ALPHARMA
U.S. Pharmaceuticals Division

MATERIAL SAFETY DATA SHEET

NDC Product(s) Code(s): 0472-0382-15
0472-0382-45
Prep. Date: June 7, 2001

Product Name: Betamethasone Dipropionate Ointment USP 0.05% (Augmented)

For Further Information Contact:

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Revision No.: New

Approved by: Erik Bish
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Approval Date: JUNE 7, 2001

1. Manufacturer:

Lincolnton Facility
1877 Kawai Road
Lincolnton, NC 28092

EMERGENCY TELEPHONE:

(800) 638-9096 or
(410) 298-1000

Hazard Rating

4 = Extreme
3 = Severe
2 = Moderate
1 = Slight
0 = Minimal

2. Product Identification:

Product Name:	**Betamethasone Dipropionate Ointment USP 0.05% (Augmented)**
Product NDC Code:	0472-0382-15, 0472-0382-45
Chemical Name:	Mixture
Synonyms:	Diprosone® Augmented Ointment 0.05%
Product Category:	Glucocorticoid; anti-inflammatory

3. Composition/Ingredient Information:

Ingredient	Common Name	% By Weight	CAS #	Exposure Limit(s)
1.	Betamethasone Dipropionate	0.5%	5593-20-4	Not Determined

Other inactive ingredients: Propylene glycol, propylene glycol monostearate, white petrolatum, and white wax.

4. Physical and Chemical Properties

Appearance/ Physical State:	White Cream
Boiling Point:	Not determined
Volatility:	Not determined

5. Stability and Reactivity

Stability:	Stable
Physical Conditions To Avoid:	Open flame, high temperatures
Incompatibility With Other Materials:	Not determined
Hazardous Decomposition Products:	Not determined. The active ingredient, betamethasone dipropionate, emits toxic fumes of fluorine when heated to decomposition.
Hazardous Polymerization:	Does not occur

6. Hazards Identification

Primary Routes Of Exposure:	Absorption, Ingestion, Inhalation
Signs of Overexposure:	Toxic signs and symptoms rarely occur with administration of less than three weeks duration; even a massive single does of this material is unlikely to cause adverse effects. Possible allergic reaction could occur if ingested, inhaled or absorbed through the skin.

Medical Conditions Aggravated By Exposure: Hypersensitivity to any of the ingredients, infection or herpes simplex at site of exposure, diabetes mellitus, glaucoma or cataracts, tuberculosis and systemic fungal infections.

7. Emergency and First Aid Measures

Skin Contact: Irritation unlikely to occur but if it does wash affected areas with soap and water after removing contaminated clothing. Obtain medical treatment if contamination is significant and/or skin reaction is evident.

Eye Contact: Not expected route of exposure, but if inadvertent eye contact occurs, flush with water for 15 minutes. If irritation develops, consult a medical provider.

Inhalation: If not breathing give artificial respiration or Cardio Pulmonary Resuscitation (CPR). If having difficulty breathing, provide oxygen.

Ingestion: Not an expected route of exposure. If awake and able to swallow, rinse mouth with water. Do not give anything by mouth to a person who is unconscious or convulsing.

8. Fire Fighting Measures

Flash Point: Unspecified
Lower Explosion Limit (LEL): Unspecified
Upper Explosion Limit (UEL): Unspecified
Extinguishing Media: Use waterspray or dry chemical as appropriate for surroundings.
Fire Fighting Procedures: Use full firefighting turnout gear and self contained breathing apparatus. Keep personnel upwind and away from the fire.
Unusual Fire Or Explosion Hazards: None
Hazardous Combustion Products: Unspecified

9. Pharmacology

Physiochemical Characteristics: Molecular Weight – 504.59 (Betamethasone Dipropionate)
Mechanism of Action/Effect: Corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA and stimulate transcription of messenger RNA and subsequent protein synthesis of various inhibitory enzymes responsible for anti-inflammatory effects of topical corticosteroids. These anti-inflammatory effects include inhibition of early processes such as edema, fibrin deposition, capillary dilation, movement of phagocytes into the area and phagocytic activities. Later processes, such as capillary production, collagen deposition and keloid formation, are also inhibited by corticosteroids. The overall action of topical corticosteroids is catabolic.
Absorption: Absorbed systematically across the stratum corneum.

10. Toxicological Information

Acute Studies:
Subcutaneous LD50 (rat): >4g/Kg (betamethasone dipropionate)
Oral LD50 (rat): >4g/Kg (betamethasone dipropionate)

Other Studies:
Carcinogenicity: Long-term animal studies have not been conducted on the carcinogenity of topical corticosteroids.
Mutagenicity: There is no evidence that betamethasone dipropionate is mutagenic.
Fertility/Pregnancy: Although pregnancy studies in humans have not been done, studies in animals have shown that topical corticosteroids, especially the more potent agents, should not be used extensively, in large amounts in pregnant patients or patients who are planning to become pregnant. The studies have shown that topical corticosteroids are systemically absorbed and may cause fetal abnormalities, especially when used in large amounts, with occlusive dressings, for prolonged periods of time.

Breast-feeding:	It is not known whether topical corticosteroids are excreted in breast milk. However, problems have not been documented in humans. Topical corticosteroids should not be applied to the breasts prior to nursing.
Pediatrics:	Children and adolescents have a large skin surface area to bodyweight ratio and less developed, thinner skin, which may result in absorption of greater amounts of topical corticosteroids compared with older patients. Adrenal suppression, Cushing's Syndrome, intracranial hypertension and growth retardation due to the systemic absorption of topical corticosteriods have been documented in children. Therefore, special consideration must be exercised when these agents are used in children and growing adolescents.

11. Spill and Leak Procedures

Steps to be taken in case material is released or spilled:

Use proper personal protective equipment to avoid overexposure. Keep the product out of the drain. Prevent the entry to surface water, ground water and soil. Small spills can be absorbed with appropriate material e.g. rags, paper towels. Dispose of the spilled material in compliance with federal, state and local regulations.

12. Waste Disposal Methods

Dispose in accordance with applicable international, national, state and local waste disposal regulations.

Proper Shipping Name: Not regulated
EPA Waste Code: N/A

13. Storage and Handling Procedures

As with any drug/medicine, keep this drug out of the reach of the children. Keep the container tightly closed and store in a cool, dry place at a temperature between 59 and 86 degrees Fahrenheit (15 and 30 degrees Celsius) Keep away from light. Protect package/container from physical damage.

14. Process Handling Precautions

Use appropriate OSHA/MSMA approved safety equipment. Wear chemical goggles, face shield, gloves, and chemical resistant clothing such as a laboratory coat and/or a rubber apron to prevent contact with eyes, skin and clothing. Keep tightly closed and store in a cool, dry place.

15. Personal Protection/Exposure Controls

Respiratory Protection:	Once packaged, none required. Approved respirator when a potential for exposure exists.
Ventilation:	Adequate ventilation is required to protect personnel from exposure during manufacturing.
Protective Gloves:	None required once packaged. Chemical resistance gloves for manufacturing, packaging or spill clean up.
Eye Protection:	None required once packaged. Safety glasses are considered minimum protection for manufacturing or packaging operations. Goggles or face shield may be necessary depending on quantity of material and conditions of use.

16. Shipping Regulations (Ref: 49 CFR §172.101)

This product is not regulated when offered for transportation by air and highway nationally.

17. Other Information

Labeling: This product (drug/medicine) is subject to the labeling requirements of FDA and therefore is exempt from the labeling requirements of OSHA Hazardous Communication Standard (29 CFR 1910.1200).

18. Disclaimer

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