# SAFETY DATA SHEET



## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Anidulafungin for Injection

**Product Code(s)** PZ00406
**Trade Name:** ERAXIS; ECALTA; EQUALTHA
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antifungal agent

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

| | |
|---|---|
| **Serious eye damage/eye irritation** | Category 2A - (H319) |
| **Hazardous to the aquatic environment - acute** | Category 2 - (H401) |
| **Hazardous to the aquatic environment - chronic** | Category 2 - (H411) |

**OSHA Classification**

**Physical Hazard** Combustible Dust

**Hazards not otherwise classified (HNOC)**
Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**
Not applicable

### 2.2. Label elements

**Signal word** Warning

**Hazard statements**
H319 - Causes serious eye irritation
H411 - Toxic to aquatic life with long lasting effects
OSHA - May form combustible dust concentrations in air

**Precautionary Statements - EU (§28, 1272/2008)**
P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear eye protection/ face protection
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
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

### 2.3. Other hazards

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

**Anidulafungin**
Pfizer OEL TWA-8 Hr: 200 µg/m³

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

**Unknown acute toxicity**
10 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
10 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Substances** Not applicable

### 3.2 Mixtures

Hazardous

| Chemical name | Weight-% | REACH registration number | EC No. (Index No.) | Classification according to Regulation (EC) No. | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|---|---|---|---|---|---|---|

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | 1272/2008 [CLP] | | | |
| Anidulafungin (CAS #: 166663-25-8) | 10 | | Not Listed | Eye Irrit.2A (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) | Not classified | 1 | 1 |
| Sodium hydroxide (CAS #: 1310-73-2) | ** | - | 215-185-5 (011-002-00-6) | Skin Corr.1A (H314) | Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2% | No data available | No data available |
| + Hydrochloric Acid (CAS #: 7647-01-0) | ** | - | 231-595-7 (017-002-00-2) (017-002-01-X) | Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331) | Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10% | No data available | No data available |

NonHazardous

| Chemical name | Weight-% | REACH registration number | EC No. (Index No.) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|---|---|---|---|---|---|---|
| Mannitol (CAS #: 69-65-8) | * | - | 200-711-8 | Not classified | Not classified | No data available | No data available |
| Polysorbate 80 (CAS #: 9005-65-6) | * | - | 500-019-9 | Not classified | Not classified | No data available | No data available |
| Fructose (CAS #: 57-48-7) | * | | 200-333-3 | Not classified | Not classified | No data available | No data available |
| Tartaric acid (CAS #: 87-69-4) | * | | 201-766-0 | Not classified | Not classified | No data available | No data available |

**Full text of H- and EUH-phrases: see section 16**

***Acute Toxicity Estimate***

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|---|---|---|---|---|
| Mannitol 69-65-8 | 13500 | No data available | No data available | No data available | No data available |
| Polysorbate 80 9005-65-6 | 34.5 mL/kg | No data available | No data available | No data available | No data available |
| Anidulafungin 166663-25-8 | > 500 | >1000 | No data available | No data available | No data available |
| Tartaric acid 87-69-4 | No data available | 2000 | No data available | No data available | No data available |

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|---|---|---|---|---|
| Sodium hydroxide 1310-73-2 | 325 | 1350 | No data available | No data available | No data available |
| + Hydrochloric Acid 7647-01-0 | 238 | 5010 | No data available | No data available | 563.3022 |

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

**Additional information**
+ Substance with a Union workplace exposure limit
* Proprietary
** to adjust pH
Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

**Inhalation** Remove to fresh air. Seek immediate medical attention/advice.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**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.

### 4.2. Most important symptoms and effects, both acute and delayed

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

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** May include oxides of carbon and products of nitrogen

**Explosion data**

**Sensitivity to mechanical impact** No information available.
**Sensitivity to static discharge** No information available.

### 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.
**Methods for cleaning up** Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

**Advice on safe handling** Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.
**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging. Do not freeze.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1. Control parameters**

**Exposure Limits**
Refer to available public information for specific member state Occupational Exposure Limits.

**Anidulafungin**

| | |
|---|---|
| Pfizer OEL TWA-8 Hr: | 200 µg/m³ |

**Mannitol**

| | |
|---|---|
| Russia | MAC: 10 mg/m³ |

**Tartaric acid**

| | |
|---|---|
| Germany DFG | TWA-MAK: 2 mg/m³; I(2);inhalable fraction<br>Peak: 4 mg/m³; inhalable fraction |
| Germany TRGS | TWA-AGW; 2 mg/m³ (2(I)); inhalable fraction |
| Switzerland | TWA-MAK: 2 mg/m³; inhalable dust<br>STEL-KZGW: 4 mg/m³; inhalable dust |

