

Safety Data Sheet

Pulp Canal Sealer Powder

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Pulp Canal Sealer Powder

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

Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T 00-800-41-050-505

Manufacturer

SybronEndo
1332 S. Lone Hill Avenue
Glendora, CA 91740 - USA
T +1.714.516.7979

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Eye Irrit. 2 H319

Aquatic Acute 1 H400

Aquatic Chronic 1 H410

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07



GHS09

Signal word (CLP)	: Warning
Hazard statements (CLP)	: H319 - Causes serious eye irritation. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling. P273 - Avoid release to the environment. P280 - Wear eye 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. P337+P313 - If eye irritation persists: Get medical advice/attention. P391 - Collect spillage. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Extra phrases	: The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	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 (REACH-no) 01-2119463881-32	10 - 75	Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Silver	(CAS-No.) 7440-22-4 (EC-No.) 231-131-3 (REACH-no) 01-2119555669-21	1 - 30	Eye Irrit. 2, H319
5,5'-diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodite	(CAS-No.) 552-22-7 (EC-No.) 209-007-5	< 25	Acute Tox. 4 (Oral), H302

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.
 Hazardous decomposition products in case of fire : zinc oxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment. Exercise caution when fighting any chemical fire.
 Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes.

For non-emergency personnel

Protective equipment : See Heading 8.
 Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Discharging into rivers and drains is forbidden. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.
 Methods for cleaning up : Sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Ensure good ventilation of the work station. Do not breathe dust. Avoid dust formation. Avoid contact with skin and eyes.
 Hygiene measures : Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store in a closed container. Store in original container.
 Incompatible products : Oxidizing agent.
 Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

zinc oxide (1314-13-2)		
EU	Local name	Zinc oxide
EU	Notes	SCOEL Recommendations (Ongoing)
Ireland	Local name	Zinc oxide, fume
Ireland	OEL (8 hours ref) (mg/m³)	2 mg/m³
Ireland	OEL (15 min ref) (mg/m³)	10 mg/m³
Silver (7440-22-4)		
EU	Local name	Silver, metallic
EU	IOELV TWA (mg/m³)	0.1 mg/m³
Gibraltar	Eight hours mg/m3	0.1 mg/m³
Ireland	Local name	Silver (metallic)
Ireland	OEL (8 hours ref) (mg/m³)	0.1 mg/m³

Silver (7440-22-4)		
Ireland	Notes (IE)	IOELV
Malta	Local name	Silver,metallic
Malta	OEL TWA (mg/m ³)	0.1 mg/m ³
United Kingdom	Local name	Silver
United Kingdom	WEL TWA (mg/m ³)	0.01 mg/m ³ soluble compounds as Ag 0.1 mg/m ³ metallic

8.2. Exposure controls

- Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.
- Personal protective equipment : Gloves. Safety glasses. Avoid all unnecessary exposure. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.
- Hand protection : Wear suitable gloves. Wear rubber gloves or Latex gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. Wear protective gloves.
- Eye protection : Chemical goggles or safety glasses. STANDARD EN 166.
- Skin and body protection : Wear suitable protective clothing
- Respiratory protection : Respiratory protection not applicable. Dust production: dust mask with filter type P2. Standard EN 143.



Other information : Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

- Physical state : Solid
- Appearance : Powder.
- Colour : Beige.
- Odour : none to slight.
- Odour threshold : Not determined
- pH : Not determined
- Relative evaporation rate (butylacetate=1) : Not determined
- Melting point : Not determined
- Freezing point : Not determined
- Boiling point : Not determined
- Flash point : Not determined
- Auto-ignition temperature : Not determined
- Decomposition temperature : Not determined
- Flammability (solid, gas) : Non flammable
- Vapour pressure : Not determined
- Relative vapour density at 20 °C : Not determined
- Relative density : Not determined
- Solubility : insoluble in water.
- Log Pow : Not determined
- Viscosity, kinematic : Not determined
- Viscosity, dynamic : Not determined
- Explosive properties : Product is not explosive.
- Oxidising properties : Non flammable.
- Explosive limits : Not determined

9.2. Other information

Additional information : None to our knowledge.

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 polymerization.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

oxidizing materials.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Acute toxicity : Not classified

zinc oxide (1314-13-2)	
LD50 oral rat	> 15000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 inhalation rat (mg/l)	5.7 mg/l/4h

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: Not determined
Serious eye damage/irritation	: Causes serious eye irritation. pH: Not determined
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
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
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity**

Ecology - water : Very toxic to aquatic life with long lasting effects.

zinc oxide (1314-13-2)	
LC50 fish 1	1.1 mg/l (96 hours - Rainbow trout)
EC50 Daphnia 1	98 µg/l (48 hours - Daphnia magna)
NOEC (chronic)	0.017 mg/l 72 hours - Pseudokirchnerella subcapitata

12.2. Persistence and degradability

Pulp Canal Sealer Powder	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Pulp Canal Sealer Powder	
Log Pow	Not determined
Bioaccumulative potential	Not established.
zinc oxide (1314-13-2)	
Bioconcentration factor (BCF REACH)	60960

12.4. Mobility in soil

Pulp Canal Sealer Powder	
Ecology - soil	Material insoluble in water.

12.5. Results of PBT and vPvB assessment

Pulp Canal Sealer Powder	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects : None to our knowledge.
 Additional information : Avoid release to the environment.





SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose as hazardous waste.
 Waste treatment methods : Do not discharge into drains.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
 Ecology - waste materials : Avoid release to the environment.
 European List of Waste (LoW) code : 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: TRANSPORT INFORMATION


In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
3077	3077	3077	3077
14.2. UN proper shipping name			
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description			
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III, (E)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT		
14.3. Transport hazard class(es)			
9	9	9	9
			
14.4. Packing group			
III	III	III	III
14.5. Environmental hazards			
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available			

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : M7
 Special provisions (ADR) : 274, 335, 601, 375

Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: E
EAC code	: 2Z

- Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002, LP02
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1, BK1, BK2, BK3
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

- Contains no REACH substances with Annex XVII restrictions
- Contains no substance on the REACH candidate list
- Contains no REACH Annex XIV substances

National regulations

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Indication of changes:

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.2	Symptoms/effects after eye contact	Added	
6.1	Emergency procedures	Added	
6.2	Environmental precautions	Modified	
6.3	Methods for cleaning up	Added	
7.1	Precautions for safe handling	Modified	
7.2	Incompatible materials	Removed	
8.2	Eye protection	Modified	
8.2	Hand protection	Modified	
11.1	Potential adverse human health effects and symptoms	Modified	

Data sources : EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

Other information : None.

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Version : 2.0

Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.