SAFETY DATA SHEET

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

126598
Salbutamol inhaler
Approved/Revised 09-Dec-2004
Material
SDS Number Version 06
Salbutamol aerosol Material
Synonyms ASMAVENT (SALBUTAMOL) INHALER CFC FREE 100MCG/DOSE X 200 DOSES FP; SALBO (SALBUTAMOL) INHALER 100 MCG BY 200 DOSES CFC FREE
Company Name
Jewim Pharmaceutical (Shandong) Co.,Ltd.
Tel:0538-8512277
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Taian Hi-Tech Industrial Development Zone, Shandong, China

2. COMPOSITION / INFORMATION ON INGREDIENTS

CAS RN	Ingredients
18559-94-9	SALBUTOMOL

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is classified as non-flammable.
Health Caution - Potent pharmaceutical agent. Exposure might occur via inhalation; skin; eyes.
Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Inhaler propellant can cause skin irritation or frostbite.
Environment No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

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Material
SDS Number Version 06
Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
Skin Contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
NOTES TO HEALTH PROFESSIONALS
Medical Treatment Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist.
Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

Medical Conditions Caused or Aggravated by Exposure
This material may cause or aggravate cardiac arrhythmias allergy to any hazardous components.
Health Surveillance Procedures
Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes No specific antidotes are recommended.
HANDLING
General Requirements Normal room ventilation is expected to be adequate for the routine control
of fire and explosion hazards during handling of this material.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards
Aerosol containers may violently rupture when exposed to the heat of fire.
This product is non-flammable.
Special Firefighting Procedures
Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products
Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Ventilate area to dispel vapours present. Wear protective clothing and equipment consistent with the degree of hazard. Instruct all personnel not involved in clean-up operations to keep at a designated safe distance.
Environmental Precautions Prevent entry into waterways, sewers, surface drainage systems and poorly
ventilated areas.
Clean-up Methods Allow any released liquid to evaporate.
Decontamination Procedures
No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

STORAGE No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. Store in a well ventilated area away from heat. The recommended temperature for storage is 15-25 °C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT SALBUTAMOL
Hazard Category
3
Exposure Limit
10 mcg/m3 (8 HR TWA)
PERSONAL PROTECTIVE EQUIPMENT
Eye Protection Wear approved safety glasses with side shields if eye contact is possible.

Other Equipment or Procedures
None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Physical Form Aerosol.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.
Conditions to Avoid Avoid direct sunlight, conditions that might generate heat and sources of ignition.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.
Inhalation Toxicity Adverse effects might occur following inhalation.
Skin Effects Irritation is not expected following direct contact.
Eye Effects Irritation is not expected following direct contact with eyes.
Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: cardiovascular system; respiratory system.
Sensitisation Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects Contains components which have been classified as: Toxicity to developing human offspring is not expected under occupational exposure conditions.
Pharmacological Effects This material is a beta 2 adrenergic agonist. It is an agent intended for the treatment of asthma. Adverse effects of overexposure might include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) increased heart rate; hallucinations; muscle cramps; nausea; vomiting; headache; dizziness; insomnia.
Other Adverse Effects Inhaler propellant can cause skin irritation or frostbite.

12. ECOLOGICAL INFORMATION

*** Summary** This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.
ECOTOXICITY
Aquatic
*** Activated Sludge**
Respiration
IC50: > 830 mg/l, 3 Hours, Activated sludge
This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
*** Daphnid**
EC50: 243 mg/l, 48 Hours, Daphnia magna, Static test
NOEL: 83.2 mg/l, 48 Hours, Daphnia magna, Static test
This material contains an active pharmaceutical ingredient that is not toxic to daphids.
MOBILITY
*** Solubility** This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

*** Volatility** This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. This material contains an active pharmaceutical ingredient that will not readily enter into air from water.
Henry's Law Constant 5.00E-14 atm m^3/mol, Calculated at 20 C
*** Adsorption**
-1.6 to -1.15, Measured Soil Sediment Sorption
(log Koc):
This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.
*** Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
PERSISTENCE/DEGRADATION
*** Hydrolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.
Half-Life, Neutral: > 1 Years, Measured
*** Photolysis** This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.
UV/Visible Spectrum: 225 nm
*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).
Percent Degradation: 1 %, 28 days, Modified Sturm test.
Aerobic - Ready
Aerobic - Soil
Percent Degradation: 1.3 to 38.7 %, 64 days

13. DISPOSAL CONSIDERATIONS

Disposal
Recommendations
Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.
Regulatory Requirements Observe all local and national regulations when disposing of this material.
The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only
authorised persons trained and competent in accordance with appropriate national and international
regulatory requirements may prepare dangerous goods for transport.

14. TRANSPORT INFORMATION

Proper Shipping Name
Packing Group
Class/Division
Inhalers, non-flammable
Risk Label(s)
Not applicable
International Air Transport (IATA Requirements)
Proper Shipping
Name/Description

Consumer Commodity
Subsidiary Risk None
Packing Group Not applicable (use packing instruction 910).
International Maritime Transport (IMDG Requirements)
Proper for Maritime transport
Classification and
Labelling
Not subject to provisions of IMDG Code, see SP 190 and 191.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be
considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.
EU Classification and Labelling
Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal
product, cosmetic product or medical device.
US OSHA Standard (29 CFR Part 1910.1200)
Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
Other US Regulations
TSCA Status Exempt

16. OTHER INFORMATION

US Domestic Transport (DOT Requirements)
Consumer Commodity, ORM-D
ORM-D
Not applicable.
Not applicable
Proper Shipping Name
DOT Hazard
Class/Division
UN/NA Number
Packing Group
Marine Pollutant Status Not listed
US Emergency Response
Guide Number
171
European Ground Transport (ADR/RID Requirements)
Classification and
Labelling
Not subject to provisions of ADR, see SP 190 and 191.

Sections Subsections
Emergency Action Code TRANSPORT INFORMATION
Emergency Response Guide Number
EMS Number
European Ground Transport
Exceptions
Hazard Identification Number
Item
Marginal
Marine Pollutant
MFAG Number
NA Number
Packing Group

Packing Instructions
Proper Shipping Name
Reportable Quantity (RQ)
Special Precautions for Transport
Subsidiary Risk
Summary
Technical Name
Transport Category
Transport Classification and Labelling
Transport Label(s)
Tremcard Number
UN Number
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate
as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the
responsibility of the user to determine the applicability of this information and the suitability of the material
or product for any particular purpose.