

CRCS Calciobiotic Root Canal Sealer Powder

Issue Date: September 2014

Internal Document Number: 48286A

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Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product Name: CRCS Calciobiotic Root Canal Sealer (Powder)

Product Code(s): H03534, H03535, H05694, , 50007725, 3-CP002, 50007634, 3-CP001

Relevant identified uses of the mixture and uses advised against: CRCS Powder is intended to be mixed with a liquid component and used in conjunction with Gutta Percha Points for the sealing of root canals.

Synonyms: CRCS

Manufacturer

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USA & Canada: 1 800 535 5053

Copies of this SDS can be found at
www.coltene.com

Section 2: HAZARDS IDENTIFICATION

Classifications:

U.S.A. Not Regulated (Classification and labeling is not recognized by the US EPA)

EEA Member Countries: Classified as H400 Aquatic Acute 1, H410 Aquatic Chronic 1

Appearance: White Powder

Contains: Zinc Oxide

Labeling Elements:

Hazard Category

H400 Aquatic Acute 1
H410 Aquatic Chronic 1

Signal Word:

Warning

Hazard Statements:

Very toxic to aquatic life with long lasting effects



GHS09

Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Storage:

(Not specified)

Disposal:

P501 Dispose of contents/container as hazardous or special waste in accordance with applicable law.

Classification in accordance with Directives 67/548/EEC and 1999/45/EC:

Symbol – N; Warning; Risk Phrases R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Safety Phrases S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

Other hazards which do not result in classification: None

PBT/vPvB Assessment: This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substance (Synonyms)	CAS	EC Number	Index Number	Percent (w/w)
Zinc Oxide	1314-13-2	215-222-5	030-013-00-7	30%

Section 4: FIRST AID MEASURES

Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician

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Eyes: Flush with large amounts of water. Seek medical attention immediately.

Skin: Wash with soap and water.

Ingestion: Drink plenty of water; do not induce vomiting; call a physician.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media: CO₂, dry chemical or foam

Specific Hazards Arising from the Chemical: None known.

Protective Equipment and Precautions for Firefighters: Wear NIOSH approved self-contained breathing respirator in positive pressure mode.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: See personal protective equipment listed in section 8.

Methods for Containment and Clean-up: Vacuum small spills. Spills not mixed with other chemicals may be recyclable. Remove persons to safety. Suitable material for taking up wet product: absorbing material, organic, sand

Other Information: Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Retain contaminated washing water and dispose it. In case of escape or of entry into waterways, soil or drains, inform the responsible authorities as required.

US Only: CRCS Powder contains 30% Zinc Oxide which is **CERCLA & SARA Section 313 Listed** (N982 Zinc Compounds Includes any unique chemical substance that contains zinc as part of that chemical's infrastructure).

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling: Always wear gloves and eye protection. Wear protective clothing and dust respirator in bulk dust conditions. Keep container closed when not in use.

Conditions for Safe Storage, Including Incompatibilities: Keep out of reach of children. Keep container closed. Store in cool, dry place.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits:

Component:	Concentration:	Country:	8hr TWA (Dust)	15 min-STEL mg/m ³
Zinc Oxide	30%	Germany (MAK)	6 mg/m ³	Einatembbarer Staub (Dust) = 10 mg/m ³ Alveolengängiger Staub = 3 mg/m ³
		France (INRS)	10 mg/m ³	Not listed
		UK (OEL)	10 mg/m ³	TWA – 8 hour: 5 mg/m ³ (nuisance dust) STEL – 15 minutes: 10 mg/m ³ (nuisance dust)
		US	15 mg/m ³ (dust; total) 5 mg/m ³ (dust; respirable)	Not listed

Appropriate Engineering Controls: Use with local ventilation.

Personal Protective Equipment (Eyes and Face): Safety glasses or goggles recommended if risk of excess dust in face

Personal Protective Equipment (Skin): Wear gloves when handling in bulk dust conditions.

