



# MATERIAL SAFETY DATA SHEET

Revision date: 12-Nov-2007

Version: 1.0

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  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

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

### Material Name: Ipratropium Bromide Inhalation Solution

**Trade Name:** IPRAVENT  
**Chemical Family:** Not determined  
**Intended Use:** Pharmaceutical product used as bronchodilator

## 2. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless solution

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

### Additional Hazard Information:

**Short Term:** May be harmful if swallowed. May cause eye irritation (based on components) .  
**Known Clinical Effects:** Common adverse effects include headache, nausea, and dry mouth.  
**EU Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ipratropium bromide	22254-24-6	244-873-8	Xn;R22	0.01-0.05
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

# MATERIAL SAFETY DATA SHEET

Material Name: Ipratropium Bromide Inhalation Solution  
Revision date: 12-Nov-2007

Page 2 of 5  
Version: 1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** 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

**General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

**Storage Conditions:** Store as directed by product packaging.

# MATERIAL SAFETY DATA SHEET

Material Name: Ipratropium Bromide Inhalation Solution  
Revision date: 12-Nov-2007

Page 3 of 5  
Version: 1.0

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

### Sodium chloride

Latvia OEL - TWA

= 5 mg/m<sup>3</sup> TWA

Lithuania OEL - TWA

= 5 mg/m<sup>3</sup> IPRV

### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

### Personal Protective Equipment:

#### Hands:

Wear impervious gloves if skin contact is possible.

#### Eyes:

Wear safety glasses or goggles if eye contact is possible.

#### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### Respiratory protection:

Not required for the normal use of this product. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

### Physical State:

Solution

### Color:

Clear, colorless

### Molecular Formula:

Mixture

### Molecular Weight:

Mixture

## 10. STABILITY AND REACTIVITY

### Stability:

Stable under normal conditions of use.

### Conditions to Avoid:

Fine particles (such as dust and mists) may fuel fires/explosions.

### 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)

#### Ipratropium bromide

Rat Oral LD50 1663 mg/kg

Rat Subcutaneous LD50 635 mg/kg

Mouse Oral LD50 1001 mg/kg

Mouse Subcutaneous LD50 300 mg/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD 50 4000 mg/kg

## MATERIAL SAFETY DATA SHEET

Material Name: Ipratropium Bromide Inhalation Solution  
Revision date: 12-Nov-2007

Page 4 of 5  
Version: 1.0

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

#### **Ipratropium bromide**

Eye Irritation Rabbit Moderate

#### **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

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

#### **Ipratropium bromide**

Fertility and Embryonic Development Rat Oral 1000 mg/kg/day NOAEL Not teratogenic

Fertility and Embryonic Development Rabbit Oral 125 mg/kg/day NOAEL Not Teratogenic

Fertility and Embryonic Development Mouse Oral 10 mg/kg/day NOAEL Not Teratogenic

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

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

## 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: Ipratropium Bromide Inhalation Solution  
Revision date: 12-Nov-2007

Page 5 of 5  
Version: 1.0

## 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.

### Ipratropium bromide

EU EINECS/ELINCS List	244-873-8
-----------------------	-----------

### Sodium chloride

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

### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

**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. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**