

FLUTICASONE PROPIONATE

MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006
Revision: 04 – Revision date: April 5, 2012

SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product identifier

Product name: Fluticasone Propionate
CAS Number: 80474-14-2
EC Number: 617-082-4
INDEX Number: No data available
Registration Number: Not applicable
Molecular Weight: 500.58
Molecular Formula: C₂₅ H₃₁ F₃ O₅ S

1.2 Relevant identified uses of the substance

Common use: Anti - inflammatory API (Active Pharmaceutical Ingredient)

1.3 Details of the supplier of the safety data sheet

Company name: STERLING S.r.l
Address: Via della Carboneria, 30
06073 Solomeo di Corciano (PG) – Italy

E-mail address: qa.safety@sterling.it
Telephone: 075/5294001
Fax: 075/5294000

1.4 Emergency telephone number

Italy: +39 02 66101029 (Poison Information Centre Niguarda Ca' Granda – Milano)
Foreign countries: Contact the closest Poisons Information Centre.

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) N. 1272/2008 (CLP/GHS)

Repr. 1B - H360D
EUH066

2.1.2 Classification of the substance according to Directive 67/548/EEC

Repr. Cat. 1; R61
R66

Full text of R and H-phrases: see section 16

2.2 Label elements



Signal Word: **DANGER**

Hazard Statement

H360D : May damage the unborn child
EUH066 : Repeated exposure may cause skin dryness or cracking

Precautionary Statement

Prevention

P201 : Obtain special instructions before use
P202 : Do not handle until all safety precautions have been read and understood
P281 : Use personal protective equipment as required

Response

P308 + P313 : IF exposed or concerned: Get medical advice/attention

Storage

P405 : Store locked up

Disposal

P501 : Dispose of contents/container in accordance with local/regional/national/international

2.3. Other hazards

No data available

SECTION 3**COMPOSITION/INFORMATION ON INGREDIENTS****3.1. Substance**

Product name :	Fluticasone Propionate
Chemical name :	S-fluoromethyl-6 α ,9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxyandrosta-1,4-diene-17 β -carbothioate
Molecular Weight:	500.58
Molecular formula:	C ₂₅ H ₃₁ F ₃ O ₅ S
CAS No.:	80474-14-2
EC No:	617-082-4
Concentration:	Pure substance

3.2. Mixture

Not applicable

SECTION 4**FIRST AID MEASURES****4.1 Description of first aid measures**

General advice:	In case of contact with the substances immediately change contaminated clothing.
Ingestion:	In case of ingestion, if conscious, rinse mouth with water. If the casualty is unconscious, place in the recovery position.
Inhalation:	Remove casualty to fresh air as quickly as possible. Keep warm and at rest. If breathing is difficult, give oxygen if possible, or assisted ventilation.
Skin contact:	In case of skin contact with powders or solutions immediately rinse affected area with copious amount of water and then wash with soap and water. Remove contaminated clothing and shoes.
Eye contact:	Irrigate eyes with copious amounts of water for at least 10-15 min, holding eyelids apart to ensure thorough rinsing.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. However, the most frequent adverse effects of fluticasone propionate nasal spray involve the nasal mucous membranes. Epistaxis or sensations of nasal burning/irritation, nasopharyngeal or respiratory effects including nasal secretions containing blood have been reported. Rhinorrhea, sinusitis, sore throat, throat irritation and dryness, alteration or loss of sense of taste and/or smell, nasal congestion or blockage, or nasal dryness has been reported in patients receiving fluticasone propionate nasal spray in controlled studies or during postmarketing surveillance. Nasal septum excoriation, ulceration, or nasal septum crusting also has been reported. Reported effects on reproduction. (see sec. 11)

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER or doctor/physician for all cases of contact. Induce vomiting only if indicated by your doctor.

SECTION 5 FIRE-FIGHTING MEASURES

5.1 *Extinguishing media*

Suitable extinguishing media: Carbon Dioxide (CO₂), foam, dry chemical powder, water spray, and water jet, unless otherwise stated.

Unsuitable extinguishing media: None

5.2 *Special hazards arising from the substance*

Specific hazard(s): The product is combustible and, like the dust in general, can make an explosive mixture with air. When heated or in the event of a fire, vapors may be harmful to health: carbon oxides (CO_x) and sulphur oxides (SO_x).

5.3 *Advice for firefighters*

Special fire fighting procedures: Protective Equipment: Wear full fire resistant self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 *Personal precautions, protective equipment and emergency procedures*

Procedure(s) of personal precaution(s): Keep non-involved personnel away from the area of spillage.
Avoid the generation and spreading of dust.
Ventilate area.
Eliminate sources of ignition.
Avoid contact with skin, eyes and inhalation of dust.
Avoid contact with eyes and skin.
See also sections 8 (protective equipment)

6.2 *Environmental precautions*

Prevent product from entering sewers, rivers or other bodies of water.
If required, notify relevant authorities according to all applicable regulations.

