



Material Safety Data Sheet

Issuing Date 07-Mar-2011

Revision Date 20-May-2011

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Betamethasone Dipropionate Ointment USP (Augmented) 0.05%
Product Code(s) 0472-0382-15; 0472-0382-45
Recommended Use Anti-Inflammatory, Anti-Pruritic, Vasoconstrictor
Synonyms 9-Fluoro-11beta,17,21-trihydroxy-16 beta-methylpregna-1,4-diene-3,20-dione
17,21-dipropionate

Supplier Address

Actavis Mid Atlantic LLC
1877 Kawai Road
Lincolnton, NC 28092
TEL: 704-735-5700

Chemical Emergency Phone Number Chemtrec 1-800-424-9300

Poison Control Center (USA): 1-800-222-1222

2. HAZARDS IDENTIFICATION

CAUTION!

Emergency Overview

May cause skin and eye irritation
Not for ophthalmic use
Contains a known or suspected reproductive toxin

Appearance Off-white

Physical State Semi-Solid, Cream.

Odor No information available

Potential Health Effects

Principle Routes of Exposure

Eye contact. Skin contact.

Acute Toxicity

Eyes
Skin

May cause irritation. May cause redness and tearing.

May cause irritation. May cause light sensitivity which appears as a skin rash when exposed to sunlight.

Inhalation
Ingestion

Not an expected route of exposure.

Not an expected route of exposure. Do not ingest. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Effects

Prolonged or repeated contact may dry skin and cause irritation.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systematically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Aggravated Medical Conditions

Skin disorders. Endocrine System. Immune System.

Environmental Hazard

See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Petrolatum (USP Grade)	8009-03-8	60-100
Propylene glycol	57-55-6	10-30
Betamethasone Dipionate	5593-20-4	0.05

Note: This section lists OSHA and WHMIS hazardous chemicals at or above threshold as well as active pharmaceutical ingredients. For a full list of ingredients, please see product packaging.

4. FIRST AID MEASURES

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
Skin Contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Inhalation	Move to fresh air in case of accidental inhalation of vapors or decomposition products. If symptoms persist, call a physician.
Ingestion	Rinse mouth. Drink plenty of water. Do NOT induce vomiting. Consult a physician.
Notes to Physician	Treat symptomatically.
Protection of First-aiders	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Flash Point	Not applicable.
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Explosion Data	
Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None
Protective Equipment and Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazard 1*	Flammability 0	Physical Hazard 0	Personal Protection B

*Indicates a chronic health hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Use personal protective equipment. Avoid contact with the skin and the eyes.
Environmental Precautions	Refer to protective measures listed in Sections 7 and 8.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Cover liquid spill with sand, earth or other noncombustible absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.
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Storage Store at room temperature. Keep at temperatures between 2 and 30 °C (36 and 86 °F). Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures Showers
Eyewash stations
Ventilation systems

Personal Protective Equipment

Eye/Face Protection

Skin and Body Protection

Respiratory Protection

Safety glasses with side-shields.

Protective gloves.

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Off-white.	Odor	No information available
Odor Threshold	No information available	Physical State	Semi-Solid Cream
pH	No information available.	Autoignition Temperature	No information available.
Flash Point	Not applicable.	Boiling Point/Boiling Range	No information available
Decomposition Temperature	No information available.	Explosion Limits	No information available.
Melting Point/Range	No information available	Evaporation Rate	No information available
Flammability Limits in Air	No information available.	Vapor Density	Not applicable
Solubility	No information available.		
Vapor Pressure	Not applicable		
VOC Content (%)	14		

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions.

Incompatible Products Oxidizing agents. Reducing agents.

Conditions to Avoid None known.

Hazardous Decomposition Products Carbon oxides.

Hazardous Polymerization Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information May cause eye and skin irritation.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Betamethasone Dipionate	> 4 g/kg (Rat)		-
Petrolatum (USP Grade)		= 3600 mg/kg (Rabbit)	
Propylene glycol	20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-

Chronic Toxicity

Chronic Toxicity Prolonged or repeated contact may dry skin and cause irritation.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systematically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Carcinogenicity	Contains no ingredients above reportable quantities listed as a carcinogen.
Teratogenic	Pregnancy: Teratogenic Effects: Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.
Target Organ Effects	Skin. Endocrine system. Reproductive system. Contains material that may adversely affect the developing fetus. Immune system.

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated. Ecotoxicity effects of component substances.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Propylene glycol	EC50 96 h: = 19000 mg/L (Pseudokirchneriella subcapitata)	LC50 96 h: 41 - 47 mL/L static (Oncorhynchus mykiss) LC50 96 h: = 51400 mg/L static (Pimephales promelas) LC50 96 h: = 51600 mg/L static (Oncorhynchus mykiss) LC50 96 h: = 710 mg/L (Pimephales promelas)	EC50 = 710 mg/L 30 min	EC50 48 h: > 1000 mg/L Static (Daphnia magna) EC50 24 h: > 10000 mg/L (Daphnia magna)

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods	This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.
Contaminated Packaging	Dispose of in accordance with local regulations. Do not re-use empty containers.
California Hazardous Waste Codes	311
California Waste Code Legend	Pharmaceutical waste

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Exempt
DSL	Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Exempt
Chronic Health Hazard	Exempt
Fire Hazard	Exempt
Sudden Release of Pressure Hazard	Exempt
Reactive Hazard	Exempt

This is an FDA regulated product and as such is exempted from SARA Tier II reporting.

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

"X" designates that the ingredients are listed on the state right to know list.

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Propylene glycol	X	-	X	-	X

International Regulations

Canada

This product is regulated by the Food and Drug Administration of Health Canada and is not subject to the WHMIS Requirements of the Hazardous Products Act and the Controlled Products Regulations.

16. OTHER INFORMATION

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
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Revision Note	(M)SDS sections updated: 2.

General Disclaimer

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet