# SAFETY DATA SHEET



## 1. Identification

Product identifier FLOVENT HFA

Other means of identification

Svnonvms

FLOVENT HFA INHALATION AEROSOL \* FLIXOTIDE AEROSOL 134A \* FLIXOTIDE INHALER CFC FREE \* FLIXOTIDE EVOHALER \* ATEMUR MITE INHALER HFA 134A 50 MCG \* ATEMUR MITE INHALER HFA 134A 125 MCG \* ATEMUR FORTE INHALER HFA 134A 250 MCG \* AXOTIDE INHALER HFA \* BREXOVENT INHALER HFA \* FLUTIDE MITE 50 DOSIER-AEROSOL \* FLUTIDE 125 DOSIER-AEROSOL FCKW-FREI \* FLUTIDE FORTE 250 DOSIER-AEROSOL FCKW-FREI \* FLIXOTAIDE INHALER HFA \* NDC NO: 0173-0718-20 \* NDC NO: 0173-0720-20 \* FLUTICASONE PROPIONATE, FORMULATED PRODUCT

Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients about deposit processing.

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient. Medicinal Product

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US 5 Moore Drive

Research Triangle Park, NC 27709 USA

US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com Website: www.gsk.com EMERGENCY PHONE NUMBERS -TRANSPORT EMERGENCIES::

US / International toll call +1 703 527 3887

available 24 hrs/7 days; multi-language response

# 2. Hazard(s) identification

# **Classified hazards**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

#### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

# Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

# 3. Composition/information on ingredients

## **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
1,1,1,2-TETRAFLUOROETHANE	1,2,2,2-TETRAFLUOROETHANE * C2H2F4 * OHS76816	811-97-2	99.66 - 99.91

Chemical name	Common name and synonyms	CAS number	%
FLUTICASONE PROPIONATE	CCI18781 * FLUTICASONE THIOACID PROPIONATE * ANDROSTA-1,4-DIENE-17-CARBOTHIOIC ACID, 6,9-DIFLUORO-11-HYDROXY-16-METHYL- 3-OXO-17-(1-OXOPROP OXY)-, S-(FLUOROMETHYL)ESTER, (6ALPHA,11BETA, 16 ALPHA, 17ALPHA)- * FLUTICASONE 17-PROPIONATE * (6ALPHA,11BETA,16ALPHA, 17ALPHA)-6,9-DIFLUORO-11-HYDROXY-1 6-METHYL-3-OXO-17-( 1-OXOPROPOXY)ANDROSTA-1,4 -DIENE-17-CARBOTHIOIC ACID S-(FLUOROMETHYL) ESTER * S-FLUOROMETHYL) ESTER * S-FLUOROMETHYL 6ALPHA,9ALPHA-DIFLUORO-11BETA-HYD RXXYPHAAPRORIANEYLXXY-3-OXOANDRO STA-1,4-DIENE-17BETA-C ARBOTHIOATE * S-FLUOROMETHYL 6 ALPHA, 9 ALPHA-DIFLUORO-11 BETA-HYDROXY-16 ALPHA-METHYL-3-OXO-17 ALPHA-PROIONYLOXYANDRIOSTA-1,4-DI ONE-17 BETA-CARBOTHIOATE * 151 (GW ACN) * RTECS BV7980000 * (6ALPHA,11BETA,16ALPHA, 17ALPHA)-6,9-DIFLUORO-17-{[(FLUOROMETHYL-3-OXOANDR OSTA-1,4-DIEN-17-YL PROPANOATE * FLUTICASONE PROPIONATE (MICRONISED)	80474-14-2	0.09< 0.34

<sup>\*</sup>Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

# 4. First-aid measures

**Inhalation** If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended

use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing

and shoes. Take off contaminated clothing and wash before reuse. Get medical attention if

symptoms occur.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**Ingestion** If swallowed, rinse mouth with water (only if the person is conscious). Never give anything by

mouth to a victim who is unconscious or is having convulsions. If ingestion of a large amount does

occur, call a poison control center immediately.

