

MATERIAL SAFETY DATA SHEET

MSDS No.: 000100

ProAir[®] HFA (Albuterol Sulfate) Inhalation Aerosol

Revision No.: 004

Date: 12/20/07

PRODUCT AND COMPANY INFORMATION - SECTION 1

Distributor:	TEVA Specialty Pharmaceuticals
	425 Privet Road
	Horsham, PA 19044
Product Name:	ProAir [®] HFA (Albuterol Sulfate) Inhalation Aerosol
Synonyms:	N/A
Intended Use:	Medicinal

**FOR CHEMICAL EMERGENCY, SPILL, LEAK,
FIRE, EXPOSURE, OR ACCIDENT:
INFOTRAC, INC 1-800-535-5053**

COMPOSITION INFORMATION - SECTION 2

Chemical Name	Percent	CAS Number	Exposure Limits
Albuterol Sulfate	Proprietary	51022-70-9	None
Dehydrated Alcohol USP (Ethanol)	Proprietary	64-17-5	1000 ppm
HFA 134a	Proprietary	000811-97-2	1000 ppm

HAZARDS IDENTIFICATION - SECTION 3

EMERGENCY OVERVIEW & HAZARDS PRESENT TO MAN AND THE ENVIRONMENT

Product is an aerosol under pressure, avoid temperature extremes.

REGULATORY STATUS

This material is classified as NON hazardous under OSHA regulations.

PRIMARY ROUTES OF EXPOSURE

Inhalation, Skin, Eye.

POTENTIAL HEALTH EFFECTS

Eyes: The aerosol may produce eye discomfort and transient burning or blinking.

Skin: The aerosol / liquid may be cold on contact.

Inhalation: This is not considered to cause discomfort through normal use.

Ingestion: It is considered an unlikely route of entry in commercial/industrial environments.

MATERIAL SAFETY DATA SHEET

MSDS No.: 000190

ProAir[®] HFA (Albuterol Sulfate) Inhalation Aerosol

Revision No.: 004

Date: 12/20/07

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE

None

CHRONIC HEALTH EFFECTS

Eyes: It is considered an unlikely route of entry in commercial/industrial environments.

Skin: It is considered an unlikely route of entry in commercial/industrial environments.

Inhalation: It is considered an unlikely route of entry in commercial/industrial environments.

Ingestion: It is considered an unlikely route of entry in commercial/industrial environments.

FIRST AID MEASURES – SECTION 4
SEEK MEDICAL ATTENTION FOR ALL CASES OF OVEREXPOSURE
FIRST AID MEASURES

Eyes: If this product comes in contact with the eyes: 1) Immediately hold the eyes open and wash continuously for at least fifteen (15) minutes with fresh running water, 2) Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving eyelids by occasionally lifting the upper and lower lids,

Skin: If product comes in contact with the skin: 1) Wash affected areas thoroughly with water (and soap if applicable), 3) Seek medical attention in event of irritation.

Inhalation: If fumes or combustion products are inhaled: 1) Remove to fresh air, 2) Lay patient down, keep warm and rested, 3) If breathing is shallow or has stopped, ensure clear airway and apply resuscitation, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask, as trained. Perform CPR if necessary, 4) Transport to hospital or doctor.

Ingestion: It is considered an unlikely route of entry in commercial/industrial environments.

Instructions for Physician: Treat symptomatically. Adrenaline and similar sympathomimetic drugs should be avoided following exposure as cardiac arrhythmia may result.

FIRE FIGHTING MEASURES – SECTION 5
NFPA Classification

Health	Fire	Reactivity	Other
1	0	0	N/A

MATERIAL SAFETY DATA SHEET

MSDS No.: 000100

ProAir® HFA (Albuterol Sulfate) Inhalation Aerosol

Revision No.: 004

Date: 12/20/07

FLAMMABILITY PROPERTIES		
Flash Point: N/A	Method:	
Flammability Limits:	LEL:	UEL:

Auto-Ignition Temperature: N/A
Hazardous Combustion Products: CO, CO ₂
Extinguishing Media: Water, dry chemical, CO ₂
Prohibited Extinguishing Media: N/A
Firefighting Instructions: Firefighters should wear self-contained breathing apparatus (SCBA) and flame and chemical resistant clothing.
Unusual Fire and Explosion Hazards: Product is an aerosol under pressure avoid extreme temperatures

ACCIDENTAL RELEASE MEASURES – SECTION 6

Personnel Precautions: Control personal contact by using protective equipment
Environmental Precautions: Prevent liquid from entering sewers or waterways.
Cleanup Methods: Remove all ignition sources. Clean up all spills immediately. Avoid breathing vapors and contact with skin and eyes. Contain and absorb small quantities with vermiculite or other absorbent material.

