

Safety Data Sheet

Pulp Canal Sealer Liquid

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

1.1. Product identifier

Product name : Pulp Canal Sealer Liquid

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]

Skin Irrit. 2 H315
Eye Irrit. 2 H319
Skin Sens. 1 H317
Aquatic Chronic 3 H412

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

Signal word (CLP) :

Warning

Hazardous ingredients :

eugenol; Balsams, Canada

Hazard statements (CLP) :

H315 - Causes skin irritation.
 H317 - May cause an allergic skin reaction.
 H319 - Causes serious eye irritation.
 H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264 - Wash hands thoroughly after handling.
 P272 - Contaminated work clothing should not be allowed out of the workplace.
 P273 - Avoid release to the environment.
 P280 - Wear eye protection, protective gloves.
 P302+P352 - IF ON SKIN: Wash with plenty of water/...
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 - If eye irritation persists: Get medical advice/attention.
 P362+P364 - Take off contaminated clothing and wash it before reuse.
 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]
eugenol	(CAS-No.) 97-53-0 (EC-No.) 202-589-1	30 - 100	Eye Irrit. 2, H319 Skin Sens. 1, H317
Balsams, Canada	(CAS-No.) 8007-47-4 (EC-No.) 232-362-2	1 - 25	Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Chronic 2, H411

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 :

Remove person to fresh air and keep comfortable for breathing. 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 or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid measures after eye contact :

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 : Not expected to present a significant hazard under anticipated conditions of normal use. In all cases of doubt, or when symptoms persist, seek medical attention.

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

No specific measures identified.

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.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

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 : Wear appropriate personal protective equipment - see Section 8. Avoid all eye and skin contact and do not breathe vapour and mist.

For non-emergency personnel

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 liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Clean up immediately. Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

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 : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

Hygiene measures : Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep cool. Store in a dry place. Keep container closed when not in use.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

No additional information available

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. Nitrile rubber gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. STANDARD EN 374.
Eye protection	: Chemical goggles or safety glasses. STANDARD EN 166.
Skin and body protection	: Wear suitable protective clothing
Respiratory protection	: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Extra personal protection: A/P2 filter respirator for organic vapour and harmful dust. Standard EN 141.



Other information	: Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Colour	: amber.
Odour	: 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	: > 1
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.
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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

No data available.

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
Skin corrosion/irritation	: Causes skin irritation. pH: Not determined
Serious eye damage/irritation	: Causes serious eye irritation. pH: Not determined
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
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 : Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Pulp Canal Sealer Liquid	
Log Pow	Not determined
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Pulp Canal Sealer Liquid	
Ecology - soil	insoluble in water.

12.5. Results of PBT and vPvB assessment

Pulp Canal Sealer Liquid	
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

14.1. UN number	Not regulated for transport
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
No supplementary information available	

14.6. Special precautions for user

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

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Pulp Canal Sealer Liquid - eugenol
3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	Pulp Canal Sealer Liquid

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	
2.1	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	

2.2	Signal word (CLP)	Added	
2.3	Other hazards not contributing to the classification	Removed	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects after skin contact	Added	
4.2	Symptoms/effects after eye contact	Added	
5.3	Firefighting instructions	Modified	
6.1	General measures	Modified	
7.1	Precautions for safe handling	Modified	
8.2	Respiratory protection	Modified	
8.2	Appropriate engineering controls	Modified	
8.2	Personal protective equipment	Modified	
8.2	Eye 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:

Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful 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.