Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Fluticasone Propionate USP Micronized
Commercial Name Flixotide; Flovent; Flutide; Flutide-N
Product Use Not available.
Restrictions On Use Not available.

Product Code 30-4330

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Hazardous to the aquatic environment Aquatic Chronic 1

Signal Word WARNING

Hazard Statement(s) VERY TOXIC TO AQUATIC LIFE WITH LONG LASTING EFFECTS.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

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. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.

Storage Store locked up

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

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Fluticasone Propionate USP Micronized
% By Weight 100
CAS# 80474-14-2
Molecular Weight 500.57
Chemical Formula C25H31F3O5S
Synonym(s) Fluticasone 17-propionate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Fluticasone Propionate USP Micronized	80474-14-2	100		

PCCA

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Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately
Symptoms/Effects	
Acute	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials

Unsuitable Extinguishing Media

None known.

Products of Combustion

No unusual fire or explosion hazards noted.

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Wash spill site. Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 3 micrograms/m3 (skin)
Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

Section 9: Physical and Chemical Properties

Appearance	White powder.
Odor	Not available.
Odor Threshold	Not available.

Melting Point	501.8 - 523.4 °F (261 - 273 °	**pH**	Not available.
Freezing Point	501.8 - 523.4 °F (261 - 273 °	**Vapor Pressure**	Not available.
Boiling Point/Range	Not available	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	2.78	**Evaporation Rate**	Not available.
Flash Point	Not available	**Autoignition temperature**	Not available.
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	Insoluble in water. Dimethyl Sulfoxide: Freely soluble. Dimethylformamide: Freely soluble. 95 % Ethanol: Slightly soluble. Methanol: Slightly soluble. Dichloromethane: Sparingly soluble.
Other	Not available

Section 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.
Hazardous Polymerization	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Strong oxidising agents.
Hazardous Decomposition Products	F-, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS BV7980000

Acute Toxicity
Acute Oral: LD50 Rat > 2000 mg/kg

Skin Corrosion/Irritation
Not available.

Serious Eye Damage/Irritation
Not available.

Respiratory or Skin Sensitization
Not available.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
Suspected of damaging fertility or the unborn child. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.

Routes of Entry
Inhalation. Ingestion.

Symptoms Related to Exposure
Glucocorticoid effects: Bone fractures. Back pain. Joint pain or stiffness. Weakness. Increased appetite. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Increased hair growth. Acne. Redistribution of body fat. Menstrual irregularities. Impotence. Headache. Increased sweating. Eye pain. Change in vision. Mental or behavioral changes. Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.

Potential Health Effects
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Target Organ(s) Not available.

Section 12: Ecological Information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistance and Degradability
Not available.

Bioaccumulative Potential
Octanol/water partition coefficient log Kow 2.78

Mobility in Soil
Not available.

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

Waste Disposal
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal of Container
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner. 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

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information

Regulations
California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Fluticasone Propionate California prop. 65: This product contains the following ingredients for which the State of California has found to cause birth defects which would require a warning under the statute: Fluticasone Propionate

Other

WHMIS (Canada): Not controlled under WHMIS (Canada). DSCL (EEC): This product is not classified according to the EU regulations. - Exposure scenario attached X - Chemical Safety Assessment (CSA) attached X All other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet. Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

Section 16: Other Information

Revisions: - Edition n. 06 dated 03/04/2013 (General Revision) - Revision n. 05 Bibliographic sources: [1] The Merck Index-Thirteenth Edition [2] Data Bank ChemSpider [http://www.chemspider.com/Search.aspx] [3] USP-Material Safety Data Sheet: Fluticasone propionate [4] Daily Med- Current Medication Information-Cutivate (fluticasone propinate) cream [http://dailymed.nlm.nih.gov/dailymed/search.cfm?startswith=fluticasone+propionate] [5] Data Bank ChemIDplus Lite [http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp] [6] Edqm- European Directorate for the Quality of Medicines&HeathCare – Safety Data Sheet-Fluticasone propionate [http://crs.edqm.eu/] Data Bank HSDB- Hazardous Substances Data Bank [http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen] pubchem.ncbi.nlm.nih.gov stneasy.fiz-karlsruhe.de Acronyms - ACGIH: American Conference of Governmental Industrial Hygienists - ADR: Agreement concerning the carriage of dangerous goods by Road - BCF: Bioaccumulative factor - BEI : Biological Esposure Indices - CAS: Chemical Abstract Service (division of the American Chemical Society - CLP: Classification, Labelling and Packaging - CMR: Carcinogens, Mutagens, Toxic for re production substances - EINECS: European Inventory of existing Commercial Substances - EPA: US Environmental Protection Agency - GHS: Globally Harmonised System - IARC: International Agency for Research on Cancer - IATA: International Air Transport Association Code - IMDG: International Maritime Dangerous Goods Code - IUPAC: International Union of Pure and Applied Chemistry - LOEL: Lowest Observed Effect Level - N.A.: Not Applicable - N.A.: Not Available - NOAEL: No Observed Adverse Effect Level) - NTP: National Toxicology Program - OEL: Occupational Exposure Limit - OSHA: Occupational Safety and Health Administration - PPE : Personal protective Equipment - PBT: Persistent, Bioaccumulative and Toxic substances - RID: Regulation concerning the International carriage of Dangerous goods by rail - TLV/TWA: Threshold Limit Value/Threshold Weighte This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless adequate written information on how to handle the material are given. The provider of this document can not provide any warnings about the dangers of use or interaction with other chemicals or materials. It is responsibility of the user the safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.