**Sodium hydroxide**

| | |
|---|---|
| ACGIH OEL (Ceiling) | 2 mg/m³ |
| ACGIH TLV | Ceiling: 2 mg/m³ |
| Austria | TWA-TMW: 2 mg/m³; inhalable fraction<br>STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction |
| Bulgaria | TWA: 2.0 mg/m³; alkaline aerosols |
| Czech Republic | 1 mg/m³<br>Ceiling: 2 mg/m³ |
| Denmark | Ceiling: 2 mg/m³; |
| Estonia | TWA: 1 mg/m³;<br>STEL: 2 mg/m³; |
| Finland | Ceiling: 2 mg/m³; |
| France | 2 mg/m³ |
| Hungary | TWA-AK: 1 mg/m³;<br>STEL-CK: 2 mg/m³; |
| Ireland | STEL: 2 mg/m³; |
| Ceiling Limit Value | 2 mg/m³ |
| Latvia | TWA: 0.5 mg/m³; |
| Poland | TWA-NDS: 0.5 mg/m³;<br>STEL-NDSCh: 1 mg/m³; |
| Romania | TWA: 1 mg/m³;<br>STEL: 3 mg/m³; |
| Slovakia | TWA: 2 mg/m³; |
| Spain | STEL (VLA-EC): 2 mg/m³; |
| Switzerland | TWA-MAK: 2 mg/m³; inhalable dust<br>STEL-KZGW: 2 mg/m³; inhalable dust |
| OSHA PEL | TWA: 2 mg/m³<br>(vacated) Ceiling: 2 mg/m³ |
| United Kingdom | STEL: 2 mg/m³; |

**+ Hydrochloric Acid**

| | |
|---|---|
| ACGIH OEL (Ceiling) | 2 ppm |
| ACGIH TLV | Ceiling: 2 ppm |
| Austria | TWA-TMW: 5 ppm;<br>TWA-TMW: 8 mg/m³;<br>STEL-KZGW: 10 ppm (8 X 5 min);<br>STEL-KZGW: 15 mg/m³ (8 X 5 min); |
| Bulgaria | TWA: 5 ppm;<br>TWA: 8.0 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15.0 mg/m³; |
| Czech Republic | 8 mg/m³<br>Ceiling: 15 mg/m³ |
| Denmark | STEL: 5 ppm; |

| | |
|---|---|
| | STEL: 8 mg/m³; |
| Estonia | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| European Union | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Finland | STEL: 5 ppm;<br>STEL: 7.6 mg/m³; |
| Germany DFG | TWA-MAK: 2 ppm; I(2);<br>TWA-MAK: 3.0 mg/m³; I(2);<br>Peak: 4 ppm;<br>Peak: 6 mg/m³; |
| Germany TRGS | TWA-AGW; 2 ppm (2(I));<br>TWA-AGW; 3 mg/m³ (2(I)); |
| Hungary | TWA-AK: 8 mg/m³;<br>TWA-AK: 5 ppm;<br>STEL-CK: 165 mg/m³;<br>STEL-CK: 10 ppm; |
| Ireland | TWA: 8 mg/m³;<br>TWA: 5 ppm;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Italy MDLPS | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Ceiling Limit Value | 2 ppm<br>3.0 mg/m³ |
| Latvia | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Netherlands | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Poland | TWA-NDS: 5 mg/m³;<br>STEL-NDSCh: 10 mg/m³; |
| Romania | TWA: 5 ppm;<br>TWA: 8 mg/m³;<br>STEL: 10 ppm;<br>STEL: 15 mg/m³; |
| Russia | MAC: 5 mg/m³ |
| Slovakia | TWA: 5 ppm;<br>TWA: 8.0 mg/m³;<br>Ceiling: 15 mg/m³; |
| Spain | TWA-(VLA-ED): 5 ppm;<br>TWA-(VLA-ED): 7.6 mg/m³;<br>STEL (VLA-EC): 10 ppm;<br>STEL (VLA-EC): 15 mg/m³; |
| Switzerland | TWA-MAK: 2 ppm;<br>TWA-MAK: 3 mg/m³;<br>STEL-KZGW: 4 ppm;<br>STEL-KZGW: 6 mg/m³; |
| U.S. - OSHA - Final PELs - Ceiling Limits | 5 ppm |

| | |
|---|---|
| | 7 mg/m³ |
| OSHA PEL | Ceiling: 5 ppm<br>Ceiling: 7 mg/m³<br>(vacated) Ceiling: 5 ppm<br>(vacated) Ceiling: 7 mg/m³ |
| United Kingdom | TWA: 1 ppm; gas and aerosol mist<br>TWA: 2 mg/m³; gas and aerosol mist<br>STEL: 5 ppm; gas and aerosol mist<br>STEL: 8 mg/m³; gas and aerosol mist |

