

SAFETY DATA SHEET

Complies with European Regulation EC
453/2010 Dental Use

J.RIPOLL S.L



Q CREAM

Publication date: 05/11/2019

Review date: 31/10/2019

Revision number: 6

SECTION 1. IDENTIFICATION OF THE SUBSTANCE / PREPARED AND OF THE COMPANY / COMPANY

1.1 Product Identification

Product Name: Q EDTA CREAM

Product Description: Root canal preparation for endodontics for professional use.

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

Main identification of use: EDTA gel for professional use.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

J.RIPOLL S.L.
C/RIO TIETAR Nº20
POLIGONO EL NOGAL
ALGETE (MADRID)
SPAIN

Supplier:

J.RIPOLL S.L.
C/RIO TIETAR Nº20
POLIGONO EL NOGAL
ALGETE (MADRID)
SPAIN
Email:
info@dentaflux.com
Emergency phone: +34 916289399

1.4 Emergency telephone

Emergency Tel .: +34 916289399

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to EC Regulation No. 1272/2008

Skin irritation, category 3, H315
Serious eye damage Category 2, H318

Signal word: Danger

2.2 Label elements

Classification according to EC Regulation No. 1272/2008 (CPL) Hazard pictograms:



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Signal word: Danger

Danger phrases:

H315: Causes skin irritation

H318: Causes serious eye damage.

Precautionary statements

Prevention: P280: Wear gloves / clothing / glasses / protective mask.

Answer: P305+351+338: IF IN EYES: Clarify carefully with water for several minutes. Remove contact lenses, If it leads and is easy. Continue rinsing.
P302+P352: In skin contact chaos: Wash with plenty of soap and water.
P313: Consultate a doctor.

Storage: P273: Avoid release to the environment

Classification according to Directive 1999/45/EC

The mixture has been evaluated and / or verified for physical, health and environmental risks and is

The following classification applies.

Classification according to Directive 1999/45/EC Hazard Pictograms:

Xi Irriating R37/38 – 41, S26-39



IRRIATING

The full text of the R and S phrases mentioned in this section is indicated in section 16.

2.3 Other hazards

General recommendations: No information available.

SECTION 3. COMPOSITION / COMPONENT INFORMATION

3.1 Substances

Not applicable

3.2 Mixtures

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Chemical name	CAS	EINECS	Content %	Classification according to directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 CLP
EDTA, Disodium Salt 2-Hydrate	6381-92-6	205-358-3	> 99	R:48/20	Not dangerous
Hydrogen peroxide-urea	124-43-6	204-701-4	>99	Xi Irriating, R37/38-41	Skin irritation; 2; H315 Serious eye damage 1B; H318

The full text of the R phrases is found in section 16

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid

Eye contact: Immediately flush eyes with plenty of water, also under the eyelid, for at least 15 minutes. Call the ophthalmologist immediately.

Skin contact: Take off immediately all contaminated clothing. In case of contact with the eyelid, for at least 15 minutes. Call the ophthalmologist immediately.

Ingestion: If swallowed, drink plenty of water, (maximum 2 glasses) rinse mouth with Water DO NOT induce vomiting without medical advice. Call a doctor or a control center immediately of poisoning / poisoning.

Inhalation: No specific treatment is required since the material is not dangerous if inhaled. If exposure to excessive levels of dust or gases occurs, take the affected person to a place with fresh air and get medical assistance in case of symptoms such as cough or others

4.2 Main symptoms and effects, both acute and delayed

Eyes: Risk of serious damage to eyes, risk of turbidity in the cornea.

Skin: Irritation and corrosive, causes skin burns

Ingestion: Harmful if swallowed

Inhalation: No expected effect

4.3 Indication of all medical care and special treatments that must be dispensed immediately

Notes to the doctor:
Irriating.

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SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Extinguishing media: Water, Carbon dioxide, Dry powder, Foam.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Flammable. It favors the formation of fires by oxygen evolution. Possibility of formation of flue gases and hazardous vapors by fire in the surroundings. Nitrogen oxides and toxic gases can be produced.

5.3 Recommendations for firefighters

Fire Procedure: General: Evacuate all personnel; use protective equipment fires.

Fire fighting equipment: Use self-contained breathing apparatus.

Other information: Suppress gases / vapors / mists with water spray. Prevent the penetration of extinguishing water in surface or underground aquifers.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Special protective equipment: Avoid contact with the substance.

