

Product Name:
Issued:

Azmacort Triamcinolone Acetonide Inhalation Aerosol
Apr-01-2009



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address:

Manufactured for:

Abbott Laboratories
Pharmaceutical Products Group
100 Abbott Park Road
Abbott Park, IL 60064

Emergency Telephone:

CHEMTREC (USA): 1 - 800 - 424 - 9300

Product Name:

Azmacort Triamcinolone Acetonide Inhalation Aerosol

Synonyms:

Triamcinolone Acetonide

List Number:

3014

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Dichlorodifluoromethane 75-71-8	98.7	1000 ppm 8-hr TWA	1000 ppm 8-hr TWA	Not Applicable	Not Applicable	None
Ethyl Alcohol 64-17-5	1	1000 ppm TWA mg/m ³ TWA	1000 ppm TWA	1000	Not Applicable	None
Triamcinolone acetonide 76-25-5	0.3	Not Listed	Not Listed	Not Applicable	1 mcg/m ³ 8-hr TWA	None

Notes:

OSHA PEL: US Occupational Safety and Health Administration-Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

Emergency Overview:

Metered dose inhaler unit

Not determined.

CAUTION: COMPRESSED GAS

Routes of Exposure:

Oral: Not determined.

Dermal: Unlikely

Inhalation: Yes

Hazard Information:

Ingestion Rating: Not determined.

Skin Absorption Rating: Not determined.

Inhalation Rating: Not determined.

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3. HAZARDS IDENTIFICATION

Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Not determined.

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Dichlorodifluoromethane	98.7	Not Listed	Not Listed	Not Listed	A4 - Not Classifiable as a Human Carcinogen
Ethyl Alcohol	1	Not Listed	Listed	Listed	Not Listed
Triamcinolone acetonide	0.3	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating:

Health: 1
Fire: 0
Reactivity: 0

Signs and Symptoms: None known from occupational exposure.

Medical Conditions None known from occupational exposure.

Aggravated by Exposure:

4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability:

Lower Explosive Limit: Not determined.
Autoignition Temp. (°C): Not determined.

Fire-Fighting Information:

Suitable Extinguishing Media: Waterspray, foam, or dry chemical.

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Special Protective Equipment:	Fire fighters should wear full protective clothing, including self-contained breathing equipment.
Special Exposure Hazards:	Keep away from heat, sparks and flame.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting:	Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.
Personal Precautions:	Use personal protective equipment identified in Section 8.
Environmental Precautions:	Not determined.

7. HANDLING AND STORAGE

Handling:	Prevent physical damage to package. Protect from heat. Keep away from flame.
Storage:	Store at controlled room temperature of 15-30 deg. C (59-86 deg. F).
Special Precautions:	Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls:	No special provisions are required under normal conditions. Use inside a process enclosure when handling the bulk formulation.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the product formulation.
Other PPE Data:	Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Metered dose inhaler unit
Odor:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	-29.8 (dichlorodifluoromethane)
Melting/Freezing Point (°C):	-157.7 (dichlorodifluoromethane)
Vapor Pressure (mm Hg)	94.9 psia @ 21 degrees C (dichlorodifluoromethane)
Bulk Density at 20°C:	Not determined.
Solubility:	Not determined.
Specific Gravity:	1.34 @ 30 degrees C (dichlorodifluoromethane)
pH:	Not determined.
Viscosity (centipoise):	Not determined.

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10. STABILITY AND REACTIVITY

Chemical Stability: Alkali, alkaline earth metals

Self-Heating Tendency: Not determined.

Materials to Avoid: Chemically active metals such as powdered aluminum, zinc, potassium, calcium and magnesium.

Hazardous Decomposition Products: When heated to decomposition it emits : CO, CO₂, Phosgene, Oxides of Nitrogen and Sulfur.

Hazardous Polymerization: Not known to occur.

