



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

Page 1 of 5

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Sodium Cromoglicate 2% Allergy Eye Drops**

**Trade Name:** REACTINE Eye Drops  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as Ophthalmic allergy medication

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Cromolyn Sodium	15826-37-6	239-926-7	2.0

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Purified water	7732-18-5	231-791-2	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear liquid

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** May cause irritation (based on components) .  
**Known Clinical Effects:** Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.  
**EU Indication of danger:** Not classified

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## MATERIAL SAFETY DATA SHEET

Material Name: Sodium Cromoglicate 2% Allergy Eye Drops  
Revision date: 05-Jan-2007

Page 2 of 5  
Version: 1.1

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention. Remove clothing and wash affected skin with soap and water.
<b>Ingestion:</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

<b>General Handling:</b>	Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use with adequate ventilation.
<b>Storage Conditions:</b>	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
<b>Storage Temperature:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.**

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation (LEV) should be used to control airborne levels. For laboratory use, handle in a lab fume hood.
------------------------------	--

# MATERIAL SAFETY DATA SHEET

Material Name: Sodium Cromoglicate 2% Allergy Eye Drops  
Revision date: 05-Jan-2007

Page 3 of 5  
Version: 1.1

## Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Clear
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### **Cromolyn Sodium**

Rat Oral LD50 > 11 g/kg  
Rat Intraperitoneal LD50 > 4 g/kg  
Rat Intravenous LD50 > 4 g/kg  
Mouse Oral LD50 > 11 g/kg  
Mouse Intravenous LD50 3300 mg/kg

#### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD 50 4000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### **Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### **Sodium chloride**

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

## MATERIAL SAFETY DATA SHEET

Material Name: Sodium Cromoglicate 2% Allergy Eye Drops  
Revision date: 05-Jan-2007

Page 4 of 5  
Version: 1.1

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Cromolyn Sodium**

Reproductive & Fertility-Males	Rat	Subcutaneous	175 mg/kg	NOAEL	Fertility
Reproductive & Fertility - Females	Rat	Subcutaneous	100 mg/kg	NOAEL	Fertility
Embryo / Fetal Development	Rat	Subcutaneous	164 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	485 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Mouse	Subcutaneous	540 mg/kg	NOAEL	Not Teratogenic

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### **Cromolyn Sodium**

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative  
Mitotic Gene Conversion Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Cromolyn Sodium**

1 Year(s)	Hamster	Intraperitoneal	11.4 mg/kg/day	NOAEL	Not carcinogenic
1 Year(s)	Mouse	Intraperitoneal	65 mg/kg/day	NOAEL	Not carcinogenic
18 Month(s)	Rat	Subcutaneous	65 mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

# MATERIAL SAFETY DATA SHEET

Material Name: Sodium Cromoglicate 2% Allergy Eye Drops  
Revision date: 05-Jan-2007

Page 5 of 5  
Version: 1.1

## OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

## Canada - WHMIS: Classifications

### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

### Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3

### Cromolyn Sodium

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4
EU EINECS List	239-926-7

### Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 6 - Accidental Release Measures. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

**End of Safety Data Sheet**