6.3 *Methods and material for containment and cleaning up*

Collect free product with suitable mechanical means. Avoid creating dust by spraying the product with water, if there is no contraindication. Ventilate area and wash spill site after material pickup is complete. Transfer the gathered product and the washings to suitable tanks or containers and store/dispose according to relevant regulations.

6.4 *Reference to other sections*

See also sections 8 (protective equipment) and 13 (disposal).

SECTION 7

HANDLING AND STORAGE

7.1 Precautions for safe handling

Use of personal protective equipment must be consistent with good occupational hygiene practices.

Avoid contact with skin, eyes and clothing.

Avoid prolonged or repeated exposure.

Do not breathe dust.

Do not reuse contaminated clothing.

Do not eat, drink or smoke when using this product.

Wash hands thoroughly with soap and water before meals and after work shift.

7.2 Conditions for safe storage

Store at controlled room temperature. Store away from all heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials.

Fluticasone propionate is not intended for long-term storage. Keep container tightly closed in a cool, well ventilated place.

SECTION 8

EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameter

Exposure limit values (ACGIH 2010):

- TLV TWA: No data available
- TLV STEL: No data available

Monitoring procedures: Refer to Dir. 96/82/EC.

8.2 Exposure Controls

8.2.1 Appropriate engineering controls

When feasible, use closed loop systems or with local exhaust. When inside buildings or confined spaces, ensure adequate ventilation.

The lyophilized powder should be used in biological safety cabinets or in systems with equivalent content.

Provide eyewash fountains at the workplace.

8.2.2 Personal protection measures, such as personal protective equipment

Personal Protective Equipment: The personal protective equipment should be chosen in the configuration according to the concentration and quantity of hazardous substances specifically for the workplace.

a) Eye / Face Protection: Wear safety goggles (EN 166).

b) Skin and body Protection: Protective clothing global. Use rubber or synthetic gloves (EN 374).

c) Respiratory Protection: Avoid inhalation of dust, respiratory protection: dust mask with filter type P3 (EN 143).
Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

d) Heat Dangers: The product is not handled hot.

8.2.3 Environmental Exposure Controls

Use according to good manufacturing practices avoiding litter.

Take all the technical precautions necessary to prevent the spread of the product into the surrounding.



SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance	White crystalline powder
b) Odor	Petroleum odor
c) Odor threshold	No data available
d) pH	No data available
e) Melting point/freezing point	272-273 °C (decomposes)
f) Initial boiling point and boiling range	No data available
g) Flash point	Not applicable
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	No data available
l) Vapor density	No data available
m) Relative density	No data available
n) Solubility(ies)	Insoluble in water. Freely soluble in dimethylsulfoxide, dimethyl formate; slightly soluble in methanol, 95% ethanol.
o) Partition coefficient: n-octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	> 273 °C
r) Viscosity	Not applicable
s) Explosive properties	No data available
t) Oxidising properties	No data available

9.2. Other information

No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present additional dangers of reactivity than those reported in the next subtitles.

10.2 Chemical stability

Store at controlled room temperature. Store away from all heat sources, including direct sunlight, open flame, sources of ignition and sparks.

Fluticasone propionate is not intended for long-term storage. Keep container tightly closed in a cool, well ventilated place.

10.3 Possibility of hazardous reactions

Product does not polymerise.

10.4 Conditions to avoid

Heat. Static Electricity.

10.5 Incompatible materials

Store separately from oxidizing agents.

10.6 Hazardous decomposition products

Carbon oxides (CO_x), sulphur oxides (SO_x).

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. However, the most frequent adverse effects of fluticasone propionate nasal spray involve the nasal mucous membranes. Epistaxis or sensations of nasal burning/irritation, nasopharyngeal or respiratory effects including nasal secretions containing blood have been reported. Rhinorrhea, sinusitis, sore throat, throat irritation and dryness, alteration or loss of sense of taste and/or smell, nasal congestion or blockage, or nasal dryness has been reported in patients receiving fluticasone propionate nasal spray in controlled studies or during postmarketing surveillance. Nasal septum excoriation, ulceration, or nasal septum crusting also has been reported.

