MATERIAL SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Company</th>
<th>Address</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Inc</td>
<td>Pfizer Pharmaceuticals Group</td>
<td>235 East 42nd Street</td>
<td>New York, New York 10017</td>
</tr>
<tr>
<td>Pfizer Ltd</td>
<td>Ramsgate Road</td>
<td>Sandwich, Kent</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>Emergency telephone number:</td>
<td>CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number:</td>
<td>ChemSafe (24 hours): +44 (0)208 762 8322</td>
</tr>
<tr>
<td>Contact E-Mail:</td>
<td><a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

**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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol Sulfate</td>
<td>51022-70-9</td>
<td>256-916-8</td>
<td>Repr.Cat3;R63</td>
<td>0-1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>0-0.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Aqueous solution</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2500 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intravenous</td>
<td>LD50</td>
<td>59.1 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD50</td>
<td>295 mg/kg</td>
</tr>
</tbody>
</table>

PZ00700
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.
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

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

PZ00700
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