SAFETY DATA SHEET

Section 1: Identification

Day of issue: 2020-08-27

Product identifier:
Ceramir® Restore QuikCap
Recommended use of the chemical and restrictions on use:
For dental use. Self-curing bioceramic restorative material of glass ionomer type
Uses advised against: Applications other than the intended use.
Details of the supplier of the safety data sheet:

Manufacturer:
Doxa Dental AB
Axel Johanssons gata 4-6 Tel.: +46 (0) 18 478 20 00
SE-754 50 Uppsala
SWEDEN
Responsible for SDS (e-mail): info@doxa.se

US importer:
Doxa Dental Inc.
1(855) Doxa – USA (369-2872)
www.ceramirdental.com

Emergency phone number:
Poison Emergency call 1-800-222-1222 (anywhere in the US)
CHEMTREC Tel. No.US: 1-800-424-9300

Section 2: Hazard(s) identification

The product is not controlled under GHS or OSHA Hazard Communication Standard, 29 CFR 1910.1200, but under Federal Food, Drug, and Cosmetic Act as Medical Device. The labelling text is therefore shown below for safety purposes.

Classification of the chemical:
None

Signal word
None

Pictogram(s)/Symbol(s)
None

Hazard statement(s)
None.

Precautionary statement(s)
None

Other hazards not otherwise classified:
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.

Ingredients with unknown acute toxicity:
Not relevant.

Section 3: Composition/Information on Ingredients

Mixtures: The product consist of a powder base and a liquid base enclosed in a capsule.

% w/w	Substance name	CAS No.	Note
5-<10	Polyacrylic acid	9003-01-4	1
<5	Ytterbium trifluoride	13760-80-0	1
<5	Tartaric acid	87-69-4	1
<0.5	Disodium hexafluorosilicate	16893-85-9	1

1) The exact percentage of this component is withheld and considered a trade secret information.

Section 4: First-Aid Measures

Description of necessary measures:

Inhalation: Remove to fresh air. Get medical attention if any discomfort continues.

Skin contact: Wash skin thoroughly with soap and water. If irritation occur: Seek medical advice.

Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. **Do not induce vomiting.** Keep at rest. Get medical attention if any discomfort continues.

Most important symptoms/effects, acute and delayed:

Inhalation of dust may irritate throat and respiratory system and cause coughing. May cause slight irritation of skin and eyes. May cause hypersensitivity symptoms in some patients.

Indication of immediate medical attention and special treatment needed:

Show this safety data sheet to a physician or emergency ward. Treat symptomatically.

Section 5: Fire-Fighting Measures

Suitable (and unsuitable) extinguishing media:

Dry-powder, water mist (never water jet), alcohol resistant foam or carbon dioxide (CO_2).

Specific hazards arising from the chemical:

Not combustible. In case of surrounding fire, the product may form hazardous decomposition products such as hydrofluoric acid.

Special protective equipment and precautions for fire-fighters:

When extinguishing fires use breathing apparatus with an independent source of air.

Section 6: Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures:

Use personal protective equipment - see section 8.

Do not empty into drains. Inform appropriate authorities in accordance with local regulations.

Methods and materials for containment and cleaning up:

Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

Section 7: Handling and Storage

Precautions for safe handling:

Use only as described in “Instruction for use”.

Provide adequate ventilation. Avoid contact with skin and eyes. Wash with water and soap after work. Do not eat, drink, or smoke during use.

Conditions for safe storage, including any incompatibilities:

Storing dry at temperatures between +4 and +20°C. Keep away from substances mentioned in section 10.

Section 8: Exposure Controls/Personal Protection

OSHA Permissible Exposure Limits (PEL):

Substance	OSHA PEL	Cal/OSHA PEL	NIOSH REL	ACGIH TLV
Ytterbium trifluoride (as F) (listed under Fluorides)	2.5 mg/m^3 (as dust)	2.5 mg/m^3	2.5 mg/m^3	2.5 mg/m^3

National Institute for Occupational Safety and Health = NIOSH Recommended Exposure Limit = REL

American Conference of Governmental Industrial Hygienists = ACGIH Threshold Limit Value = TLV

Other exposure limit used or recommended: None known.

Appropriate engineering controls (e.g., use local exhaust ventilation, or use only in an enclosed system):

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Provide adequate ventilation in working areas to keep airborne concentrations low.

Section 8: Exposure Controls/Personal Protection (continued)

Individual protection measures, such as personal protective equipment (PPE):
PPE must follow OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment. The recommended PPE and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation may lead to other control measures.

Eye/face protection
Wear tight fitting safety goggles (as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or EN166) when risk of dust formation.

Skin/hand protection
By prolonged contact: Wear protective gloves of for instance nitrile rubber. Breakthrough time of the ingredients is not available. Discard gloves at any suspicion of contamination.

