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.

It is used as a diagnostic radiopharmaceutical.

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

Supplier

Company name Curium Canada Inc.

Address 2572 Daniel-Johnson Boulevard
Suites 217 & 220
Laval, QC H7T 2R3
Canada

Telephone number Customer Service phone number: 866-885-5988

E-mail NuclearMedicine@curiumpharma.com

Emergency telephone number: 24 Hour Emergency 314-595-3700

Chemtrec 800-424-9300

2. Hazard identification

Physical hazards Not classified.

Health hazards Reproductive toxicity Effects on or via lactation

Label elements

Hazard symbol None.

Signal word None.

Hazard statement May cause harm to breast-fed children.

Precautionary statement

Prevention Obtain special instructions before use. Do not breathe mist/vapours. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy and while nursing. 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.

Other hazards None known.

Supplemental information 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		7732-18-5	> 99
Benzyl alcohol		100-51-6	< 1
Sodium chloride		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

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. Hydrogen chloride. In the event of fire and/or explosion, HCl gas can form flammable or explosive mixtures with alcohols or metals.

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 or equivalent authority. 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 in the US or equivalent authority in your country 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. Provide adequate ventilation. Do not breathe mist or vapour. Do not get in eyes, on skin, or on 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 at 20–25 ºC (68-77ºF). 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
No exposure limits noted for ingredient(s).

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 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. Suitable gloves can be recommended by the glove supplier.

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

Respiratory protection
No personal respiratory protective equipment normally required.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Follow all guidances provided by the US Nuclear Regulatory Commission 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.

Colour
Colourless.

Odour	Odourless.
Odour 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	100 °C (212 °F)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1
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.
Explosive properties	Not explosive.
Half-Life	78.26 hours (Radioactive)
Oxidising properties	Not oxidising.
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 oxidising agents.
Hazardous decomposition products	May emit radioactive fumes containing Ga 67 when heated to decomposition.

11. Toxicological information

Information on likely routes of exposure

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.

Ingestion Exposure to radioactive materials may produce adverse effects. May cause asymptomatic physiological uptake by thyroid gland or other tissues.

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.

Components	Species	Test Results
Benzyl alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Guinea pig	<= 5 ml/kg
	Rabbit	2000 mg/kg
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
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Other		
LD50	Mouse	2602 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 sensitisation

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

Skin sensitisation 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, leukaemia, 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 health risks associated with chronic radiation exposure (cancer, leukaemia, genetic and teratogenic effects) 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.

Chronic effects The health risks associated with chronic radiation exposure (cancer, leukaemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

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
Sodium chloride (CAS 7647-14-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	6020 - 7070 mg/l, 96 hours
SODIUM CITRATE DIHYDRATE (CAS 6132-04-3)			
Aquatic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	655 - 825.9 mg/l, 48 hours

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)
Benzyl alcohol (CAS 100-51-6) 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

TDG

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class	7
Subsidiary risk	-
Packing group	Not available.
Environmental hazards	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

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 available.
Environmental hazards	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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 available.
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	This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies 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

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Version No. 03

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