

Section 1: Identification

Product Name BUDESONIDE USP MICRONIZED
Commercial Name Budesonide
Product Use Active Pharmaceutical Ingredient (API). Corticosteroid with glucocorticoid activity (treatment of as
Restrictions On Use Other uses are not expected
Product Code 55-4475
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: Reproductive toxicity Category 2 Aquatic Chronic 3
CFR 1910.1200

Signal Word WARNING

Hazard Statement(s) Suspected of damaging fertility or the unborn child. Harmful to aquatic life with long lasting effects.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P273 - Avoid release to the environment 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 regulation

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Budesonide Micronize
% By Weight 100
CAS# 51333-22-3
Molecular Weight 430.59 g/mole
Chemical Formula C25-H34-O6
Synonym(s) (11-beta, 16-alpha)-16,17-(Buthlid nebis(oxy))-11,21-dihydroxypregna ,4-diene-3,20-dione

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
1) Budesonide	51333-22-3	100	Not available.	ORAL (LD50): Acute: 3200 mg/kg [Rat]. 4750 mg/kg [Mouse].

Section 4: First-Aid Measures

Inhalation	In case of hazardous vapors formation, immediately remove the person from the exposed area to fresh air. Get medical advice if adverse symptoms will appear.
Skin Contact	Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice immediately.
Eye Contact	Wash immediately with large amounts of water or normal saline solution. Keep eyelids open with the finger. Get medical advice and show the label.
Ingestion	If swallowed wash mouth with water provided person is conscious. Get medical advice immediately and show container or label.
Symptoms/Effects	
Acute	Possible acute effects are: headache, dizziness, cough, nausea, abdominal pain, vomiting, fatigue, backache. More serious possible effects are itching, rash, swelling of face and neck, difficulty in breathing, distorted vision, acne, bruising.
Delayed	Delayed effects and symptoms related to this substance are not foreseen.

Immediate Medical Attention

- Medical monitoring: Foreseen on the base of the classification of the substance. - Antidotes, if known: Unknown -
Contraindications: Unknown - Immediate treatment at workplace: Not foreseen

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Nebulised water, chemical powder, foam, CO2

Unsuitable Extinguishing Media

Not available

Products of Combustion

Not available.

Firefighters Special Equipment and Precautions

- Technical actions for protection: Do not try to extinguish the fire without an autonomous respiratory device (SCBA) and suitable protective clothes. - Special protective equipment for firefighters: Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in the highest conditions of protection on the basis of the information reported in the previous sub-sections

Section 6: Accidental Release Measures

For non-emergency personnel: - Eye: Wear suitable protective devices. (see section 8) - Skin: Wear suitable clothes with full body protection. - Inhalation: In case of fire and/or explosions avoid to breathe smokes and vapors. Use an autonomous respiratory device (SCBA) and suitable protective clothes. The vapors can be eliminated with nebulized water. Environmental precautions: In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Containment procedures: Collect all the material scattered on the ground with suitable protective equipment and put it in a clean and dry container. Cleaning up procedures: Recover the substance by suction or with other mechanic means and wash the area with plenty of water and cleanings. Store the recovered product in wait of the skilled disposal society. If the effusion happened in highway or in a public place, suitable expedients should be adopted in order to protect people from any risks.

Section 7: Handling and Storage

Recommendation for handling: Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place Avoid contact with incompatible materials Wear suitable Personal Protection Equipment (see section 8) Keep the substance away from drains, surface or ground waters Recommendation for personal hygiene: Do not eat, drink and smoke in the working areas Wash hands after handling the substance Remove contaminated clothing and protective equipment before entering eating areas Condition for safe storage including any incompatibilities: The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9. The substance is not classified for any physical and chemical properties and no risk management is foreseen. Risk Management measures related to : - Potential ignition sources: Do not expose to heat sources. Procedure to control other effects - Weather conditions: No procedure of restriction is expected. - Ambient pressure: No procedure of restriction is expected. - Temperature: Store at room temperature. - Sunlight: Do not expose to the direct light of the sun. - Humidity Do not store in a damp place. - Vibration: No procedure of restriction is expected. The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available (ingredients in the substance are not yet REACH registered). Material to keep the integrity of the substance - Stabilisers: Use of stabilisers is not expected - Antioxidants: Use of antioxidants is not expected Other advices - Ventilation requirements Requested on the base of the storage of the substance

Section 8: Exposure Controls/Personal Protection**Exposure Limits**

Exposure Limits Not present in data banks consulted - Other National/European Occupational Exposure Limits Not present in data banks consulted - National/European Biological Limits (BEI): Not present in data banks consulted - Other National/European Biological Limits (BEI): Not present in data banks consulted - Recommended monitoring procedures The measurement of substances in the workplace should be performed with standardized methods (eg UNI EN 689:1997: Atmosphere at work - Guidance on assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, UNI EN 482:2006: atmospheres in the workplace - General requirements for performance of procedures for the measurement of chemical agents) or, in their absence, with appropriate methods. - DNEL values (components) Chemical Safety Report has not been performed - PNEC values (components) Chemical Safety Report has not been performed

Engineering Controls

The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario described in the Reach registration Dossier is not available.