Most important

symptoms/effects, acute and

delayed

The following adverse effects have been noted with therapeutic use of this material: increased susceptibility to infection; headache; drying of the nasal passages; Irritation of nose and throat.

Indication of immediate medical attention and special

treatment needed

**General information** 

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Treat according to locally accepted protocols. For additional guidance, refer to

the current prescribing information or to the local poison control information centre.

The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed

individuals should receive health surveillance focused on detecting skin conditions.

In the event of overexposure, individuals should receive post-exposure health surveillance focused

on detecting skin conditions and adrenal suppression.

## 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

media

Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

None known.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed. Pressurized container may explode when exposed to heat or flame.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Aerosol containers may violently rupture when exposed to the heat of fire.

# 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Prevent product from entering drains. Following product recovery, flush area with water.

**Environmental precautions** 

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

# 7. Handling and storage

Precautions for safe handling

Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Do not empty into drains. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

The pressure in sealed containers can increase under the influence of heat. Keep away from heat and flame. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). The recommended temperature for storage is 15 - 25 °C.

# 8. Exposure controls/personal protection

### **Occupational exposure limits**

G	S	K

Components	Туре	Value	Note
FLUTICASONE PROPIONATE (CAS 80474-14-2)	8 HR TWA	3 mcg/m3	
•	OHC	4	SKIN
		4	REPRODUCTIVE HAZARD
US. AIHA Workplace Environment	tal Exposure Level (WEEL) Guides		
Components	Туре	Value	
1,1,1,2-TETRAFLUOROET HANE (CAS 811-97-2)	TWA	4240 mg/m3	
,		1000 ppm	

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

Skin protection

**Hand protection** Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or

contamination.

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing

concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding

the exposure limits.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

For advice on suitable monitoring methods, seek guidance from a qualified environment, health

and safety professional.

# 9. Physical and chemical properties

**Appearance** 

Liquid. Physical state Aerosol. **Form** Color Not available. Odor Not available. Odor threshold Not available. Not available. Melting point/freezing point Not available.

Initial boiling point and boiling

-14.8 °F (-26 °C)

range

Flash point Not available. **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

Not available.

(%)

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available. Vapor pressure Not available. Not available. Vapor density

Relative density Solubility(ies)

Not available. Solubility (water) Partition coefficient Not available.

(n-octanol/water)

**Auto-ignition temperature** Not available. Not available. **Decomposition temperature** Viscosity Not available.

# 10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. **Chemical stability** Possibility of hazardous Hazardous polymerization does not occur.

reactions

Conditions to avoid

Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and

sources of ignition.

Strong oxidizing agents. Incompatible materials

Hazardous decomposition

products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

# 11. Toxicological information

Information on likely routes of exposure

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Pharmacological effects might occur following direct contact with skin. Repeated contact may

increase sensitivity of skin to bruising.

**Eye contact** May be irritating to eyes.

Ingestion Health injuries are not known or expected under normal use. However, ingestion is not likely to be

a primary route of occupational exposure. Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

The following adverse effects have been noted with therapeutic use of this material: increased susceptibility to infection; headache; drying of the nasal passages; Irritation of nose and throat.

Information on toxicological effects

Acute toxicity Harmful if swallowed. May be harmful in contact with skin.

Components Species Test Results

1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)

Acute

Inhalation

LCL0 Rat 567000 ppm, 4 hour

LOEC Rat 200000 mg/day CNS depression.

**Subchronic** 

Inhalation

NOAEC Rat 50000 ppm, 13 weeks

FLUTICASONE PROPIONATE (CAS 80474-14-2)

**Acute** 

Oral

LD50 Rat > 1000 mg/kg

**Subacute** 

Inhalation

NOAEL Rat 0.2 mcg/L/day, 28 Day

**Subchronic** 

Inhalation

 LOEL
 Rat
 3 mcg/kg/day, 26 weeks

 NOAEL
 Dog
 68 mcg/kg/day, 26 weeks

 Rat
 14 mcg/kg/day, 26 weeks

Skin corrosion/irritation Repeated contact may increase sensitivity of skin to bruising.

