



MATERIAL SAFETY DATA SHEET

National Fire Protection Association (NFPA) Rating: Health: 1 Flammability: 0 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: AZELEX[®] (Azelaic Acid) 20% Cream
Chemical Class: Dicarboxylic acid
Manufacturer's Name: Allergan, Inc.
Address: 2525 Dupont Drive
Irvine, CA 92612
Preparation Date: June, 20, 2001 (*Supersedes May 8, 1996*)

SECTION 2: COMPOSITION/HAZARDOUS INGREDIENT INFORMATION

Chemical Name	CAS Number	Percent (By Weight)	Exposure Limits in Air	
			OSHA PEL	ACGIH TLV
Azelaic Acid	123-99-9	20	N/E	N/E

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: AZELEX[®] (Azelaic Acid) 20% Cream causes moderate to severe irritation of the eyes. Do not allow contact with the eyes.

Potential Health Effects:

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

SKIN CONTACT: Contact with the skin may result in mild irritation and slight reddening.

INHALATION: The product is non-volatile and inhalation is not likely to occur.

INGESTION: May cause irritation, nausea and vomiting.

CHRONIC EFFECTS: Repeated oral dosing in laboratory animals resulted in no signs of toxicity.

Azelaic acid was shown to be non-sensitizing in the guinea pig, and exhibited no teratogenic or genotoxic effects when tested in laboratory animals. Azeleic acid is not listed as a carcinogen by OSHA, IARC, or NTP.

SECTION 4: FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention.

Skin Contact: Wash skin thoroughly with soap and water if irritation develops. Discontinue use and consult a physician

Wash contaminated clothing before reuse. Get medical attention if symptoms persist.

Inhalation: Inhalation is not likely to occur. If symptoms occur, move to fresh air and obtain medical attention. Treat symptomatically.

Ingestion: Consult a physician or poison control center immediately.

SECTION 5: FIRE FIGHTING MEASURES

Flash Point and Method: Greater than 200°F (Seta Flash Cup)

Flammable Limits: Not determined

Autoignition Temperature: No data for this product

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

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

Unusual Fire and Explosion Hazards: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

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

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.
Eye Protection:	None required for normal product handling. Avoid eye contact.
Protective Clothing:	None required for normal product handling. Clinicians repeatedly applying the product to patients should wear latex gloves when handling AZELEX® (Azelaic Acid) 20% Cream .
Hygienic Work Practices:	Wash hands thoroughly after handling. No eating, drinking or smoking in area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Vapor Density (Air = 1):	No data for this product
Boiling Point:	Not Applicable
Solubility in Water:	Dispersible
Specific Gravity:	0.95
pH:	3.3 (Neat)
Vapor Pressure (mm Hg at 20° C):	No data for this product
Appearance and Odor:	White opaque cream, mild odor

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 **AZELEX® (Azelaic Acid) 20% Cream** was determined to be in excess of 5000 mg/kg when tested in mice and rats. Chronic administration of high oral doses of azelaic acid did not produce any toxicity: 1000 mg/kg/day oral (by gavage) suspension of azelaic acid administered to rats and 800 mg/kg/day (by capsule) to dogs for six months as well as 250 mg/kg/day administered to monkeys (by gavage) for four weeks were very well tolerated. The rat dose represents approximately 300 times the clinical dose, on a mg/kg basis. The dose of 800 mg/kg/day in dogs resulted in blood concentrations (135 µg/mL) approximately 1000 times those in humans (136 mg/mL).
- Skin:** No dermal irritation was observed in rats following twice-daily dermal administration of **AZELEX® (Azelaic Acid) 20% Cream** at volumes up to 0.3 mL for ten days. Daily dermal administration of **AZELEX® (Azelaic Acid) 20% Cream** to rabbits (250 mg/day) for four weeks produced slight reddening on intact and scarified skin. Doses up to 1500 mg/kg/day of **AZELEX® (Azelaic Acid) 20% Cream** administered dermally in rats and dogs for six months were well tolerated. This dose represents approximately 90 times the human dose on a mg/kg/day basis, assuming a 60 kg person. In addition, blood concentrations of azelaic acid in rats (866 ng/mL) following topical administration were approximately six times as high as compared with maximal drug concentrations in humans (136 ng/mL).
- Ocular:** Ocular tolerance studies in rabbits and monkeys with **AZELEX® (Azelaic Acid) 20% Cream** showed ocular irritation. The pain reaction produced in monkeys disappeared after rinsing with water.
- Sensitization:** No sensitization potential of azelaic acid was demonstrated in the Guinea pig maximization test.
- Reproduction:** Azelaic acid administered orally to rats, rabbits, or monkeys during embryogenesis did not produce teratogenic effects. Embryolethal effects were noted only after high oral dosages in rats (2500 mg/kg/day), rabbits (150 mg/kg/day), and monkeys (500 mg/kg/day). Postnatal development and reproductive performance of F₁ animals were slightly disturbed after oral administration of azelaic acid at dose levels of 500 and 2500 mg/kg/day. However, these dosages were already clearly toxic for the dams. No teratogenic effects were observed.
- Mutagenicity:** Mutagenicity tests were conducted with azelaic acid by a number of techniques, both *in vitro* and *in vivo*. Genotoxic effects of azelaic acid could not be demonstrated either in the *in vitro* (Ames, HGPRT, and human lymphocyte tests) or in *in vivo* studies (mouse dominant lethal assay).

SECTION 12: ECOLOGICAL INFORMATION

No ecological information is available for the product. The following data pertains to Azelaic acid as reported by the raw material supplier:

- Persistence and Degradability:** Readily and rapidly degradable. All individual organic substances contained in the product achieve values in tests for ready degradability (e.g. OECD 301 A-F) of at least 60% BOD/COD or 70% DOC reduction (tolerance value for classification as "readily degradable": $\geq 70\%$ DOC reduction or $\geq 60\%$ BOD/COD in 28 days.)

Aquatic Toxicity

Acute fish toxicity: LC₅₀ >10 to 100 mg product/L.
Acute bacteria toxicity: EC₅₀ >10 to 100 mg product/L.

SECTION 13: DISPOSAL CONSIDERATIONS

For small quantities of **AZELEX® (Azelaic Acid) 20% Cream**, discard as ordinary trash. For large quantities, contact Allergan for information on disposal options.

SECTION 14: TRANSPORT INFORMATION

Not a hazardous material for DOT, IATA, IMO or TDG shipment.

SECTION 15: REGULATORY INFORMATION**TSCA (Toxic Substances Control Act):**

Components of this product are listed on the TSCA Inventory.

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: Immediate Health

313 Reportable Ingredients: None

WHMIS (Workplace Hazardous Materials Information System - Canada):

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

SECTION 16: OTHER INFORMATION

Revision Summary: MSDS revised 6/20/01; Supersedes 5/8/96

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.