Respiratory protection
Respiratory equipment is normally not required. In case of dust formation: Use a NIOSH/MSHA or EN149 approved respirator with a particle filter type P2. The filter has a limited lifetime and must be changed. Read the instruction.

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.

Section 9: Physical and Chemical Properties

Appearance (physical state, color, etc.):	Capsules
Odor:	No characteristic odour
Odor threshold:	Not determined
pH:	Not determined
Melting point/freezing point (°C):	Not determined
Initial boiling point and boiling range (°C):	Not determined
Flash point (°C):	Not determined
Evaporation rate:	Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (vol-%):	Not determined
Vapor pressure:	Not determined
Vapor density:	Not determined
Relative density:	Not determined
Solubility(ies):	Not determined
Partition coefficient: n-octanol/water:	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
Viscosity:	Not relevant

Section 10: Stability and Reactivity

Reactivity:
Capsule content reacts with water.
Chemical stability:
Stable under normal conditions and recommended use.
Possibility of hazardous reactions:
None known.
Conditions to avoid:
Water and moisture.
Incompatible materials:
Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products:
When heated to high temperatures (decomposition), the product emits very toxic fumes such as oxides of carbon and corrosive hydrogen fluoride.

Section 11: Toxicological Information

Information on toxicological (health) effects:

Likely routes of exposure: Inhalation, skin, and ingestion.

Symptoms:
Symptoms may occur if dust is released from the capsule by accident.
Inhalation:
Inhalation of disodium hexafluoro silicate may cause irritation of the respiratory system. Symptoms may include coughing, sneezing, chest tightness, and difficulty in breathing. Inhaling excessive amounts may result in severe inflammation of the lung, which may be fatal. Acute effects of fluoride inhalation include irritation of nose and throat, coughing and chest discomfort. A single acute over-exposure may even cause nosebleed.

Skin Contact:
May cause slight irritation with redness. Skin contact with inorganic fluorides may cause a burning sensation.

Eye Contact:
May cause slight irritation with redness and stinging.

Ingestion:
May cause irritation of the gastrointestinal tract, nausea, vomiting, salivation, fever, and headache. Ingestion of disodium hexafluoro silicate may cause excessive salivation, thirst, stomach and intestinal irritation, nausea, vomiting, diarrhoea, abdominal pain, shortness of breath, weak irregular pulse, and fast heart rate. Headaches, difficulty speaking, disturbed colour vision, muscle weakness, convulsions, loss of consciousness, numbness and cramps of the palms, feet, and legs may occur as well as damage to the liver and kidney, bleeding and low calcium levels, and death.
Fluorides causes severe loss of calcium in the blood, with symptoms appearing several hours later including painful and rigid muscle contractions of the limbs. Cardiovascular collapse can occur and may cause death with increased heart rate and other heart rhythm irregularities.

Delayed (chronic) effects:
High concentration of inorganic fluorides may cause skeletal fluorosis with symptoms such as periodical pain and stiffness in the joints, headache, abdominal pain, muscle weakness, tooth discolouration, nausea and vomiting, loss of appetite, diarrhoea or constipation, weight loss, anaemia, weakness and general unwellness. There may also be frequent urination and thirst. Later osteoporosis and bone damages may occur. Anorexia and anaemia are common findings in fluorine poisoning. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema.

Acute Toxicity

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	No available data	-	-
Dermal	LD_{50} (rat) > 2000 mg/kg (Tartaric acid)	OECD 402	RTECS
Oral	LD_{50} (rat) = 2500 mg/kg (Polyacrylic acid)	No data	Supplier
	LD_{50} (rat) > 2000 mg/kg (Ytterbium trifluoride)	OECD 420	ECHA
	LD_{50} (mouse) = 70 mg/kg (Disodium hexafluoro silicate)	No data	ECHA
	LD_{50} (rat) > 2000 mg/kg (Tartaric acid)	OECD 423	RTECS
Corrosion/irritation:	Irritant to skin and eyes (Polyacrylic acid)	No data	Supplier
	No eye irritation, in vitro (Ytterbium trifluoride)	OECD 437	ECHA
	Non corrosive to skin, in vitro (Ytterbium trifluoride)	OECD 431	ECHA
	In vitro eye irritant (Tartaric acid)	OECD 437	ECHA
	No skin irritation, rabbit (Tartaric acid)	OECD 404	RTECS
	Slight eye irritation, in vitro (Disodium hexafluoro silicate)	OECD 437	ECHA
Sensitization:	Not a skin sensitizer (Tartaric acid)	OECD 429	RTECS
	Not a skin sensitizer, guinea pig (Ytterbium trifluoride)	OECD 406	ECHA

Mutagenic toxicity
No available data/insufficient data.

Reproductive toxicity
No available data/insufficient data.

Section 11: Toxicological Information (continued)

Carcinogenic toxicity
No available data/insufficient data.
Substances are not mentioned on NTP's Report on Carcinogens (RoC), latest ed.
Substances are not found to be potential carcinogens in IARC Monographs, or by OSHA.

