

SAFETY DATA SHEET

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

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

1.1. Product identifier:

Ceramir[®] Crown & Bridge QuikMix Powder

UFI: Not relevant

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

Dental cement intended for permanent cementation of restorations.

Powder component to mix with Liquid before final use.

Uses advised against: Applications other than the intended use.

The ready to use mixture is a medical device.

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

Directa AB

Box 723

Tel. +46 850650575

SE-194 27 Upplands Väsby

Responsible person for the safety data sheet (e-mail): info@directadental.com

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)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

CLP (1272/2008): None.

2.2. Label elements:

EUH210: Safety data sheet available on request.

2.3. Other hazards:

PBT/vPvB: Components are not PBT/vPvB according to the criteria set out in Regulation 2023/707.

Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2023/707.

SECTION 3: Composition/information on ingredients

3.2. Mixtures: Inorganic powder base.

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.-no.	Classification	Note
5-<10	Strontium fluoride	7783-48-4	232-000-3	-	01-2120766880-45	Acute Tox. 4;H302+H312+H332	1,2

1) The substance has an occupational exposure limit.

2) ATE (oral) = 500 mg/kg; ATE (dermal) = 1100 mg/kg; ATE (inhalation, dust) = 1.5 mg/l.

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.

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 (CO₂).

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. Avoid generation and spreading of dust.

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".

Avoid inhalation of dust. 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 (2024):

Fluorides, inorganic	8-hour TWA	15-min STEL	Notes
	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:	Exposure	Value	Population	Effects
Strontium fluoride	Long-term, inhalation	1 mg/m ³	Workers	Local/Systemic
	Short-term, inhalation	4 mg/m ³	Workers	Local/Systemic
	Long-term, dermal	0.14 mg/kg/d	Workers	Systemic
	Short-term, dermal	0.14 mg/kg/d	Workers	Systemic

PNEC:

No data established.

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 ISO 16321-1) when risk of dust formation.

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:	Powder
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:

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 strontium oxides 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.

Strontium fluoride: LD₅₀ = 10.600 mg/kg (oral, rat). Source: RTECS.

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

Information on likely routes of exposure: Inhalation and ingestion.

Symptoms:

Inhalation: Inhalation of dust 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.

11.2. Information on other hazards: None known.

SECTION 12: Ecological information

12.1. Toxicity:

No available or applicable data.

12.2. Persistence and degradability:

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

12.3. Bioaccumulative potential:

No available or applicable data.

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 in Regulation 2023/707.

12.6. Endocrine disrupting properties:

None known.

12.7. Other adverse effects:

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Not considered as hazardous waste. 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:

H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC₅₀ = Effect Concentration 50 %

FW = Fresh Water

LC₅₀ = Lethal Concentration 50 %

LD₅₀ = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

Literature:

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.

SECTION 16: Other information (continued)

Changes since the previous edition:

3, 8, 13 & 16

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