



SAFETY DATA SHEET

NFPA Rating: Health: 2 Flammability: 1 Reactivity: 0 Special: 0

TELEPHONE CONTACTS: Product Technical and Medical Information: (800) 433-8871 Transportation Emergency 24-Hour Response (CHEMTREC): (800) 424-9300

SECTION 1: PRODUCT IDENTIFICATION

Compound Name: **ACZONE[®] (Dapsone) Gel, 5%**
Chemical Class: Sulfone for dermatologic application
Manufactured For: Allergan, Inc.
Address: 2525 Dupont Drive
Irvine, CA 92612
Preparation Date: September 10, 2008

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Exposure to Dapsone may increase the risk of anemia, agranulocytosis, hemolysis or other related blood disorders. Overexposure may result in methemoglobin depression, convulsions and cyanosis requiring prompt treatment. Dapsone is excreted in breast milk, and nursing mothers should avoid exposure to this material by observing all precautions indicated.

Hazard Classification (GHS):	Target Organ Systemic Toxicity – Repeated Exposure (Category 2) Reproductive Toxicant (Category 2)	
Signal Word and Hazard Statements (GHS):	Warning – May cause anemia and peripheral neuropathy through prolonged or repeated exposure. Warning – Suspected of decreasing fertility. May cause hemolysis in breast-fed infants.	

Potential Health Effects:

EYE CONTACT: Contact with the eyes may result in moderate to severe irritation.

SKIN CONTACT: Prolonged contact with the skin may result in mild to moderate irritation, resulting in erythema and peeling in severe instances.

INHALATION: Not likely to occur under normal conditions of use.

INGESTION: May cause irritation, nausea and vomiting if swallowed.

CHRONIC EFFECTS: Adverse effects of exposure may include back, leg or stomach pain, loss of appetite, tiredness and weakness, fever, skin rash, difficulty breathing, sore throat and unusual bleeding or bruising.

Prolonged or repeated overexposure to dapsone may result in hemolytic anemia, agranulocytosis and peripheral neuropathy as well as various skin reactions.

Dapsone has not been listed by IARC, NTP or OSHA as a carcinogen, and this material is not classifiable as to its carcinogenicity in humans. However, dapsone has been shown to cause tumors in laboratory animals.

No evidence of mutagenicity has been shown by dapsone or **ACZONE® (Dapsone) Gel, 5%**. At high levels, dapsone induced impairment of fertility in male laboratory rats due to reduced sperm motility.

SECTION 3: COMPOSITION/HAZARDOUS INGREDIENTS

Chemical Name	CAS Number	Percent (By Weight)	Exposure Limits in Air (8 hr. TWA)		
			OSHA PEL	ACGIH TLV	ALLERGAN OEL
Diethylene glycol monoethyl ether	111-90-0	25	N/E	N/E	N/E
Dapsone	80-08-01	5.0	N/E	N/E	N/E

N/E = Not established

SECTION 4: FIRST AID MEASURES

Eye Contact: If contact or irritation occurs, flush eyes with plenty of water for at least 15 minutes. Obtain medical attention if irritation or other symptoms occur.

Skin Contact: Wash skin thoroughly with soap and water. If irritation develops consult a physician. Thoroughly launder contaminated clothing before reuse.

Inhalation: Not likely to occur under normal conditions of use. If symptoms occur, move to fresh air and obtain medical attention. Treat symptomatically.

Ingestion: Treatment of an oral overdose includes supportive and symptomatic therapy. Consult a physician or poison control center immediately if symptoms develop.

SECTION 5: FIRE FIGHTING MEASURES

Flash Point and Method: > 200 °F (Pensky Martens Closed Cup)

Flammable Limits: Not applicable

Autoignition Temperature: Not determined

Fire-Extinguishing Materials: Use extinguishing media suitable for materials supporting combustion such as water fog, CO₂, foam, or dry chemical.

Fire fighting Procedures: Use self-contained breathing apparatus in enclosed or confined spaces or as otherwise needed.

Unusual Fire and Explosion Hazards: None known. Product is non-flammable.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Sweep up or take up with absorbent material and wash with water. If large quantities are spilled, flush spill area with water after all material is removed.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid unintentional contact with skin surfaces. Do not allow contact with eyes. Wash thoroughly after handling. Observe all labeling precautions and protective equipment recommendations.

Storage: Store in a cool, dry location out of direct sunlight. Keep container closed when not in use.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls: None necessary for normal product handling.

Respiratory Protection: None necessary for normal product handling. In the event of large spill clean-up, wear an approved air-purifying respirator with organic vapor cartridges when working with this material.

Eye Protection: None necessary for normal product handling. For large spill clean-up, use safety glasses to avoid eye contact.

Protective Clothing: None necessary for normal product handling. Clinicians repeatedly applying the product to patients should wear latex gloves when handling ACZONE[®] (Dapsone) Gel, 5%.

