


Section 1: Identification

Common Name/Trade Name	CLOBETASOL PROPIONATE USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	N/A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Reproductive toxicity (Category 2)	
Signal Word	Warning	
Hazard Statement(s)	H361d Suspected of damaging the unborn child	
Pictogram(s)		
Precautionary Statement(s)	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/protective clothing/eye protection/face protection. P281 Use personal protective equipment as required. P308+P313 IF exposed or concerned Get medical advice/attention. P405 Store locked up. P501 Dispose of contents/container to an approved waste disposal plant.	
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	N/A
Common Name	Clobetasol propionate
CAS Number	25122-46-7
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet the doctor in attendance.
If Inhaled	Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
In Case of Skin Contact	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
In Case of Eye Contact	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
If Swallowed	Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorized by a doctor.
Most Important Symptoms and Effects	INGESTION: possible abdominal and stomach pain. INHALATION EXPOSURE: possible mucous membranes and upper breathing intakes irritation. CONTACT WITH SKIN: possible redness. CONTACT WITH EYES: possible burning sensation, redness of conjunctiva. Indication of any immediate medical attention and special treatment needed. Provide an emergency shower with face and eye wash station.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT None in particular
Special Hazards Arising From the Substance/Mixture	Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition. In case of thermal decomposition related to the effect of high temperatures may develop toxic substances for human health: toxic fumes of fluorine and chlorine.
Special PPE and/or Precautions for Firefighters	GENERAL INFORMATION Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations. PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS Normal firefighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	For non-emergency personnel Alert personnel responsible for the management of such emergencies. Move away from the vicinity if you are not in possession of the personal protective equipment listed in Section 8. For emergency responders Keep away all staff not adequately equipped to deal with the emergency. Wear suitable protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Block the leakage if to do so. Make available to workers the area affected by the incident only occurred to appropriate cleansing. Ventilate the premises concerned by the accident.
Methods and Materials Used for Containment	The product must not penetrate into the sewer system or come into contact with surface water or ground water.
Cleanup Procedures	Collect the leaked product and place it in containers for recovery or disposal. If the product is flammable, use explosion-proof equipment. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

Section 7: Handling and Storage

Precautions for Safe Handling	Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.
Conditions for Safe Storage	Store only in the original container. Store the containers sealed, in a well-ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details. Do not store above 25°C. Store in a dry place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m ³ ; PNOC inhalable fraction: 10 mg/m ³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.
Appropriate Engineering Controls	The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
PPE - Eye/Face Protection	Wear airtight protective goggles (see standard EN 166).
PPE - Skin Protection	In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Material: nitrile rubber, hypoallergenic Thickness: not inferior to 0.12 mm
PPE - Body Protection	Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
PPE - Respiratory Protection	Use a type P1, P2 or P3 filtering facemask (see standard EN 149) or equivalent device, must be defined according to the outcome of risk assessment.

Section 9: Physical and Chemical Properties

Appearance	White or almost white crystalline powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless.
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	6,8 – 7 (10% suspension at 20°C)
Relative Density	No data available
Melting Point/Freezing Point	195 - -197°C
Solubility	Insoluble in water. Sparingly soluble in alcohol dehydrate; soluble in acetone, chloroform, dimethyl sulfoxide, dioxane, methyl alcohol; slightly soluble in benzene and diethyl ether.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	3,5
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	There are no particular risks of reaction with other substances in normal conditions of use.
Chemical Stability	The product is stable in normal conditions of use and storage.
Possibility of Hazardous Reactions	The powders are potentially explosive when mixed with air.
Conditions to Avoid	Avoid exposure to: air, heat, light, moisture.
Incompatible Materials	Avoid contact with: strong oxidizing agents, acids, bases.
Hazardous Decomposition Products	In case of thermal decomposition related to the effect of high temperatures may develop toxic substances for human health: toxic fumes of fluorine and chlorine.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. LD50 (Oral) – Mouse: > 3000 mg/kg LD50 (Oral) – Rat: > 3000 mg/kg LD50 (Intraperitoneal) – Mouse: 118 mg/kg LD50 (Intraperitoneal) – Rat: 351 mg/kg LD50 (Subcutaneous) – Mouse: 81.7 mg/kg LD50 (Subcutaneous) – Rat: 366 mg/kg
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.
Serious Eye Damage/Irritation	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.
Respiratory or Skin Sensitization	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.
Germ Cell Mutagenicity	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. Clobetasol propionate was non-mutagenic in three different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay, and the E.coli B WP2 fluctuation test.
Carcinogenicity IARC	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. No experimental studies available after bibliographic research. No data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.
Carcinogenicity ACGIH	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. No experimental studies available after bibliographic research. No data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.
Carcinogenicity NTP	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. No experimental studies available after bibliographic research. No data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.
Carcinogenicity OSHA	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class. No experimental studies available after bibliographic research. No data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.
Reproductive Toxicity	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is classified for this hazard class Repr.2 H361d. 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. A related material has caused birth defects in animals. [5] Topical administration of corticosteroids during pregnancy in laboratory animals can cause abnormalities in fetal development. The relevance of this experimental data has not been found in humans. The administration of clobetasol propionate during pregnancy should be considered only if the expected benefit to the mother outweighs any possible risk to the fetus. It must be used the least amount for the shortest time possible.
Specific Target Organ Toxicity - Single Exposure	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.
Specific Target Organ Toxicity - Repeated Exposure	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.
Aspiration Hazard	Based on the assessment of the classification of the substance and classification provisions of Annex I, Part 3 of the reg. (EC) 1272/2008 and subsequent amendments, the product is not classified for this hazard class.

Section 12: Ecological Information

Toxicity	EC50 Pesce: > 0,75 mg/l Oncorhynchus mykiss (96h) EC50 Crostacei: > 1,4 mg/l Daphnia Magna (48h)
Persistence and Degradability	NOT rapidly biodegradable
Bio-accumulative Potential	Information not available
Mobility in Soil	Information not available
Other Adverse Effects	Information not available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorized waste management firm, in compliance with national and local regulations.
Waste Treatment Methods Packaging	Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

Seveso Category - Directive 2012/18/EC: Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006. None. Substances in Candidate List (Art. 59 REACH). On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%. Substances subject to authorization (Annex XIV REACH). None. Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None. Substances subject to the Rotterdam Convention: None. Substances subject to the Stockholm Convention: None. Healthcare controls. Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Section 16: Other Information

Additional Information	N/A
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Disclaimer

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