Axis|SybronEndo

SAFETY DATA SHEET

Pulp Canal Sealer EWT Liquid

Section 1. Identification

Product identifier : Pulp Canal Sealer EWT Liquid

Product code : Not available.

Other means of identification : Not available.

Product type : Paste.

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

Product use : Dental product: Endodontic Obturation Systems and Fill Products

Area of application : Professional applications.

Manufacturer : **SybronEndo Endodontics**
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Australia
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Emergency telephone number (with hours of operation) : 61 401 690 670 (24 hours)

Section 2. Hazard(s) identification

Classification of the substance or mixture : H319 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A

GHS label elements

Hazard pictograms :

Signal word : WARNING

Hazard statements : H319 - Causes serious eye irritation.

Precautionary statements

Prevention : P280 - Wear eye or face protection.
P264 - Wash hands thoroughly after handling.

Response : 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 attention.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : Not applicable.

Section 2. Hazard(s) identification

Other hazards which do not result in classification : None known. Health effects are based on the uncured material.

Section 3. Composition and ingredient information

Substance/mixture : Mixture

Other means of identification : Not available.

Ingredient name	% (w/w)	CAS number
eugenol	≥75 - ≤90	97-53-0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

Inhalation : No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

Skin contact : No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water if material has been swallowed and the exposed person is conscious. Give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

Section 4. First aid measures

Protection of first-aiders : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

Suitable extinguishing media : In case of fire, use water spray (fog), foam, dry chemical or CO_2.

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : In case of major fire and large quantities: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

For emergency responders : Low release. For professional use only. See also the information in "For non-emergency personnel".

Environmental precautions : Low release. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and material for containment and cleaning up

Small spill : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose of in a safe manner.

Section 7. Handling and storage

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : No special measures are required for small quantities under normal and intended conditions of product use.

Environmental exposure controls : No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures : No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Paste.]

Colour : Amber.

Odour : Oil of cloves

Odour threshold : Not available.

pH : Not available.

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not applicable.

Lower and upper explosive (flammable) limits : Not available.

Vapour pressure : Not available.

Vapour density : Not available.

Relative density : >1 [Water = 1]

Solubility : Insoluble in the following materials: cold water and hot water.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerisation will not occur.

Conditions to avoid : Avoid excessive heat.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis. (Eugenol)

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

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
eugenol	LD50 Oral	Rat	1930 mg/kg	-

Conclusion/Summary : Based on the criteria of the protocol, this product is considered cytotoxic per USP 23.

Irritation/Corrosion

Conclusion/Summary

Skin : Not available.

Eyes : Not available.

Respiratory : Not available.

Sensitisation

Conclusion/Summary

Skin : Kligman score: Grade I (weak sensitizer)

Respiratory : Not available.

Mutagenicity

Conclusion/Summary : Not mutagenic in Ames test.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Section 11. Toxicological information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	2477.5 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
eugenol	Acute LC50 24000 µg/l Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours

Conclusion/Summary : Not available.

Persistence and degradability

Conclusion/Summary : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
eugenol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
eugenol	2.27	-	low

Mobility in soil

Section 12. Ecological information

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

	ADG	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of Marpol and the IBC Code : Not available.

Section 15. Regulatory information

Standard Uniform Schedule of Medicine and Poisons

Not regulated.

Model Work Health and Safety Regulations - Scheduled Substances

No listed substance

Australia inventory (AICS) : All components are listed or exempted.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Section 15. Regulatory information

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Any other relevant information

History

Date of issue/Date of revision : ***

Date of previous issue : No previous validation

Version : ***

Key to abbreviations : ADG = Australian Dangerous Goods
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
NOHSC = National Occupational Health and Safety Commission
SUSMP = Standard Uniform Schedule of Medicine and Poisons
UN = United Nations

Procedure used to derive the classification

Classification	Justification
Eye Irrit. 2A, H319	Calculation method

References : Work Health and Safety Regulations 2011, as ammended
Preparation of Safety Data Sheets for Hazardous Chemicals, Code of Practice, Safe Work Australia
Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG), National Transport Commission

Indicates information that has changed from previously issued version.

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