Hygienic Work Practices: Wash hands thoroughly after handling. No eating, drinking, or smoking in area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Semi-solid, white to yellowish cream. Mild, sweet odor.

pH: 6.0 - 8.0

Melting Point/Freezing Point: No data for this product

Vapor Density (Air = 1): No data for this product

Boiling Point: No data for this product

Evaporation Rate: No data for this product

Solubility in Water: Dispersible

Specific Gravity: No data for this product

Vapor Pressure (mm Hg at 20° C): No data for this material

SECTION 10: STABILITY AND REACTIVITY

- General:** This product is stable and hazardous polymerization will not occur.
- Incompatible Materials and Conditions to Avoid:** Store away from oxidizers and heat. Store below 30 °C.
- Hazardous Decomposition:** None known

SECTION 11: TOXICOLOGICAL INFORMATION

- Oral:** The oral LD₅₀ for dapsone is 1 g/kg in rats and 250 mg/kg in mice. Nausea, vomiting and hyperexcitability can occur within minutes or hours of ingestion overdose. Other serious effects of overexposure can include peripheral neuropathy (motor weakness), convulsions, and a blue discoloration of fingernails, lips or skin caused by low oxygen due to methemoglobinemia. Oral dapsone treatment has produced dose-related agranulocytosis, hemolysis and hemolytic anemia.
- Skin:** This product is not considered acutely toxic via dermal application. Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These reactions were not observed in clinical trials with **ACZONE**[®] (Dapsone) Gel, 5%. Dermal application during clinical trials resulted in some cases of mild to moderate erythema, dryness and skin peeling.
- Although systemic absorption of dapsone following topical application of **ACZONE**[®] Gel, 5%, is minimal relative to oral dapsone administration, it is known that dapsone is excreted in human milk. Because of the potential for oral dapsone to cause adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue **ACZONE**[®] Gel, 5%, taking into account the importance of the drug to the mother.
- Ocular:** Product may produce moderate to severe irritation upon contact with eyes.
- Reproduction:** The effects of dapsone on fertility and general reproduction performance were assessed in male and female rats following oral (gavage) dosing. Dapsone reduced sperm motility at dosages of 3 mg/kg/day or greater. The mean numbers of embryo implantations and viable embryos were significantly reduced in untreated females mated with males that had been dosed at 12 mg/kg/day or greater, presumably due to reduced numbers or effectiveness of sperm, indicating impairment of fertility. Dapsone had no effect on fertility at dosages of 2 mg/kg/day or less. When administered to female rats at a dosage of 75 mg/kg/day for 15 days prior to mating and for 17 days thereafter, dapsone reduced the mean number of implantations, increased the mean early resorption rate, and reduced the mean litter size. These effects were probably secondary to maternal toxicity.
- Teratogenicity:** There are no adequate and well controlled studies in pregnant women. Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally in doses of 75 mg/kg/day and 150 mg/kg/day. These effects were probably secondary to maternal toxicity.

Mutagenicity: Dapsone was not mutagenic in a bacterial reverse mutation assay (Ames test) using *S. typhimurium* and *E. coli*, with and without metabolic activation and was negative in a micronucleus assay conducted in mice. Dapsone increased both numerical and structural aberrations in a chromosome aberration assay conducted with Chinese hamster ovary (CHO) cells.

Carcinogenicity: Dapsone is not listed as a carcinogen by OSHA, IARC or NTP, and is not classifiable as to its carcinogenicity in humans. Dapsone was not carcinogenic to rats when orally administered to females for 92 weeks or males for 100 weeks at dose levels up to 15 mg/kg/day. However, studies in male rats and female mice have shown that Dapsone causes mesenchymal tumors of the spleen and peritoneum. It has also been shown to cause thyroid carcinoma in female rats.

SECTION 12: ECOLOGICAL INFORMATION

Persistence and Degradability: Readily and rapidly degradable.

Aquatic Toxicity: No data available on this product.

SECTION 13: DISPOSAL CONSIDERATIONS

This product is not a hazardous waste when disposed of. For small quantities, discard in a municipal landfill as ordinary trash. For large quantities, contact Allergan for information on return, recycle or disposal options.

SECTION 14: TRANSPORT INFORMATION

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):

As defined by U.S. Code Title 15, Chapter 53 (TSCA), Section 2602 and TSCA Regulations at 40CFR, Subchapter R, Part 710, this drug product is exempt from regulations under TSCA.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

This product contains no components subject to reporting or notification requirements.

SARA Title III (Superfund Amendments and Reauthorization Act):

311/312 Hazard Categories: Acute Health, Chronic Health

313 Reportable Ingredients: None

WHMIS (Workplace Hazardous Materials Information System - Canada):

Not Regulated (Product is regulated by the Food and Drugs Act)

California Proposition 65:

This product contains no components known to the State of California to cause cancer or reproductive effects.

European Information In Accordance With EU Classification and Packaging Directives:

Hazard Symbol: Xn (Harmful)

Risk Phrases:

R 48/22 – Harmful: danger of serious damage to health by prolonged exposure if swallowed

R 64 – May cause harm to breast-fed babies

Safety Phrases:

S 2 – Keep out of the reach of children.

S 7 – Keep container tightly closed.

S 25 – Avoid contact with the eyes.

S 46 - If swallowed, seek medical advice immediately and show this container or label.

SECTION 16: OTHER INFORMATION

Revision Summary: MSDS prepared September 10, 2008

The preceding information is based on available data and is believed to be correct. However, no warranty is expressed or to be implied regarding the accuracy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Allergan does not assume any responsibility for the results of its use. This information is furnished upon the condition that the persons receiving it shall make their own determinations of the effects, properties, and protections which pertain to their particular conditions.