Personal Protection

Eye and Face protection: Safety goggles as for EN 166; facial shield Skin protection - Hands protection Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/EEC. The gloves material must be waterproof and stable against the substance content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness. Material: nitrile (nitrile rubber), hypoallergenic Thickness: not inferior to 0.12 mm - Other, body protection Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of sketches or EN 13982 in case of powders Respiratory protection When the risk evaluation foresees the need to use respiratory devices with assisted ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU). In case of brief exposure or low pollution use respiratory filter. In case of deeper and longer exposures use self-contained breathing apparatus. Thermal hazards Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

Section 9: Physical and Chemical Properties

Appearance	White or almost white crystalline powder		
Odor	Odorless.		
Odor Threshold	Not available.		
Melting Point	221-232 °C	pH	Not available.
Freezing Point	Not available.	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	2.180	Evaporation Rate	Not available.
Flash Point	202 °C	Autoignition temperature	Not available.
Flammability	Not available.	Flammability or Explosive Limits:	
		Lower	Not available.
		Upper	Not available.
Solubility(ies)	Practically insoluble in water. Freely soluble in methylene chloride, sparingly soluble in ethanol (96%)		
Other	Henry's Law Constant: 6.56 x10 ⁻¹³ atm-m ³ /mol		

Section 10: Stability and Reactivity

Reactivity	This substance is considered not reactive under the normal conditions of the usage.
Chemical Stability	The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.
Hazardous Polymerization	Not available.
Conditions to Avoid	Avoid exposure to light, air, moisture and excessive heat.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	If heated at high temperatures, the substance decomposes releasing fumes and toxic gases of COx.

Section 11: Toxicological Information

RTECS	TU3723000
Acute Toxicity	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged): - Ingestion: -Inhalation: -Skin contact: -Eye contact: Ingestion: possible abdominal and stomach pain Inhalation exposure: possible irritation of the mucous membranes and upper breathing intakes Contact with skin: possible redness Contact with eyes: possible burning sensation, redness of conjunctiva - Toxicokinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion): Peak plasma levels appears about 30 minutes after inhalation. Systemic bioavailability after inhalation is 73% and the concentration in human plasma after inhalation of a single dose of 1600 mcg is 0.63 nmol/l. Binding to plasma proteins is 85 to 90% and the volume of distribution about 3 l/kg. Plasma elimination half-life is approximately 2.8 hours in adults and significantly lower in children (1.5 hours). In healthy individuals, about 20 - 30% of the administered dose of budesonide reaches the lungs, on the basis of the dose declared. The remaining part is deposited in the mouth, nose and throat, and a considerable portion of it is swallowed. The swallowed portion is subjected to a high first pass effect in the liver. Budesonide is metabolized primarily in the liver by oxidation, catalyzed primarily by the enzyme CYP3A4. The major metabolites are the 6b-hydroxybudesonide and the 16a-hydroxyprednisolone that have a much lower pharmacological activity. This factor limits the systemic bioavailability and toxicity. [7] - Acute Toxicity - Oral: - Dermal: - Inhalation: - Other information: LD50 (rat): > 3200 mg / kg [3] LD50 (mouse): 4750 mg / kg [3] Not found after bibliographic research. TCL0 (man): 34 µg/kg[3] LD50 (subcutaneous-rat): 58.4 mg/kg [3] LD50 (intraperitoneal-rat): 138 mg/kg [3] - Acute Toxicity - Oral: - Dermal: - Inhalation: - Other information: LD50 (rat): > 3200 mg / kg [3] LD50 (mouse): 4750 mg / kg [3] Not found after bibliographic research. TCL0 (man): 34 µg/kg[3] LD50 (subcutaneous-rat): 58.4 mg/kg [3] LD50 (intraperitoneal-rat): 138 mg/kg [3] - Corrosion/Irritation effects: May be irritant - Severe ocular lesion : May be irritant - Sensitisation: - Dermal: May cause dermal sensitisation.[4] - Respiratory: Not found after bibliographic research - Repeated dose toxicity (experimental.): Risk of increased blood pressure, risk of eye damage, liver damage and edema[4] - CMR effects: - Germinal cell mutagenicity Ames test: negative.[6] Chromosome aberration test: negative.[6] Micronucleous test: negative.[6] - Reproductive toxicity: Experimental studies in rabbits and rats have shown defects in the offspring and death of fetuses at low and high doses[6] Aspiration hazards: May cause possible irritation of the mucous membranes and upper breathing intakes

Skin Corrosion/Irritation

Not available.

Serious Eye Damage/Irritation

Not available.

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity

Not found after bibliographic research

Reproductive Toxicity

Not available.

Routes of Entry

Absorbed through skin. Eye contact. Inhalation. Ingestion.

Symptoms Related to Exposure

Not available.

Potential Health Effects

May cause possible irritation of the mucous membranes and upper breathing intakes

Target Organ(s)

Not available.

Section 12: Ecological Information**Ecotoxicity**

Acute[4] LC50 (Fish): > 19 mg/l – 96 hours Aquatic invertebrates Acute[4] EC50 (Daphnia magna): 20 mg/l-48 hours Algae and aquatic plants Acute[4] IC50 (Algae): > 19 mg/l – 72 hours

Persistence and Degradability

Minimally biodegradable.

Bioaccumulative Potential

- Partition coefficient Octanol/water (Log Kow): 2.180 [3]

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

Sewage disposal is not allowed. Refers to Community/National/Local requirements concerning the waste disposal.

Disposal of Container

Not available.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

RID/ADR Non-hazardous for road transport IMDG Non-hazardous for sea transport IATA Non-hazardous for air transport

Section 15: Regulatory Information**Regulations**

Classification and labelling according to EU directives. Indication of danger. Xn Harmful R-Phrases; 63 Possible risk of harm to the unborn child. S-Phrases; 22 Do not Breathe dust. 36131 Wear suitable protective clothing and gloves.

Other

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

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 cannot provide any warnings about the dangers of the 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 reported information 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.