SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Gallium Citrate Ga-67 Injection

Version 3.1 11/4/2015

Product Uses This material is used as a radioactive tracer. It is a radioactive isotope of Gallium (Ga-67).

COMPANY IDENTIFICATION:

Lantheus Medical Imaging
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

EMERGENCY OVERVIEW:

Appearance Clear, colorless liquid

Signal Word Danger!

Hazard Statements Radioactive

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Wear eye protection when handling Wash hands after handling to minimize exposure. Care should be taken to minimize radiation exposure. Pregnant or nursing women should avoid exposure. Appropriate radiation shielding should be used. Keep material in a lead container. Avoid direct handling by using remote manipulation tools.

Potential Health Effects

Eyes	Not Available
Skin	Not Available
Ingestion	Exposure to radioactive materials may produce adverse effects.
Inhalation	Exposure to radioactive materials may produce adverse effects.
Target Organs	Not Available
Signs and Symptoms	Acute: Nausea, vomiting, allergic reactions, itching, Redness, rash, bleeding. Chronic: Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity.

Environmental Effects Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance Gallium Citrate GA-67

Chemical Identity Aqueous Mixture

Common Name/Synonym: Gallium Citrate Ga-67; Gallium Citrate Ga 67; Gallium-67; Gallium 67; Ga-67; Ga 67

Hazardous Components

Component	Concentration	CAS
Gallium Citrate GA-67	<0.001%	41183-64-6

Other Components

Sodium Chloride	<1%	7647-14-5
Benzyl Alcohol	<1%	100-51-6
Sodium Citrate Dihydrate	<1%	6132-04-3
Water	>99%	7732-18-5

Other Information: Gallium-67 is a gamma emitting radionuclide with significant gamma rays up to 393 KeV. The gamma ray constant is 1.1 R/hr per mCi at a distance of 1 cm. It has a physical half-life of 78.3 hours.
Sodium hydroxide and/or hydrochloric acid are used for pH adjustment.
Each mililiter of the isotonic solution contains 74 MBq (2 mCi) of Gallium Ga 67 on the calibration date.

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.
Skin contact	Remove contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Dispose of contaminated clothing according to company procedures and governmental regulations for radioactive waste or alternately hold contaminated clothing for radioactive decay 10 half-lives or 1 month.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
Note to Physicians	This material is used as a radioactive tracer. It is a radioactive isotope of Gallium (Ga-67). This product can cause: Nausea, vomiting, allergic reactions, itching, Redness, rash, bleeding, Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, adverse effects on lactation. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties	Material is an aqueous solution. Not expected to be flammable.
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	*Specific hazards:* Radioactive. Heating can release hazardous gases. *Protective equipment:* Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes. Specific hazards: Not available. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products	Radioactive gallium, radioactive breakdown products, Carbon oxides, Hydrogen halides
Other Information	Decontaminate protective clothing and equipment before reuse or dispose of as radioactive waste. See Section 6.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions	Contact the company Radiation Safety Officer. Care should be taken to minimize radiation exposure. Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental Precautions	Prevent release to drains and waterways. Prevent release to the environment.

Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see section 13).
Cleanup Methods	Contact the company Radiation Safety Officer. Dispose of cleanup materials as radioactive waste. Isolate waste in sealed, clearly labeled containers and dispose of according to company procedures and governmental regulations. Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Contact the company Radiation Safety Officer. Label as radioactive material. Store and handle in a designated area. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination. Obtain appropriate governmental licenses to possess and handle radioactive material. Highly potent material. Avoid exposure. Handling time should be kept to a minimum. Appropriate radiation shielding should be used. Avoid inhalation of vapor or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways. *For a complete discussion of Handling and Storage information, please consult the full prescribing information.*
Storage Conditions	Storage and disposal of product should be controlled in a manner compliant with applicable governmental regulations pertaining to radionuclides. Store and handle in a designated area. Store at room temperature. 20 - 25°C Keep away from heat, sparks and flames.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Gallium- 67	---	---	---	---
Gallium Citrate GA-67	---	---	---	---
Sodium Chloride	---	---	---	---
Benzyl Alcohol	---	---	---	---
Sodium Citrate Dihydrate	---	---	---	---
Water	---	---	---	---

Exposure Control Banding Not Available

Lantheus Medical Imaging Exposure Guidelines Summary
Gallium Citrate Ga-67
A specific exposure guideline has not yet been established. Materials require particular care and handling.

Recommended Industrial Hygiene Monitoring Methods
Contact the Lantheus Medical Imaging Radiation Protection Office at 978-671-8672 or 8673.

Engineering Controls and Ventilation
Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.

Respiratory Protection
Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient to control exposure to below the exposure limit, wear an approved supplied air respirator. Note: Exposure to radioactive materials may produce adverse effects.

Eye Protection
Chemical safety goggles and face shields are recommended. Note: Choice of eye protection may be influenced by the type of respirator which is selected.

