SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006.

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

Day of issue: 2022-11-04

1.1. Product identifier:
Ceramir® Bioceramic Implant Cement QuikCap (Article No.: 40037)
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:
Doxa Dental
Axel Johanssons gata 4-6 Tel.: +46 (0) 18 478 20 00
SE-754 50 Uppsala
SWEDEN
Responsible for the safety data sheet (e-mail): info@doxa.se
1.4. Emergency telephone number:
NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): Dial 111
National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week)
Healthcare Professionals: +353 (1) 809 2566 (24-hour service)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:
CLP (1272/2008): None
The preparation is covered by EU Regulation 2017/745 of 05.04.2017 on medical devices and must fulfil the requirement set forth in this Regulation. Thus, the preparation does not require labelling according to CLP Regulation 1272/2008, however the labelling is shown below for safety purposes.
2.2. Label elements:
EUH210: Safety data sheet available on request.
2.3. Other hazards:
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.
PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.
Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

SECTION 3: Composition/information on ingredients

3.2. Mixtures: The product consist of a powder base and a liquid base enclosed in a capsule (content 0.5 g).

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.-no.	Classification	Note
5-<10	Polyacrylic acid	9003-01-4	618-347-7	-	-	Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335	-
<5	Strontium fluoride	7783-48-4	232-000-3	-	-	-	1
<5	Tartaric acid	87-69-4	201-766-0	-	-	Eye Irrit. 2;H319	-

1) The substance has an occupational exposure limit.
Wording of hazard statement(s) – see Section 16.

SECTION 4: First-aid measures

4.1. Description of first aid 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.
4.2. Most important symptoms and effects, both 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.
4.3. Indication of any immediate medical attention and special treatment needed:
Show this safety data sheet to a physician or emergency ward. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media:
Dry-powder, water mist (never water jet), alcohol resistant foam or carbon dioxide (CO_2).
5.2. Special hazards arising from the substance or mixture:
Not combustible. In case of surrounding fire, the product may form hazardous decomposition products such as hydrofluoric acid.
5.3. Advice for firefighters:
When extinguishing fires use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment - see section 8.
6.2. Environmental precautions:
Do not empty into drains. Inform appropriate authorities in accordance with local regulations.
6.3. Methods and material 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.
6.4. Reference to other sections:
See above.

SECTION 7: Handling and storage

7.1. 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.
7.2. Conditions for safe storage, including any incompatibilities:
Store dry at temperatures between +4 and +25°C. Keep away from substances mentioned in section 10.5.
7.3. Specific end use(s):
See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:
Occupational exposure limits, UK (EH40/ed.2020):

Substance	8-hour TWA	15-min STEL	Comments
Fluoride (inorganic as F)	2.5 mg/m^3	-	E

Occupational exposure limit values, Ireland (2021):	8-hour TWA	15-min STEL	Notes
Fluorides, inorganic	2.5 mg/m^3	-	IOELV

E: An European value has been established.
IOELV: Indicative Occupational Exposure Limit Values set under the EU Chemical Agents Directive 98/24/EC.

DNEL/PNEC: No CSR.
8.2. Exposure controls:
Appropriate engineering controls: Provide effective process ventilation.
Personal protective equipment:
Inhalation: Respiratory equipment is normally not required. In case of dust formation: Use an approved mask with a particle filter type P2 (EN 140). The filter has a limited lifetime and must be changed. Read the instruction.
Skin: By prolonged contact: Wear protective gloves of for instance nitrile rubber (EN 374). Breakthrough time of the ingredients is not available. Discard gloves at any suspicion of contamination.
Eyes: Use safety goggles (EN 166) when risk of eye contact.
Environmental exposure controls: See section 6 and 13.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state:	Capsules
Colour:	Not determined
Odour:	No characteristic odour
Melting point/freezing point (°C):	Not determined
Boiling point or initial boiling point and boiling range (°C):	Not determined
Flammability (solid, gas):	Not determined
Lower and upper explosion limit (vol-%):	Do not apply to solids
Flash point (°C):	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
pH:	Not determined
Kinematic viscosity:	Not determined
Solubility:	Insoluble in water (reacts with water)
Partition coefficient n-octanol/water (log value):	Not determined
Vapour pressure:	Not determined
Density and/or relative density:	Not determined
Relative vapour density:	Not determined
Particle characteristics:	Not determined
9.2. Other information:	No further information is available

