

**SECTION 1: PRODUCT IDENTIFICATION**

|                        |  |
|------------------------|--|
| <b>PRODUCT NAME</b>    | <b>CROMOLYN SODIUM, USP</b>  |
| <b>PRODUCT CODE</b>    | <b>0301</b>  |
| <b>SUPPLIER</b>        | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>661 Route 3, Unit C, Plattsburgh, NY, 12901<br>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118<br>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b> | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126   |
| <b>USES</b>            | Anti-asthmatic; Prophylaxis of allergic conditions.  |

**SECTION 2: HAZARDS IDENTIFICATION**

|                                   |  |                |                            |   |
|-----------------------------------|--|----------------|----------------------------|---|
| <b>GHS CLASSIFICATION</b>         | Acute Toxicity - Oral (Category 5)   |                |                            |   |
| <b>PICTOGRAM</b>                  | Not Applicable   |                |                            |   |
| <b>SIGNAL WORD</b>                | Not applicable   |                |                            |   |
| <b>HAZARD STATEMENT(S)</b>        | May be harmful if swallowed.<br>Exposure may produce an allergic reaction. |                |                            |   |
| <b>AUSTRALIA-ONLY HAZARDS</b>     | Not Applicable.  |                |                            |   |
| <b>PRECAUTIONARY STATEMENT(S)</b> | <b>Prevention</b>  | Not applicable |                            |   |
|                                   | <b>Response</b>  | Not applicable |                            |   |
|                                   | <b>Storage</b>   | Not applicable |                            |   |
|                                   | <b>Disposal</b>  | Not applicable |                            |   |
| <b>HMS CLASSIFICATION</b>         | <b>Health Hazard</b>   | 1              | <b>Flammability</b>        | 0 |
|                                   | <b>Reactivity</b>  | 0              | <b>Personal Protection</b> | E |

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

|                         |   |
|-------------------------|---|
| <b>CHEMICAL NAME</b>    | 4H-1-Benzopyran-2-carboxylic acid,5,5'-[(2-hydroxy-1,3-propanediyl)bis(oxy)bis[4-oxo-, disodium salt] |
| <b>BOTANICAL NAME</b>   | Not applicable  |
| <b>SYNONYM</b>          | Sodium cromoglicate; Chromoglycate disodium; Sodium cromoglycate                                      |
| <b>CHEMICAL FORMULA</b> | C <sub>23</sub> H <sub>14</sub> Na <sub>2</sub> O <sub>11</sub>                                       |
| <b>CAS NUMBER</b>       | 15826-37-6  |

ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT 512.3326

COMPOSITION

| CHEMICAL NAME   | CAS NUMBER | % BY WEIGHT |
|-----------------|------------|-------------|
| CROMOLYN SODIUM | 15826-37-6 | 100         |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

Chemical family: Coumarin.

Although its precise mode of action remains uncertain, it is believed to act primarily by preventing release of mediators of inflammation from sensitised mast cells through stabilisation of mast-cell membranes. It has no direct antihistamine or anti-inflammatory action.

## SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS

Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS &amp; MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Recommended storage temperature: (15-30)°C, (59-86)°F. Preserve in tight, light resistant containers.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: CROMOLYN SODIUM CAS #: 15826-37-6

|                          | TWA | Ceiling | STEL | REL | IDLH | Remarks |
|--------------------------|-----|---------|------|-----|------|---------|
| OSHA PEL                 | N/L | N/L     | -    | -   | -    | -       |
| ACGIH TLV                | N/L | N/L     | N/L  | -   | -    | -       |
| NIOSH                    | N/L | N/L     | N/L  | N/L | N/L  | -       |
| AIHA WEEL                | N/L | N/L     | N/L  | -   | -    | -       |
| Safe Work Australia HSIS | N/L | N/L     | N/L  | -   | -    | -       |
| HSE                      | N/L | N/L     | N/L  | -   | -    | -       |

N/L = Not Listed

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**NOTES**

USP TWA: 0.1 mg/m<sup>3</sup>

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White, odorless, crystalline powder. Is hygroscopic.

