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

Product Identifier

Material Name: Anidulafungin for Injection

Trade Name: ERAXIS; ECALTA; EQUALTHA
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antifungal agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
Serious Eye Damage/Eye Irritation: Category 2B

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning
Hazard Statements:
H320 - Causes eye irritation
May form combustible dust concentrations in air

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anidulafungin</td>
<td>166663-25-8</td>
<td>Not Listed</td>
<td>Eye Irrit. 2 (H320)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1 (H400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1 (H410)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1A (H314)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Press. Gas</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (H331)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fructose</td>
<td>57-48-7</td>
<td>200-333-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Tartaric acid</td>
<td>87-69-4</td>
<td>201-766-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

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: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: May include oxides of carbon and products of nitrogen.

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

Advice for Fire-Fighters

During all firefighting 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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. Do not freeze.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Anidulafungin

Pfizer OEL TWA-8 Hr: 200µg/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
Switzerland OEL - TWAs 2 mg/m³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m³
Austria OEL - MAKs 5 ppm
8 mg/m³
Belgium OEL - TWA 5 ppm
8 mg/m³
Bulgaria OEL - TWA 5 ppm
8.0 mg/m³
Cyprus OEL - TWA 5 ppm
8 mg/m³
Czech Republic OEL - TWA 8 mg/m³
Estonia OEL - TWA 5 ppm
8 mg/m³
Germany - TRGS 900 - TWAs 2 ppm
3 mg/m³
Germany (DFG) - MAK 2 ppm
3.0 mg/m³
Greece OEL - TWA 5 ppm
7 mg/m³
Hungary OEL - TWA 8 mg/m³
Ireland OEL - TWAs 5 ppm
8 mg/m³
Italy OEL - TWA 5 ppm
8 mg/m³
Japan - OELs - Ceilings 2 ppm
3.0 mg/m³
Latvia OEL - TWA 5 ppm
8 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Analytical Method:**
Analytical method available for anidulafungin. Contact Pfizer Inc for further information.

**Exposure Controls:**
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**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.)

---

<table>
<thead>
<tr>
<th>Material Name: Anidulafungin for Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tartaric acid</strong></td>
</tr>
<tr>
<td><strong>Germany (DFG) - MAK</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lithuania</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Malta</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Luxembourg</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Netherlands</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Poland</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Portugal</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Romania</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Slovakia</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Slovenia</strong></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Switzerland</strong></td>
<td>7.6 mg/m³</td>
</tr>
<tr>
<td><strong>Vietnam</strong></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Netherlands</strong></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Poland</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Romania</strong></td>
<td>5 ppm</td>
</tr>
<tr>
<td><strong>Slovakia</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Slovenia</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td><strong>Switzerland</strong></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td><strong>Vietnam</strong></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Lyophilized powder
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: Slightly soluble: Ethanol
Water solubility: \(<= 0.1\ \text{mg/mL}
Water Solubility: No data available
pH: 3.5-5.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

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: 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.

Short Term: May cause eye irritation. May cause slight skin irritation. (based on components). The active ingredient is not acutely toxic.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: May cause allergic reaction, nausea, headache, and diarrhea.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anidulafungin</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>Oral</td>
<td>&gt; 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>&gt; 1000 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>IV</td>
<td>71 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Mannitol</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>22 g/kg</td>
<td></td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Rat</td>
<td>Oral</td>
<td>25 g/kg</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Mouse</td>
<td>IP</td>
<td>&gt; 40 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anidulafungin</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Oral</td>
<td>&gt; 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Oral</td>
<td>&gt; 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Oral</td>
<td>&gt; 1000 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Oral</td>
<td>&gt; 1000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Anidulafungin

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month(s)</td>
<td>Rat</td>
<td>Oral 250 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Monkey</td>
<td>Intravenous 10 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>3 Month(s)</td>
<td>Mouse</td>
<td>Oral 100 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>3 Month(s)</td>
<td>Rat</td>
<td>Intravenous 10 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>6 Month(s)</td>
<td>Dog</td>
<td>Oral 100 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
</tbody>
</table>

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Anidulafungin
Reproductive & Fertility  Rat  Intravenous 20 mg/kg/day  NOAEL  No effects at maximum dose
Peri-/Postnatal Development  Rat  Intravenous 2 mg/kg/day  NOEL  Maternal Toxicity
Embryo / Fetal Development  Rabbit  Intravenous 10 mg/kg/day  NOAEL  Maternal Toxicity, Developmental toxicity

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

Anidulafungin
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Micronucleus  Mouse Bone Marrow  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Hydrochloric Acid
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  In the environment, the active ingredient in this formulation is expected to bind to soil or sediment. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Anidulafungin
Daphnia magna (Water Flea)  OECD  EC50  48 Hours  0.3 mg/L
Oncomirynchus mykiss (Rainbow Trout)  OECD  LC50  96 Hours  0.13 mg/L
Anabaena flos-aquae (Cyanobacteria)  OECD  EC50  96 Hours  > 0.11 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD  EC50  72 Hours  > 0.19 mg/L
Ceriodaphnia dubia (Daphnids)  EPA  ErC50  7 Days  > 0.260 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Anidulafungin
Aspergillus niger (Fungus)  OECD  EC-50 MIC  0.0005 mg/L
Clostridium perfringens (Bacterium)  OECD  MIC  8.4 mg/L
Trichoderma viride (Fungus)  OECD  MIC  > 210 mg/L
Bacillus subtilis (Bacterium)  OECD  MIC  >210 mg/L
Nostoc sp. (Freshwater Cyanobacteria)  OECD  MIC  > 210 mg/L

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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (anidulafungin)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:
* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

15. REGULATORY INFORMATION

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

Anidulafungin
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

Fructose
- 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
## 15. REGULATORY INFORMATION

### 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**: 200-333-3

### Hydrochloric Acid
- **CERCLA/SARA 313 Emission reporting**: 1.0 %
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 5000 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 6
- **EU EINECS/ELINCS List**: 231-595-7

### Mannitol
- **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**: 200-711-8

### Polysorbate 80
- **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

### Tartaric acid
- **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**: 201-766-0
16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Serious eye damage/eye irritation-Cat. 2B; H320 - Causes eye irritation
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date:
30-Nov-2018

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End of Safety Data Sheet