SAFETY DATA SHEET

Ceramir® Crown & Bridge Single Cap, Ceramir® Crown & Bridge

SECTION 1: Identification of the substance/mixture and of the company/undertaking

SDS Creation Date: 05/10/2011 Revision Date: 30/05/2014

1.1. Product identifier

Ceramir® Crown & Bridge Single Cap, Ceramir® Crown & Bridge

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

Dental cement intended for permanent cementation of restorations

Uses advised against : Applications other than the intended use

1.3. Details of the supplier of the safety data sheet

Manufacturer

Doxa Dental AB
Axel Johanssons gata 4-6
SE-754 51 Uppsala
Sweden
Phone: +46 18 478 2000
E-mail: kontakt@ceramir.se
Website: http://www.ceramir.se

1.4. Emergency telephone number

For a POISON EMERGENCY call 1-800-222-1222 ANYWHERE IN THE US

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

GHS classification

Classification of the contents of the capsule:
Skin Irrit. 2; H315
Eye Irrit. 2; H319
STOT SE3; H335

Classification of the capsule:
Exempt. Medical device. This product is not a controlled under GHS, but under the Federal Food, Drug, and Cosmetic Act.

Hazardous properties of the contents

May cause eye, skin, and respiratory tract irritation.
Do not use in patients who have an allergy to polyacrylic acid. In very rare cases, the product may cause hypersensitivity symptoms in some patients. Discontinue use of the product if such symptoms occur and consult a doctor.

Additional information

The classification and the hazardous properties above apply to the ingredients in the enclosed capsule.
Exposure to the uncured ingredients is not likely by intended use.

2.2. GHS Label elements

Pictogram

Signal word

Warning

GHS Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

GHS Precautionary statements

P261 Avoid breathing dust.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Special labeling information GHS

The hazard statements and the precautionary statements may be omitted from the label when the contents of the package do not exceed 125 ml.

Exemption	GHS labeling exemption. Medical devices are not controlled under GHS, but under the Federal Food, Drug, and Cosmetic Act.

2.3. Other hazards

The mixture does not meet current criteria for PBT (Persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative).

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	Identification	Classification	Contents
Polyacrylic acid	CAS No: 9003-01-4	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE3; H335	5 - 10 %
Strontium fluoride	CAS No: 7783-48-4	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE3; H335	1 - 5 %
Butanedioic acid, 2,3-dihydroxy-[R-(R*,R*)]-	CAS No: 87-69-4	Skin Irrit. 2;H315; Eye Irrit. 2;H319; STOT SE3;H335;	0,5 - 1,5 %

Description of the mixture:
The product consists of a powder base and a liquid base enclosed in a capsule (content 0.5 g).

See section 8.1 for the OSHA PEL values of the ingredients.
See section 16 for explanation of hazard statements (H) listed above.

SECTION 4: First aid measures

4.1. Description of first aid measures

General	Emergency telephone number: see section 1.4.
Inhalation	Fresh air. Get medical attention if any discomfort continues.
Skin contact	Wash skin thoroughly with soap and water. Consult a physician if hypersensitivity symptoms appear.
Eye contact	Flush immediately with plenty of water for at least 5 minutes. Remove any contact lenses. Contact physician if discomfort continues.
Ingestion	Not likely. Rinse mouth thoroughly. Do not induce vomiting. Get medical attention if any discomfort continues.

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

The uncured product will never be exposed when used as intended. The symptoms below may occur if the uncured product is exposed by accident.

Inhalation of dust may irritate throat and respiratory system and cause coughing.
Skin contact may cause irritation of the skin.
Eye contact may irritate and cause redness and pain.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Dry-powder, carbon dioxide (CO_2), water mist, alcohol resistant foam.
Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

The chemical is not classified as flammable. In case of fire, toxic and irritating gases may be formed.

5.3. Advice for firefighters

Self-contained breathing apparatus may be required by rescue workers. In case of evacuation, use escape mask where possible. Containers close to fire should be removed immediately or cooled with water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate well. Avoid generation and spreading of dust. Use protective equipment as referred to in section 8.

6.2. Environmental precautions

Avoid discharge into drains.

6.3. Methods and material for containment and cleaning up

For waste disposal, see section 13.
After completed curing reaction, no special measures to collect or deliver waste are necessary.

6.4. Reference to other sections

See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ceramir Crown & Bridge is intended for dental practitioners and only for the indicated use. For more information, please see the Instructions for use.
NB: Do not use in patients who have an allergy to polyacrylic acid.
Avoid contact with eyes and skin.

