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

GHS product identifier

Product Name ACZONE® (Dapsone) Gel, 5%

Other means of identification
Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use No information available
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
Chemtrec 1-800-424-9300
Number

2. HAZARDS IDENTIFICATION

Classification

This product is considered hazardous by the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Eye Damage/Eye Irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>Category 2</td>
</tr>
<tr>
<td>Specific Target Organ Toxicity (Repeated Exposure)</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

GHS Label elements, including precautionary statements

**Emergency Overview**

<table>
<thead>
<tr>
<th>Signal Word</th>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements</td>
<td></td>
</tr>
<tr>
<td>• Causes serious eye irritation</td>
<td></td>
</tr>
<tr>
<td>• Suspected of damaging fertility or the unborn child</td>
<td></td>
</tr>
<tr>
<td>• May cause damage to organs through prolonged or repeated exposure</td>
<td></td>
</tr>
<tr>
<td>• Effects on or via lactation</td>
<td></td>
</tr>
</tbody>
</table>
Appearance White to yellowish cream  Physical State Gel.  Odor Mild sweet odor

Precautionary Statements

Prevention
• Wash face, hands and any exposed skin thoroughly after handling.
• Wear eye/face protection.
• Do not breathe dust/fume/gas/mist/vapors/spray.
• Obtain special instructions before use.
• Do not handle until all safety precautions have been read and understood.
• Use personal protective equipment as required.
• Avoid contact during pregnancy/while nursing
• Do not eat, drink or smoke when using this product.

General Advice
• If exposed or concerned: Get medical attention/advice

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
• Store locked up.

Disposal
• Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information
None known

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>Diethylene glycol monoethyl ether</td>
<td>111-90-0</td>
<td>25</td>
<td>*</td>
</tr>
<tr>
<td>Dapsone</td>
<td>80-08-0</td>
<td>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 Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation persists.

Skin Contact Wash skin with soap and water. Remove and wash contaminated clothing before re-use. Get medical attention if symptoms occur.

Inhalation Not an expected route of exposure. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.
Ingestion
Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Get medical attention.

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

**Most Important Symptoms/Effects**

**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**
No information available.

**Specific Hazards Arising from the Chemical**
No information available.

**Explosion Data**

<table>
<thead>
<tr>
<th>Sensitivity to Mechanical Impact</th>
<th>None.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity to Static Discharge</td>
<td>None.</td>
</tr>
</tbody>
</table>

**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**
Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Refer to Section 8 for personal protective equipment.

**Environmental Precautions**
See Section 12 for additional Ecological Information.

**Methods and materials for containment and cleaning up**

**Methods for Containment**
Small spills: Wipe up with absorbent material (e.g. cloth, fleece). Large spills: Prevent further leakage or spillage if safe to do so. Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

**Methods for Cleaning Up**
Clean contaminated surface thoroughly.

---

### 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Handling**
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8.

**Conditions for safe storage, including any incompatibilities**

**Storage**
Keep containers tightly closed in a dry, cool and well-ventilated place.

**Incompatible Products**
Oxidizing agents.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

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

Appropriate engineering controls

Engineering Measures
- Showers
- Eyewash stations
- Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection
No special protective equipment required. Risk of contact, wear: Safety glasses with side-shields.

Skin and Body Protection Lightweight protective clothing. Latex gloves. Chemical resistant gloves.

Respiratory Protection None required under normal usage.

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. Provide regular cleaning of equipment, work area and clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and immediately after handling the product.

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>Gel</td>
<td>Appearance</td>
</tr>
<tr>
<td>Odor</td>
<td>Mild sweet odor</td>
<td>Odor Threshold</td>
</tr>
<tr>
<td>pH</td>
<td>6.0 - 8.0</td>
<td>None known</td>
</tr>
<tr>
<td>Melting Point/Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Boiling Point/Boiling Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flash Point</td>
<td>&gt; 93.3 °C / &gt; 200 °F</td>
<td>None known</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
<td>None known</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>None known</td>
</tr>
<tr>
<td>lower flammability limit</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No data available.</td>
<td>None known</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Dispersible</td>
<td>None known</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
<td>None known</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>Other information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY
Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Heat.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation
Not an expected route of exposure.

Eye Contact
Expected to be an irritant based on components.

Skin Contact
May be absorbed through the skin. May cause skin irritation and/or dermatitis. Prolonged or repeated contact may dry skin and cause irritation.

Ingestion
Nausea, vomiting and hyperexcitability can occur within minutes or hours of ingestion overdose. Other serious effects of overexposure can include periphera Ineupathy (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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>LD50 Oral</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethylene glycol monoethyl ether</td>
<td>1920 mg/kg (Rat)</td>
<td>9143 mg/kg (rat)</td>
<td>&gt; 5240 mg/m³ (Rat) 4 h</td>
</tr>
<tr>
<td>Dapsone</td>
<td>1 g/kg (Rat)</td>
<td>&gt; 4 g/kg (Rabbit)</td>
<td>-</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms
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. See additional effects listed for ingestion and chronic toxicity.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization
No information available.

Mutagenic Effects
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 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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dapsone</td>
<td></td>
<td>Group 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reproductive Toxicity

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 tomaternal toxicity.

Developmental Toxicity

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.

STOT - single exposure
Based on available data, the classification criteria are not met.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure. See listed target organs below.

Chronic Toxicity

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

Target Organ Effects

Peripheral Nervous System (PNS). Blood.

Aspiration Hazard
No information available.

Numerical measures of toxicity - Product

The following values are calculated based on chapter 3.1 of the GHS document:
LD50 Oral 5549 mg/kg; Acute toxicity estimate
LD50 Dermal 21122 mg/kg; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

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

<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>Diethylene glycol monoethyl ether 111-90-0</td>
<td>LC50 96 h: 11400-15700 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: 11600-16700 mg/L flow-through (Pimephales promelas) LC50 96 h: 19100-23900 mg/L flow-through (Lepomis macrochirus) LC50 96 h: = 10000 mg/L static (Lepomis macrochirus) LC50 96 h: = 13400 mg/L flow-through (Salmo gairdneri)</td>
<td>EC50 = 108 mg/L 15 min EC50 = 119 mg/L 5 min EC50 = 98.9 mg/L 30 min</td>
<td>EC50 48 h: 3940 - 4670 mg/L (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>Dapsone 80-08-0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Persistence and Degradability
No information available.

Bioaccumulation
No information available.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethylene glycol monoethyl ether</td>
<td>-0.8</td>
</tr>
</tbody>
</table>
Other Adverse Effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods
Dispose of in accordance with local regulations.

Contaminated Packaging
Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT
Not regulated

TDG
Not regulated.

MEX
Not regulated.

IATA
Not regulated.

IMDG/IMO
Not regulated.

15. REGULATORY INFORMATION

International Inventories
TSCA
Exempt

DSL
Exempt

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

Acute Health Hazard  Yes
Chronic Health Hazard Yes
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

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>Diethylene glycol monoethyl ether</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Dapsone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>X</td>
<td>X</td>
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</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>2</td>
<td>0</td>
<td>0</td>
<td>Physical Hazard 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Physical Hazard</th>
<th>Personal Protection</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2*</td>
<td>0</td>
<td>0</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Prepared By

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

Issuing Date 10-Sep-2008
Revision Date 22-Dec-2014
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.

End of Safety Data Sheet