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:
Acute toxicity: Based on available data, the classification criteria are not met.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/irritation: Based on available data, the classification criteria are not met.
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.
STOT-single exposure: Based on available data, the classification criteria are not met.
STOT-repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

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) > 10600 mg/kg (Strontium fluoride)	No data	RTECS
	LD_{50} (rat) > 2000 mg/kg (Tartaric acid)	OECD 423	RTECS
Corrosion/irritation:	Irritant to skin and eyes (Polyacrylic acid)	No data	Supplier
	In vitro eye irritant (Tartaric acid)	OECD 437	ECHA
	No skin irritation, rabbit (Tartaric acid)	OECD 404	RTECS
Sensitization:	Not a skin sensitizer (Tartaric acid)	OECD 429	RTECS
CMR:	No CMR effects	No data	ECHA

The chemical, physical and toxicology properties of strontium fluoride have not been thoroughly investigated and recorded.

SECTION 11: Toxicological information (continued)

Information on likely routes of exposure: Inhalation, skin and ingestion. Symptoms may occur if dust is released from the capsule by accident.

Symptoms:

Inhalation: Inhalation may cause irritation of the respiratory system.

Skin: May cause slight irritation with redness.

Eyes: May cause slight irritation with redness and stinging.

Ingestion: May cause irritation of the gastrointestinal tract, nausea, vomiting, salivation, fever and headache.

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 and muscle weakness. Later osteoporosis and bone damages may occur. Loss of weight. Anorexia and anaemia are common findings in fluorine poisoning. Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema.

11.2. Information on other hazards: None known.

SECTION 12: Ecological information

12.1. Toxicity:

Aquatic	Data	Test (Media)	Data source
Fish	LC_{50} (Brachydanio rerio, 96h) > 100 mg/l (Polyacrylic acid)	No data (FW)	Supplier
Crustaceans	EC_{50} (Daphnia magna, 48h) > 100 mg/l (Polyacrylic acid) EC_{50} (Daphnia magna, 48h) = 93.3 mg/l (Tartaric acid)	No data (FW) OECD 202 (FW)	Supplier 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

12.2. Persistence and degradability:

Methods for determination of degradability are not valid for inorganic compounds.

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.

12.3. Bioaccumulative potential:

Polyacrylic acid: Log K_{ow} = 0.44 (no significant bio accumulative effect).

Tartaric acid: Log K_{ow} = 0.24 (no significant bio accumulative effect).

12.4. Mobility in soil:

Low mobility in soil is expected.

12.5. Results of PBT and vPvB assessment:

The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties:

None known.

12.7. Other adverse effects:

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose through authority facilities or pass to a chemical disposal company.

EWC-Code:

18 01 07 (Powder itself)

15 02 03 (Paper, inert material, etc. contaminated with the product)

SECTION 14: Transport information

Not dangerous goods (ADR/RID/IMDG/IATA).

14.1. UN number or ID number: None.

14.2. UN proper shipping name: None.

14.3. Transport hazard class(es): None.

14.4. Packing group: None.

14.5. Environmental hazards: No.

14.6. Special precautions for user: None.

14.7. Maritime transport in bulk according to IMO instruments: Not relevant.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
The preparation is covered by EU Regulation 2017/745 of 05.04.2017 on medical devices and must fulfil the requirement set forth in this Regulation.
15.2. Chemical safety assessment:
No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 3:
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
Abbreviations:
CMR = Carcinogenicity, mutagenicity and reproductive toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC_{50} = Effect Concentration 50 %
FW = Fresh Water
LC_{50} = Lethal Concentration 50 %
LD_{50} = Lethal Dose 50 %
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative
Literature:
ECHA = REACH Registration dossier from ECHA's home page
RTECS = Register of Toxic Effects of Chemical Substances
Training advice:
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.
Changes since the previous edition:
Revision of the format according to Regulation 2020/878

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