

SAFETY DATA SHEET

as per 1907/2006/ES

SpofaDental
A Kerr Company

Caryosan

Date of Issue: 16/07/2015

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 *Product identifiers:* **Caryosan**

1.2 *Relevant identified uses of the substance or mixture and uses advised against:*
Cement, which allows you to create a good seal cavity and also irritate the surrounding tissue. Due to the content of eugenol reliable analgesic and disinfectant effect.

1.3 *Details of the supplier of the safety data sheet:*

Business Name: **SpofaDental a.s.**
Company Headquarters: **Markova 238, 506 01 Jičín, The Czech Republic**
Company Identification Nr.: **63999447**
Telephone: +420 - 493 583 111
Fax: +420 - 493 583 333
E-mail: info@spofadental.com

1.4 *Telephone number for urgent situations:* +420 - 224 919 293
(National Toxicological Centre, Na bojišti 1, 120 00 Praha 2, CR)

2. INFORMATION REGARDING THE DANGERS OF THE SUBSTANCE OR PRODUCT

2.1 *Classification of the substance or mixture (accord. to CLP):*

- a) Caryosan plv.:
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
- b) Caryosan liq.:
Acute Tox. 4 H302 Harmful if swallowed.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Irrit. 2 H315 Causes skin irritation.
Skin. Sens. 1 H317 May cause an allergic skin reaction.
Resp. Sens. 1A H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
STOT SE 3 H335 May cause respiratory irritation.

2.2 *Label elements:*

Hazard symbols:

Caryosan plv.:



Caryosan liq.:



Signal word:

WARNING

DANGER

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Hazard statements:

- a) Caryosan plv.: H410
Very toxic to aquatic life with long lasting effects.
- b) Caryosan liq.: H302, H319, H315, H317, H334, H335
Harmful if swallowed. Causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.

Safety phrases:

Caryosan plv.:

P273 - Avoid release to the environment.

Caryosan liq.:

P262 - Do not get in eyes, on skin, or on clothing.

P270 - Do not eat, drink or smoke when using this product.

2.3 Other hazards: Not known.

3. INFORMATION REGARDING THE COMPOSITION OF THE SUBSTANCE OR PRODUCT

The powder contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
Zinc oxide	< 85	215-222-5	1314-13-2	N R50/53	Aquatic Chronic 1 H410
Zinc acetate	< 1	209-170-2	5970-45-6	Xn R22 Xi R36	Acute Tox. 4 H302 Eye Irrit. 2 H319

The liquid contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
Eugenol	< 95	202-589-1	9003-01-4	Xn R22 Xi R42/43- 36/37/38	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin. Sens. 1 H317 Resp. Sens. 1A H334 STOT SE 3 H335

For R-phrases and H-phrases, see sect. 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures:

Ensure the safety of all persons present. Provide mental rest and calm to anyone affected. Avoid further exposure. Provide a sufficient supply of fresh air. When breathing is difficult, seek medical assistance. Upon contact with skin wash with water and soap. If the skin is

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affected to a greater extent, seek medical assistance. Affected eyes wash out with plenty of lukewarm water, seek medical assistance. Unconscious person Never give anything by mouth. Upon ingestion wash the mouth out thoroughly. When problems seek medical assistance.

4.2 Most important acute and delayed symptoms and effects:

The best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed: N/D

5. MEASURES FOR FIRE EXTINCTION

5.1 Extinguishing agents: powder, heavy or medium foam, CO₂
Unsuitable extinguishing agents: direct stream of water

5.2 Special danger arising from the substance or mixture:
Oxides of carbon.

5.3 Instructions for fire workers:
For fire fighting if necessary breathing apparatus.

6. MEASURES TO BE TAKEN IN CASE OF RANDOM LEAK

6.1 Regulations for the protection of persons, protective equipment and emergency procedures:

Use appropriate protective equipment. Prevent the spread of gas/mist/vapors.
Provide a sufficient supply of fresh air. Evacuate personnel to safe.

6.2 Regulations for the protection of the environment:
Prevent further leakage or spillage if this is not associated with risk.
Avoid leakage to public sewerage systems. Discharge into the environment.

6.3 Methods and material for containment and cleaning:
Soak up with inert absorbent material and dispose of as hazardous waste.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections: See sect. 13.

7. INSTRUCTIONS FOR HANDLING AND STORAGE

7.1 Instructions for safe handling:
Contact with the skin and eyes must be avoided. Don't breathe vapor or mist.
Normal measures for preventive fire protection.

7.2 Conditions for safe storage of substances and mixtures, including any incompatibilities:
The product must be stored in a cool place. Keep container tightly-sealed in a dry, well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

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7.3 Specific use:

See 1.2 herein. The product is classified as a medical device as per directive 93/42/EHS (in the Czech Republic: Government Decree 336/2004 Coll.).

The product is intended for professional use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters: No information is available for the product.

Zinc oxide:

Permissible exposure limit PEL (mg/m^3): 2

Maximum permissible concentration NPK-P (mg/m^3): 5

8.2 Reduction of exposition: The product must be handled in a well-ventilated area.

Eye protection: Goggles or shield.

Hand protection: Gloves.