Specific Target Organ Toxicity
No known effects.

Section 12: Ecological Information

Ecotoxicity:

Aquatic	Data	Test (Media)	Data source
Fish	LC_{50} (Brachydanio rerio, 96h) > 100 mg/l (Polyacrylic acid) LC_{50} (Lepomis macrochirus, 96h) = 16.6 mg/l (Disodium hexafluoro silicate)	No data (FW) No data	Supplier IUCLID
Crustaceans	EC_{50} (Daphnia magna, 48h) > 100 mg/l (Polyacrylic acid) EC_{50} (Daphnia magna, 48h) = 93.3 mg/l (Tartaric acid) EC_{50} (Daphnia magna, 48h) > 0.52 mg/l (Ytterbium trifluoride) NOEC (Daphnia magna, 48h) = 0.52 mg/l (Ytterbium trifluoride) EC_{50} (Daphnia magna, 48h) = 35.4 mg/l (Disodium hexafluoro silicate)	No data (FW) OECD 202 (FW) OECD 202 (FW) OECD 202 (FW) No data (FW)	Supplier Supplier ECHA ECHA Supplier
Algae	EC_{50} (Scenedesmus subspicatus, 72h) > 180 mg/l (Polyacrylic acid) EC_{50} (Algae, 72h) = 51.4 mg/l (Tartaric acid)	No data (FW) OECD 201 (FW)	Supplier Supplier

Persistence and degradability
Methods for determination of degradability are not valid for inorganic compounds such as ytterbium trifluoride and disodium hexafluoro silicate.
Polyacrylic acid is not considered readily biodegradable.
Tartaric acid was degraded 85% in 28 days at an OECD 306 test and is considered rapidly degradable.
The cured product is not expected to be biodegradable.

Bioaccumulative potential
Polyacrylic acid: Log K_{ow} = 0.44 (no significant bioaccumulative effect).
Tartaric acid: Log K_{ow} = 0.24 (no significant bioaccumulative effect).

Mobility in soil
Low mobility in soil is expected.

Other adverse effects
None known.

Section 13: Disposal Considerations

Disposal considerations
Dispose of contents/container in accordance with applicable local/regional/national/international regulations. See Section 8 for guidance on PPE.

Incinerate and dispose of waste product in a permitted waste incineration facility/industrial waste facility.

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

Not dangerous goods according to US DOT.
UN-no.: None.
UN proper shipping name: None.
Hazard Class: None.
Packing Group: None.
IMDG: None.

Canadian Transportation of Dangerous Goods (TDG): None.

Section 15: Regulatory Information

US Federal Regulations
NATIONAL INVENTORY STATUS - U.S. Inventory (TSCA):
All ingredients are listed on TSCA inventory.

TSCA section 12b:
None of the chemicals in the product are listed.

SARA Title III (Superfund Amendments and Reauthorization Act)
SARA Title III Sect. 302 Extremely Hazardous Substances (40 CFR 355):
None of the chemicals are listed.
SARA Title III Sect. 311/312 Extremely Hazardous Categories (40 CFR 370.21):
Immediate Hazard: None of the chemicals are listed.

Clean Air Act:
This product does not contain any hazardous air pollutants, no class 1 Ozone depletors and no class 2 Ozone depletors.

Clean Water Act:
None of the chemicals in this product are listed as Hazardous Substances, as Priority Pollutants or as Toxic Pollutants under the CWA.

STATE REGULATIONS:
Proposition 65: This material is not known to contain any chemicals currently listed as carcinogens or reprotoxic.

Fluorides can be found on the following state right to know lists:
California, (listed as Fluorides) and (listed as Fluorides, inorganic)
New Jersey, (listed as Fluorides)
Pennsylvania, (listed as Fluorides)
Minnesota, (listed as Fluorides, inorganic) and (listed as Fluorides)

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Section 16: Other Information

Abbreviations:
ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association Workplace Environmental Exposure Level (WEEL)
CERCLA = Comprehensive Environmental Response Compensation and Liability Act
CMR = Carcinogenicity, mutagenicity, and reproductive toxicity.
EC_{50} = Effect Concentration 50%
FW = Fresh Water
LC_{50} = Lethal Concentration 50%
LD_{50} = Lethal Dose 50%
NFPA = National Fire Protection Association
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
STEL = Short-term exposure limits
Literature:
ECHA = REACH Registration dossier from ECHA's home page.
IARC = International Agency for Research on Cancer
IUCLID = International Uniform ChemicaL Database Information
RTECS = Register of Toxic Effects of Chemical Substances

Section 16: Other Information (continued)

Other information:
No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.
The above information, which is accurate to the best of our knowledge and belief, describes the safety aspects of our product but does not warrant any product properties.
Changes since the previous edition:
Not relevant.

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