



# MATERIAL SAFETY DATA SHEET

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## 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: Salbutamol Inhalation Solution 1.2 mg/mL and 2.4 mg/L**

<b>Trade Name:</b>	Salbutamol
<b>Synonyms:</b>	Albuterol Sulfate
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	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:** Not acutely toxic (based on animal data)

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.

**Known Clinical Effects:** Adverse effects associated with the therapeutic use include nervousness, headache, increased heart rate (tachycardia).

**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.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Salbutamol Sulfate	51022-70-9	256-916-8	Repr. Cat3;R63	0-1
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	0-1

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

<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>	Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
<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.

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**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). Wash thoroughly after handling.

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

### 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.

#### Personal Protective Equipment:

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**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:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

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

**Water Solubility:** Aqueous solution

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None known

**Incompatible Materials:** None known

### 11. TOXICOLOGICAL INFORMATION

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

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

#### Salbutamol Sulfate

Rat Oral LD50 > 2500 mg/kg  
Rat Intravenous LD50 59.1 mg/kg  
Rat Intraperitoneal LD50 295 mg/kg  
Mouse Oral LD50 1950 mg/kg  
Mouse Intravenous LD50 48.7 mg/kg

#### SODIUM CHLORIDE

Rat Inhalation LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3 g/kg  
Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/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

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

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

#### Salbutamol Sulfate

Reproductive & Fertility Rat Oral 50 mg/kg NOAEL No effects at maximum dose  
Embryo / Fetal Development Mouse Subcutaneous 0.25 mg/kg LOAEL Teratogenic  
Embryo / Fetal Development Rabbit Oral 50 mg/kg/day LOAEL Teratogenic

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

#### Salbutamol Sulfate

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

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

#### Salbutamol Sulfate

18 Month(s) Mouse Oral 500 mg/kg/day NOAEL Not carcinogenic  
22 Month(s) Hamster Oral 50 mg/kg/day NOAEL Not carcinogenic  
2 Year(s) Rat Oral 2 mg/kg/day LOAEL Benign tumors, Female reproductive system

**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 have not been thoroughly investigated. Releases to the environment should be avoided.

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## 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

### OSHA Label:

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

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

D2a - very toxic materials



#### Salbutamol Sulfate

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	4
EU EINECS/ELINCS List	256-916-8

#### SODIUM CHLORIDE

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

#### Water for Injection

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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

R63 - Possible risk of harm to the unborn child.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** New data sheet.

**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**