6.2 Environmental precautions

Water discharge: Do not allow the product to enter the sewer pipeline or in systems drainage that connect with waterways

6.3 Methods and material for containment and cleaning up

Small spill: Clean up spills immediately observing the precautions contained in the protective equipment section. Collect dry spills and proceed to waste disposal. Clear out.

Large spill: Absorb with an inert, moist and non-combustible material, then wash the area with Water.

6.4 Reference to other sections

Reference to other sections: Personal protective equipment, see section 8.

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SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

General procedures: Avoid contact with eyes, skin and clothing

Handling: Use appropriate protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Shelf life: Keep container tightly closed. To maintain product quality, keep controlled temperature indicated on the product label. Keep in a dry place.

7.3 Specific end uses

Specific end uses: Dental EDTA solution for professional use

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Control parameters: Does not contain substances with occupational exposure limit values.

8.2 Exposure controls

Face / eye protection: Wear eye protection

Skin protection: : Wear suitable protective clothing and gloves

Hygiene measures: Wash hands before breaks and immediately after Manipulate the substance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Solid/gel

Colour: White.

Smell: Slight characteristic smell.

pH ≈6

Amount of EDTA ≈15%

Amount of carbamide peroxide ≈10% .

9.2 Additional information

No data available.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity:

Reactivity: Stable

10.2 Chemical stability

Chemical stability: Stable when stored and handled under recommendations

10.3 Possibility of hazardous reactions

Hazardous Polymerization: None

10.4 Conditions to avoid

Conditions to avoid: No data available.

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10.5 Incompatible materials

Incompatible materials: No data available.

10.6 Hazardous decomposition products

Hazardous decomposition products: Does not decompose if stored in normal conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute

>Notes: The carbamide peroxide product that has an acute oral toxicity (LD50) for that of >2000 mg / kg in rats and skin irritation that causes skin burns on contactprolonged, as well as risk of turbidity in the cornea and serious eye damage. Must be used only as indicated by the PPE (personal protective equipment) and only by dental professionals.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity: Not determined

Aquatic toxicity

LC50 – 48 hours: 35mg/l

EC50 – 48 hours: Not determined

EC50 – 96 hours: Not determined

12.2 Persistence and degradability

Persistence and degradability: Not determined

12.3 Bioaccumulative potential

Bioaccumulative potential: Not determined

12.4 Mobility in soil

Mobility in soil: Not determined

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: Not determined

12.6 Other adverse effects

Environmental data: Not defined

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal method: Disposal method: Dispose in compliance with government regulation (2008/98 / CE).

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SECTION 14. TRANSPORTATION INFORMATION

14.1 UN number

UN Number: Not applicable

14.2 United Nations official designation of transport

UN proper shipping name: Not applicable

14.3 Transport hazard class (es)

Primary Hazard Class / Division: Not applicable

Hazard classification: Not applicable

14.4 Packing group

Packing group: Not applicable

14.5 Environmental hazards

Marine pollutant #1: Not applicable

14.6 Special precautions for users

ADR- Road: Not applicable

RID- Railway: Not applicable

IMDG – Maritime: Not applicable

IATA - Air: Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk: Not applicable

SECTION 15. REGULATORY INFORMATION

15.1 Regulations and legislation on safety, health and environment specific to the substance or mixture

RoHS: See Directive on medical devices 93/42 / ECC.
Type IIa medical device.

15.2 Chemical safety assessment

Chemical safety assessment: See section 11

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SECTION 16. OTHER INFORMATION

R and / or H phrases (Number and full text)

H315 Causes skin irritation.

H318 Causes eye damage.

R37 / 38 Irritating to respiratory system and skin

R41 Risk of serious damage to eyes.

S26-39 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice doctor. Wear eye / face protection.

Prepared by: José Ignacio Ripoll.

General information: NA=Not applicable

Manufacturer Disclaimer:

FOR DENTAL USE ONLY: Use as directed. Information and recommendations they come from sources (the safety data sheets of the raw materials and the knowledge of the manufacturer) that are considered accurate; however, J.Ripoll S.L. does not guarantee the accuracy of this information or the adequacy of the recommendations, and does not assume any responsibility for any damage arising. The user should review these recommendations, in the context specific to the intended use, and determine if they are appropriate.