

SAFETY DATA SHEET

Complies with the European Regulation EC 1272/2008
Dental use

J.RIPOLL S.L



Q CREMA

Publication Date: 06/07/2015
Revision date: 03/07/2015
Revision number: 5

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

1.1 Identification of the Product

Product Name: Q CREMA EDTA

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

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

Main use identification: 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

Distributor:

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 phone number

Emergency phone: +34 916289399

SECTION 2. IDENTIFICATION OF THE HAZARDS

2.1 Substance or mixture classification

Classification according to EC Regulation N°1272/2008

Skin irritation, category 3, H315
Serious eyes injuries. Category 2, H318

Signal word: Danger

2.2 Label elements

**Classification according to EC Regulation N°1272/2008
(CPL) Hazard Pictograms**



Signal word: Danger

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Hazard phrases:

H315: Causes skin irritation
H318 Causes serious eye damage.

Prudence advises

Prevention: P280: Wear protection gloves / garments / goggles / mask.

Answer: P305+351+338: IN CASE OF CONTACT WITH EYES: ARinse carefully with water for several minutes. Remove contact lenses if it takes and it is easy. Keep rinsing.
P302+P352: In case of contact with the skin: Wash with abundant water and soap.
P313: Consult a Doctor.

Storage: P273: Avoid release to the environment.

Classification according to Directive 1999/45/EC

The mixture has been evaluated and/or proven for physical, health and environmental risks and applies the following classification.

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

Xi Irritant 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 / INFORMATION OF THE COMPONENTS

3.1 Substances

No applicable

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3.2 Mixtures

Chemical name	CAS	EINECS	Content %	Classification according to directive 67/548/EEC	Classification according to the Regulation (EC) No 1272/2008 CLP
EDTA, Disodic Salt 2-Hidrate	6381-92-6	205-358-3	15	R:48/20	Not dangerous
Hydrogen peroxide-urea	124-43-6	204-701-4	10	Xi Irritant, R37/38-41	Skin irritation; 2; H315 Serious eye injuries 1B; H318

The full text of the R phrases can be found in section 16

SECTION 4. FIRST AID

4.1 Description of first aid

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

Skin contact: Take off contaminated clothing immediately. In case of contact with the skin, wash immediately and abundantly with soap and water. Seek medical attention if irritation appears or persists.

Ingestion: In case of ingestion, drink plenty of water, (maximum 2 glasses) rinse mouth with water. DO NOT induce vomiting without medical advice. Call a doctor or a poisoning center immediately.

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

4.2 Most important symptoms and effects, both acute and delayed

Eyes: Risk of serious eye injuries, risk of cornean turbidity.

Skin: Irritation and corrosive, causes skin burns.

Ingestion: Harmful if swallowed.

Inhalation: No effect expected.

4.3 Indication of all medical care and special treatments required to be dispensed immediately

Notes for the doctor:

Irritating.

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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 release of oxygen. Possibility of formation of hazardous combustion gasses and vapors fire in the environment. Nitrogen oxides and toxic gasses can be produced.

5.3 Recommendations for firefighting personnel.

Fire-fighting procedure: General: Evacuate all personnel; use protective equipment against fires.

Fire-fighting equipment: Use self-contained breathing apparatus.

Other information: Repress the gasses / vapors / mists with water spray. Avoid the spread of the extinguishing water on 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 Precautions relating to the environment

Discharged in water: Do not allow the product to enter the sewage pipe or systems drainage that connects with waterways.

6.3 Methods and material for containment and cleaning

Small spill: Clean up spills immediately observing the proceed to the elimination of waste. Clear out.

Large spill: Absorb with an inert material, moist and not combustible, 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 and safe handling

General procedures: Avoid contact with eyes, skin and clothing.

Handling: Use suitable protective equipment.

7.2 Conditions for safe storage, including possible incompatibilities

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

7.3 Final specific uses

Final specific 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 / eyes 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

Color: White.

Smell: Light characteristic odor.

pH ≈6

EDTA amount ≈15%

Amount of carbamide proxide ≈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 dangerous reactions

Hazardous polymerization: None

10.4 Conditions to be avoided

Conditions to be avoided: 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 of toxicological effects

Acute

Annotations: The carbamide peroxide that has and acute oral toxicity (LD50) for the > 2000 mg / kg in rats and an irritation of the skin that causes skin burns by contact prolonged, as well as risk of turbidity in the cornea and serious eye injuries. It must be only used by the PPE (personal protective equipment) and only by dental professionals

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity: No determined

Aquatic toxicity

LC50 – 48 hours: 35mg/l

EC50 – 48 hours: No determined

EC50 – 96 hours: No determined

12.2 Persistence and degradability

Persistence and degradability: No determined

12.3 Bioaccumulation potential

Bioaccumulation potential: No determined

12.4 Mobility in the soil

Mobility in the soil: No determined

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No determined

12.6 Other adverse effects

Environment data: Not defined

SECTION 13. CONSIDERATIONS RELATED TO ELIMINATION

13.1 Methods for waste treatment

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

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SECTION 14. INFORMATION CONCERNING TRANSPORTATION

14.1 UN number

UN number: No applicable

14.2 United Nations transport designation

Official transport designation of the United Nations: No applicable

14.3 Class (s) of danger for transport

Class/Division of primary hazard: No applicable

Hazard classification: No applicable

14.4 Packaging group

Packaging group: No applicable

14.5 Dangers for the environment

Marine pollutant #1: No applicable

14.6 Precautions for users

ADR- Road: No applicable
RID- Railway: No applicable
IMDG- Maritime: No applicable
IATA - Air: No applicable

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

Bulk transportation: No applicable

SECTION 15. REGULATORY INFORMATION

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

RoHS: See the directive of Medical Devices 93/42/ECC. Type IIa sanitary product.

15.2 Chemical safety assessment

Chemical safety assessment: See action 11

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SECTION 16. OTHER INFORMATION

Phrases R and / or H (Number and complete text)

H315 Causes skin irritation.

H318 Causes eye injuries.

R37/38 Irritates respiratory tract and skin

R41 Risk of serious eye injuries.

S26-39 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Use protection for the eyes / face.

Prepared by: José Ignacio Ripoll.

General information: NA=Not applicable

Manufacturer's disclaimer:

FOR DENTAL USE ONLY: Use as directed. Information and recommendations come from sources (safety data sheets of raw materials and knowledge of the manufacturer) that are considered accurate; however, J. Ripoll SL does not guarantee the accuracy of these information or the adequacy of the recommendations, and assumes no responsibility for any damage derived. The user should review these recommendations, in the context specific to the intended use, and determine if they are appropriate.