

SAFETY DATA SHEET

Section 1: Identification

Day of issue: 2017-04-18

Product identifier:Ceramir[®] Crown & Bridge QuikMix Liquid**Recommended use of the chemical and restrictions on use:**

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.

Details of the supplier of the safety data sheet:**Manufacturer:**

Doxa Dental

Axel Johanssons gata 4-6 Tel.: +46 (0) 18 478 20 00 1(855)Doxa – USA (369-2872)

SE-754 50 Uppsala

SWEDEN

US importer:

Doxa Dental Inc.

1(855)Doxa – USA (369-2872)

www.ceramirUS.com

Responsible for SDS (e-mail): info@doxa.se**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:

Eye Irritation Category 2A

Skin Irritation Category 2A

STOT Single Exposure Category 3

Signal word

Warning

Pictogram(s)/Symbol(s)**Hazard statement(s)**

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

Precautionary statement(s)

P280: Wear protective gloves/eye protection.

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**3.2. Mixtures:**

% w/w	Substance name	CAS No.	Note
15-<25	Polyacrylic acid	9003-01-4	1
<5	Tartaric acid	87-69-4	1
<1	Trisodium nitrilo-triacetate (NTA)	5064-31-3	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:

Irritation of skin and eyes with redness. Inhalation may irritate throat and respiratory system and cause coughing.

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:

Not combustible.

Specific hazards arising from the chemical:

Not combustible.

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:

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

Section 8: Exposure Controls/Personal Protection

OSHA Permissible Exposure Limits (PEL):

No substance listed with an exposure limit.

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 splashes.

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.

Section 9: Physical and Chemical Properties

Appearance (physical state, color, etc.):	Liquid
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 determined
Upper/lower flammability or explosive limits (vol-%):	Not determined
Vapor pressure:	Not determined
Vapor density:	Not determined
Relative density:	Not determined
Solubility(ies):	Insoluble in water
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:

None known.

Chemical stability:

Stable under normal conditions and recommended use.

Possibility of hazardous reactions:

None known.

Conditions to avoid:

Strong heat.

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.

Section 11: Toxicological Information

Information on toxicological (health) effects:

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 Contact:

May cause irritation with redness.

Eye Contact:

May cause irritation with redness and stinging.

Ingestion:

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

Delayed (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.

Acute Toxicity

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 diss.
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 diss.
Corrosion/irritation:	Irritant to skin and eyes (Polyacrylic acid)	No data.	Supplier
	In vitro eye irritant (Tartaric acid)	OECD 437	ECHA diss.
	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

Mutagenic toxicity

No available data/insufficient data.

Reproductive toxicity

No available data/insufficient data.

Carcinogenic toxicity

NTA is suspected of causing cancer (IARC monograph vol. 73: group 2B).

NTA is mentioned on NTP's Report on Carcinogens (RoC), latest ed.

Nitrilotriacetic acid and its salts are reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals

Specific Target Organ Toxicity

Polyacrylic acid may cause respiratory irritation.

Section 12: Ecological Information

Ecotoxicity:

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

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.

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).

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):

CAS No. 87-69-4 is listed on TSCA inventory.

CAS No. 5064-31-3 is listed on TSCA inventory.

CAS No. 9003-01-4 is listed on TSCA inventory (polymer).

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: Nitritoltriactic acid, trisodium salt monohydrate (NTA)

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.

EC₅₀ = Effect Concentration 50%

FW = Fresh Water

LC₅₀ = Lethal Concentration 50%

LD₅₀ = 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 diss. = REACH Registration dossier from ECHA's home page.

IARC = International Agency for Research on Cancer

IUCLID = International Uniform Chemical Information Database

RTECS = Register of Toxic Effects of Chemical Substances

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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