**8.2. Exposure controls**

**Engineering 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.

**Eye/face protection** 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.).

**Hand protection** 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.).

**Skin and body protection** 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.).

**Thermal hazards** No information available.

**Environmental exposure controls** No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

**9.1. Information on basic physical and chemical properties**

| | |
|---|---|
| **Appearance** | Lyophilized powder |
| **Physical state** | Powder |
| **Color** | White to off-white |
| **Odor** | No information available. |

| | |
|---|---|
| **Odor threshold** | No information available |

| **Property** | **Values** |
|---|---|
| **Melting point / freezing point** | No data available |
| **Boiling point or initial boiling point and boiling range** | No data available |
| **Flammability (solid, gas)** | No data available |
| **Lower and upper explosion limit/flammability limit** | |
| **Lower explosion limit** | No data available |
| **Upper explosion limit** | No data available |
| **Flash point** | No data available |
| **Autoignition temperature** | No data available |
| **Decomposition temperature** | |
| **SADT (°C)** | No data available |
| **pH** | 3.5-5.5 |
| **pH (as aqueous solution)** | No data available |
| **Kinematic viscosity** | No data available |
| **Dynamic viscosity** | No data available |
| **Solubility** | slightly soluble Ethanol |
| **Vapor pressure** | No data available |
| **Density and/or relative density** | No data available |
| **Bulk density** | No data available |
| **Liquid Density** | No data available |
| **Vapor density** | No data available |
| **Particle characteristics** | |
| **Particle Size** | No information available |
| **Particle Size Distribution** | No information available |

**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Anidulafungin**
Predicted 7.4 Log D -2.319

**9.2. Other information**

| | |
|---|---|
| **Molecular formula** | Mixture |
| **Molecular weight** | Mixture |

**9.2.1. Information with regard to physical hazard classes**
No information available

**9.2.2. Other safety characteristics**
No information available

## Section 10: STABILITY AND REACTIVITY

**10.1. Reactivity**
**Reactivity** No information available.
**10.2. Chemical stability**
**Stability** Stable under normal conditions.
**Explosion data**
**Sensitivity to mechanical impact** No information available.
**Sensitivity to static discharge** No information available.

**10.3. Possibility of hazardous reactions**
**Possibility of hazardous reactions** No information available.

**10.4. Conditions to avoid**
**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.
**10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

**10.6. Hazardous decomposition products**
**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients

**Short term** Causes eye irritation. May cause slight skin irritation. 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** Based on available data, the classification criteria are not met.
**Serious eye damage/eye irritation** Causes serious eye irritation. Classification is based on mixture calculation methods based on component data.
**Skin corrosion/irritation** Based on available data, the classification criteria are not met.
**Respiratory or skin sensitization** Not tested, the classification criteria are not met.
**STOT - single exposure** Not tested, the classification criteria are not met.
**STOT - repeated exposure** Based on available data, the classification criteria are not met.
**Reproductive toxicity** Based on available data, the classification criteria are not met.
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.
**Carcinogenicity** Not tested, the classification criteria are not met.
**Aspiration hazard** Not tested, the classification criteria are not met.

**Acute Toxicity: (Species, Route, End Point, Dose)**
**Mannitol**
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

**Polysorbate 80**
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

**Anidulafungin**
Rat Oral LD50 > 500 mg/kg
Dog Oral LD50 > 500 mg/kg
Rabbit Dermal LD50 > 1000 mg/kg
Rat IV LD50 71 mg/kg
**Sodium hydroxide**
Mouse IP LD50 40 mg/kg

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|---|---|---|
| Mannitol | = 13500 mg/kg ( Rat ) | - | - |
| Polysorbate 80 | = 34.5mL/kg ( Rat ) | - | - |
| Tartaric acid | | > 2000 mg/kg ( Rat ) | - |
| Sodium hydroxide | = 325 mg/kg ( Rat ) | = 1350 mg/kg ( Rabbit ) | - |
| + Hydrochloric Acid | 238 - 277 mg/kg ( Rat ) | > 5010 mg/kg ( Rabbit ) | = 1.68 mg/L ( Rat ) 1 h |

**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.

**Unknown acute toxicity**

10 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
10 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

