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

Product Identifier

Material Name: Dapsone Gel (Greenstone LLC)

Trade Name: Not established
Chemical Family: Sulfone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>DAPSONE</td>
<td>80-08-0</td>
<td>201-248-4</td>
<td>Acute Tox. 4 (H302)</td>
<td>5</td>
</tr>
<tr>
<td>Diethylene glycol monoethyl ether</td>
<td>111-90-0</td>
<td>203-919-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
### 4. FIRST AID MEASURES

**Description of First Aid Measures**

- **Eye Contact:**
  Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

- **Skin Contact:**
  Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

- **Ingestion:**
  Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

- **Inhalation:**
  Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

- **Symptoms and Effects of Exposure:**
  No data available

- **Medical Conditions Aggravated by Exposure:**
  None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

- **Notes to Physician:**
  None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Extinguish fires with CO₂, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

- **Hazardous Combustion Products:**
  Formation of toxic gases is possible during heating or fire.

- **Fire / Explosion Hazards:**
  Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Diethylene glycol monoethyl ether
- Austria OEL - MAKs: 6 ppm, 35 mg/m³
- Estonia OEL - TWA: 10 ppm, 50.1 mg/m³
- Germany - TRGS 900 - TWAs: 6 ppm, 35 mg/m³
- Germany (DFG) - MAK: 50 mg/m³ can occur as vapor and aerosol at the same time
- Sweden OEL - TWAs: 15 ppm, 80 mg/m³

Sodium hydroxide
- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- France OEL - TWA: 2 mg/m³
- Greece OEL - TWA: 2 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Japan - OELs - Ceilings: 2 mg/m³
- Latvia OEL - TWA: 0.5 mg/m³
- OSHA - Final PELS - TWAs: 2 mg/m³
- Poland OEL - TWA: 0.5 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Sweden OEL - TWAs: 1 mg/m³

DAPSONE
- Lithuania OEL - TWA: 5 mg/m³

Manufacturer OEB Statement:
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

DAPSONE
- Manufacturer OEB: OEB3 (control exposure to the range of >10 µg/m³ to < 100 µg/m³)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
### Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

### Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

### Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

### Respiratory protection:
Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Gel</th>
<th>Color:</th>
<th>No data available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>DAPSONE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diethylene glycol monoethyl ether</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative Density:</td>
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<td></td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available.</td>
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</tr>
<tr>
<td>Flammability:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available.</td>
<td></td>
<td></td>
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<tr>
<td>Flammability (Solids):</td>
<td>No data available.</td>
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<td></td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available.</td>
<td></td>
<td></td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Known Clinical Effects: Adverse effects associated with therapeutic use include pain, loss of appetite (anorexia), unusual tiredness or weakness, bleeding, decreased red blood cell count (anemia), sensory/motor nerve injury (peripheral neuropathy), sore throat, vomiting, skin reaction.

Acute Toxicity: (Species, Route, End Point, Dose)

**DAPSONE**
- Rat Oral LD50 1000 mg/kg
- Mouse Oral LD50 250 mg/kg

Sodium hydroxide
- Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**DAPSONE**
- Reproductive & Fertility Rat Oral2 mg/kg/day NOAEL Fertility
- Embryo / Fetal Development Rat Oral 75 mg/kg/day LOAEL Embryotoxicity, Maternal Toxicity
- Embryo / Fetal Development Rabbit Oral 150 mg/kg/day LOAEL Embryotoxicity, Maternal Toxicity
- Reproductive & Fertility Rat Oral 12 mg/kg/day NOAEL Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

**DAPSONE**
- Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
- In Vivo Micronucleus Mouse Negative
- In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

**DAPSONE**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Concentration</th>
<th>NOAEL</th>
<th>Carcinogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>92 Week(s)</td>
<td>Female Rat</td>
<td>Oral 15 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td>100 Week(s)</td>
<td>Male Rat</td>
<td>Oral 15 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
</tbody>
</table>

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

**DAPSONE**

IARC: Group 3 (Not Classifiable)

**Carbomer**

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

- Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.
- Toxicity: No data available
- Persistence and Degradability: No data available
- Bio-accumulative Potential: No data available
- Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

| WHMIS hazard class: | None required |

**Diethylene glycol monoethyl ether**

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 203-919-7 |

**Sodium hydroxide**

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | 215-185-5 |

**Methylparaben**

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 202-785-7 |

**DAPSONE**

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | 201-248-4 |

**Carbomer**

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |
15. REGULATORY INFORMATION

Water
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 15-Aug-2017


Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet