



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

Fluticasone & Salmeterol HFA Inhalation Aerosol - AR

Product Identification Numbers

EH-9000-2382-9, EH-9000-2384-5, EH-9000-2421-5, EH-9000-2422-3, EH-9000-2461-1, EH-9000-2478-5, EH-9000-2480-1, EH-9000-2482-7, EH-9000-2483-5, EH-9000-2486-8, EH-9000-2487-6, EH-9000-2488-4, EH-9000-2503-0, EH-9000-2514-7, EH-9000-2515-4, EH-9000-2516-2, EH-9000-2521-2, EH-9000-2522-0, EH-9000-2545-1

1.2. Recommended use and restrictions on use

Recommended use

Pharmaceutical

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Drug Delivery Sys Div
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number

1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

2.1. Hazard classification

Reproductive Toxicity: Category 2.

Simple Asphyxiant.

Specific Target Organ Toxicity (single exposure): Category 2.

2.2. Label elements

Signal word

Warning

Symbols

Health Hazard |

Pictograms



Hazard Statements

Suspected of damaging fertility or the unborn child.
 May displace oxygen and cause rapid suffocation.

May cause damage to organs:
 cardiovascular system |

Precautionary Statements

Prevention:

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe dust/fume/gas/mist/vapors/spray.
 Wear protective gloves.
 Do not eat, drink or smoke when using this product.
 Wash thoroughly after handling.

Response:

IF exposed or concerned: Call a POISON CENTER or doctor/physician.

Storage:

Store locked up.

Disposal:

Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

Notes to Physician:

Exposure may increase myocardial irritability. Do not administer sympathomimetic drugs unless absolutely necessary.

2.3. Hazards not otherwise classified

Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
HFA 134a	811-97-2	95 - 99 Trade Secret *
ETHYL ALCOHOL	64-17-5	1 - 5 Trade Secret *
FLUTICASONE PROPIONATE	80474-14-2	0.05 - 1 Trade Secret *
SALMETEROL	497063-94-2	0.01 - 0.1 Trade Secret *
OLEIC ACID	112-80-1	0.001 - 0.1 Trade Secret *

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:

Remove person to fresh air. Get medical attention.

Skin Contact:

Wash with soap and water. If you feel unwell, get medical attention.

Eye Contact:

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If Swallowed:

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

See Section 11.1. Information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required

Exposure may increase myocardial irritability. Do not administer sympathomimetic drugs unless absolutely necessary.

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode. Exposure to extreme heat can give rise to thermal decomposition.

Hazardous Decomposition or By-Products

Substance

Carbon monoxide
Carbon dioxide
Hydrogen Fluoride

Condition

During Combustion
During Combustion
During Combustion

5.3. Special protective actions for fire-fighters

When fire fighting conditions are severe and total thermal decomposition of the product is possible, wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

If possible, seal leaking container. Place leaking containers in a well-ventilated area, preferably an operating exhaust hood, or if necessary outdoors on an impermeable surface until appropriate packaging for the leaking container or its contents is available. Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not breathe thermal decomposition products. Do not use in a confined area with minimal air exchange. Do not handle until all safety precautions have been read and understood. Do not pierce or burn, even after use. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Use personal protective equipment (gloves, respirators, etc.) as required.

7.2. Conditions for safe storage including any incompatibilities

Protect from sunlight. Do not expose to temperatures exceeding 50C/122F. Store away from heat.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments
ETHYL ALCOHOL	64-17-5	ACGIH	STEL:1000 ppm	A3: Confirmed animal carcin.
ETHYL ALCOHOL	64-17-5	OSHA	TWA:1900 mg/m3(1000 ppm)	
HFA 134a	811-97-2	AIHA	TWA:4240 mg/m3(1000 ppm)	

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

OSHA : United States Department of Labor - Occupational Safety and Health Administration

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls

For those situations where the material might be exposed to extreme overheating due to misuse or equipment failure, use with appropriate local exhaust ventilation sufficient to maintain levels of thermal decomposition products below their exposure guidelines. Do not remain in area where available oxygen may be reduced. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Safety Glasses with side shields

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing.

Gloves made from the following material(s) are recommended: Butyl Rubber

Neoprene

Nitrile Rubber

Respiratory protection

Use a positive pressure supplied-air respirator if there is a potential for over exposure from an uncontrolled release, exposure levels are not known, or under any other circumstances where air-purifying respirators may not provide adequate protection. An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece air-purifying respirator suitable for organic vapors and particulates

For questions about suitability for a specific application, consult with your respirator manufacturer.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form:	Gas
Specific Physical Form:	Aerosol Metered Dose Inhaler (MDI)
Odor, Color, Grade:	White to off-white, slight ethereal odor
Odor threshold	<i>No Data Available</i>
pH	<i>No Data Available</i>
Melting point	<i>Not Applicable</i>
Boiling Point	-26.1 °C
Flash Point	<i>Not Applicable</i>
Evaporation rate	<i>No Data Available</i>
Flammability (solid, gas)	Non-flammable Aerosol: Category 3.
Flammable Limits(LEL)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapor Pressure	96 psia [@ 25 °C]
Vapor Density	3.6 [@ 25 °C]
Density	1.12 g/ml
Specific Gravity	1.12 [<i>Ref Std: WATER=1</i>]
Solubility In Water	<i>No Data Available</i>
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>No Data Available</i>
Autoignition temperature	<i>Not Applicable</i>
Decomposition temperature	<i>Not Applicable</i>
Volatile Organic Compounds	<i>No Data Available</i>
VOC Less H2O & Exempt Solvents	<i>No Data Available</i>

SECTION 10: Stability and reactivity

10.1. Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat

Sparks and/or flames

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

Extreme heat arising from situations such as misuse or equipment failure can generate hydrogen fluoride as a decomposition product.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:

Intentional concentration and inhalation may be harmful or fatal.

Simple Asphyxiation: Signs/symptoms may include increased heart rate, rapid respirations, drowsiness, headache, incoordination, altered judgement, nausea, vomiting, lethargy, seizures, coma, and may be fatal.

Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

May cause target organ effects after inhalation.

Skin Contact:

Contact with the skin during product use is not expected to result in significant irritation.

Eye Contact:

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion:

Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Target Organ Effects:

Single exposure may cause:

Cardiac Sensitization: Signs/symptoms may include irregular heartbeat (arrhythmia), faintness, chest pain, and may be fatal.

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

Additional Information:

This product contains ethanol. Alcoholic beverages and ethanol in alcoholic beverages have been classified by the International Agency for Research on Cancer as carcinogenic to humans. There are also data associating human consumption of alcoholic beverages with developmental toxicity and liver toxicity. Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer, developmental toxicity, or liver toxicity.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE > 5,000 mg/kg
HFA 134a	Inhalation-Gas (4 hours)	Rat	LC50 > 359,300 ppm
ETHYL ALCOHOL	Dermal	Rabbit	LD50 > 15,800 mg/kg
ETHYL ALCOHOL	Inhalation-Vapor (4 hours)	Rat	LC50 124.7 mg/l
ETHYL ALCOHOL	Ingestion	Rat	LD50 17,800 mg/kg
OLEIC ACID	Dermal	Guinea pig	LD50 > 3,000 mg/kg
OLEIC ACID	Ingestion	Rat	LD50 57,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
HFA 134a	Rabbit	No significant irritation
ETHYL ALCOHOL	Rabbit	No significant irritation
OLEIC ACID	Rabbit	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
HFA 134a	Rabbit	No significant irritation
ETHYL ALCOHOL	Rabbit	Moderate irritant
OLEIC ACID	Rabbit	Mild irritant

Skin Sensitization

Name	Species	Value
ETHYL ALCOHOL	Human	Some positive data exist, but the data are not sufficient for classification

Respiratory Sensitization

Name	Species	Value
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Germ Cell Mutagenicity

Name	Route	Value
ETHYL ALCOHOL	In Vitro	Some positive data exist, but the data are not sufficient for classification
ETHYL ALCOHOL	In vivo	Some positive data exist, but the data are not sufficient for classification
OLEIC ACID	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
ETHYL ALCOHOL	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification
OLEIC ACID	Dermal	Mouse	Not carcinogenic

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OLEIC ACID	Ingestion	Rat	Not carcinogenic
OLEIC ACID	Not Specified	Multiple animal species	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
ETHYL ALCOHOL	Inhalation	Not toxic to development	Rat	NOAEL 38 mg/l	during gestation
ETHYL ALCOHOL	Ingestion	Some positive developmental data exist, but the data are not sufficient for classification	Rat	NOAEL 5,200 mg/kg/day	prematuring & during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
HFA 134a	Inhalation	cardiac sensitization	May cause damage to organs	Dog	NOAEL 40,000 ppm	5 minutes
ETHYL ALCOHOL	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	LOAEL 2.6 mg/l	30 minutes
ETHYL ALCOHOL	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	LOAEL 9.4 mg/l	not available
ETHYL ALCOHOL	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Multiple animal species	NOAEL not available	
ETHYL ALCOHOL	Ingestion	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Dog	NOAEL 3,000 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
ETHYL ALCOHOL	Inhalation	liver	Some positive data exist, but the data are not sufficient for classification	Rabbit	LOAEL 124 mg/l	365 days
ETHYL ALCOHOL	Inhalation	hematopoietic system immune system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 25 mg/l	14 days
ETHYL ALCOHOL	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 8,000 mg/kg/day	4 months
ETHYL ALCOHOL	Ingestion	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Dog	NOAEL 3,000 mg/kg/day	7 days
OLEIC ACID	Ingestion	liver immune system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 2,250 mg/kg/day	108 weeks
OLEIC ACID	Ingestion	hematopoietic system	All data are negative	Rat	NOAEL 2,550 mg/kg/day	108 weeks

Aspiration Hazard

Name	Value
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Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

Ecotoxicological information

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. Facility must be capable of handling aerosol cans. The facility should be equipped to handle gaseous waste. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 14: Transport Information

For Transport Information, please visit <http://3M.com/Transportinfo> or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - Yes Pressure Hazard - Yes Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - Yes

15.2. State Regulations

Contact 3M for more information.

California Proposition 65

<u>Ingredient</u>	<u>C.A.S. No.</u>	<u>Classification</u>
FLUTICASONE PROPIONATE	80474-14-2	Developmental Toxin

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

15.3. Chemical Inventories

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification

Health: 3 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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