

CROMOLYN SODIUM

Code 4050

SAFETY DATA SHEET REV. 5

First issue date : November 1st, 2010
Revision n° 5: Jan. 1st, 2017

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

1.1 Product identifiers

Product name **CROMOLYN SODIUM**
Therapeutic category **antiallergic**

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

being a pharmacological active ingredient, it is used only by manufacturers of pharmaceutical products,

1.3 Details of the supplier of the safety data sheet

Company **Olon S.p.a.**
Manufacturing site: via Livelli n° 1- 26852 CASALETTO
LODIGIANO (LO) – ITALY
Telephone ++39-0371-7399209
Fax ++39-0371-73108
e-mail address ecurioni@olonspa.it

Registered office Olon S.p.a. via Rivoltana Km 6/7,
20090 RODANO (Mi) - ITALY
Telephone ++39-02-95231
e-mail address info@olonspa.it

1.4 Emergency telephone number

During normal opening times (8 am till 5:00 pm)
Phone: ++39-0371-7399209 - Fax: ++39-0371-73108
e-mail: ecurioni@olonspa.it - please contact Mr. Emiliano Curioni

From European Commission, according to Art. 45(1) Reg. (EC) No 1272/2008,
please contact:

National Poisons Information Service (NPIS) Email: director.birmingham.unit@npis.org

Email: director.birmingham.unit@npis.org

Website: <http://www.npis.org/>

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture, according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Skin Irrit. 2

Eye Irrit. 2

STOT SE 3

2.2 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

2.3 Other hazards

None

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

| | |
|-------------------|---|
| Chemical name | 4H-1-Benzopyran-2-carboxylic acid, 5,5'-((2-hydroxy trimethylene) dioxy)bis(4-oxo-, disodium salt |
| Empirical formula | C ₂₃ H ₁₄ Na ₂ O ₁₁ |
| Molecular weight | 512.35 |
| Composition | purity degree: ~100% |
| CAS number | 15826-37-6 |
| EINECS number | 239-926-7 |

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| SECTION 4 | FIRST AID MEASURES |
|------------------|---------------------------|

4.1 Description of 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. 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

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

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| SECTION 5 | FIRE-FIGHTING MEASURES |
|------------------|-------------------------------|

5.1 Extinguishing media**Suitable extinguishing media**

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

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Wear:

*-Gas masks scuba
-Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps around arms, legs and waist.
As not expected at this point, refer to the personal protective equipment recommended in Section 8 of this sheet*

5.4 Further information

No data available

SECTION 6 ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation.

6.2 Methods and materials for containment and cleaning up

Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation.

6.3 Environmental precautions

Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 HANDLING AND STORAGE**7.1 Precautions for safe handling**

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.

7.2 Conditions for safe storage, including any incompatibilities

Avoid contact with oxidising substances

For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are:

USP: Preserve in tight containers.

EP: In an airtight container, protected from light.

For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF).

7.3 Specific end uses

Laboratory investigations, testing of pharmaceutical technology. Formulation in pharmaceutical preparations

SECTION 8 EXPOSURE CONTROLS PERSONAL PROTECTION**8.1 Control parameters**

Components with workplace control parameters

Contains no substances with occupational exposure limit value

8.2 General protective and hygienic measures

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes and clothing.

8.3 Personal protective equipment

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

9.1 Information on basic physical and chemical properties

| | |
|---|---|
| a) Appearance | <i>hygroscopic crystalline powder white to almost white</i> |
| b) Odour | <i>odourless</i> |
| c) Odour Threshold | <i>No data available</i> |
| d) pH | <i>No data available</i> |
| e) Melting point/freezing point | <i>above 200 °C with decomposition</i> |
| f) Initial boiling point and boiling range | <i>No data available</i> |
| g) Flash point | <i>No data available</i> |
| h) Evaporation rate | <i>No data available</i> |
| i) Flammability (solid / gas) | <i>No data available</i> |
| j) Upper/lower flammability or explosive limits | <i>No data available</i> |
| k) Vapour pressure | <i>No data available</i> |
| l) Vapour density | <i>No data available</i> |
| m) Relative density | <i>No data available</i> |
| n) Water solubility | <i>soluble</i> |
| o) Partition coefficient: n-octanol/water | <i>No data available</i> |

| | | |
|----|---------------------------|-------------------|
| p) | Autoignition temperature | No data available |
| q) | Decomposition temperature | above 200°C |
| r) | Viscosity | No data available |
| s) | Explosive properties | No data available |
| t) | Oxidizing properties | No data available |

9.2 Other safety information

no data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

See 10.3

10.2 Chemical stability

The product is stable in usual working conditions

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Heat, flames and sparks

10.5 Incompatible materials

Strong oxidising agents. Alkali metals, bases, strong acids, halogens

10.6 Hazardous decomposition products

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

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information from ChemIDplus

Acute toxicity

| | | | |
|-----------------------|--------|-------|---------|
| Acute Oral LD 50 | rat | mg/kg | > 11000 |
| Acute Oral LD 50 | mouse | mg/kg | > 11000 |
| Acute Oral LD 50 | dog | mg/kg | > 4000 |
| Acute Oral LD 50 | rabbit | mg/kg | > 8000 |
| Acute sub. cut. LD 50 | rat | mg/kg | 6000 |
| Acute sub. cut. LD 50 | mouse | mg/kg | 4400 |
| Acute I.P. LD 50 | ratto | mg/kg | > 4000 |
| Acute I.P. LD 50 | topo | mg/kg | 1000 |
| Acute I.V. LD 50 | rat | mg/kg | > 4000 |
| Acute I.V. LD 50 | mouse | mg/kg | 3300 |
| Acute I.V. LD 50 | dog | mg/kg | > 1600 |
| Acute I.V. LD 50 | rabbit | mg/kg | 2000 |

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

Causes serious eye irritation

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Potential health effects

Inhalation *May be harmful if inhaled.*

Ingestion *May be harmful if swallowed.*

Skin *May cause skin irritation*

11.3 Signs and Symptoms of Exposure

No data available

11.4 Additional Information

No data available

| | |
|-------------------|-------------------------------|
| SECTION 12 | ECOLOGICAL INFORMATION |
|-------------------|-------------------------------|

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Product**

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

The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

SECTION 14 TRANSPORT INFORMATION**14.1 UN number**

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID -

IMDG -

IATA -

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG: no

IATA: no

14.6 Special precautions for user*no data available***SECTION 15 REGULATORY INFORMATION**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006

15.1 Safety, health and environmental regulations/legislation specific for the substance*no data available*

REACH *exempted as API (Active Pharmaceutical Ingredient)*

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

15.2 Chemical Safety Assessment*no data available***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
Revision n° 2: September 2nd 2013, new registered office. Modified section 1.
Revision n° 3: June 1st 2015, updating to CLP 2015 format
Revision n° 4: May 5th 2016 - updating to SDS format
Revision n°5: Janu. 1st 2017, new registered office. Modified section 1

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