



SAFETY DATA SHEET

1. Identification

Product identifier

FLOVENT HFA

Other means of identification

Synonyms

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: 0173-0719-20 * NDC NO: 0173-0720-20 * FLUTICASON 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 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 6ALPHA,9ALPHA-DIFLUORO-11BETA-HYD ROXY-16-PROPIONATE 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-[[[(FLUOROM ETHYL)DIPROXYRIBONY OSTA-1,4-DIEN-17-YL PROPANOATE * FLUTICASONE PROPIONATE (MICRONISED)	80474-14-2	0.09< 0.34

*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	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.
General information	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	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	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. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	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

GSK

Components	Type	Value	Note
FLUTICASONE PROPIONATE (CAS 80474-14-2)	8 HR TWA	3 mcg/m ³	
	OHC	4	SKIN REPRODUCTIVE HAZARD

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	TWA	4240 mg/m ³ 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.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

Physical state Liquid.

Form Aerosol.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range -14.8 °F (-26 °C)

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.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

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

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerization does not occur.

Conditions to avoid Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and sources of ignition.

Incompatible materials Strong oxidizing agents.

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		
<i>Inhalation</i>		
LCL0	Rat	567000 ppm, 4 hour
LOEC	Rat	200000 mg/day CNS depression.
Subchronic		
<i>Inhalation</i>		
NOAEC	Rat	50000 ppm, 13 weeks
FLUTICASONE PROPIONATE (CAS 80474-14-2)		
Acute		
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg
Subacute		
<i>Inhalation</i>		
NOAEL	Rat	0.2 mcg/L/day, 28 Day
Subchronic		
<i>Inhalation</i>		
LOEL	Rat	3 mcg/kg/day, 26 weeks
NOAEL	Dog	68 mcg/kg/day, 26 weeks
	Rat	14 mcg/kg/day, 26 weeks

* Estimates for product may be based on additional component data not shown.

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 irritation May be irritating to eyes.

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.

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

FLUTICASONE PROPIONATE

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

1,1,1,2-TETRAFLUOROETHANE

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

FLUTICASONE PROPIONATE

Test Duration: 2 years
5000 ppm Inhalation
Result: Negative
Species: Rat
Test Duration: 78 weeks
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 None known.

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.

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	Species	Test Results
FLUTICASONE PROPIONATE (CAS 80474-14-2)		
<i>Acute</i>		
IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic		
<i>Acute</i>		
Crustacea	Water flea (Daphnia magna)	> 0.55 mg/l, 48 hours Static test
Terrestrial		
<i>Acute</i>		
Earthworm	Manure worm (Eisenia foetida)	> 1000 mg/kg, 28 days

* Estimates for product may be based on additional component data not shown.

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

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 general Not available.

Other adverse effects Not 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 Aerosols, non-flammable
Transport hazard class(es)
Class 2.2
Subsidiary risk -
Label(s) 2.2
Packing group Not applicable.
Special precautions for user Not available.
Packaging exceptions 306
Packaging non bulk None
Packaging bulk None

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.

EmS

Not available.

Special precautions for user

Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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.

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)

Not regulated.

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)

Not listed.

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 chemical

No

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 (SDWA)

Not regulated.

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 listed.

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

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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
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
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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).

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

Issue date	10-21-2014
Revision date	10-21-2014
Version #	18
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

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.