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 Liquid
UFI: 8300-U0KQ-700N-8H2K
1.2. Relevant identified uses of the substance or mixture and uses advised against:
Dental cement intended for permanent cementation of restorations.
Liquid component to mix with Powder 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:
Irritant liquid. Causes serious eye damage.
CLP (1272/2008): Eye Dam. 1;H318 Skin Irrit. 2;H315 STOT SE 3;H335
2.2. Label elements:

DANGER

Contain:	Tartaric acid & Polyacrylic acid
H315:	Causes skin irritation.
H318:	Causes serious eye damage.
H335:	May cause respiratory irritation.
P280:	Wear protective gloves/eye protection.
P305+P351+P338+P310:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

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: 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:

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.-no.	Classification	Note
15-<25	Polyacrylic acid	9003-01-4	618-347-7	-	-	Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335	-
<5	Tartaric acid	87-69-4	201-766-0	-	01-2119537204-47	Eye Dam. 1;H318	-
<1	Trisodium nitrilo-triacetate (NTA)	5064-31-3	225-768-6	607-620-00-6	-	Acute Tox. 4;H302 Eye Irrit. 2;H319 Carc. 2;H351	1

1) SCL (Specific Concentration limits) for klassificering: Carc. 2;H351: C ≥ 5% (Harmonized EU)

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: Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. Get medical attention; continue to flush on the way.

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:

Irritation of skin with redness. Causes serious eye damage with redness and pain. Inhalation may irritate throat and respiratory system and cause coughing. 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:

Not combustible.

5.2. Special hazards arising from the substance or mixture:

Not combustible.

5.3. Advice for firefighters:

When extinguishing surrounding 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. Required access to water and eye wash fountain.

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): None

Occupational exposure limit values, Ireland (2024): None

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.

Skin: 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 splashes.

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:	Liquid
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-%):	Not determined
Flash point (°C):	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
pH:	Not determined
Kinematic viscosity:	Not determined
Solubility:	Miscible 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:
None known.
10.2. Chemical stability:
Stable under normal conditions and recommended use.
10.3. Possibility of hazardous reactions:
None known.
10.4. Conditions to avoid:
Strong heat.
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.

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: Skin Irrit. 2;H315 Causes skin irritation.
Serious eye damage/irritation: Eye Dam. 1;H318 Causes serious eye damage.
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: STOT SE 3;H335 May cause respiratory irritation.
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.

SECTION 11: Toxicological information (continued)

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC_{50} (rat) > 5 mg/l (NTA)	OECD 401	IUCLID
Dermal	LD_{50} (rat) > 2000 mg/kg (Tartaric acid)	OECD 402	RTECS
	LD_{50} (rabbit) > 2000 mg/kg (NTA)	OECD 402	ECHA
Oral	LD_{50} (rat) = 2500 mg/kg (Polyacrylic acid)	No data	Supplier
	LD_{50} (rat) > 2000 mg/kg (Tartaric acid)	OECD 423	RTECS
	LD_{50} (rat) > 1440 mg/kg (NTA)	OECD 403	ECHA
Corrosion/irritation:	Irritant to skin and eyes (Polyacrylic acid)	No data.	Supplier
	Strong eye irritant, in vitro (Tartaric acid)	OECD 437	ECHA
	No skin irritation, rabbit (Tartaric acid)	OECD 404	RTECS
	No skin irritation, rabbit (NTA)	OECD 404	Supplier
	Eye irritation, rabbit (NTA)	OECD 405	Supplier
Sensitization:	Not a skin sensitizer (Tartaric acid)	OECD 429	RTECS
	Not a skin sensitizer, guinea pig (NTA)	OECD 406	Supplier
CMR:	Suspected of causing cancer (NTA)	OECD 451	ECHA
	IARC group 2B (NTA)	-	Literature

Information on likely routes of exposure: Skin and ingestion.

Symptoms:

Inhalation: Inhalation is not likely to occur however, aerosols may cause irritation of the respiratory system.

Skin: May cause irritation with redness.

Eyes: Severe eye irritation with redness and pain.

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

Chronic effects: Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema. NTA is suspected of causing cancer in animals. NTA increased the incidence of kidney and urinary-tract tumours in rats (IARC monograph vol. 73).

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
	LC_{50} (Pimephales promelas, 96h) = 127 mg/l (NTA)	No data (FW)	Supplier
Crustaceans	EC_{50} (Daphnia magna, 48h) > 100 mg/l (Polyacrylic acid)	No data (FW)	Supplier
	EC_{50} (Daphnia magna, 48h) = 93.3 mg/l (Tartaric acid)	OECD 202 (FW)	Supplier
	EC_{50} (Daphnia magna, 48h): 560-1000 mg/l (NTA)	No data (FW)	Supplier
Algae	EC_{50} (Scenedesmus subspicatus, 72h) > 180 mg/l (Polyacrylic acid)	No data (FW)	Supplier
	EC_{50} (Algae, 72h) = 51.4 mg/l (Tartaric acid)	OECD 201 (FW)	Supplier
	EC_{50} (Scenedesmus subspicatus, 72h) > 100 mg/l (NTA)	No data (FW)	Supplier

12.2. Persistence and degradability:

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.

NTA was degraded >90% in 28 days at an OECD 301B 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 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:
The chemical must be treated 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 06 (Liquid itself)
15 02 02 (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:
Must not be used by persons under 18 years of age.
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: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H351: Suspected of causing cancer.
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.
IUCLID = International Uniform ChemicaL Information Database.
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.
Additional information:
The product is exempt from CLP labelling with reference to CLP (Article 1, 5d) because it is a medical device which, in ready-to-use condition, is intended for the final user to be placed in or used in direct contact with the human body. As a service to professional users, a safety data sheet and CLP labelling have been prepared for handling in the working environment.
Changes since the previous edition:
1, 2, 3, 4, 7, 8, 11, 12, 13, 15 & 16