



Section 1: Identification

Common Name/Trade Name	BETAMETHASONE ACETATE MICRON USP	
Supplier Information	Letco Medical 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)
Product Synonym(s)	Betamethasone 21-acetate	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, inhalation (Category 2), Reproductive toxicity (Category 2), Specific target organ toxicity, repeated exposure (Category 1) (endocrine system)	
Signal Word	Danger	
Hazard Statement(s)	H330 Fatal if inhaled H360 May damage fertility or the unborn child H372 Causes damage to organs through prolonged or repeated exposure	
Pictogram(s)	 	
Precautionary Statement(s)	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/protective clothing/eye protection/face protection. P284 Wear respiratory protection. P304+P340 IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308+P313 IF exposed or concerned Get medical advice/attention. P310 Immediately call a POISON CENTER or doctor/physician. P403+P233 Store in a well ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container to an approved waste disposal plant.	
Hazards Not Otherwise Classified	Not classified	
Ingredient(s) with Unknown Toxicity	No data Available	

Section 3: Composition/Information on Ingredients

Chemical Name	Pregna-1,4-diene-3,20-dione,9-fluoro-11,17-dihydroxy-16-methyl-21-(acetyloxy)-,(11beta,16beta)-
Common Name	Betamethasone Acetate
CAS Number	987-24-6
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
If Inhaled	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth to mouth method if the victim inhaled the substance. Induce artificial respiration with the aid of pocket mask equipped with one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. If ingestion of a large amount does occur, call poison control center immediately
Most Important Symptoms and Effects	No data available

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	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. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling	As a general rule, when handling chemicals, avoid all contact and inhalation of dust, mist, 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. Use a designated area is recommended for handling of potent materials.
Conditions for Safe 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

Components with Workplace Control Parameters	No exposure standards allocated.
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup material, and remove the inner gloves only after removing other personal protective equipment.
PPE - Body Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup material, and remove the inner gloves only after removing other personal protective equipment. Other: For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place. (applicable U.S. regulation OSHA 29 CFR 1910.134)

Section 9: Physical and Chemical Properties

Appearance	Form: Powder Physical state: Solid Color: White to creamy white
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless
Vapor Pressure	< 0.0000001 kPa at 25 °C
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	384.8 - 406.4 °F (196 - 208 °C) ; also reported as 210-232 °C
Solubility	Solubility in water: Practically insoluble. Solubility (other): Freely soluble in acetone; soluble in ethanol and in chloroform.
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	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	No data available
Incompatible Materials	Acids. Bases. Oxidizing agents. Reducing agents.
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. HF.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral Rat > 5000 mg/kg > 2000 mg/kg
Acute Toxicity - Inhalation	LC50 Rat 0.28 mg/l, (Max. obtainable dose)
Acute Toxicity - Dermal	Due to lack of data the classification is not possible.
Acute Toxicity - Eye	Due to lack of data the classification is not possible.
Skin Corrosion/Irritation	Due to lack of data the classification is not possible.
Serious Eye Damage/Irritation	Due to lack of data the classification is not possible.
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity	Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.
Carcinogenicity IARC	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC.
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	Due to lack of data the classification is not possible. This material is not considered to be carcinogen by NTP.
Carcinogenicity OSHA	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by OSHA.
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.
Specific Target Organ Toxicity - Single Exposure	Due to lack of data the classification is not possible.
Specific Target Organ Toxicity - Repeated Exposure	Causes damage to organs (endocrine system) through prolonged or repeated exposure.
Aspiration Hazard	Due to lack of data the classification is not possible.

Section 12: Ecological Information

Toxicity	No ecotoxicity data noted for the ingredients.
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	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.
Waste Treatment Methods Packaging	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). 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.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	
UN Proper Shipping Name	
Transport Hazard Class(es)	
Packaging Group	
Environmental Hazards	No data available

Section 15: Regulatory Information

CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance: No SARA 311/312 Hazardous chemical: No Other federal regulations: Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. Us state regulations: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. Issue date 08/10/2010 Revision Date 02/10/2014.

Section 16: Other Information

Prepared By	Lisa Russell
Revision Date	05/19/2015 16:55

Disclaimer

The Harvard Drug Group, L.L.C. ("THDG") believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. THDG shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.