1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name AZELEX® (Azelaic Acid) 20% Cream

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Pharmaceutical Product

Uses advised against No information available

Supplier's details

Supplier Address
Allergan, Inc.
2525 Dupont
Irvine, CA
TEL: 1-714-246-4500

Emergency telephone number

Emergency Telephone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200)

Serious Eye Damage/Eye Irritation Category 2B

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word Warning

Hazard Statements
• Causes eye irritation

Appearance No information available Physical State Cream. Odor No information available

Precautionary Statements

Prevention
• Wash hands thoroughly after handling
WPS-ALL-001 - AZELEX® (Azelaic Acid) 20% Cream

Revision Date 21-Nov-2013

General Advice
• None

Eyes
• IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
• If eye irritation persists: Get medical advice/attention.

Storage
• None

Disposal
• None

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information
May cause skin irritation. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No</th>
<th>Weight %</th>
<th>Trade secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azelaic acid</td>
<td>123-99-9</td>
<td>20</td>
<td>*</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>1.5</td>
<td>*</td>
</tr>
</tbody>
</table>

* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST AID MEASURES

**Description of necessary first-aid measures**

**Eye Contact**
Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If irritation persists, 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. If symptoms persist, call a physician.

**Ingestion**
Do NOT induce vomiting. Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.

**Most important symptoms/effects, acute and delayed**


**Indication of immediate medical attention and special treatment needed, if necessary**

**Notes to Physician**
Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media**
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media**
CAUTION: Use of water spray when fighting fire may be inefficient.
Specific Hazards Arising from the Chemical
No information available.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions
Use personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Environmental Precautions
See Section 12 for additional Ecological Information

Methods and materials for containment and cleaning up

Methods for Containment
Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up
Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Do not get in eyes. Avoid contact with skin. Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities

Storage
Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from direct sunlight. Keep out of the reach of children.

Incompatible Products
Strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>TWA: 10 mg/m³</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>56-81-5</td>
<td>mist</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NIOSH IDLH: Immediately Dangerous to Life or Health. ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits.

Appropriate engineering controls
Engineering Measures

Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection
None required under normal usage. Risk of contact, wear: Safety glasses with side-shields.

Skin and Body Protection
No protective equipment is needed under normal use conditions. Clinicians repeatedly applying the product to patients should wear latex gloves when handling AZELEX® (Azelaic Acid) 20% Cream.

Respiratory Protection
If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Wash hands before breaks and immediately after handling the product. Provide regular cleaning of equipment, work area and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks/ - Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Cream</td>
<td>Appearance</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>Melting Point/Range</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Boiling Point/Boiling Range</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Flash Point</td>
<td>&gt; 93 °C / &gt; 200 °F</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>upper flammability limit</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>lower flammability limit</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flammable Properties</td>
<td>Not flammable</td>
<td></td>
</tr>
<tr>
<td>Explosive Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature</td>
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<td></td>
</tr>
<tr>
<td>Decomposition Temperature</td>
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<td></td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY
Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Heat. Temperatures above 30°C.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation

Eye Contact

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.

Skin Contact

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).

Ingestion

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 mg/mL) approximately 1000 times those in humans (136 mg/mL).

LD50 Oral:

> 5000 mg/kg (rat) (mouse)

Component Information

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>LD50 Oral</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>&gt; 12600 mg/kg (Rat)</td>
<td>21900 mg/kg (Rat)</td>
<td>-</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.
Persistence and Degradability
Azelaic acid: Readily biodegradable.

Carcinogenicity
Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity
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 (500mg/kg/day). Postnatal development and reproductive performance of F1 animals were slightly disturbed after oral administration of azelaic acid at dose levels of 500and 2500 mg/kg/day. However, these dosages were already clearly toxic for the dams. No teratogenic effects were observed.

Teratogenic
Teratogenic effects: Pregnancy Category B. Azelaic acid administered orally to rats, rabbits, or monkeys during embryogenesis did not produce teratogenic effects. Embryotoxic effects were noted only at maternally toxic doses. There are, however, no adequate well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Sensitization
No sensitization potential of azelaic acid was demonstrated in the Guinea pig maximization test.

Mutagenic Effects
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 vivo studies (mouse dominant lethal assay).

Carcinogenicity
Contains no ingredients above reportable quantities listed as a carcinogen.

Bioaccumulation
No information available. No information available.

Numerical measures of toxicity - Product

12. ECOLOGICAL INFORMATION

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

Azelex (Azelaic acid 20%) Cream: Acute fish toxicity: LC50 >10 to 100 mg product/L. Acute bacteria toxicity: EC50 >10 to 100 mg product/L.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Toxicity to Algae</th>
<th>Toxicity to Fish</th>
<th>Toxicity to Microorganisms</th>
<th>Daphnia Magna (Water Flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin 56-81-5</td>
<td></td>
<td>LC50 96 h: 51 - 57 mL/L static (Onchorhynchus mykiss)</td>
<td></td>
<td>EC50 24 h: &gt; 500 mg/L (Daphnia magna)</td>
</tr>
</tbody>
</table>

Persistence and Degradability
Azelaic acid: Readily biodegradable.

Bioaccumulation
No information available.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>-1.76</td>
</tr>
</tbody>
</table>

Other Adverse Effects
No information available.

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 another 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
Do not re-use empty containers.

14. TRANSPORT INFORMATION
15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Exempt</td>
</tr>
<tr>
<td>DSL</td>
<td>Exempt</td>
</tr>
</tbody>
</table>

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
DSL/NDSL - 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

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>Yes</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Glycerin</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable
16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>NFPA</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Instability</th>
<th>Physical and Chemical Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Physical Hazard</th>
<th>Personal Protection</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>X</td>
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</tbody>
</table>

Prepared By: Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Issuing Date: 20-Jun-2001
Revision Date: 21-Nov-2013
Revision Note: Update to Format.

General Disclaimer
The information provided on this SDS 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.

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End of Safety Data Sheet