AZEDRA® (iobenguane I 131) Injection

# MATERIAL SAFETY DATA SHEET

## 1. COMPANY IDENTIFICATION

Product Name: AZEDRA® (iobenguane I 131) Injection

CAS Number: 77679-27-7

Product Code: 71258-015

Synonyms: iobenguane I 131

Manufacturer/Distributor: Sofie, Co.
110 Clyde Road
Somerset NJ, 08873

Technical information Phone No.: AZEDRA SERVICE CONNECTION™ at 1-844-AZEDRA1 (1-844-293-3721)

Emergency No.: AZEDRA SERVICE CONNECTION™ at 1-844-AZEDRA1 (1-844-293-3721)

## 2. HAZARD IDENTIFICATION

**Emergency overview**: Read package insert prior to use. AZEDRA injection is a diagnostic and therapeutic 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.

**Physical and Chemical Hazard Rating**

**NFPA: Health – 2 Fire – 0 Specific – Radioactive Stability – 0**

**HMIS: Health – 2 Flammability – 0 Reactivity/Physical – 0**
**Personal Protection – Yes**

**Potential Health Effects**

**Inhalation**: A small fraction of Iodine-131 may volatilize which may result in asymptomatic physiological uptake by thyroid gland or other tissues.

**Ingestion**: May cause symptomatic physiological uptake by thyroid gland or other tissues.

**Skin Contact**: Can contribute to your overall long-term radiation exposure.

**Eye Contact**: Not considered an acute health hazard but should be avoided since first aid measures are required as described below.

**Chronic Exposure**: The health risks associated with chronic radiation exposure (bone marrow problems and other cancers, thyroid problems, genetic and teratogenic effects) are based on exposures much higher than those permitted occupationally.

**Aggravation of Pre-existing Conditions**: May cause allergic reaction in individuals sensitive to iodine.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Each single-dose vial contains iobenguane (0.006 mg/mL), sodium ascorbate (58 mg/mL) and sodium gentisate (23 mg/mL) in Water for Injection, USP. The pH range of the solution is 4.5 to 5.5, with specific activity of ~2,500 mCi/mg (92,500 MBq/mg).

- Dosimetric (2 mL per vial): 1,110 MBq (30 mCi) of iobenguane I 131 at calibration time (NDC 71258-015-02).
- Therapeutic (22.5 mL per vial): 12,488 MBq (337.5 mCi) of iobenguane I 131 at calibration time (NDC 71258-015-22).

# 4. FIRST-AID MEASURES

**Eyes**: Immediately flush eyes with water for at least 15 minutes. Notify Radiation Safety Officer immediately. Call a physician if irritation develops.

**Skin**: Wash exposed area with approved decontamination media. Notify Radiation Safety Officer immediately. Call a physician if irritation develops.

**Ingestion**: Notify Radiation Safety Officer immediately. The amount of I-131 in the thyroid gland and other tissues should be assessed and documented. A thyroid blocking agent may need to be administered at the discretion of a physician.

# 5. FIRE-FIGHTING MEASURES

**Fire**: Not considered to be a fire hazard.

**Explosion**: Not considered to be an explosion hazard.

**Fire Extinguishing Media**: Use any means suitable for extinguishing surrounding fire.

**Special Instructions**: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

# 6. ACCIDENTAL RELEASE MEASURES

If the product is received in a leaking condition or any loss or release of the radioactive contents occurs, notify your Radiation Safety Department and AZEDRA Service Connection at 1-844-AZEDRA1 (1-844-293-3721). All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations.

# 7. HANDLING AND STORAGE

Store at -70°C (-94°F). The product vial is in a lead shielded container placed in a re-sealable plastic bag. The product is shipped on dry ice in a USA DOT Type A Radioactive package.

Handling devices such as syringe shields and tongs should be used. Disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

# 8. EXPOSURE CONTROLS/PERSONAL

**Airborne Exposure Limits**: NRC occupational concentration limit is $3 \times 10^{-6}$ μCi/mL of

air.

**Engineering Controls**: Properly sealed containers are not expected to require any special ventilation.

**Respiratory Protection**: Not expected to require personal respirator usage.

**Skin Protection**: Disposable plastic, latex, or rubber gloves; lab coat.

**Eye/Face Protection**: Safety glasses.

**Precautions**: No smoking, eating, or drinking should be allowed in any area where radioactive materials are handled or stored.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Appearance**: | Clear, colorless to pale yellow solution |
| **Odor**: | Odorless |
| **Solubility**: | Dissolves in water |
| **pH**: | 4.5 – 5.5 |
| **Boiling Point**: | > 100°C |
| **Melting Point**: | < 0°C |
| **Vapor Density (Air=1):** | No data available |
| **Vapor Pressure (mm Hg):** | < 760 |
| **Radioactivity:** | 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. |
| **Specific activity:** | ~2,500 mCi/mg (92,500 MBq/mg). |

# 10. STABILITY AND REACTIVITY

**Half-Life:** 8.021 days

**Stability**: The shelf life is 6 days post calibration time stored at -70°C (-94°F). Discard appropriately at 144 hours.

| | |
|---|---|
| **Conditions to Avoid**: | Not known. |
| **Incompatibilities**: | No information found. |
| **Hazardous Polymerization**: | Will not occur. |

**Hazardous Decomposition Products**: May emit radioactive fumes containing I-131 when heated to decomposition.

# 11. TOXICOLOGICAL 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/m2). 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 $mg/m^2$).

# 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** Because this product is intended for use by hospital patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

# 13. DISPOSAL INFORMATION

AZEDRA (iobenguane I 131) Diagnostic and Therapeutic preparations must be considered Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a Biohazard and disposed of accordingly.

# 14. TRANSPORT INFORMATION

**DOT (Department of Transportation):** UN Number: 2915, Class 7

**Proper Shipping Name:** Radioactive Material, Type A Package

**Hazard Class**: 7

**Identification Number:** UN Number: 2915, Class 7

**IATA:** UN Number: 2915, Class 7

# 15. REGULATORY INFORMATION

**OSHA Hazard Communication**: This product is a pharmaceutical, it is not regulated under the under the OSHA Hazard Communication Standard (29 CFR 1910.1200) guidelines.

**CERCLA Reportable Quantities**: I-131 = 0.01 (3.7E 8 Bq)

Releases to the environment which exceed the Reportable Quantity (RQ) must be reported to the National Response Center at (800) 424-8802.

**SARA Title III:**

302 Extremely Hazardous Substances: None

311 / 312 Hazard Categories: Chronic

313 Toxic substances subject to annual release reporting requirements: None

**RCRA Hazardous Waste Status**: Non-hazardous (See Section 13 for additional details)

**California Proposition 65 Warning**: This product contains a substance known to the State of California to cause cancer.

**WHMIS**: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

# 16. OTHER INFORMATION

Issue Date: 07Sep2018

Revision Date: N/A

Disclaimer:

Progenics provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgement in determining it appropriateness for a particular purpose.

**Progenics Pharmaceuticals, Inc.**
**One World Trade Center, 47th floor, Suite J**
**New York, NY 10007**