

Ficha de Datos de Seguridad de acuerdo el Reglamento (CE) No. 1907/2006

CROMOGLICATO DISODICO

SECTION 1) IDENTIFICATION OF SUBSTANCE

Nombre del producto : Cromoglicato disodico

Compañía : METAPHARMACEUTICAL IND. S. L.

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General use: being a pharmacological active ingredient, it is used only by manufacturers of pharmaceutical products, under GMP and strictly controlled conditions.

Therap. category: antiallergic

SECTION 2) HAZARDS IDENTIFICATIONS

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]



Xi: IRRITANT

R36/37/38

Information pertaining to particular dangers for man and environment:

- irritating to eyes, respiratory system and skin

GHS LABEL ELEMENTS



Warning

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation

Prevention

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash thoroughly after handling
P271 Use only outdoors or in a well-ventilated area
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Reaction

P305+ P351+ P338 IF IN EYES: Rinse continuously with water for several minutes.
Remove contact lenses if present and easy to do – continue rinsing
P337+P313 If eye irritation persists: Get medical advice/attention.

Storage

P404: Store in a closed container

Disposal

P501: Dispose of contents/container in a site approved for chemical and hazardous waste or burned in a specialised burning centre

SECTION 3) COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name 4H-1-Benzopyran-2-carboxylic acid, 5,5'-(2- hydroxy trimethylene dioxy)bis(4-oxo-, disodium salt)

Empirical formula C₂₃ H₁₄ Na₂ O₁₁

Molecular weight 512.35

Composition purity degree: ~100%

CAS number 15826-37-6

EINECS number 239-926-7

SECTION 4) FIRST AID MEASURES

Eye Contact:

Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Skin Contact:

After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Inhalation:

Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is

difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention.

Ingestion:

Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

SECTION 5) FIRE-FIGHTING MEASURES

Extinguishing media:

In case of fire use water, chemical type foam, carbon dioxide, dry chemical. Prevent run off of water from entering drains

Hazardous combustion products:

The substance evolves toxic fumes due to the presence of CO, CO₂

Fire-fighting equipment:

Respiratory and eye protection for fire-fighting personnel

SECTION 6) ACCIDENTAL RELEASE MEASURES

Person-related safety precautions:

- Wear protective equipment
- Keep unprotected persons away

Measures for cleaning / collecting:

- Damp down to avoid dust generation
- Do not allow to enter public sewers and watercourses
- Sweep or shovel-up spillage and remove to a safe place
- Absorb spillage in earth or sand

SECTION 7) HANDLING AND STORAGE

- This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet.
- It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment.
- Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing.
- Keep in unopened containers in a cool, dry and well ventilated place.
- This material should be handled and stored per label instructions to ensure product integrity.
- Avoid contact with oxidising substances

SECTION 8) EXPOSURE CONTROLS PERSONAL PROTECTION

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Skin and body protection

The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Complete suit protecting against chemicals, flame retardant antistatic protective clothing.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9) PHYSICAL AND CHEMICALS PROPERTIES

Form	hygroscopic powder
Colour	white to almost white
Odour	odourless
Melting point	above 200 °C with decomposition
Auto-ignition point	not applicable
Solubility in water	soluble
Solubility in solvents	insoluble in alcohol
Coeff. oil / water	not available

SECTION 10) STABILITY AND REACTIVITY

Hazardous polymerization	not occurs
Conditions to avoid	heat, flames and sparks
Incompatible materials	strong oxidising agents
Stability	the product is stable at room temperature and in usual working conditions
Hazardous decomposition products	the substance evolves toxic fumes due to the presence of CO, CO ₂

SECTION 11) TOXICOLOGICAL INFORMATION

Carcinogenicity:	not listed
Mutagenicity:	no evidence
Reproductive effects:	no evidence
Teratogenic effects:	no evidence
Acute toxicity data	
Acute Oral LD 50 (rat):	>11 gm/kg

Acute Oral LD 50 (mouse): >11 gm/kg
Acute Oral LD 50 (dog): >4 gm/kg
Acute Oral LD 50 (rabbit): >8 gm/kg

SECTION 12) ECOLOGICAL INFORMATION

Environmental data	may cause adverse environmental impact if material reaches waterways
Ecotoxicological information	not available
Distribution	not available

SECTION 13) DISPOSAL CONSIDERATIONS

Product wastes	Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation
Wasted containers / drums	Wastes have to be disposed in a site approved for chemical and hazardous waste or burned in a specialised burning centre

SECTION 14) TRANSPORT INFORMATION

Special precautions:

Classification: NOT RESTRICTED

SECTION 15) REGULATORY INFORMATION

Code letter and hazard designation of product:

Xi IRRITATING

Risk phrases

R 36/37/38 irritating to eyes, respiratory system and skin

Safety phrases

S 36/37 wear gloves and protective clothing

EUROPEAN REGULATIONS

REACH exempted as “Active Pharmaceutical Ingredient”

CLP notified with submission nr. **VV858074-96** reference nr. **02-2119449950-33-0000**

SECTION 16) OTHER INFORMATION

Historical:

First issue date : November 1st, 2010. Updating to CLP regulation

Revision n°1: April 16, 2012, more information on Individual Protection. Modified section 8

Manufacturer disclaimer:

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