

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Dosage Form:** Powder for injection

**Product Name:** CRESEMBA® (isavuconazonium sulfate) for Injection

### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical research, manufacture of clinical drug product, and clinical use.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Astellas US LLC  
1 Astellas Way  
Northbrook, IL 60062  
Tel.: 800-888-7704

[www.us.astellas.com](http://www.us.astellas.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : 800-727-7003  
Medical Communications

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### Classification (GHS-US)

Comb. Dust  
Acute Tox. 4 (Oral) H302  
Skin Irrit. 2 H315  
Eye Irrit. 2A H319  
Repr. 2 H361  
STOT RE 1 H372  
Aquatic Chronic 1 H410

### 2.2. Label Elements

#### GHS-US Labeling

##### Hazard Pictograms (GHS-US)



##### Signal Word (GHS-US)

: Warning

##### Hazard Statements (GHS-US)

: May form combustible dust concentrations in air.  
H302 - Harmful if swallowed.  
H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H361 - Suspected of damaging the unborn child.  
H372 - Causes damage to organs (liver, adrenals, thyroid) through prolonged or repeated exposure.  
H410 - Very toxic to aquatic life with long lasting effects.

##### Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P273 - Avoid release to the environment.  
P280 - Wear eye protection, protective clothing, protective gloves.  
P301+P312 - If swallowed: Call a doctor, a POISON CENTER if you feel unwell.  
P302+P352 - If on skin: Wash with plenty of water.  
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P314 - Get medical advice/attention if you feel unwell.

# CRESEMBA® (isavuconazonium sulfate) for Injection

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

P321 - Specific treatment (see Section 4 on this SDS).  
P330 - Rinse mouth.  
P332+P313 - If skin irritation occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P391 - Collect spillage.  
P405 - Store locked up.  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

### 2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Isavuconazonium sulfate	(CAS No) 946075-13-4	80	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Repr. 2, H361 STOT RE 1, H372 Aquatic Chronic 1, H410
D-Mannitol	(CAS No) 69-65-8	<= 20	Comb. Dust
Mannitol	(CAS No) 87-78-5	<= 20	Comb. Dust

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

**First-aid Measures After Inhalation:** Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Gently wash with plenty of soap and water followed by rinsing with water for at least 15 minutes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

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

**Symptoms/Injuries:** Harmful if swallowed. Suspected of damaging the unborn child. Causes serious eye irritation. Causes skin irritation. Causes damage to organs (liver, adrenals, thyroid) through prolonged or repeated exposure.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** Causes skin irritation.

**Symptoms/Injuries After Eye Contact:** Causes serious eye irritation.

**Symptoms/Injuries After Ingestion:** Harmful if swallowed.

**Chronic Symptoms:** Suspected of damaging the unborn child. Prolonged or repeated exposure may cause damage to the liver, thyroid, or adrenals.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

# CRESEMBA® (isavuconazonium sulfate) for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Combustible dust. Fine dust clouds may form explosive mixtures with air.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

## 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers. Do not allow run-off from fire fighting to enter drains or water courses.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Other Information:** Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all contact with skin, eyes, or clothing. Avoid breathing (dust). Avoid generating dust.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and Material for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clear up spills immediately and dispose of waste safely. Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Take up large spills with vacuum. Contact competent authorities after a spill. Avoid generation of dust during clean-up of spills.

### 6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Local exhaust is recommended where dust may occur.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof electrical, ventilating, and lighting equipment.

**Storage Conditions:** Store in a dry, cool and well-ventilated place at 2 - 8 °C (35.6 - 46.4 °F). Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Products:** Strong oxidizers.

**Storage Temperature:** 2 - 8 °C (35.6 - 46.4 °F)

### 7.3. Specific End Use(s)

Pharmaceutical research, manufacture of clinical drug product, and clinical use of drug product.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment.

# CRESEMBA® (isavuconazonium sulfate) for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing. Dust formation: dust mask.



## Materials for Protective Clothing

: Chemically resistant materials and fabrics.

## Hand Protection

: Wear chemically resistant protective gloves.

## Eye Protection

: Chemical goggles or safety glasses.

## Skin and Body Protection

: Wear suitable protective clothing.

## Respiratory Protection

: In case of inadequate ventilation wear respiratory protection.

## Environmental Exposure Controls

: Do not allow the product to be released into the environment.

## Consumer Exposure Controls

: Do not eat, drink or smoke during use.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White to yellow cake
Odor	: Odorless
Odor Threshold	: No data available
pH	: 1.9 - 2.6
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: In water: > 1 g/mL
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available
Molecular Weight	: 814.84 g/mol (Isavuconazonium sulfate)

### 9.2. Other Information

No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Sulfur oxides. Hydrogen fluoride.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

Acute Toxicity: Harmful if swallowed.

