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.

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. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Anidulafungin	10		Not Listed	Eye Irrit.	Not classified	1	1

(CAS #: 166663-25-8)				2A(H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			
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
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid	238	5010	No data available	No data available	563.3022

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
7647-01-0					

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 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 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 STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m³; alkaline aerosols
Czech Republic	1 mg/m³ Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³;
Estonia	TWA: 1 mg/m³; STEL: 2 mg/m³;
Finland	Ceiling: 2 mg/m³;
France	2 mg/m³
Hungary	TWA-AK: 1 mg/m³; 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; STEL-NDSCh: 1 mg/m³;
Romania	TWA: 1 mg/m³; STEL: 3 mg/m³;
Slovakia	TWA: 2 mg/m³;
Spain	STEL (VLA-EC): 2 mg/m³;
Switzerland	TWA-MAK: 2 mg/m³; inhalable dust STEL-KZGW: 2 mg/m³; inhalable dust
OSHA PEL	TWA: 2 mg/m³ (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; TWA-TMW: 8 mg/m³; STEL-KZGW: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm; TWA: 8.0 mg/m³; STEL: 10 ppm; STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³ Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm; STEL: 8 mg/m³;
Estonia	TWA: 5 ppm; TWA: 8 mg/m³;

	STEL: 10 ppm; STEL: 15 mg/m³;
European Union	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Finland	STEL: 5 ppm; STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m³; I(2); Peak: 4 ppm; Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (2(I)); TWA-AGW; 3 mg/m³ (2(I));
Hungary	TWA-AK: 8 mg/m³; TWA-AK: 5 ppm; STEL-CK: 165 mg/m³; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m³; Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m³;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m³; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m³;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m³

United Kingdom	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m^3 TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m^3; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m^3; 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

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

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

+ Hydrochloric Acid
IARC Group 3

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties Based on available data, 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 EC50 72 Hours > 0.19 mg/L
Bacterial Inhibition: (Inoculum, Method, End Point, Result)
Anidulafungin
Aspergillus niger (Fungus) OECD MIC 0.0005 mg/L
Clostridium perfingens (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
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

Anidulafungin
Predicted 7.4 Log D -2.319

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

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 Based on available data, 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.

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.

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 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 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 Schedule 6

National regulations

Chemical name	French RG number
+ Hydrochloric Acid 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 1310-73-2	75	-
+ Hydrochloric Acid 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 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 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 57-48-7	Product-type 18: Insecticides, acaricides and products to control other arthropods Product-type 19: Repellents and attractants
Tartaric acid 87-69-4	Simplified procedure - Category 1
+ Hydrochloric Acid 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.

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 12 - Ecological Information.
Revision date	01-Nov-2025
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.