Hand Protection
Impervious nitrile, rubber and latex gloves are recommended. Double gloving for all manufacturing personnel potentially in direct contact with the compound should be considered. If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

Skin and Body Protection
Wear disposable coverall, polyethylene apron and sleeves, and shoe covers.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Liquid
Color	Clear, colorless
Odor	Odorless

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
pH	4.5-8
Boiling Point	100C
Freezing Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended storage conditions. Gallium-67 is a gamma emitting radionuclide with significant gamma rays up to 393 KeV. The gamma ray constant is 1.1 R/hr per mCi at a distance of 1 cm. It has a physical half-life of 78.3 hours.
Conditions to Avoid	Heat, flames and sparks
Incompatible Products	Not available

Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: Radioactive gallium, radioactive breakdown products, Carbon oxides, Hydrogen halides
Hazardous Reactions	Hazardous polymerisation does not occur. Heating can release hazardous gases. HCl gas can form flammable or explosive mixtures with alcohols or metals.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Not Available
Skin Irritation	Not Available
Respiratory Irritation	Not Available
Sensitization	Not Available

Acute Toxicity

Acute toxicity (other routes of administration)

Gallium Citrate

LD50 (mouse, subcutaneous): 600 mg/kg
LD50 (rat, intravenous): > 220 mg/kg
LD50 (rat, subcutaneous): 100 mg/kg
LD50 (rabbit, intravenous): > 20 - 25 mg/kg
LD50 (rabbit, subcutaneous): 45 mg/kg
LD50 (dog, intravenous, 15 Days): 18.2 mg/kg
LD50 (dog, subcutaneous): 10 - 15 mg/kg

Repeated Dose Toxicity

Gallium Citrate

13 Weeks Dietary rat study : LOAEL = 1,000 mg/kg Effects include: death.

Genetic Toxicity

Not Available

Carcinogenicity

Gallium-67

Carcinogenicity Assessment

Gamma radiation is carcinogenic to humans.

Carcinogenity	ACGIH	OSHA	NTP	IARC
Gallium-67	---	---	---	1
Gallium Citrate GA-67	---	---	---	1
Gallium Citrate	---	---	---	---

Reproductive/Developmental Toxicity

Gallium Citrate Ga-67

Assessment Reproductive Toxicity

See also "Developmental Toxicity" for information on reproductive effects.

Gallium Citrate Ga-67

Developmental Toxicity Assessment

Limited data are available. This material has been shown to cross the placenta. This compound and/or its metabolites may be excreted into the milk. See "Human Experience". Exposure to radioactive materials may produce adverse effects.

Human Experience

Experiences with Human Exposure

Gallium Citrate Ga-67

General effects therapeutic use - Symptoms: Nausea, vomiting, allergic reactions, itching, Redness, rash, bleeding. Other effects include: adverse effects on lactation. This material has been shown to cross the placenta.

Target Organs *Gallium Citrate Ga-67*: embryo/fetus

Symptoms *Gallium Citrate Ga-67*: See “Human Experience”

Other Toxicity Information Not Available

Section 12 ECOLOGICAL INFORMATION

Environmental Fate: Not available

Environmental Toxicity: Ecotoxicological Information (Aquatic) Not available
Ecotoxicological Information (Terrestrial) Not available

SECTION 13: Disposal Considerations

Advice on Disposal and Packaging	Segregate and label radioactive waste. 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.
Other Information	The information presented below only applies to the material as supplied.

SECTION 14: TRANSPORT INFORMATION

US DOT Transportation Classification for All Modes

The classification for transportation of radioactive materials will depend on the specific activity level of the material, type of isotope, as well as the quantity shipped. Specific site procedures should be followed for shipping radioactive materials or seek advice from your site radiation safety officer.

SECTION 15: REGULATORY INFORMATION

United States of America

OSHA Hazard Classification	No OSHA hazards Note: This regulation does not address hazards related to radioactivity
CERCLA/SARA RQ	Gallium-67 RQ = 100 Ci Gallium-67 RQ = 3.7 TBq Gallium-67 RQ = 1 lb Gallium-67 RQ = 0.454 kg
311/312 SARA Hazard Classes	Gallium Citrate Ga-67 Injection 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.
California Prop. 65	Carcinogen Radionuclides

International

Canada

WHMIS	Not Rated Note: This regulation does not address hazards related to radioactivity
DSL/NDSL	Not Listed

Mexico

Mexico Classification	Health classification - Minimal hazard - 0 – Substances that do not pose a hazard under emergency conditions other than that of ordinary combustible materials. Note: This regulation does not address hazards related to radioactivity.

Europe

EINECS/ELINCS Number	Gallium Citrate Ga-67: 255-248-4 Sodium Chloride: 231-598-3 Benzyl alcohol: 202-859-9 Water: 231-791-2
R-phrase(s)	C-snft: Caution - substance not yet fully tested. Note: This regulation does not address hazards related to radioactivity.
S-phrase(s)	S23: Do not breathe gas/fumes/vapour/spray. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S38: In case of insufficient ventilation, wear suitable respiratory equipment. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by	Environment, Health and Safety 1-978-671-8673
Prepared on	11/4/2015

Other Information:

HMIS

Health	0
Flammability	Not Determined
Reactivity	Not Determined
Personal Protective Equipment	See Section 8

NFPA

Health	0
Fire	Not Determined
Reactivity	Not Determined
Special	Not Determined

The information contained in this MSDS 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.