



## SAFETY DATA SHEET

Version 2.0 12/1/2022

### SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** AZEDRA® (iobenguane I 131) Injection

**Synonyms** iobenguane I 131

**Product Uses** diagnostic radiopharmaceutical

**COMPANY IDENTIFICATION:** Progenics Pharmaceuticals, Inc., a Lantheus company  
331 Treble Cove Road  
Billerica, MA 01862  
United States of America  
1-800-299-3431

**EMERGENCY PHONE:** CHEMTREC 1-800-424-9300.  
For International Transportation Emergencies Call  
CHEMTREC @ 1-703-527-3887.  
Collect Calls are accepted

### SECTION 2: HAZARDS IDENTIFICATION

#### Classification

This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### Label Elements

None Required

#### Hazards not otherwise classified (HNOC)

AZEDRA® (iobenguane I 131) Injection is a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to household contacts consistent with institutional good radiation safety practices and patient management procedures.

### SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Component	Concentration	CAS
Water	99%	7732-18-5



Sodium Ascorbate	<1%	134-03-2
Sodium Gentsiate	<1%	4955-90-2
iobenguane	<0.1%	NA

**SECTION 4: FIRST AID MEASURES**

**Eye contact**

Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

**Skin contact**

Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

**Inhalation**

Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

**Ingestion**

Do not induce vomiting. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

**SECTION 5: FIRE-FIGHTING MEASURES**

**Flammable Properties**

Material is an aqueous solution. Not expected to be flammable.

**Suitable Extinguishing Media**

Use agent most appropriate to extinguish surrounding fire.

**Protection of Firefighters**

In the event of fire, wear self-contained breathing apparatus.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**Personal Precaution**

Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing

**Environmental Precautions**

Avoid release to the environment

**Methods for Containment and Clean Up**

Soak up with inert absorbent material. Keep in suitable, closed container for disposal.



### Other Information

If loss or release of the radioactive contents occurs, notify your Radiation Safety Department

## SECTION 7: HANDLING AND STORAGE

### Handling Precautions

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

### Storage Conditions

Store at -70°C (-94°F). The product vial is in a lead shielded container placed in a resealable plastic bag. The product is shipped on dry ice in a USA DOT Type A Radioactive package. Store and handle in a designated area. Keep away from heat, sparks and flames.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### Engineering Controls and Ventilation

Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. Ensure that eye wash stations and safety showers are close to the workstation location.

### Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### Eye/Face Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133

### Skin and Body Protection

Wear appropriate protective gloves and clothing to prevent skin exposure

### Hygiene Measures

Wash hands and face before breaks and immediately after handling the product.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State</b>	Liquid
<b>Appearance</b>	Clear, colorless to pale yellow
<b>Odor</b>	Odorless
<b>pH</b>	4.5-5.5
<b>Molecular Weight</b>	Not Available
<b>Solubility</b>	Soluble
<b>Flashpoint</b>	Not Available



<b>Density</b>	Not Available
<b>Boiling Point</b>	Not Available
<b>Melting Point</b>	Not Available
<b>Melting Point</b>	Not Available
<b>Vapor Density</b>	Not Available
<b>Vapor Pressure</b>	<760
<b>Radioactivity</b>	Dosimetric: 1,110 MBq (30 mCi) of iobenguane I 131 at calibration time. Therapeutic: 12,488 MBq (337.5 mCi) of iobenguane I 131 at calibration time.
<b>Specific Activity</b>	2500 mCi/ $\mu$ mole (92,500 MBq/mg)
<b>Half Life</b>	8.021 days

#### SECTION 10: STABILITY AND REACTIVITY

<b>Stability</b>	The shelf life is 6 days post calibration time stored at -70°C (-94°F). Discard appropriately at 144 hours
<b>Conditions to Avoid</b>	Not Available
<b>Incompatible Products</b>	Not Available
<b>Hazardous Decomposition Products</b>	None under normal use conditions
<b>Hazardous Reactions</b>	None under normal processing

#### SECTION 11: TOXICOLOGICAL INFORMATION

<b>Routes of Entry</b>	Ingestion, Inhalation, Eye Contact, Skin Contact
<b>Eye Irritation</b>	Not Available
<b>Skin Irritation</b>	Not Available
<b>Respiratory Irritation</b>	Not Available
<b>Sensitization</b>	Not Available
<b>Acute Toxicity</b>	Not Available
<b>Chronic Toxicity</b>	Not Available
<b>Carcinogenicity</b>	Not Available
<b>Reproductive Toxicity</b>	Not Available



### Other Toxicity Information

In a 28-day repeat dose IV toxicity study in dogs, iobenguane I 127 was well-tolerated at concentrations of 0.22, 0.66, and 1.085 mg/kg/day (4.4, 13.2 and 21.7 mg/m<sup>2</sup>). As anticipated due to the mechanism of action of iobenguane, transient irregular respiration was noted in animals administered iobenguane I 127 at all doses at the time of dosing.

The irregular respiration was considered test article-related, however, it was not considered adverse because the sign was generally seen only at dosing, and no other correlating clinical signs were observed. No other test article-related findings were noted. Therefore, the NOAEL in this study was 1.085 mg/kg/day (21.7 mg/m<sup>2</sup>).

## Section 12: ECOLOGICAL INFORMATION

**Environmental Fate:** Not Available

**Environmental Toxicity:** Not Available

## SECTION 13: DISPOSAL CONSIDERATIONS

### Advice on Disposal and Packaging

Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

## SECTION 14: TRANSPORT INFORMATION

### DOT

UN Number: 2915, Class 7

### IATA

UN Number: 2915, Class 7

## SECTION 15: REGULATORY INFORMATION

### United States of America

OSHA Hazard Classification: No OSHA Hazards, Radioactive—This regulation does not address hazards related to radioactivity.

CERCLA RQ: I-131 = 0.01 (3.7E 8 Bq)

SARA 302: The following components are subject to reporting levels established by SARA Title III, Section 302: None

311/312 SARA Hazard Classes: Chronic Health Hazard



313 Toxic Release Inventory.  
Listed Chemicals/Compounds

No components listed on the SARA 313 inventory.

TSCA Inventory

Not listed. Food, drug and cosmetic products are exempt from TSCA.

## SECTION 16: OTHER INFORMATION

### SDS preparation information

**Prepared by** Environment, Health and Safety 1-978-671-8673

**Prepared on** 12/1/2022

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information and we assume no liability from its use.