

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION		
<i>Product Information</i>		
Product name	Gallium Citrate Ga-67 Injection	
Version	2.0, 01/31/2007	
Active substance	Gallium Citrate Ga-67	
Synonyms	Gallium Citrate Ga-67; Gallium Citrate Ga 67; Gallium-67; Gallium 67; Ga-67; Ga 67	
Product Uses	This material is used as a radioactive tracer. It is a radioactive isotope of Gallium (Ga-67).	
<i>Company/Undertaking Identification</i>		
Address	Lantheus Medical Imaging 331 Treble Cove Road Billerica, MA 01862 United States of America 1-800-299-3431	
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergencies call CHEMTREC at 1-703-527-3887. Collect calls accepted.	
2. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Concentration	CAS-No.
<i>Hazardous components</i>		
Gallium Citrate Ga-67	<0.001 %	41183-64-6
<i>Other ingredients</i>		
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 milliliter of the isotonic solution contains 74 MBq (2 mCi) of Gallium Ga 67 on the calibration date.		
3. HAZARDS IDENTIFICATION		
<i>Emergency Overview</i>		
Appearance	liquid : clear colourless	
Signal Word	Danger	
Hazard Statements	Radioactive.	

3. HAZARDS IDENTIFICATION

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.
<i>Potential Health Effects</i>	
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.
<i>Environmental Effects</i>	Not available

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	Take off 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	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.
Notes to physician	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.

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.

5. FIRE-FIGHTING MEASURES

Protection of Firefighters	<p>Specific hazards: Radioactive. Heating can release hazardous gases.</p> <p>Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.</p> <p>Hazardous Combustion Products: Radioactive gallium, radioactive breakdown products, Carbon oxides, Hydrogen halides</p> <p>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.</p>
Other information:	Decontaminate protective clothing and equipment before reuse or dispose of as radioactive waste. See Section 6.

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.

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 - obtain special instructions before use. Handling time should be kept to a minimum. Appropriate radiation shielding should be used. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
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.

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 Band	Not available			
Lantheus MI Exposure Guidelines Summary	<u>Gallium Citrate Ga-67</u> 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.			

9. PHYSICAL AND CHEMICAL PROPERTIES

<i>Appearance</i>	
Physical State	liquid
Color	clear colourless
Form	Not available

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9. PHYSICAL AND CHEMICAL PROPERTIES*Descriptive properties*

Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	odorless
Odor Threshold	Not available
pH	4.5 - 8
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	Not available
Viscosity	Not available

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C
Oxidizing Potential	Not available

Vapor Properties

Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY*Stability*

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.

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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 Study **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.

Carcinogenicity	ACGIH	OSHA	NTP	IARC
Gallium-67	--	--	--	1
Gallium Citrate Ga-67	--	--	--	1
Gallium Citrate	--	--	--	--

Reproductive Toxicity Gallium Citrate Ga-67
Assessment Reproductive Toxicity
 See also "Developmental Toxicity" for information on reproductive effects.

Developmental Toxicity 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.

11. TOXICOLOGICAL INFORMATION

Target Organs	<u>Gallium Citrate Ga-67</u> embryo/fetus
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Symptoms	<u>Gallium Citrate Ga-67</u> See "Human Experience".
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Other Toxicity Information	Not available
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12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic)	Not available
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Ecotoxicological Information (Terrestrial)	Not available
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Chemical fate information	Not available
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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.
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Other information	This information presented below only applies to the material as supplied.
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14. TRANSPORT INFORMATION**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.

15. REGULATORY INFORMATION**United States of America**

OSHA Hazard Classification	No OSHA Hazards, Note: This regulation does not address hazards related to radioactivity..	
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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
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313 Toxic Release Inventory. Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
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TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.
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California Prop. 65	Carcinogen	Radionuclides
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International

Canada

WHMIS	Not Rated
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15. REGULATORY INFORMATION

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-phrases)

C-snft: Caution - substance not yet fully tested.

Note: This regulation does not address hazards related to radioactivity.

S-phrases)

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).

16. OTHER INFORMATION*MSDS preparation information*

Prepared by

Environmental Health & Safety 1-978-671-8673

Prepared on

01/31/2007

This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

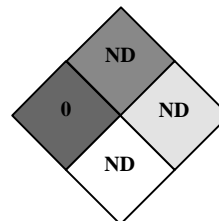
Other information

HMIS

Health	0
Flammability	Not Determined (ND)
Reactivity	Not Determined (ND)
Personal protective equipment	See Section 8.

NFPA

Health 0
Fire ND
Reactivity ND
Special ND



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.