CRESEMBA® (isavuconazonium sulfate) for Injection	
ATE (Oral)	885.00 mg/kg body weight
LD50 Intravenous Rat	≈ 10 mg/kg (i.v. bolus)
LD50 Intravenous Rat	> 20 mg/kg (i.v. slow bolus)
LD50 Intravenous Monkey	64 mg/kg (i.v. bolus)
LD50 Intravenous Monkey	120 mg/kg (i.v. infusion)

# CRESEMBA® (isavuconazonium sulfate) for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<b>Isavuconazonium sulfate (946075-13-4)</b>	
<b>LD50 Oral Rat</b>	708 - 1024 mg/kg
<b>D-Mannitol (69-65-8)</b>	
<b>LD50 Oral Rat</b>	13500 mg/kg

**Skin Corrosion/Irritation:** Causes skin irritation. Slight irritant at high concentrations, no irritation at  $\leq 1$  mg/mL. (pH: 1.9 - 2.6)

**Serious Eye Damage/Irritation:** Causes serious eye irritation. Slight irritant at high concentrations, no irritation at  $\leq 1$  mg/mL. (pH: 1.9 - 2.6)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

<b>Isavuconazonium sulfate (946075-13-4)</b>	
<b>Ames test</b>	Negative
<b>ML/TK</b>	Borderline positive at cytotoxic concentrations
<b>MNT in vivo</b>	Negative
<b>Assessment</b>	Not mutagenic

**Carcinogenicity:** Not classified. Isavuconazonium sulfate is not listed by NTP, OSHA, or IARC as a carcinogen.

**Reproductive Toxicity:** Suspected of damaging the unborn child. Based on animal data, isavuconazonium is predicted to have the potential teratogenic risk. Skeletal anomalies consistent with azole anti-fungal agents were reported in both rats and rabbits at systemic exposures below that observed for the clinical maintenance dose of 200 mg/day.

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Causes damage to organs (liver, adrenals, thyroid) through prolonged or repeated exposure.

<b>Isavuconazonium sulfate (946075-13-4)</b>	
<b>Liver</b>	Increased liver weight, hypertrophy
<b>Adrenals</b>	Increased adrenal weight, cortical hypertrophy
<b>Thyroid</b>	Increased thyroid weight, increased activity

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** Causes skin irritation.

**Symptoms/Injuries After Eye Contact:** Causes serious eye irritation.

**Symptoms/Injuries After Ingestion:** Harmful if swallowed.

**Chronic Symptoms:** Suspected of damaging the unborn child. Prolonged or repeated exposure may cause damage to the liver, thyroid, and adrenals.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Very toxic to aquatic life with long lasting effects.

<b>Isavuconazonium sulfate (946075-13-4)</b>	
<b>NOEC chronic fish</b>	0.1 mg/l (Pimephales promelas)
<b>NOEC chronic crustacea</b>	0.1 mg/l (Daphnia magna)
<b>EC<sub>10</sub> algae</b>	0.02 mg/l (Pseudokirchneriella subcapitata)
<b>EC<sub>50</sub> microorganisms</b>	> 100

### 12.2. Persistence and Degradability

<b>Isavuconazonium sulfate (946075-13-4)</b>	
<b>Persistence and Degradability</b>	Not readily biodegradable.
<b>DT<sub>50</sub> water</b>	3.3/4.4 d
<b>DT<sub>90</sub> water</b>	11/15 d
<b>DT<sub>50</sub> sediment</b>	222/33 d
<b>DT<sub>90</sub> sediment</b>	737/109 d
<b>DT<sub>50</sub> system</b>	204/13 d
<b>DT<sub>90</sub> system</b>	842/107 d
<b>Additional information</b>	The drug substance shifted from the water phase to the sediment phase with a maximum of 71% and 47% after 30 days and 7 days in system 1 and 2, respectively.  Two relevant metabolites (> 10% of applied radioactivity) were present in the sediment layer of one water/sediment system.

# CRESEMBA® (isavuconazonium sulfate) for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## 12.3. Bioaccumulative Potential

<b>Isavuconazonium sulfate (946075-13-4)</b>	
Log Kow	3.86

## 12.4. Mobility in Soil

<b>Isavuconazonium sulfate (946075-13-4)</b>	
Log Koc	2180 - 2660 L/kg (sludge); 2,020 - 2,830 L/kg (soil)

## 12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste Disposal Recommendations:** Dispose of contents and container according to local, regional, national, and international regulations.

**Ecology – Waste Materials:** This material is hazardous to the aquatic environment. Keep out of sewers and waterways. Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

### 14.1. In Accordance with DOT

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, SOLID, N.O.S. (Isavuconazonium sulfate)  
Hazard Class : 9  
Identification Number : UN3077  
Label Codes : 9  
Packing Group : III  
Marine Pollutant : Marine pollutant  
ERG Number : 171



### 14.2. In Accordance with IMDG

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Isavuconazonium sulfate)  
Hazard Class : 9  
Identification Number : UN3077  
Packing Group : III  
Label Codes : 9  
EmS-No. (Fire) : F-A  
EmS-No. (Spillage) : S-F  
Marine Pollutant : Marine pollutant



### 14.3. In Accordance with IATA

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Isavuconazonium sulfate)  
Packing Group : III  
Identification Number : UN3077  
Hazard Class : 9  
Label Codes : 9  
ERG Code (IATA) : 9L



## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

<b>CRESEMBA® (isavuconazonium sulfate) for Injection</b>	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard Immediate (acute) health hazard
<b>D-Mannitol (69-65-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Mannitol (87-78-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

### 15.2 US State Regulations

Neither this product nor its chemical components appear on any US state lists.

# CRESEMBA® (isavuconazonium sulfate) for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision Date** : 09/16/2016  
**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H361	Suspected of damaging the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*