HANDLING & STORAGE – SECTION 7

Handling: Keep away from heat, spark, flame, and other ignition sources. Do not break or puncture canisters. Avoid contact with skin and eyes. Avoid inhalation.
Storage: Store away from incompatible materials store in a cool, dry, well-ventilated area. Protect containers against physical damage.
Specific Uses: Metered Dose Inhaler for bronchial use.

EXPOSURE CONTROLS / PERSONAL PROTECTION – SECTION 8

EXPOSURE CONTROLS:		
Exposure Limit Values:		
	OSHA PEL	ACGIH TLV
Albuterol	1000 ppm	N/A
Formoterol	1000 ppm	1000 ppm
Engineering Controls:		
N/A		

MATERIAL SAFETY DATA SHEET

MSDS No.: 000100

ProAir[®] HFA (Albuterol Sulfate) Inhalation Aerosol

Revision No.: 004

Date: 12/20/07

PERSONAL PROTECTIVE EQUIPMENT:

Respiratory Protection: Use engineering controls. If exposure to ethanol and mist is expected, wear a positive air pressure respirator (PAPR) with an organic vapor cartridge, High Efficiency Particulate Air (HEPA) filter or use a positive pressure air-line supply.

Hand Protection: Nitrile Gloves.

Eye/Face Protection: Wear chemical safety goggles and/or a face shield.

Skin Protection: Wear proper protective clothing and gloves to prevent exposure to the skin.

General Hygiene Considerations: Wash hands following use. No eating, drinking, or smoking when using this product.

Other Protective Equipment: Lab coat.

PHYSICAL & CHEMICAL PROPERTIES – SECTION 9

PRODUCT: ProAir[®] HFA (Albuterol Sulfate) Inhalation Aerosol

General Information:

Appearance _____ Aerosol

Odor _____ Mild

Important Health, Safety, and Environmental Information:

Boiling Point _____ Not Applicable

Melting Point _____ Not Applicable

Flash Point _____ Not Applicable

Specific Gravity ($H_2O = 1$) _____ Not Available

Water Solubility _____ Miscible (Ethanol)

Vapor Pressure (mm Hg) _____ Not Available

Evaporation Rate _____ Not Available

% Volatile (by Volume @ 20 °C) - Not Applicable

STABILITY & REACTIVITY – SECTION 10

Stability: Stable.

Conditions to Avoid: Excessive heat, open flame, poorly ventilated areas.

Materials to Avoid: Oxidizers, alkali and fines of metals.

Hazardous Decomposition Products: CO, CO₂

Hazardous Polymerization: Will not occur.

TOXICOLOGICAL INFORMATION – SECTION 11

High exposures of HFA 134a may cause an abnormal heart rhythm and prove suddenly fatal. Very high atmospheric concentrations may cause anesthetic effects and asphyxiation. **Acute Toxicity:** Low acute toxicity

MATERIAL SAFETY DATA SHEET

MSDS No.: 000100

ProAir[®] HFA (Albuterol Sulfate) Inhalation Aerosol

Revision No.: 004

Date: 12/20/07

ECOLOGICAL INFORMATION – SECTION 12

Eco-toxicity: Not available.

Mobility: Not available

Persistence and Degradability: Not available

Bioaccumulative Potential: Not available

DISPOSAL CONSIDERATION – SECTION 13

Dispose of in accordance with federal, state and local regulations.

TRANSPORT INFORMATION - SECTION 14

For all modes of transportation this product is not regulated.

REGULATORY INFORMATION – SECTION 15

US REGULATIONS

ACGIH	ACGIH TLV: 1860 mg/m ³ , 1000 PPM
CAA Section 112	No Applicable Information
CERCLA	No Applicable Information
IARC	No Applicable Information
NTP	No Applicable Information
OSHA	1860 mg/m ³ , 1000 PPM
SARA Title III	No Applicable Information
TSCA	Not Listed

OTHER INFORMATION - SECTION 16

Revision Number	Revision Date
004	12/20/07

To the best of our knowledge, the information contained herein is accurate. However, neither TEVA nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Author: R. Scroggins, Teva Specialty Pharmaceuticals