**Irritation / Sensitization: (Study Type, Species, Severity)**
**Anidulafungin**
Eye Irritation Rabbit Positive
Skin Irritation Rabbit Mild
**Sodium hydroxide**
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe
**+ Hydrochloric Acid**
Skin irritation Severe
Eye irritation Severe

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**
**Anidulafungin**
1 Month(s) Rat Oral 250 mg/kg/day NOAEL No effects at maximum dose
13 Week(s) Monkey Intravenous 10 mg/kg/day NOAEL Liver
3 Month(s) Mouse Oral 100 mg/kg/day NOAEL Liver
3 Month(s) Rat Intravenous 10 mg/kg/day NOAEL Liver
6 Month(s) Dog Oral 100 mg/kg/day NOAEL Liver
6 Month(s) Rat Oral 350 mg/kg/day NOAEL None identified

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**
**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
Fertility and Embryonic Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 100 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity

**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
**+ Hydrochloric Acid**
Bacterial Mutagenicity (Ames) *Salmonella* Negative
*In Vivo* Micronucleus Rat Negative

**Carcinogenicity** See below
**+ Hydrochloric Acid**
IARC Group 3

**11.2. Information on other hazards**
**11.2.1. Endocrine disrupting properties**
**Endocrine disrupting properties** Not tested, the classification criteria are not met.

**11.2.2. Other information**
**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Toxic to aquatic life with long lasting effects. In the environment, the active ingredient in this formulation is expected to. bind to soil or sediment. Releases to the environment should be avoided.

**12.1. Toxicity**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**
**Anidulafungin**
*Daphnia magna* (Water Flea) OECD 202 EC50 48 hours 0.3 mg/L
*Oncorhynchus mykiss* (Rainbow Trout) OECD 203 LC50 96 hours 0.13 mg/L
*Anabaena flos-aquae* (Cyanobacteria) OECD 201 EC50 96 hours > 0.11 mg/L
*Pseudokirchneriella subcapitata* (Green Alga) OECD 201 ErC50 72 Hours > 0.19 mg/L
*Pseudokirchneriella subcapitata* (Green Alga) OECD 201 NOEC 72 hours 0.19 mg/L

**Bacterial Inhibition: (Inoculum, Method, End Point, Result)**
**Anidulafungin**
*Aspergillus niger* (Fungus) TAD 4.02 MIC 0.0005 mg/L
*Clostridium perfingens* (Bacterium) TAD 4.02 MIC 8.4 mg/L
*Trichoderma viride* (Fungus) TAD 4.02 MIC > 210 mg/L
*Bacillus subtilis* (Bacterium) TAD 4.02 MIC > 210 mg/L
*Nostoc sp.* (Freshwater Cyanobacteria) TAD 4.02 MIC > 210 mg/L

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**
**Anidulafungin**
*Ceriodaphnia dubia* (Daphnids) EPA 1002.0 7 Day(s) EC50 > 0.260 mg/L Reproduction
*Ceriodaphnia dubia* (Daphnids) EPA 1002.0 7 Day(s) NOEC 0.260 mg/L Reproduction
*Pimephales promelas* (Fathead Minnow) OECD 210 20 Day(s) NOEC 0.05 mg/L Survival

**12.2. Persistence and degradability**

**Persistence and degradability**

**Anidulafungin**
OECD 302B Activated sludge Die-away, Mineralization ($CO_2$ Evolution) 9.17 % in 28 Day(s)
OECD 302B Activated sludge Die-away DT50 3.6 Hour(s)

**12.3. Bioaccumulative potential**

**Bioaccumulation**

**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Anidulafungin**
Predicted 7.4 Log D -2.319

**12.4. Mobility in soil**

**Mobility in soil** Not considered mobile in the environment.

**Sorption:**
**Anidulafungin (166663-25-8)**

| Method | Inoculum | End Point | Result | Log Koc |
|---|---|---|---|---|
| OECD 106 | Clay Loam Soil | Koc | 52427 | 4.72 |
| OECD 106 | Sandy Soil | Koc | 25729 | 4.41 |
| OECD 106 | Silty Loam sediment | Koc | 28067 | 4.45 |
| OECD 106 | Sandy sediment | Koc | 80807 | 4.91 |

**12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

| Chemical name | PBT and vPvB assessment |
|---|---|
| Tartaric acid | Not PBT/vPvB |
| Sodium hydroxide | Not PBT/vPvB PBT assessment does not apply |
| + Hydrochloric Acid | Not PBT/vPvB PBT assessment does not apply |

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Not tested, the classification criteria are not met.

