SAFETY DATA SHEET

1. Identification

Product identifier GALLIUM CITRATE Ga 67 INJECTION

Other means of identification

SDS number GA67I

Synonyms Gallium 67 * Gallium Citrate Ga 67

Recommended use The content of this kit as sold is radioactive.

Gallium Citrate Ga 67 Injection may be useful to demonstrate the presence and extent of Hodgkin's disease, lymphoma, and bronchogenic carcinoma. Gallium Citrate Ga 67 Injection may be useful as an aid in detecting some acute inflammatory lesions.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Manufacturer

Company name Mallinckrodt Nuclear Medicine LLC

Address 2703 Wagner Place
Maryland Heights, MO 63043
United States

Telephone number Customer Service 888-744-1414

Emergency telephone number 24 Hour Emergency 314-654-1600

Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Reproductive toxicity — Effects on or via lactation

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Labeling

Contains BENZYL ALCOHOL

Label elements

Hazard symbol None.

Signal word None.

Hazard statement May cause harm to breast-fed children.

RADIOACTIVE MATERIAL HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL

Precautionary statement

Prevention Obtain special instructions before use. Do not breathe mist or vapor. Avoid contact during pregnancy/while nursing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

Response If exposed or concerned: Get medical advice/attention.

Storage Store away from incompatible materials.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations. Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Comission (NRC) is the Federal agency responsible protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
WATER	HYDROGEN OXIDE DIHYDROGEN OXIDE WATER, DISTILLED	7732-18-5	> 99
BENZYL ALCOHOL	Benzenecarbinol; benzenemethanol; alpha-hydroxytoluene; Phenylmethyl alcohol; Phenyl carbinol	100-51-6	<1
SODIUM CHLORIDE	Salt; Rock Salt; Saline; Table Salt	7647-14-5	< 1
SODIUM CITRATE DIHYDRATE		6132-04-3	< 1
Gallium Citrate Ga 67		41183-64-6	< 0.001

Composition comments

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Gallium Citrate Ga 67 Injection is supplied in a 10 milliliter vial as an isotonic, sterile, non-pyrogenic solution. Each milliliter of the isotonic solution contains 74 megabecquerels (2 millicuries) of Gallium Ga 67 on the calibration date as a complex formed from 8.3 nanograms gallium chloride Ga 67, 1.9 milligrams of sodium citrate dihydrate, 7.8 milligrams of sodium chloride and 0.9 percent benzyl alcohol (v/v) as a preservative. The pH is adjusted to between 5.5 to 8.0 with hydrochloric acid and/or sodium hydroxide solution.

4. First-aid measures

Inhalation

Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.

Skin contact

Wash off with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion

Notify radiation safety personnel immediately. Rinse mouth. The amount of material ingested should be assessed and documented.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Rare occurrences of allergic reactions, skin rash and nausea have been reported in association with Gallium Citrate Ga 67 use.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Flammable properties	No unusual fire or explosion hazards noted.
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Radioactive. During fire, gases hazardous to health may be formed such as: Radioactive gallium, radioactive breakdown products, Carbon oxides, and Hydrogen chloride. HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion.
Special 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.
Fire-fighting equipment/instructions	Ensure and follow all guidance provided in handling fire involving radioactive materials. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. In case of fire and/or explosion do not breathe fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Follow all guidances provided by NRC. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs. Appropriate radiation shielding should be used. Provide adequate ventilation. Do not breathe mist or vapor. Do not get this material in your eyes, on your skin, or on your clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Wash hands thoroughly after handling. Observe good industrial hygiene practices. All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority.
Conditions for safe storage, including any incompatibilities	Store at controlled room temperature 20-25°C (68-77°F). Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Storage and 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 protection

Occupational exposure limits

U.S. - WEEL

Components	Type	Value
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44 mg/m3
		10 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines The specific gamma ray constant for Gallium Ga 67 is 1.6 R/mCi-hour at 1 cm.

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Chemical resistant gloves.

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection Not expected to require personal respirator usage.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Follow all guidances provided by NRC or equivalent authority and your radiation safety personnel. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Clear, colorless liquid in a 10 mL glass vial.

