



MATERIAL SAFETY DATA SHEET

Revision date: 28-Mar-2012

Version: 6.0

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

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Material Name: Anidulafungin for Injection

Trade Name:	ERAXIS; ECALTA
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antifungal agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white sterile lyophilized powder
Signal Word: WARNING

Statement of Hazard: Toxic to aquatic life with long lasting effects.

Additional Hazard Information:

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.

EU Indication of danger: Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Anidulafungin	166663-25-8	Not Listed	N;R50/53 Xi;R36	10
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Fructose	57-48-7	200-333-3	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Tartaric acid	87-69-4	201-766-0	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.
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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	May include oxides of carbon and products of nitrogen.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Anidulafungin

Pfizer OEL TWA-8 Hr: 200µg/m³

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	5 ppm 7.5 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³

Analytical Method:

Analytical method available for anidulafungin. Contact Pfizer Inc for further information.

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized powder	Color:	White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	Slightly soluble: Ethanol		
Water solubility:	<= 0.1 mg/mL		
pH:	3.5-5.5		

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

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

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

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

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Positive
Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit 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

Reproduction & Developmental Toxicity: (Study Type, 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

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.

Bioaccumulation and Toxicity:

This material has potential to bioaccumulate and long-term adverse effects to aquatic organisms are possible.

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

Anidulafungin

Daphnia magna (Water Flea) OECD EC50 48 Hours 0.3 mg/L
Oncorhynchus 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 EC-50 7 Days > 0.260 mg/L

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

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12. ECOLOGICAL INFORMATION

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

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

15. REGULATORY INFORMATION

EU Indication of danger: Dangerous for the Environment

EU Risk Phrases: R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

OSHA Label:

WARNING

Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:
 Class D, Division 2, Subdivision B



Anidulafungin	
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Fructose	
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	200-333-3
Mannitol	
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	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Tartaric acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-766-0
Sodium hydroxide	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5
Hydrochloric Acid	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Present

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15. REGULATORY INFORMATION

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.

R35 - Causes severe burns.

R36 - Irritating to eyes.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Reasons for Revision: Updated Section 14 - Transport Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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