7.2. Conditions for safe storage, including any incompatibilities

Store dry at temperatures between +4 and +25 ºC.
Keep away from substances as mentioned in section 10.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure limit values

Substance	Value
Fluorides (as F)	8-hour TWA: 2,5 mg/m³ OSHA PEL
Particulates Not Otherwise Regulated (Respirable Fraction)	8-hour TWA: 5 mg/m³ OSHA PEL

8.2. Exposure controls

Avoid exposure to uncured powder. The capsules must not be emptied before activation and mixing, see the Instructions for use.
Personal protective equipment must follow the OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment.
The recommended protective equipment and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation (the actual risk) may lead to other control measures.

Respiratory protection

Normally not required.
In case of risk of inhalation of dust, use dust respirator with fine particle filter.
Recommended standard: ANSI/AIHA/ASSE Z88.7-2010 (Color Coding of Air Purifying Respirator Canisters, Cartridges and Filters)

Hand protection

Disposable gloves.
The glove material has to be impermeable and resistant to the product.
Recommended standard: ANSI/ISEA 105-2011 (Hand Protection Selection Criteria)

Eye / face protection

Wear dust resistant safety goggles where there is danger of eye contact.
Recommended standard: ANSI/ISEA Z87.1-2010 (Eye and Face Protection Devices).

Skin protection

Ordinary workwear.
Recommended standard : ANSI/ISEA 103-2010 (Chemical Protective Clothing)

Appropriate environmental exposure control

Do not allow to enter into sewer, water system or soil.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Capsules
Colour	Not specified
Odour	No characteristic odour
pH (as supplied)	Not determined
Melting point / melting range	Not determined
Boiling point / boiling range	Not determined
Flash point	Not determined
Specific gravity	Not determined
Solubility in water	The powder in the capsule reacts with water.
Partition coefficient: n-octanol / water	Not relevant for a mixture.
Explosive properties	Not classified as an explosive.
Oxidising properties	Not oxidising.

9.2. Other physical and chemical properties

Comments No further information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity

The powder in the capsule reacts with water.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Water, moisture.

10.5. Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

10.6. Hazardous decomposition products

None under normal conditions. See also section 5.2.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information for ingredients:

Polyacrylic acid (CAS No 9003-01-4):
Oral mouse: LD50 = 4600 mg/kg
Oral rat: LD50 = 2500 mg/kg
Carcinogenicity: Not listed by ACGIH, IARC, NTP, or CA Prop 65
Epidemiology: No information found
Teratogenicity: No information found
Reproductive Effects: No information found
Mutagenicity: No information found
Neurotoxicity: No information found

Tartaric acid (CAS No 87-69-4):
LD50/LC50: Not available
Oral rat: LDLo = 7500 mg/kg
Oral rabbit: LDLo = 5000mg/kg
Oral dog: LDLo = 5000 mg/kg
Carcinogenicity: Not listed by ACGIH, IARC, NTP, or CA Prop 65
Epidemiology: No information available
Teratogenicity: No information available
Reproductive Effects: No information available
Mutagenicity: No information available
Neurotoxicity: No information available

Strontium fluoride (CAS No 7783-48-4)

Oral, rat: LD50 = 10600 mg/kg
Carcinogenicity: Not listed by ACGIH, IARC, NTP, or CA Prop 65
Epidemiology: No information found
Teratogenicity: No information found
Reproductive Effects: No information found
Mutagenicity: No information found
Neurotoxicity: No information found

General information regarding health hazards

Test results according to ISO10993 have shown that Ceramir Crown & Bridge is biocompatible.
The uncured product will never be exposed when used as intended. The symptoms below may occur if the uncured product is exposed by accident.

Acute toxicity, mixture estimate

The classification criteria are not met, the acute toxicity estimate (ATE) for the mixture is > 5000 mg/kg (oral).

Potential acute effects

Inhalation	Dust may irritate respiratory system.
Skin contact	Irritating to skin.
Eye contact	Irritant to eyes. May cause stinging and redness.
Ingestion	Not likely, due to the packaging.
Irritation	Irritating to eyes and skin.
Corrosivity	Classification criteria are not met.
Aspiration hazard	Classification criteria are not met.

Delayed effects / repeated exposure

Sensitisation	In very rare cases, the product may cause hypersensitivity symptoms in some patients. In very rare cases, the product may cause hypersensitivity symptoms in some patients.
STOT-single exposure	Irritating to the respiratory system (STOT SE3).
STOT-repeated exposure	Classification criteria are not met.

Carcinogenic, mutagenic or reprotoxic effects

Carcinogenicity	Based on available data, the classification criteria are not met.
Mutagenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Ecotoxicity

Not classified as dangerous to the environment.

Ecotoxicological data for substances

Polyacrylic acid

Acute aquatic, fish, LC50 (96h) > 100 mg/l
Species: Brachydanio rerio

Acute aquatic, algae, IC50 (72h) > 180 mg/l
Species: Scenedesmus subspicatus

Acute aquatic, Daphnia, EC50 (48h) > 100 mg/l
Species: Daphnia magna

Biodegradable, but not readily biodegradable.