Personal Protective Equipment (Respiratory): Wear NIOSH/MSHA approved respirator if dusty environment is present.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES**Appearance:** White Powder**Odor:** Slight**Odor Threshold:** no data**pH:** no data**Melting Point:** no data**Specific Gravity:** no data**Octanol / H₂O Coefficient (log K_{ow}):** no data**Molecular Weight:** no data**Auto Ignition:** no data**Flash Point:** no data**Vapor Density:** no data**Viscosity:** no data**VOC:** no data**Boiling Point:** no data**Solubility (H₂O):** no data**Density:** no data**Evaporation Rate:** no data**Decomposition Temp:** no data**LFL:** no data**UFL:** no data**Vapor Pressure: (25°C)** no data**Flammability Class:** non-flammable**Section 10: STABILITY AND REACTIVITY****Chemical Stability:** Stable under normal dry air conditions**Possibility of Hazardous Reactions:** None known**Conditions to Avoid:** Acids**Incompatibility:** None known**Hazardous Decomposition Products:** Not known**Section 11: TOXICOLOGICAL INFORMATION****Likely Routes of Exposure:** dermal (skin)**Acute Effects:** Not a primary dermal irritant. Not an ocular irritant. Not an acute inhalation hazard**Sensitization:** Not a known sensitizer.**Carcinogenicity:** This product does not contain any substances classified as carcinogens by NTP, ACGIH, IARC or OSHA.**Mutagenicity:** Not a mutagen**Reproductive Toxicity:** Not toxic for reproduction**Specific Target Organ Toxicity - Single Exposure (STOT-SE):** No data available**Specific Target Organ Toxicity - Repeated or Prolonged Exposure (STOT-RE):** No data available**Section 12: ECOLOGICAL INFORMATION****Ecotoxicity:** Toxicity (zinc oxide), Acute EC50 0.413 mg/l Zn, 48 hour – Ceriodaphnia dubia, Acute LC50 0.136 mg/l Zn, 72 hour – Selenastrum capricornutum**Persistence / Degradability:** no data available**Aquatic Toxicity:** no data available**Bioaccumulative Potential:** no data available**Mobility in Soil:** no data available**Other Adverse Effects:** no data available**This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).****Section 13: DISPOSAL CONSIDERATIONS****Disposal:** The generation of waste should be avoided or minimized wherever possible.**US:** Not considered a RCRA hazardous waste as identified in Fed. Reg. 40CFR261. If this product cannot be used as directed by the label, contact the local Environmental Control Agency or Agent.

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EEA: Keep waste separate. Because of possible pollution, remove as industrial waste or hazardous waste (EWC code 060316, 150110).

Additional Disposal Considerations: Dispose if shelf-life has been exceeded.

Section 14: TRANSPORT INFORMATION

Not hazardous for transportation in quantities provided.

Section 15: REGULATORY INFORMATION

SARA Sections 302 and 304: This product does not contain Extremely Hazardous Substances (EHS) and is not subject to emergency planning requirements.

CERCLA: Zinc Compounds (N982) - no RQ is assigned to this generic or broad class, although the class is a CERCLA hazardous substance. See 50 Federal Register 13456 (April 4, 1985).

SARA Section 313: N982 Zinc Compounds Includes any unique chemical substance that contains zinc as part of that chemical's infrastructure.

California Proposition 65: There are no chemicals within this mixture on the Proposition 65 List.

Canadian Regulations require the inclusion of the following statements under "Regulatory Information": This product has been classified in accordance with the hazard of the controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

International Inventories:

US (TSCA): The components within this product are included on the TSCA Inventory of Chemical Substances

Canada (DSL): All ingredients are on the inventory or exempt from listing.

European Union (EINECS): All ingredients conform to the EU requirements.

Japan (ENCS): All other ingredients are on the inventory or exempt from listing.

Philippines (PICCS): All other ingredients are on the inventory or exempt from listing.

South Korea (KECL): All ingredients are on the Inventory or exempt from listing.

Australia (AICS): All ingredients are on the Inventory or exempt from listing.

New Zealand (NZIoC): All ingredients are on the Inventory or exempt from listing.

China (IECSC): All ingredients are on the Inventory or exempt from listing.

Section 16: OTHER INFORMATION

National Fire Protection Association (NFPA)

Hazardous Material Information System (HMIS®)

NFPA Ratings:**Health: 1****Fire: 0****Reactivity: 0****HMIS Ratings:****Health: 1****Fire: 0****Reactivity: 0**

(NFPA and HMIS Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe)

REVISION HISTORY

REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE
A	9/25/14	14400	SBL	SBL	Updated MSDS to GHS/SDS Format. 48286 Revision A supersedes 48092 Revision C.

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof. Coltène/Whaledent Inc., however, makes no representations as to the completeness of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Coltène/Whaledent Inc. be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.