



# SAFETY DATA SHEET

Revision date: 02-Oct-2017

Version: 1.0

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

### Product Identifier

**Material Name:** Isavuconazonium sulfate Powder for Injection

**Trade Name:** Not established  
**Synonyms:** Cresemba  
**Chemical Family:** Not determined

### 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  
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**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (repeated exposure): Category 1  
Acute aquatic toxicity: Category 1  
Chronic aquatic toxicity: Category 1

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:**  
H302 - Harmful if swallowed  
H361d - Suspected of damaging the unborn child  
H372 - Causes damage to organs through prolonged or repeated exposure liver and adrenal gland  
H410 - Very toxic to aquatic life with long lasting effects

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### Precautionary Statements:

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P270 - Do not eat, drink or smoke when using this product  
P264 - Wash hands thoroughly after handling  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P314 - Get medical attention/advice if you feel unwell  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

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

### Note:

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

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Isavuconazonium sulfate	946075-13-4	619-052-8	Acute tox.4 (H302) Repro 2 (H361d) STOT RE 1 (H372) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	> 50
SULPHURIC ACID ... %	7664-93-9	231-639-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*

### 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

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

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

<b>Notes to Physician:</b>	None
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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

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

<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	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

<b>Measures for Cleaning / Collecting:</b>	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.
<b>Additional Consideration for Large Spills:</b>	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

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### 7. HANDLING AND STORAGE

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

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical product used as antifungal agent

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### SULPHURIC ACID ... %

ACGIH Threshold Limit Value (TWA)	0.2 mg/m <sup>3</sup>
Australia STEL	3 mg/m <sup>3</sup>
Australia TWA	1 mg/m <sup>3</sup>
Austria OEL - MAKs	0.1 mg/m <sup>3</sup>
Belgium OEL - TWA	0.2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	0.05 mg/m <sup>3</sup>
Cyprus OEL - TWA	0.05 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Denmark OEL - TWA	0.05 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	0.05 mg/m <sup>3</sup>
France OEL - TWA	0.05 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.1 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup>
Greece OEL - TWA	0.05 mg/m <sup>3</sup>
Hungary OEL - TWA	0.05 mg/m <sup>3</sup>
Ireland OEL - TWAs	0.05 ppm
Italy OEL - TWA	0.05 mg/m <sup>3</sup>
Japan - OELs - Ceilings	1 mg/m <sup>3</sup>
Latvia OEL - TWA	0.05 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.05 mg/m <sup>3</sup>
Luxembourg OEL - TWA	0.05 mg/m <sup>3</sup>
Malta OEL - TWA	0.05 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.05 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA	0.05 mg/m <sup>3</sup>
Portugal OEL - TWA	0.05 mg/m <sup>3</sup>
Romania OEL - TWA	0.05 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.1 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.05 mg/m <sup>3</sup>
Spain OEL - TWA	0.05 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1 mg/m <sup>3</sup>

#### Exposure Controls

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.
<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	Impervious disposable 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.)
<b>Respiratory protection:</b>	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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Powder	<b>Color:</b>	White to yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Isavuconazonium sulfate</b>			
No data available			
<b>Mannitol</b>			
No data available			
<b>SULPHURIC ACID ... %</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		

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### 10. STABILITY AND REACTIVITY

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

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**Known Clinical Effects:** diarrhea headache constipation Based on clinical trials in humans, common possible adverse effects following exposure to this compound may include: nausea vomiting shortness of breath (dyspnea) cough and back pain

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

##### Isavuconazonium sulfate

Rat Oral LD 50 708 mg/kg  
Rat IV LD 50 10mg/kg  
Non-human Primate Intravenous LD 50 120mg/kg

##### Mannitol

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

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

##### Isavuconazonium sulfate

N/A Rat Oral 20 mg/kg/day NOAEL Liver, Adrenal gland  
N/A Monkey IV infusion 20 mg/kg/day NOAEL Liver, Adrenal gland

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

##### Isavuconazonium sulfate

Fertility & Embryonic Development (Male/Female) Rat Oral 90 mg/kg/day NOAEL Fertility  
Fertility & Embryonic Development (Male/Female) Rat Oral 90 mg/kg/day LOAEL Teratogenic, Developmental toxicity

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

##### Isavuconazonium sulfate

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Micronucleus Rat Bone Marrow Negative

**Carcinogen Status:** See below

**SULPHURIC ACID ... %**

**IARC:** Group 1 (Carcinogenic to Humans)

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### 11. TOXICOLOGICAL INFORMATION

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

**Toxicity:**

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

**Isavuconazonium sulfate**

Fish	N/A	NOEC	N/A	0.1 mg/L
<i>Daphnia magna</i> (Water Flea)	N/A	NOEC	N/A	0.1 mg/L
Algae	N/A	NOEC	N/A	0.081 ug/L

**Persistence and Degradability:**

**Biodegradation:**

**Isavuconazonium sulfate** Not readily biodegradable.

**Bio-accumulative Potential:** No data available

**Mobility in Soil:**

**Sorption: (Method, Inoculum, Sorption Endpoint, Endpoint, Results)**

**Isavuconazonium sulfate**

N/A	Activated sludge	Adsorption	KOC	2180 - 2660
N/A	Soil (various)	Adsorption	KOC	2,020 - 2,830

### 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.

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

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### 5 kg/5L Exception:

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

#### Isavuconazonium sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	619-052-8

#### 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

#### SULPHURIC ACID ... %

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	454 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	1000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 6
	231-639-5

## 16. OTHER INFORMATION

### Text of CLP/GHS Classification abbreviations mentioned in Section 3



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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
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  
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child  
Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure

**Data Sources:** Pfizer proprietary drug development information.

**Revision date:** 02-Oct-2017

Product Stewardship Hazard Communication

**Prepared by:** 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**