No bioaccumulation of the substance is expected.

Distribution coefficient: Log Pow: 0,44

Butanedioic acid, 2,3-dihydroxy- [R-(R*,R*)]-

Distribution coefficient: Log Pow: 0,24

12.2. Persistence and degradability

The cured product is not expected to be biodegradable.

12.3. Bioaccumulative potential

The chemical does not contain any substances that are considered bioaccumulative.

12.4. Mobility in soil

Expected to have relatively low mobility in soil. The product hardens to a solid immobile substance.

12.5. Results of PBT and vPvB assessment

PBT or vPvB assessment has not been performed.

12.6. Other adverse effects

Do not allow to enter into sewer, water system or soil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste.
US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.
RCRA P-Series: None listed.
RCRA U-Series: None listed.

SECTION 14: Transport information

14.1. UN number

Not relevant, not regulated as dangerous goods by transportation according to DOT regulation.

14.2. UN proper shipping name

Not relevant.

14.3. Transport hazard class(es)

Not relevant.

14.4. Packing group

Not relevant.

14.5. Environmental hazards

Not relevant.

14.6. Special precautions for user

Not relevant.

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

Not relevant.

SECTION 15: Regulatory information

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

US FEDERAL

TSCA

CAS-No 9003-01-4 is listed on the TSCA inventory
CAS-No 87-69-4 is listed on the TSCA inventory.
CAS-No 7783-48-4 is listed on the TSCA inventory.

Health & Safety Reporting List

None of the chemicals in this product are on the Health & Safety Reporting List.

Chemical Test Rules

None of the chemicals in this product are under a Chemical Test Rule.
Section 12b
None of the chemicals in this product are under TSCA Section 12b.

TSCA Significant New Use Rule

None of the chemicals in this product have a SNUR under TSCA.

CERCLA Hazardous Substances and corresponding RQs

None of the chemicals in this product have an RQ.

SARA Section 302 Extremely Hazardous Substances

None of the chemicals in this product have a TPQ.

SARA Codes

CAS-No 87-69-4: immediate.
Section 313 No chemicals are reportable under Section 313.

Clean Air Act:

This product does not contain any hazardous air pollutants.
This product does not contain any Class 1 Ozone depletors.
This products does not contain any Class 2 Ozone depletors.

Clean Water Act:

None of the chemicals in this product are listed as Hazardous Substances under the CWA.
None of the chemicals in this product are listed as Priority Pollutants under the CWA.

None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

OSHA:

None of the chemicals in this product are considered highly hazardous by OSHA.

STATE

CAS-No 87-69-4 is not present on state lists from CA, PA, MN, MA, FL, or NJ.

CAS-No 7783-48-4 can be found on the following state right to know lists: California, (listed as Fluorides), California, (listed as Fluorides, inorganic), Pennsylvania, (listed as Fluorides), Minnesota, (listed as Fluorides), Minnesota, (listed as Fluorides, inorganic).

CAS-No 9003-01-4 is not present on state lists from CA, PA, MN, MA, FL, or NJ.

California Prop 65

California No Significant Risk Level: None of the chemicals in this product are listed.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed

SECTION 16: Other information

Supplier's notes	SDS Creation Date: 15/06/2010 Revision Date: 30/05/2014 The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Doxa Dental AB be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Doxa Dental AB has been advised of the possibility of such damages.
Explanation of GHS hazard classes from section 2.1:	Skin Irrit. 2; Category 2 Irritant to skin Eye Irrit. 2; Category 2 Irritant to eyes STOT SE3; Category 3 Toxic for specific target organ by single exposure
List of relevant H-phrases (under sections 2 and 3)	H319 Causes serious eye irritation. H315 Causes skin irritation. H335 May cause respiratory irritation.
Abbreviations and acronyms used	Abbreviations used in section 8: AIHA: American Industrial Hygiene Association ANSI: American National Standards Institute ASSE: American Society of Safety Engineers ISEA: International Safety Equipment Association Abbreviations used in section 11: LD50: Lethal dose, is the amount of a substance given to a group of test animals, which causes the death of 50%. LDL0: Lowest published lethal dose Abbreviations used in section 12: EC50: The effective concentration of substance that causes 50% of the maximum response IC50: The concentration of compound that results in 50% inhibition of a biological or biochemical function. LC50: Concentration in water having 50% chance of causing death to aquatic life PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
Information revised since the previous version of the SDS	Layout changed according to European Commission Regulation No 453/2010 amending REACH Annex II (Safety Data Sheets). Classification changed according to GHS.
Responsible for safety data sheet	Doxa Dental AB

10205-AC