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

Zinc oxide (1314-13-2)	
LOAEL (dermal, rat/rabbit, 90 days)	75 mg/kg bodyweight (rat) (OECD 410 method) (Nanoform)
NOAEL (oral, rat, 90 days)	31.52 mg/kg bodyweight (OECD 408 method)

Silver (7440-22-4)	
LOAEL (oral, rat, 90 days)	125 mg/kg bodyweight (OECD 408 method)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : None known

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Avoid release to the environment.
Hazardous to the aquatic environment, short–term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long–term (chronic) : Very toxic to aquatic life with long lasting effects.

Zinc oxide (1314-13-2)	
LC50 - Fish [1]	0.78 mg/l
LC50 - Fish [2]	0.169 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 - Crustacea [1]	0.147 mg/l
NOEC chronic fish	0.025 mg/l
NOEC chronic algae	0.0299 mg/l

Silver (7440-22-4)	
LC50 - Fish [1]	4.7 µg/l Pimephales promelas (Fathead minnow)
LC50 - Fish [2]	89.4 µg/l Pimephales promelas (Fathead minnow)

Thymol iodide (552-22-7)	
EC50 - Crustacea [1]	> 100 mg/l Daphnia magna (Water flea)

12.2. Persistence and degradability

Pulp Canal Sealer Powder	
Persistence and degradability	Biodegradation is not applicable to inorganic compounds.

Zinc oxide (1314-13-2)	
Persistence and degradability	Biodegradation is not applicable to inorganic compounds.

Silver (7440-22-4)	
Persistence and degradability	Not rapidly degradable

Thymol iodide (552-22-7)	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations.
Sewage disposal recommendations : Do not dispose of waste into sewer. Disposal must be done according to official regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
Note: Inner packages containing net quantities of less than 5 kg/5 L are exempt per IMDG Code 2.10.2.7, ICAO Special Provision A197, and ADR Special Provision 375.		

14.6. Special precautions for user

Overland transport
Not regulated

Transport by sea
Not regulated

Air transport
Not regulated

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)
Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:
New format.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS-No.	Chemical Abstracts Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
SDS	Safety Data Sheet
TWA	Time Weighted Average
vPvB	Very Persistent and Very Bioaccumulative
DNEL	Derived-No Effect Level

Data sources : ECHA (European Chemicals Agency). Supplier's safety documents.

Full text of H- and EUH-statements:	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1B	H317	Expert judgement
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

Safety Data Sheet (SDS), EU

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date of preparation, however, KERR Corporation makes no warranty with respect to the accuracy or suitability of the recommendations, and assumes no liability to any use thereof.

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Signature Manifest

Document Number: DC-SDS-603318 **Revision:** 2
Title: Pulp Canal Sealer Powder (EU)
Effective Date: 10 Aug 2026

All dates and times are in Pacific Standard Time.

2026 April Batch EU Endo SDS

01. Collaboration (SDS Admin & Approvers)

Name/Signature	Title	Date	Meaning/Reason
Holly Cheeseman (HOLLY.CHEESEMAN)	Lab Manager	06 Aug 2026, 02:04:41 PM	Complete
Mya Nguyen (MYA.NGUYEN)	CHEMIST RESEARCH	06 Aug 2026, 02:57:39 PM	Complete

02. Approve (SDS Approvers)

Name/Signature	Title	Date	Meaning/Reason
Patricia Becker (PATRICIA.BECKER)	EH&S Manager	07 Aug 2026, 07:51:13 AM	Approved
Pamela Pummill (PAMELA.PUMMILL)	ASSOCIATE RA	07 Aug 2026, 09:00:57 AM	Approved
Grace Huang (GRACE.HUANG)	Director	07 Aug 2026, 02:46:28 PM	Approved
Holly Cheeseman (HOLLY.CHEESEMAN)	Lab Manager	10 Aug 2026, 08:11:23 AM	Approved

03. Oracle (SDS Section 14 Updated - DOC CONTROL)

Name/Signature	Title	Date	Meaning/Reason
Mya Nguyen (MYA.NGUYEN)	CHEMIST RESEARCH	10 Aug 2026, 08:51:01 AM	Reviewed

04. Web Publishing & Closure (SDS Admin)

Name/Signature	Title	Date	Meaning/Reason
Carlos Aloise (CARLOS.ALOISE)	DIRECTOR PRODUCT DEVELOPMENT	10 Aug 2026, 02:22:50 PM	Approved

05. Notification (Distribution List)

Name/Signature	Title	Date	Meaning/Reason
Alessandra Bufo (ALESSANDRA.BUFO)		10 Aug 2026, 02:22:50 PM	Email Sent
Carlos Aloise (CARLOS.ALOISE)	DIRECTOR PRODUCT DEVELOPMENT	10 Aug 2026, 02:22:50 PM	Email Sent
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Sandra Capurso (SANDRA.CAPURSO)		10 Aug 2026, 02:22:50 PM	Email Sent