Skin protection: Working garment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Powder:

Appearance: white powder

State (at 20°C): solid

No other information available.

Liquid:

Appearance: yellowish liquid

State (at 20°C): viscous

No other information available.

Eugenol:

a) Appearance, form: clear, liquid

Colour: light yellow

b) Odour: no data available

c) Odour threshold: no data available

d) pH: no data available

e) Melting point/freezing point: $-12 \div -10$ °C

f) Initial boiling point: 254 °C

g) Flash point: 112 °C - closed cup

h) Evaporation rate: no data available

i) Flammability (solid, gas): no data available

j) Upper/lower flammability or explosive limits: no data available

k) Vapour pressure: < 0.1 hPa at 25 °C

l) Vapour density: no data available

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m) Relative density	1.067 g/cm ³ at 25 °C
n) Water solubility	no data available
o) Partition coefficient	n-octanol/water log POW: 2.7
p) Auto-ignition temperature	no data available
q) Decomposition temperature	no data available
r) Viscosity	no data available
s) Explosive properties	no data available
t) Oxidizing properties	no data available

9.2 Other informations:

No other information is available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: No information is available.

10.2 Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions: N/D

10.4 Conditions to avoid: Caryosan liq. - free access of air.

10.5 Incompatible materials: Caryosan liq. - strong oxidizers.

10.6 Dangerous decomposition products: N/D

11. TOXICOLOGICAL INFORMATION

No information is available for the product.

Zinc oxide:

Acute toxicity

LD₅₀ per os, brown rat: 7950 mg/kg

LD₅₀ inhaled, brown rat, 4 hrs: 2500 mg/m³

Eugenol:

Acute toxicity LD₅₀ per os - brown rat - 1930 mg/kg

Notes: Altered sleep time (including change in righting reflex). Behavioral: Coma. Lungs, Thorax, or Respiration: Dyspnea.

Skin corrosion/irritation: Skin - rabbit - Severe skin irritation - 24 h - Draize test

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

May cause allergic respiratory and skin reactions.

Germ cell mutagenicity: Genotoxicity in vitro - rat - Liver. DNA damage.

Genotoxicity in vitro - mouse - lymphocyte. Mutation in mammalian somatic cells.

Genotoxicity in vitro - Hamster - Embryo. Unscheduled DNA synthesis

Genotoxicity in vitro - Hamster - Embryo. Morphological transformation.

Genotoxicity in vitro - Hamster - Embryo. Sister chromatid exchange.

Genotoxicity in vivo - mouse - Oral. Micronucleus test.

Carcinogenicity: Carcinogenicity - mouse - Oral.

Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Liver: Tumors.

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This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (Eugenol)

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Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Potential health effects:

Inhalation - May be harmful if inhaled. Causes respiratory tract irritation.

Ingestion - Harmful if swallowed.

Skin - May be harmful if absorbed through skin. Causes skin irritation.

Eyes - Causes serious eye irritation.

Signs and Symptoms of Exposure:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information: RTECS: SJ4375000

12. ENVIRONMENTAL INFORMATION

No information available for the product.

12.1 Toxicity:

Zinc oxide: Toxicity to fish LC50 - *Oncorhynchus mykiss* (rainbow trout) - 1.1 mg/l - 96 hrs

Eugenol: Toxicity to fish LC50 - *Oncorhynchus mykiss* (rainbow trout) - 60.8 mg/l - 96 hrs

12.2 Persistence and degradability: No information available.

12.3 Bioaccumulation potential: No information available.

12.4 Soil mobility: No information available.

12.5 PBT and vPvB assessment: No information available.

12.6 Other adverse effects: Harmful to aquatic organisms.

13. DISPOSAL

13.1 Waste treatment methods:

Unusable powder are waste number 160315 Metal oxides containing heavy metals.

Liquid is waste number 160305 Organic wastes containing dangerous substances.

Contaminated packages must be burnt in an incineration plant or handled by a company authorised for dangerous waste disposal.

14. TRANSPORT INFORMATION

The product is not classified as dangerous for transport - less than limit amount.

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15. INFORMATION CONCERNING LEGAL REGULATIONS

15.1 Regulations applicable to safety, health and environment / specific regulations regarding the substance or mixture:

European Parliament and Council Directive (ES) 1907/2006

Act No. 350/2012 Coll. (applicable in the Czech Republic)

Act No. 201/2012 Coll., On air protection

Act No. 258/2000 Coll., On protection of public health, as amended

15.2 Chemical Safety Assessment: No information available.

16. OTHER INFORMATION

R-phrases used:

R22 - Harmful if swallowed

R36 - Irritating to eyes

R36/37/38 - Irritating to eyes, respiratory system and skin

R42/43 - May cause sensitisation by inhalation and skin contact

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

H-phrases used:

H302 - Harmful if swallowed

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H335 - May cause respiratory irritation

H410 - Very toxic to aquatic life with long lasting effects

Updates in the safety data sheet: Update of Section 2, P-phrase for powder added. Completed numbers of waste in Section 13.

The above information applies to customer packages unless stated otherwise, and fully expresses our current knowledge and experience. The product is assumed for use at worksites corresponding to its designation, and the instructions on the enclosed instruction sheet as well as the standard labour safety regulations for the handling of chemical products are assumed to be adhered to.