### 12.7. Other adverse effects

**Other adverse effects** No information available.
**PMT or vPvM properties** Based on available data, the classification criteria are not met.

| Chemical name | PMT and vPvM assessment |
|---|---|
| Anidulafungin | Not PMT/vPvM |

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste from residues/unused products**
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 wastewater 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.

## Section 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.**

**14.1 UN number:** UN 3077
**14.2 UN proper shipping name:** Environmentally Hazardous Substance, Solid, n.o.s (Anidulafungin)
**14.3 Transport hazard class(es):** 9
**14.4 Packing group:** III
**14.5 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 subject to the dangerous goods transportation regulations 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.

## Section 15: REGULATORY INFORMATION

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Mannitol

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | 200-711-8 |
| **AICS** | Present |

Polysorbate 80

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | Not Listed |
| **AICS** | Present |

Anidulafungin

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EINECS** | Not Listed |
| **Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)** | Schedule 4 |

Fructose

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | 200-333-3 |
| **AICS** | Present |

Tartaric acid

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | 201-766-0 |
| **AICS** | Present |

Sodium hydroxide

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | Not Listed |
| **Hazardous Substances RQs** | 1000 lb |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | 215-185-5 |
| **AICS** | Present |
| **Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)** | Schedule 5<br>Schedule 6 |

+ Hydrochloric Acid

| | |
|---|---|
| **CERCLA/SARA Section 313 de minimus %** | 1.0 % |
| **Hazardous Substances RQs** | 5000 lb |
| **California Proposition 65** | Not Listed |
| **TSCA** | Present |
| **EINECS** | 231-595-7 |
| **AICS** | Present |
| **Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)** | Schedule 5<br>Schedule 6 |

**National regulations**

**France**

**Occupational Illnesses (R-463-3, France)**

| Chemical name | French RG number |
|---|---|

| | |
|---|---|
| + Hydrochloric Acid<br>7647-01-0 | RG 66 |

**Germany**
**Chemical Prohibition Ordinance (ChemVerbotsV)**
Not applicable

**TRGS 905** Not applicable

**Switzerland**
**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable
**Storage of Hazardous Material** Not applicable
**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable
**Major Accidents Ordinance SR 814.012** Not applicable

**European Union**
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
**Authorizations and/or restrictions on use:**
This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

| Chemical name | Restricted substance per REACH Annex XVII | Substance subject to authorization per REACH Annex XIV |
|---|---|---|
| Sodium hydroxide<br>1310-73-2 | 75 | - |
| + Hydrochloric Acid<br>7647-01-0 | 75 | - |

**Persistent Organic Pollutants**
Not applicable

**Named dangerous substances per Seveso Directive (2012/18/EU)**

| Chemical name | Lower-tier requirements (tons) | Upper-tier requirements (tons) |
|---|---|---|
| + Hydrochloric Acid<br>7647-01-0 | 25 | 250 |

**Ozone-depleting substances (ODS) Regulation (EU) 2024/590**
Not applicable.

**EU - Plant Protection Products (1107/2009/EC)**

| Chemical name | EU - Plant Protection Products (1107/2009/EC) |
|---|---|
| Fructose<br>57-48-7 | Plant protection agent |

**Biocidal Products Regulation (EU) No 528/2012 (BPR)**

| Chemical name | Biocidal Products Regulation (EU) No 528/2012 (BPR) |
|---|---|
| Fructose<br>57-48-7 | Product-type 18: Insecticides, acaricides and products to control other arthropods Product-type 19: Repellents and attractants |
| Tartaric acid<br>87-69-4 | Simplified procedure - Category 1 |
| + Hydrochloric Acid<br>7647-01-0 | Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals |

**Explosives Precursors Marketing and Use (2019/1148)**
Not applicable

**Legend:**
**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
**ENCS** - Japan Existing and New Chemical Substances
**IECSC** - China Inventory of Existing Chemical Substances
**KECL** - Korean Existing Chemicals Inventory
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**AICS** - Australian Inventory of Chemical Substances
**NZIoC** - New Zealand Inventory of Chemicals
**TCSI** - Taiwan Chemical Substance Inventory

**15.2. Chemical safety assessment**
**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Full text of any hazard and/or precautionary statements referred to under Sections 2-15**
H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects. H314 - Causes severe skin burns and eye damage. H331 - Toxic if inhaled.

**Classification procedure**
Calculation method

| | |
|---|---|
| **Data Sources:** | Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients. |
| **Reason for revision** | Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. |
| **Revision date** | 27-May-2026 |
| **Prepared By** | Pfizer Global Environment, Health, and Safety |

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