


Issue date: September 2016	<b>SAFETY DATA SHEET</b> <b>Axumin™</b> <b>Fluciclovine F 18 Injection</b>	 <b>BLUE EARTH</b> <small>DIAGNOSTICS</small>
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<b>SECTION 1 – CHEMICAL PRODUCT &amp; COMPANY IDENTIFICATION</b>
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**Product name:** Axumin™

**Synonyms:** Fluciclovine F 18 injection

**Manufacturer:** Manufactured for Blue Earth Diagnostics Limited by:

PETNET Solutions, Inc.  
810 Innovation Drive  
Knoxville, TN 37932

**Phone:** 1-888-473-8638

**Emergency phone:** 1-800-255-3924 (CHEMTEL)

<b>SECTION 2 – HAZARD IDENTIFICATION</b>
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**Emergency Overview:** Read package insert prior to use. Axumin™ is a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to clinical personnel and patients. Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose training and experience has been approved by the appropriate government agency authorized to license the use of radionuclides.

**Physical & Chemical Hazard Ratings**

(0 = minimal, 1 = slight, 2 = moderate, 3 = serious, 4 = severe)

**NFPA:** Health 1      Flammability 0      Stability 0

**HMIS:** Health 1      Flammability 0      Stability 0

**Potential Health Effects:**

**Inhalation:** Axumin™ does not easily become airborne. Not expected to be a health hazard via inhalation.

**Ingestion:** May cause asymptomatic physiological uptake by specific target organs or tissues.

**Skin Contact:** Not considered an acute health hazard.

**Eye Contact:** May cause eye irritation on contact.

**Chronic Exposure:** Data on biological effects of ionizing radiation are based on exposures much higher than those permitted occupationally. No effects are expected from exposures received as a result of normal use.

<b>SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS</b>
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<b><u>Ingredient</u></b>	<b><u>CAS Number</u></b>	<b><u>%Wt</u></b>
Fluciclovine F18	222727-39-1	<0.1%
Sodium citrate	6132-04-3	2%
Sodium hydroxide	1310-73-2	0.3%
Hydrochloric acid	7647-01-0	0.8%
Water	7732-18-5	96.9%

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**SECTION 4 – FIRST AID MEASURES**

**Eyes:** In case of eye contact, 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 soap and water or other approved decontamination media. Notify Radiation Safety Officer immediately. Call a physician if irritation develops.

**Ingestion:** Notify radiation safety personnel immediately. The amount of material ingested should be assessed and documented.

**Inhalation:** Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented.

**SECTION 5 – FIRE FIGHTING MEASURES**

**Flammable Properties:** Not flammable

**Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Explosion Data:** None.

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus operated in pressure-demand or positive pressure mode and full protective clothing.

**SECTION 6 – ACCIDENT RELEASE MEASURES**

Any clean-up of spilled radioactive material should be conducted under the direction of site radiation safety personnel.

**SECTION 7 – HANDLING AND STORAGE**

**Handling:** Always observe good health physics and hygiene practice when handling radioactive material.

**Storage:** Store at 15 - 30° C. Do not freeze or expose to heat. Material should be shielded when not in use.

**SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION**


**Exposure Limits:** Exposure limits have not been established for this product

**Engineering Measures:** Eyewash station and good general room ventilation

**Eye/Face Protection:** Avoid contact with eyes & face, use eye protection

**Skin & Body Protection:** Disposable latex, nitrile or rubber gloves, lab coat

**Respiratory Protection:** Not required under normal conditions of use.

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**Hygiene Measures:** No smoking, eating, drinking or application of cosmetics should be allowed in areas where radioactive materials are handled or stored.

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State:</b>	Liquid	<b>Autoignition Temperature:</b>	None
<b>Appearance:</b>	Clear, colorless	<b>Flammable Limits:</b>	None
<b>Odor:</b>	Odorless	<b>Boiling Point:</b>	ca 100°C (212°F)
<b>Solubility:</b>	Soluble in water	<b>Melting Point:</b>	ca 0°C (32°F)
<b>Specific Gravity:</b>	1 g/mL	<b>Vapor Pressure (mm Hg):</b>	No data available
<b>Viscosity:</b>	No data available	<b>Evaporation Rate:</b>	No data available
<b>pH:</b>	4 - 6	<b>Vapor Density:</b>	No data available
<b>Flash Point:</b>	None		
<b>Radioactivity:</b>	10 mCi at calibration date and time, or as specified		
<b>Specific Activity:</b>	>1 mCi/μg fluciclovine at time of calibration		
<b>Half-Life:</b>	109.7 minutes		

**SECTION 10 – STABILITY AND REACTIVITY**

**Stability:** Stable under specified conditions of use and storage.

**Conditions to Avoid:** None known

**Incompatible Products:** None known

**Hazardous Decomposition Products:** May emit radioactive fumes containing F-18 when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

**SECTION 11 – TOXICOLOGICAL INFORMATION**


It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia, and genetic and teratogenic effects. Axumin™ is an amino acid analogue, which concentrates in cells that actively transport amino acids.

**SECTION 12 – ECOLOGICAL INFORMATION**

**Ecotoxicity:** Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

**SECTION 13 – DISPOSAL CONSIDERATIONS**

Axumin™ is 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 Program. Consult local, state and federal regulations for proper disposal.

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<b>SECTION 14 – TRANSPORT INFORMATION</b>
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**DOT:** Domestic US Ground Shipments  
**Proper Shipping Name:** Radioactive Material, Type A package  
**Hazard Class:** 7  
**Identification Number:** UN2915

**IATA and ICAO:** Commercial Air or International  
**Proper Shipping Name:** Radioactive Material, Type A package  
**Hazard Class:** 7  
**Identification Number:** UN2915

<b>SECTION 15 – REGULATORY INFORMATION</b>
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**OSHA Hazard Communication:** This product is a pharmaceutical, it is not regulated under the OSHA Hazard Communication Standard (29 CFR 1910.1200) guidelines.

**CERCLA Reportable Quantities:**  
 Fluorine-18 = 1,000 Ci (3.7 x 10<sup>13</sup> Bq)  
 Releases to air, land or water of these hazardous substances, 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 Hazardous Categories: Acute, Chronic  
 313 Toxic Substances subject to annual reporting requirements: None

**CWA:** Not regulated

**RCRA hazardous Waste Status:** Non-hazardous (See Section 12 for details)

**California Proposition 65:** This product contains a substance (radioactive material) known to the State of California to cause cancer.

**Canada:** This MSDS contains all of the information required by the Controlled Products Regulations (CPR).

<b>SECTION 16 – OTHER INFORMATION</b>
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**Revision Date: September 2016**

**Disclaimer:**

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**End of SDS**