

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: Fluticasone Propionate**
- **Article number:** 105883
- **CAS Number:**  
80474-14-2
- **EC number:**  
617-082-4
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Repr. 2                    H361d Suspected of damaging the unborn child.  
Aquatic Chronic 1   H410   Very toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS08   GHS09

- **Signal word** Warning
- **Hazard statements**  
H361d Suspected of damaging the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.
- **Precautionary statements**  
P273                    Avoid release to the environment.  
P280                    Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P308+P313 IF exposed or concerned: Get medical advice/attention.

**Trade name: Fluticasone Propionate**

(Contd. of page 1)

P391 Collect spillage.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### **SECTION 3: Composition/information on ingredients**

- **3.1 Substances**
- **CAS No. Description**  
CAS: 80474-14-2 Fluticasone Propionate
- **Identification number(s)**
- **EC number:** 617-082-4

### **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Carbon dioxide  
Foam  
Fire-extinguishing powder  
Water spray  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear fully protective suit.  
Wear self-contained respiratory protective device.

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.

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(Contd. on page 3)

Trade name: Fluticasone Propionate

(Contd. of page 2)

- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage:**
  - **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
  - **Information about storage in one common storage facility:** Not required.
  - **Further information about storage conditions:** Store receptacle in a well ventilated area.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Not required.
- **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not determined.

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(Contd. on page 4)  
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Trade name: Fluticasone Propionate

(Contd. of page 3)

· Melting point/freezing point:	273°C
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Product is not flammable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	297,5°C
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Not determined.
· Partition coefficient n-octanol/water (log value)	0,3962
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	
See section 3.	

· 9.2 Other information	
· Appearance:	
· Form:	Crystalline powder
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void

Trade name: Fluticasone Propionate

(Contd. of page 4)

· **Desensitised explosives** Void

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** Forms explosive gas mixture with air.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>2000 mg/kg (rat)
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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Suspected of damaging the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.

**Trade name: Fluticasone Propionate**

Also poisonous for fish and plankton in water bodies.

(Contd. of page 5)

## SECTION 13: Disposal considerations

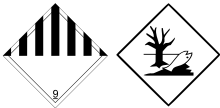
- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP10	Toxic for reproduction
HP14	Ecotoxic

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

- |                                                                                                                                                                                                         |                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR, IMDG, IATA</b>                                                                                                                                        | UN3077                                                                                                                                                              |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, IMDG</b><br><br>· <b>IATA</b>                                                                                                                        | ENVIRONMENTALLY HAZARDOUS<br>SUBSTANCE, SOLID, N.O.S. (Fluticasone<br>Propionate)<br>Environmentally hazardous substance, solid,<br>n.o.s. (Fluticasone Propionate) |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, IMDG, IATA</b><br><br><br><br>· <b>Class</b><br>· <b>Label</b> | 9 Miscellaneous dangerous substances and<br>articles.<br>9                                                                                                          |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                                                                                                                                 | III                                                                                                                                                                 |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b><br>· <b>Special marking (ADR):</b><br>· <b>Special marking (IATA):</b>                                                               | Symbol (fish and tree)<br>Symbol (fish and tree)<br>Symbol (fish and tree)                                                                                          |
| · <b>14.6 Special precautions for user</b><br><br>· <b>Hazard identification number (Kemler code):</b><br>· <b>EmS Number:</b><br>· <b>Stowage Category</b><br>· <b>Stowage Code</b>                    | Warning: Miscellaneous dangerous substances<br>and articles.<br>90<br>F-A,S-F<br>A<br>SW23 When transported in BK3 bulk container,<br>see 7.6.2.12 and 7.7.3.9.     |

(Contd. on page 7)

Trade name: Fluticasone Propionate

(Contd. of page 6)

· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· Transport category	3
· Tunnel restriction code	(-)
· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FLUTICASONE PROPIONATE), 9, III

## SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I Substance is not listed.
  - Seveso category E1 Hazardous to the Aquatic Environment
  - Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
  - DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II  
Substance is not listed.
  - REGULATION (EU) 2019/1148
  - Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))  
Substance is not listed.
  - Annex II - REPORTABLE EXPLOSIVES PRECURSORS Substance is not listed.
  - Regulation (EC) No 273/2004 on drug precursors Substance is not listed.
  - Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors  
Substance is not listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS: Fagron Česká republika

**Trade name: Fluticasone Propionate**

(Contd. of page 7)

- **Contact:** msds@fagron.cz
- **Abbreviations and acronyms:**
  - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Repr. 2: Reproductive toxicity – Category 2
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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