**SOLUBILITY**

Soluble in water; insoluble in alcohol and in chloroform.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

**ODOR THRESHOLD**

Not available

**pH**

4 - 7

**MELTING POINT**

261 °C, 501.8 °F

**BOILING POINT**

Not available

**FREEZING POINT**

261 °C, 501.8 °F

**FLASH POINT**

Not available

|  |               |  |               |                                  |               |
|--|---------------|--|---------------|----------------------------------|---------------|
| <b>SPECIFIC GRAVITY</b>                        | Not available | <b>EVAPORATION RATE</b>                        | Not available | <b>EXPLOSIVE LIMIT</b>           | Not available |
| <b>UPPER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available | <b>LOWER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available | <b>VAPOR PRESSURE</b>            | Not available |
| <b>VAPOR DENSITY<br/>(AIR = 1)</b>             | Not available | <b>RELATIVE DENSITY<br/>(WATER = 1)</b>        | Not available | <b>log P<br/>(OCTANOL-WATER)</b> | Not available |
| <b>AUTO-IGNITION<br/>TEMPERATURE</b>           | Not available | <b>DECOMPOSITION<br/>TEMPERATURE</b>           | Not available | <b>VISCOSITY</b>                 | Not available |

## SECTION 10: STABILITY AND REACTIVITY

|  |   |
|--|---|
| <b>REACTIVITY</b>                            | Not established   |
| <b>STABILITY</b>                             | Stable under recommended storage conditions   |
| <b>MATERIALS TO AVOID</b>                    | Strong oxidants, alkaline solutions.  |
| <b>HAZARDOUS DECOMPOSITION<br/>PRODUCTS</b>  | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur |
| <b>HAZARDOUS POLYMERIZATION</b>              | Will not occur  |
| <b>POSSIBILITY OF HAZARDOUS<br/>REACTION</b> | Not established   |
| <b>CONDITIONS TO AVOID</b>                   | Moisture, sunlight and extreme temperatures   |

## SECTION 11: TOXICOLOGICAL INFORMATION

|   |  |
|---|--|
| <b>ACUTE TOXICITY</b>                             | Oral: Rat: LD50: (mg/kg): 2150<br>Dermal: Rabbit: LD50: (mg/kg): Not available<br>Inhalation: Rat: LD50: (mg/L/4hr): Not available   |
| <b>SKIN CORROSION/IRRITATION</b>                  | Due to lack of data the classification is not possible.  |
| <b>SERIOUS EYE DAMAGE/EYE<br/>IRRITATION</b>      | Due to lack of data the classification is not possible.  |
| <b>RESPIRATORY OR SKIN<br/>SENSITIZATION</b>      | Based on available data, the classification criteria are not met. Severe hypersensitivity reactions such as marked bronchospasm, laryngeal oedema, angioedema, and anaphylaxis have been reported rarely.  |
| <b>GERM CELL MUTAGENICITY</b>                     | Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. Negative in Ames Salmonella typhimurium, in mouse lymphomas, in chromosomal aberration, and in an in-vivo cytogenetic study in human peripheral lymphocytes.  |
| <b>CARCINOGENICITY</b>                            | <p><b>OSHA</b> CROMOLYN SODIUM is not listed.</p> <p><b>NTP</b> CROMOLYN SODIUM is not listed.</p> <p><b>IARC</b> CROMOLYN SODIUM is not evaluated.</p> <p><b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p> |
| <b>ADDITIONAL CARCINOGENICITY<br/>INFORMATION</b> | Long term studies of cromolyn sodium in mice, hamsters, and rats showed no neoplastic effects. These doses correspond to approximately 1.0, 0.3, and 2 times, respectively, the maximum recommended human daily inhalation dose on a mg/m <sup>2</sup> basis.  |