CLASS OF RELEVANT RISK FOR SUBSTANCE:

a) Acute toxicity:

Route	Specie	Results	Note	Reference
Oral	Rodent - rat	LD50 > 2 gm/kg	Nutrition and metabolism - weight loss or weight gain reduced.	YACHDS 20,1493,1992
Subcutaneous	Rodent - rat	LD50 >1 gm/kg	Nutrition and metabolism - weight loss or weight gain reduced.	YACHDS 20,1493,1992

			Endocrine - other changes. Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)	
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- b) *Skin corrosion / irritation:* May cause skin irritation.
- c) *Serious eye damage / serious eye irritation:* May cause eye irritation.
- d) *Respiratory / skin sensitization:* Not reported evidence concerning this effect
- e) *Germ cell mutagenicity* Not reported evidence concerning this effect
- f) *Carcinogenicity* Not reported evidence concerning this effect
- g) *Reproductive toxicity:*

Route	Specie	Results	Note	Reference
Subcutaneous	Rodent – rat female 7-17 day(s) after conception	TDLo - Lowest published toxic dose 1100 ug/kg	Effects on Embryo or Fetus – fetotoxicity (except death, e.g., stunted fetus). Specific Developmental - Abnormalities body wall. - Abnormalities musculoskeletal system. Maternal Effects – postpartum. Effects on Newborn – stillbirth Effects on Newborn – viability index (e.g., # alive at day 4 per # born alive)	YACHDS 20,1597,1992
Oral	Rodent – rat female 7-17 day(s) after conception	TDLo – Lowest published toxic dose 105 ug/kg	Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities - musculoskeletal system	YACHDS 20,1573,1992
Subcutaneous	Rodent – rat female 6-18 day(s) after conception	TDLo - Lowest published toxic dose 52 ug/kg	Specific Developmental Abnormalities - musculoskeletal system, respiratory system, hepatobiliary system	YACHDS 20,1643,1992

- h) *Specific target organ toxicity (STOT)-Single exposure-* The product may cause mild irritation of the mucous membranes and upper respiratory tract
- h) *Specific target organ toxicity (STOT)-Repeated exposure-* Not reported evidence concerning this effect
- j) *Aspiration hazard* Not applicable
- Other information* RTECS N. **BV7980000**

SECTION 12 ECOLOGICAL INFORMATION

Ecological Information: Use according to good manufacturing practices, avoid dispersion into the environment. Notify relevant authorities according to all applicable regulations if the product can reach waterways or sewers or contaminate soil or vegetation.

12.1 Toxicity

Not reported evidence concerning this effect

12.2 Persistence and degradability

Not reported evidence concerning this outcome

12.3 Bioaccumulative potential

Not reported evidence concerning this outcome

12.4 Mobility in soil

Not reported evidence concerning this outcome

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Prevent environmental discharge.
Dispose of waste or used sacks/containers according to local regulations.

SECTION 14 TRANSPORT INFORMATION

The substance is not considered dangerous within the meaning of the regulations governing the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and by air (IATA/ICAO).

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Authorizations according to REACH Regulation: the substance is not subjected

Restrictions according to REACH Regulation: the substance is not subjected

Other UE:

The substance is not dangerous under the Seveso Regulation (Dir. 96/82/CE and f.a.)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this product.

SECTION 16	OTHER INFORMATION
<i>List of relevant phrases</i>	Classification according to Regulation (EC) No 1272/2008 (CLP/GHS) as amended H360D: May damage the unborn child EUH066: Repeated exposure may cause skin dryness or cracking Classification according to European Directive 67/548/CEE as amended R61: May cause harm to the unborn child R66: Repeated exposure may cause skin dryness or cracking
<i>Guidelines for the formation</i>	Workers potentially exposed to this substance must be trained adequately on the basis of the contents of this MSDS.
<i>More information</i>	No data available
<i>Bibliography</i>	THE MERCK INDEX-XI Ed.(1989)- Merck & Co. Inc.-Rahway, N.J.- USA RTECS- Registry of Toxic Effects of Chemical Substances EDQM MSDS NCBI – PUBCHEM Compound Database BANCA DATI SOSTANZE CHIMICHE - ICARO S.R.L. - CORTONA (AR) Hazardous Substances Data Bank (HSDB®). Internal MSDS.
<i>Update Reason</i>	Update according to Annex I of Regulation UE453/2010 which amended Annex II of EC Regulation 1907/2006 (REACH).

Update 21/02/2011
Update Num. 3

The contained information is based upon our current understanding. It is applicable only to the indicated product and does not constitute any guarantee of the properties of the product. The user is responsible to ensure his or her own fitness and completeness of such information in relation to the specific use. The contained information is intended for the use of the product exclusively by appropriately qualified personnel. STERLING S.r.l. shall not be held liable for any damages caused from handling or from contact with the substance.

STERLING S.r.l.