



GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

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TECHNICAL DATA SHEET

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93556-SODIUM CROMOGLICATE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation

Name: Sodium Cromoglicate

Bulk code: 93556

1.2 Synonyms

Natrii cromoglicas; Disofium cromoglicate; Cromolyn sodium.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White, almost white.

Smell: Odourless

Flavour: Initially insipid with a bitter aftertaste.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{23}H_{14}Na_2O_{11}$

CAS: 15826-37-6

Molecular weight: 512.3 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Soluble in 20 p. water, practically insoluble in alcohol, chloroform and ether.

Melting point: 241-242°C with decomposition.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is a cromolyn derivate with anti-allergy properties. It acts by stabilising the membrane of the mast cells, preventing slow-reaction mediators of anaphylaxis from being released. It does not present inherent antihistamine or anti-inflammatory activity, nor does it have a bronchodilator effect.

Orally, it is used to prevent food allergies along with a restrictive diet, used in capsule format or as an extemporaneous solution prepared by diluting the contents of the capsules in water.

It has also been used to treat mastocytosis.

93556-SODIUM CROMOGLICATE**6. DOSAGE.**

Orally:

In adults, the dose is 200 mg, four times a day.

In children over 2 years old, the dose is 100 mg, four times a day. If the result is unsatisfactory, the dose may be doubled, but without exceeding 40 mg/kg of weight per day.

Later, once symptoms are under control, the dose may be reduced.

It is usually administered 15-20 minutes before meals and before bed.

7. REMARKS.

STORAGE:

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in hermetically sealed containers.

Hygroscopic.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).