|   |  |
|---|--|
| <b>REPRODUCTIVE TOXICITY</b>                              | Based on available data, the classification criteria are not met. Reproduction studies with cromolyn sodium administered subcutaneously to pregnant mice and rats at maximum daily doses of 540 mg/kg and 164 mg/kg, respectively, and intravenously to rabbits at a maximum daily dose of 485 mg/kg produced no evidence of fetal malformations.  |
| <b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>   | Due to lack of data the classification is not possible.  |
| <b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b> | Due to lack of data the classification is not possible.  |
| <b>ASPIRATION HAZARDS</b>                                 | Based on available data, the classification criteria are not met.  |
| <b>SIGNS AND SYMPTOMS OF EXPOSURE</b>                     | Not expected to present a significant hazard under anticipated conditions of normal use.<br><br>Symptoms related to the physical, chemical, and toxicological characteristics: Coughing. Wheezing. Difficulty breathing. Sneezing. Nasal congestion. Nausea. Diarrhea. Abdominal pain. Headache. Dizziness. Insomnia. Skin rash. Muscle pain. Irritability.<br><br>Medical conditions aggravated by exposure: Impaired kidney function. Impaired liver function. |
| <b>POTENTIAL HEALTH EFFECTS</b>                           | <b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation.<br><b>Ingestion</b> May be harmful if swallowed.<br><b>Skin</b> May be harmful if absorbed through skin. May cause skin irritation.<br><b>Eyes</b> May cause eye irritation.  |

## SECTION 12: ECOLOGICAL INFORMATION

|                                      |  |
|--------------------------------------|--|
| <b>TOXICITY</b>                      | EC50: 48 Hr: Daphnia magna: (mg/L): 620<br>LC50: 96 Hr: Fish: (mg/L): Not available<br>IC50: 72 Hr: Algae: (mg/L): Not available |
| <b>PERSISTENCE AND DEGRADABILITY</b> | Not available  |
| <b>BIOACCUMULATIVE POTENTIAL</b>     | Not available  |
| <b>MOBILITY IN SOIL</b>              | Soluble in water. Water Solubility: >= 1 mg/l.   |
| <b>OTHER ADVERSE EFFECTS</b>         | Not available<br><br>This product is not intended to be released into the environment  |

## SECTION 13: DISPOSAL CONSIDERATIONS

|                       |   |
|-----------------------|---|
| <b>WASTE DISPOSAL</b> | Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment. |
|-----------------------|---|

## SECTION 14: TRANSPORT INFORMATION

|  |                    |
|--|--------------------|
| <b><u>UNITED STATES &amp; CANADA</u></b> |                    |
| <b>UN PROPER SHIPPING NAME</b>           | Not dangerous good |
| <b>UN NUMBER</b>                         | Not applicable     |
| <b>CLASS</b>                             | Not applicable     |
| <b>PACKING GROUP</b>                     | Not applicable     |

**AUSTRALIA**

|                                     |                    |
|-------------------------------------|--------------------|
| <b>UN PROPER SHIPPING NAME</b>      | Not dangerous good |
| <b>UN NUMBER</b>                    | Not applicable     |
| <b>CLASS</b>                        | Not applicable     |
| <b>PACKING GROUP</b>                | Not applicable     |
| <b>HAZCHEM</b>                      | Not applicable     |
| <b>ENVIRONMENTAL HAZARDS</b>        | Not available      |
| <b>SPECIAL SHIPPING INFORMATION</b> | Not applicable     |

## SECTION 15: REGULATORY INFORMATION

| Chemical Name & CAS           | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 |            | Right-to-know |            |               | California Prop 65 |
|-------------------------------|--------------------------|-------------------------------------|---------------------|------------|---------------|------------|---------------|--------------------|
|                               |                          |                                     | Appendix A          | Appendix B | Pennsylvania  | New Jersey | Massachusetts |                    |
| CROMOLYN SODIUM<br>15826-37-6 | N/L                      | N/L                                 | N/L                 | N/L        | N/L           | N/L        | N/L           | N/L                |

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

| Chemical Name & CAS           | Poisons and Therapeutic Goods Regulation | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors |
|-------------------------------|--|-----------------------|---|
| CROMOLYN SODIUM<br>15826-37-6 | Not Listed                               | Listed as Schedule 4* | Not Listed                                  |

### NOTES

\*Listed as sodium cromoglycate.

## SECTION 16: OTHER INFORMATION

### REFERENCES

Available upon request

### ABBREVIATIONS AND ACRONYMS

**CAS** – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

### LAST REVISION

02/2016

### SUPERSEDES

08/2013



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## SAFETY DATA SHEET

### DISCLAIMER

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