Corrosivity

FLUTICASONE PROPIONATE

OECD 404

Result: Negative

Irritation Corrosion - Skin: P.I.I. value

FLUTICASONE PROPIONATE 0

Serious eye damage/eye

May be irritating to eyes.

irritation

Eye

FLUTICASONE PROPIONATE OECD 405
Result: Negative

Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization None known.

**Skin sensitization** Allergic skin reactions might occur following repeated contact with this material in susceptible

individuals.

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<sup>\*</sup> Estimates for product may be based on additional component data not shown.

Sensitization

FLUTICASONE PROPIONATE 0 % OECD 406

Result: Negative Species: Guinea pig

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

1,1,1,2-TETRAFLUOROETHANE Ames

Result: Negative

FLUTICASONE PROPIONATE Ames

Result: Negative

Bacterial High Throughput Fluctuation Test

Result: Negative

Chinese Hamster Ovarian Cell Test

Result: Negative

1,1,1,2-TETRAFLUOROETHANE Chromosomal Aberration Assay In Vivo

Result: Negative

Dominant lethal assay, Inhalation study.

Result: Negative Species: Rat In vivo cytogenetics Result: Negative Micronucleus Assay

FLUTICASONE PROPIONATE Micronucleus Assay
Result: Negative
Result: Negative

Species: Mouse Micronucleus Test Result: Negative Species: Mouse SOS/umu Assay Result: Negative

1,1,1,2-TETRAFLUOROETHANE Unscheduled DNA Synthesis in vivo, Inhalation study.

Result: Negative Species: Rat

FLUTICASONE PROPIONATE Yeast

Result: Negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to

carcinogenicity to humans.

1,1,1,2-TETRAFLUOROETHANE 2500 - 5000 ppm Inhalation

Result: Negative Species: Rat Test Duration: 2 years 5000 ppm Inhalation Result: Negative Species: Rat

Test Duration: 78 weeks

FLUTICASONE PROPIONATE Inhalation

Result: Negative Species: Rat dermal Result: Negative Species: Mouse oral

Result: Negative

Species: Mouse

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in

laboratory animals.

Reproductivity

FLUTICASONE PROPIONATE 100 mcg/kg/day Embryofetal Development

Result: reduced foetal bodyweight, minor skeletal variations

Species: Rat

100 mcg/kg/day Female fertility (Segment I)

Result: reduced foetal bodyweight, minor skeletal variations

Species: Rat

Reproductivity

1,1,1,2-TETRAFLUOROETHANE 40000 ppm Foetal development - inhalation

Result: Maternal toxicity; Foetal NOAEL

Species: Rabbit

FLUTICASONE PROPIONATE 50 mcg/kg/day Pre- and Post-natal development

Result: maternal toxicity

Species: Rat

1,1,1,2-TETRAFLUOROETHANE 50000 ppm Foetal development - inhalation

Result: Maternal toxicity, delayed foetal development.

Species: Rat

FLUTICASONE PROPIONATE >= 25.7 mcg/kg/day Embryofetal Development

Result: maternal toxicity, reduced foetal body weight; no

malformations or other variations

Species: Rat

>= 45 mcg/kg/day Embryofetal Development

Result: cleft palate Species: Mouse

>= 50 mcg/kg/day Embryofetal Development

Result: maternal toxicity; reduced foetal weight; foetal

resorptions Species: Rabbit

SAR / QSAR, Glucocorticoid

Specific target organ toxicity -

single exposure 1,1,1,2-TETRAFLUOROETHANE

Species: Dog

Organ: Heart

Specific target organ toxicity -

repeated exposure

May cause damage to organs through prolonged or repeated exposure. Adrenal glands. Bone

tissue. Immune system.

Aspiration hazard Not established. Not likely, due to the form of the product.

**Chronic effects** Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause

adverse effects.

None known.

