



MATERIAL SAFETY DATA SHEET

Revision date: 29-Nov-2012

Version: 2.0

Page 1 of 6

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Salbutamol Inhalation Solution

Trade Name:	Salbutamol
Synonyms:	Albuterol Sulfate
Chemical Family:	Mixture
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: 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 therapeutic use include nervousness, headache, increased heart rate (tachycardia).

EU Classification

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.

MATERIAL SAFETY DATA SHEET

Material Name: Salbutamol Inhalation Solution
Revision date: 29-Nov-2012

Page 2 of 6
Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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	EU 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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Fire / Explosion Hazards: Not applicable

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 spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

MATERIAL SAFETY DATA SHEET

Material Name: Salbutamol Inhalation Solution
Revision date: 29-Nov-2012

Page 3 of 6
Version: 2.0

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. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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 ³
Lithuania OEL - TWA	5 mg/m ³

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

Physical State:	Liquid	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Water Solubility:	Aqueous solution		

10. STABILITY AND REACTIVITY

Chemical 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

MATERIAL SAFETY DATA SHEET

Material Name: Salbutamol Inhalation Solution
Revision date: 29-Nov-2012

Page 4 of 6
Version: 2.0

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)

Salbutamol Sulfate

Rat Oral LD50 > 2500 mg/kg
Rat Para-periosteal 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 Sub-tenon injection (eye) LC50/1hr > 42 g/m³
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.

MATERIAL SAFETY DATA SHEET

Material Name: Salbutamol Inhalation Solution
Revision date: 29-Nov-2012

Page 5 of 6
Version: 2.0

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

MATERIAL SAFETY DATA SHEET

Material Name: Salbutamol Inhalation Solution
Revision date: 29-Nov-2012

Page 6 of 6
Version: 2.0

15. REGULATORY INFORMATION

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

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: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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