

# Advanced Accelerator Applications USA, Inc.

## SAFETY DATA SHEET

**Creation Date** 20 Dec. 2016

**Revision Date: N/A Issue**

**Information Telephone Number:** 212-235-2395

**Emergency Telephone Number:** 1-844-367-3222

Distributed by:

Advanced Accelerator Applications USA, Inc.

57 E. Willow Street

Milburn, NJ 07041

### 1. Identification

**Product Name** NETSPOT® Kit for the Preparation of Gallium Ga 68 Dotatate Injection

**Cat No.:** Not available

**Synonyms** Kit for the preparation of Gallium Ga 68 Dotatate Injection

**Recommended Use** Preparation of radiolabeled diagnostic solution

**Uses advised against** No Information available

### 2. Composition, Information on Ingredients

#### Classification

This chemical is considered Non-hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

This kit contains two vials and a silica containing cartridge. The contents of the kit are not radioactive.

Vial 1: A lyophilized solid whose composition is:

<u>Component</u>	<u>CAS</u>	<u>Wt. %</u>
Dotatate	177943-89-4	0.2
1,10-Phenanthroline	5144-89-8	0.025
Gentisic Acid	490-79-9	0.03
Mannitol	69-65-8	99.75

Vial 2: An aqueous solution of:

Formic Acid	64-18-6	6.0
Sodium Hydroxide	1310-73-2	5.65

### 3. Hazard(s) identification

#### **Emergency Overview**

Read the Package Insert prior to use. Promptly remove any contamination from the skin, eyes or clothing. Avoid unnecessary exposure to the chemical substances.

#### **Potential Health Effects**

The hazardous, non-radioactive ingredients found in NETSPOT Kit for the Preparation of Gallium Ga68 Dotatate are skin and/or eye irritants. However, the small quantities present in each container are expected to present no adverse health effects from exposure.

**Inhalation**

**Eye Contact**

Not expected to be a health hazard

Not expected to be a health hazard

**Ingestion**

Not expected to be a health hazard

**Chronic Exposure**

Not expected to be a chronic health hazard

**Skin Contact**

Not expected to be a health hazard

**Aggravation of Pre-Existing Conditions**

No information available

## 5. Fire-fighting measures

**Suitable Extinguishing Media** The components are not considered to be a fire hazard.

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

**Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. Accidental Release Measures

Collect non-radioactive spills and dispose of material as non-hazardous waste. **For NETSPOT Gallium 68 Ga Dotatate reconstituted** with Gallium 68, if any loss or release of the radioactive contents occurs notify your Radiation Safety Department. All cleanup operations should be performed according to Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations.

## 7. Handling and storage

For prolonged storage, store NETSPOT in its original packaging at room temperature below 25°C (do not freeze). After reconstitution keep Ga 68 Dotatate injection upright with an appropriate shielding to protect from radiation, at a temperature below 25 °C (do not freeze), and for a maximum of 4 hours. The storage of the radiolabeled product must comply with regulatory requirements for radioactive materials.

## 8. Exposure controls / Personal protection

<b>Engineering Measures</b>	Not expected to require special ventilation before radiolabeling.
<b>Eye/face Protection</b>	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
<b>Skin and body protection</b>	Wear appropriate protective gloves and clothing to prevent skin exposure.
<b>Respiratory Protection</b>	Not expected to require personal respirator before radiolabeling.
<b>Hygiene Measures</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Physical State</b>	2 Vials – one containing a sterile aqueous liquid and the other a sterile lyophilized solid cake
<b>Appearance</b>	White and clear liquid
<b>Odor</b>	Odorless
<b>Melting Point/Range</b>	approximately 0°C (reconstituted)
<b>Boiling Point/Range</b>	approximately 100°C (reconstituted)
<b>Flash Point</b>	Not applicable
<b>Evaporation Rate</b>	No information available
<b>Flammability or explosive limits</b>	

Upper  
Lower  
Solubility

No data available  
No data available  
Soluble in water

## 10. Stability and reactivity

<b>Reactive Hazard</b>	None known, based on information available
<b>Stability</b>	Stable
<b>Conditions to Avoid</b>	Avoid prolonged storage above 25° C. Do not freeze.
<b>Incompatible Materials</b>	No information available
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> )
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous Reactions</b>	None under normal processing.

## 11. Toxicological information

For detailed toxicological information on specific components write to the address listed in Section 1 – Attn.: Regulatory Affairs Department.

## 12. Ecological information

This product is intended for use by hospital or clinic personnel; it is expected to be treated before radiolabeling by standard wastewater treatment facilities with no adverse environmental impacts.

## 13. Disposal considerations

**Waste Disposal Methods** Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

## 14. Transport information

DOT Not Regulated

## 15. Regulatory information

**CERCLA Reportable Quantities** None for non-radiolabeled material

### SARA Title III

302 Extremely Hazardous Substances: None

311/312 Hazard Categories: None

313 Toxic Substances subject to annual release reporting requirements: Formic Acid, Sodium Hydroxide

**RCRA Hazardous Waste Status:** Non-hazardous

**California Proposition 65 Warning:** When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

## 16. Other information

**Product Use:** Diagnostic Imaging Agent

**Revision Information:** No Changes – Initial Issue

**NFPA Ratings:** Health: 0 Flammability: 0 Reactivity: 0

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of SDS**