1,1,1,2-TETRAFLUOROETHANE 0, Asphyxiant

# 12. Ecological information

**Ecotoxicity**No information is available about the potential of this material to produce adverse environmental

effects. Contains a substance which causes risk of hazardous effects to the environment.

Components

FLUTICASONE PROPIONATE (CAS 80474-14-2)

Acute

IC50

Activated sludge

Acute

Acute

Crustacea EC50

Water flea (Daphnia magna) > 0.55 mg/l, 48 hours Static test

**Terrestrial** 

Acute

Earthworm EC50 Manure worm (Eisenia foetida) > 1000 mg/kg, 28 days

# Persistence and degradability

**Hydrolysis** 

Half-life (Hydrolysis-neutral) FLUTICASONE PROPIONATE

> 1 Years Measured

**Biodegradability** 

Percent degradation (Aerobic biodegradation-soil)

FLUTICASONE PROPIONATE 9 - 50 %, 64 days

**Bioaccumulative potential** 

Partition coefficient n-octanol / water (log Kow)

1,1,1,2-TETRAFLUOROETHANE 1.274

Material name: FLOVENT HFA

<sup>\*</sup> Estimates for product may be based on additional component data not shown.

Partition coefficient n-octanol / water (log Kow)

FLUTICASONE PROPIONATE 2.78

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

FLUTICASONE PROPIONATE 3.13 - 3.55 Estimated

Soil/sediment sorption - log Koc

FLUTICASONE PROPIONATE 3.41 - 3.83 Measured

Mobility in generalNot available.Other adverse effectsNot available.

13. Disposal considerations

**Disposal instructions**Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in

accordance with all applicable regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

# 14. Transport information

**DOT** 

UN number UN1950

UN proper shipping name

Transport hazard class(es)

Aerosols, non-flammable

Class 2.2 Subsidiary risk -Label(s) 2.2

Packing group Not applicable. Special precautions for user Not available.

Packaging exceptions306Packaging non bulkNonePackaging bulkNone

**IATA** 

UN number UN1950

**UN proper shipping name** Aerosols, non-flammable

Transport hazard class(es) 2.2 Subsidiary class(es) -

Packaging group Not available.

**Environmental hazards** No. Labels required 2.2 **ERG Code** 2L

Special precautions for user Not available.

Other information

Cargo aircraft only Allowed.

Passenger & cargo Allowed.

IMDG

UN number UN1950

UN proper shipping name AEROSOLS, asphyxiant

Transport hazard class(es)

Class 2 Subsidiary risk 5A Label(s) 2.2

Packing group Not applicable.

**Environmental hazards** 

Marine pollutant No.

Material name: FLOVENT HFA

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**EmS** 

Special precautions for user Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and Not available.

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

the IBC Code

DOT



IATA



**General information** 

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

# 15. Regulatory information

**US** federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

No

chemical

SARA 313 (TRI reporting)

Not regulated.

## Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

# Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

#### US state regulations

# US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

#### **US. Massachusetts RTK - Substance List**

Not regulated.

# US. New Jersey Worker and Community Right-to-Know Act

Not lieted

# US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

## **US. Rhode Island RTK**

Not regulated.

## **US. California Proposition 65**

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

### US - California Proposition 65 - CRT: Listed date/Developmental toxin

Inventory name

FLUTICASONE PROPIONATE (CAS 80474-14-2) Listed: May 15, 1998

#### **International Inventories**

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Toxic Substances Control Act (TSCA) Inventory

# 16. Other information, including date of preparation or last revision

 Issue date
 10-21-2014

 Revision date
 10-21-2014

Version # 18

United States & Puerto Rico

**Further information** HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 1\*
Flammability: 0
Physical hazard: 3

NFPA ratings Health: 1

Flammability: 0 Instability: 3

References GSK Hazard Determination

Material name: FLOVENT HFA SDS US

No

On inventory (yes/no)\*

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

# Disclaimer

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.

# **Revision Information**

This document has undergone significant changes and should be reviewed in its entirety.

Material name: FLOVENT HFA