



MATERIAL SAFETY DATA SHEET

Revision date: 03-Dec-2007

Version: 1.0

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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 6 mg/mL

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) . May cause eye irritation, May cause skin irritation. (based on components) .
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.
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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
Benzalkonium chloride	8001-54-5	Not listed	Not Listed	0-0.1

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

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.

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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

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

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:

Physical State:	Liquid	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	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.

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

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Mouse Oral LD50 1950 mg/kg
Mouse Intravenous LD50 48.7 mg/kg

Benzalkonium chloride

Rat Oral LD50 240 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)

Benzalkonium chloride

Skin Irritation Rabbit Moderate

Eye Irritation Rabbit Severe

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.

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.

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

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

Benzalkonium chloride

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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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

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End of Safety Data Sheet