Physical state Liquid.

Form Liquid.

Color Colorless.

Odor Odorless.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 46.42 °F (8.01 °C) estimated / 32 °F (0 °C)
32 °F (0 °C) / 46.42 °F (8.01 °C) estimated

Initial boiling point and boiling range 212 °F (100 °C)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	Specific Activity: 2 mCi/8.3 ng of gallium on the calibration date and time.
Concentration	2 mCi/mL on the calibration date and time.
Half-Life	78.26 hours
Radioactivity	3, 6 or 12 mCi/vial on the calibration date and time.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. Gallium Ga 67 with a physical half-life of 78.26 hours1 decays by electron capture to stable Zinc Zn 67. The specific gamma ray constant for Gallium Ga 67 is 1.6 R/mCi-hour at 1 cm.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	May emit radioactive fumes containing Ga 67 when heated to decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Exposure to radioactive materials may produce adverse effects. May cause asymptomatic physiological uptake by thyroid gland or other tissues.
Inhalation	Exposure to radioactive materials may produce adverse effects. Gallium Citrate does not easily become airborne.
Skin contact	Exposure to radioactive materials may produce adverse effects. May be irritating to the skin.
Eye contact	Direct contact with eyes may cause temporary irritation. Exposure to radioactive materials may produce adverse effects.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Rare occurrences of allergic reactions, skin rash and nausea have been reported in association with Gallium Citrate Ga 67 use.

Information on toxicological effects

Acute toxicity	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
Chronic effects	The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Components	**Species**	**Test Results**
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
Dermal		
LD50	Guinea pig	<= 5 ml/kg
	Rabbit	2000 mg/kg

Components	Species	Test Results
Inhalation		
LC100	Rat	200 - 300 mg/l, 8 Hours
LC50	Rat	1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rabbit	1940 mg/kg
	Rat	1230 - 3100 mg/kg
Other		
LD50	Guinea pig	>= 400 mg/kg
	Mouse	324 mg/kg
		<= 0.5 ml/kg
	Rat	53 mg/kg

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Rare occurrences of allergic reactions, skin rash and nausea have been reported in association with Gallium Citrate Ga 67 use.

Skin sensitization Rare occurrences of allergic reactions, skin rash and nausea have been reported in association with Gallium Citrate Ga 67 use.

Germ cell mutagenicity No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is a potential mutagen to human. The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Carcinogenicity No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is carcinogenic to humans. The cancer risks associated with chronic radiation exposure are believed to involve levels of radiation exposure which are much higher than those permitted occupationally. Risk of cancer cannot be excluded with prolonged exposure.

Reproductive toxicity No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. This drug is known to be excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feedings. Animal reproductive studies have not been conducted with Gallium Citrate Ga 67. It is also not known whether Gallium Citrate Ga 67 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Gallium Citrate Ga 67 should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature of women of childbearing capability, should be performed during the first few (approximately ten) days following the onset of menses.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Further information No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females.

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

Components		Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)			
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 Hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL	1.1

Mobility in soil No data available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions Gallium Citrate Ga 67 Injection is 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. If not a biohazard, consult local, state and federal regulations for proper disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk -

Label(s) 7

Packing group Not applicable.

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Special provisions A56, W7, W8

Packaging exceptions None

Packaging non bulk 415, 418, 419

Packaging bulk 415, 418, 419

IATA

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk -

Packing group Not applicable.

Environmental hazards No.

ERG Code 7L

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Other information

Passenger and cargo aircraft Allowed.

Cargo aircraft only Allowed.

IMDG

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not applicable.
Environmental hazards	
Marine pollutant	No.
EmS	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA; IMDG

15. Regulatory information

US federal regulations

Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Comission (NRC) is the Federal agency responsible protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

BENZYL ALCOHOL (CAS 100-51-6)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

BENZYL ALCOHOL (CAS 100-51-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-21-2016

Version # 01

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Revision Information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Data
Ecological Information: Ecotoxicity
HazReg Data: North America
GHS: Classification