Conditions to Avoid: Keep away from heat, sparks and flame.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Dichlorodifluoromethane	98.7	LD50 >	1000	mg/kg	Rats
Ethyl Alcohol	1	LD50 =	5560-13,700	mg/kg	Guinea Pigs Rats Mice Rabbits
Triamcinolone acetonide	0.3	LD50 =	5000	mg/kg	Mice

Acute Toxicity - Dermal: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Ethyl Alcohol	1	LD50 =	20000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Dichlorodifluoromethane	98.7	LC 50 =	620000	ppm , 3 hour	Mice
Ethyl Alcohol	1	LC 50 =	20000	ppm	Rats

Other Toxicology Data: Data for component (s) given below:

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Triamcinolone acetonide	0.3	LD50 (sc) = LD50 (ip) =	13.1 - 132 105	mg/kg	Rats Mice Mice	None.

Corrosivity: Not determined.

Dermal Irritation: Major ingredient: Reported to not produce skin irritation.

Eye Irritation: Major ingredient: Reported to produce eye irritation.

Sensitization: Not determined.

Target Organ Effects: Data for component (s) given below.

Ingredients	Percent	Target Organs:	Species	Dosage	Units	Route	Duration
Dichlorodifluoromethane	98.7	Heart	Dogs	50000	ppm	Inhalation	Not Specified
Triamcinolone acetonide	0.3	Kidney	Dogs	2.5	mg/kg	Oral	6 weeks

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Reproductive Effects: Data for component (s) given below.

Ingredients	Percent	Reproductive Effects	Species	Dosage	Units	Route	Duration
Dichlorodifluoromethane	98.7	No adverse effect.	Rats Dogs	11 - 150	mg/kg	Oral	Variable Treatment Regimens
Triamcinolone acetonide	0.3	Embryotoxicity, Fetal Abnormalities.	Rats	5	mcg/kg	Not specified	During Gestation

Carcinogenicity: No effect anticipated from intact clinical product.
Data for component(s) given below.

Ingredients	Percent	Site of Tumors	Species	Dosage	Units	Route	Duration
Dichlorodifluoromethane	98.7	None.	Rats Mice	5000 & 1000	ppm	Inhalation	78 weeks to 104 weeks

Mutagenicity: Data for component (s) given below.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Dichlorodifluoromethane	98.7	Negative	No Data.	No Data.	No Data.

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Data for component (s) given below.

Ingredients	Percent	EC50 (mg/l)	Species	Duration
Triamcinolone acetonide	0.3	> 100	Daphnia magna	48 Hours

Biodegradation: Data for component (s) given below.

Ingredients	Percent	% Degradation	Duration
Triamcinolone acetonide	0.3	4.8	28 days

General Notes: Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Disposal should be made in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT/ADR:

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14. TRANSPORT INFORMATION

Status: DOT: Not regulated per 49 CFR 173.306(j)
ADR: Not regulated per Special Provision 190

ICAO/IATA:
Status: Not restricted as per Special Provision A98.

IMDG:
Status: Not regulated per Special Provision 190

TDG (Canada):
Status: Not determined.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Dichlorodifluoromethane	98.7	1.0 % de minimis concentration	2270 kg 5000 lb	Not applicable
Ethyl Alcohol	1	1000	1000	1000
Triamcinolone acetonide	0.3	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: Not determined.
Delayed Health: Not determined.
Fire: No
Sudden Pressure: Yes
Reactivity: No

TSCA Inventory Status: Exempt.

CERCLA Status: Not determined.

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Ingredients	Percent	Proposition 65 Listed Materials
Ethyl Alcohol	1	Developmental toxicity (when in alcoholic beverages); initial date 10/1/87.

EC HAZARD CLASSIFICATION:

Category of Danger: Irritant

Indication of danger: Xi - Irritant.

Risk Combination Phrases: R36/38 - Irritating to eyes and skin.

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GHS CLASSIFICATION: Warning: Category 5 - May be harmful if swallowed.

Warning: Category 2B - Causes mild eye irritation

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Not determined.

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

16. OTHER INFORMATION

Document Authored By: Global Occupational Toxicology (D-03QW)

Supersedes the MSDS dated: Jul-16-2008

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