SAFETY DATA SHEET



1. Identification

Product identifier Gallium Citrate Ga 67 Injection

Other means of identification

SDS number GA67I

Gallium 67 * Gallium Citrate Ga 67 **Synonyms**

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

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

Curium US LLC Company name **Address** 2703 Wagner Place

Maryland Heights, MO 63043

United States

Customer Service 888-744-1414 Telephone number E-mail NuclearMedicine@curiumpharma.com 24 Hour Emergency 314-595-3700

Emergency telephone number:

Chemtrec 800-424-9300

2. Hazard(s) identification

Not classified. **Physical hazards**

Health hazards Reproductive toxicity Effects on or via lactation

OSHA defined hazards Not classified.

Label elements

None. **Hazard symbol** 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

Obtain special instructions before use. Do not breathe mist/vapors. Do not eat, drink or smoke Prevention

when using this product. Avoid contact during pregnancy/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.

Hazard(s) not otherwise

classified (HNOC)

None known.

Gallium Citrate Ga 67 Injection SDS US 1/9

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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 Commission (NRC) is the Federal agency responsible for 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

mical name 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	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 Unsuitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.

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

Fire fighting equipment/instructions

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

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 methodsUse 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 vapor. 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 °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

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44.2 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 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.

Skin protection

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

Respiratory protectionNo 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.
Color Colorless.
Odor Odorless.
Odor threshold Not available.
pH Not available.

Melting point/freezing point $46.42 \, ^{\circ}\text{F} \, (8.01 \, ^{\circ}\text{C}) \, \text{estimated} \, / \, 32 \, ^{\circ}\text{F} \, (0 \, ^{\circ}\text{C})$

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 applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower Not av

(%)

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.

Not available.

Relative density

Solubility(ies)

Solubility (water) Soluble.

Partition coefficient Not available

(n-octanol/water)

Not available.

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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)

Oxidizing properties Not oxidizing.

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.

Gallium Citrate Ga 67 Injection

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

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)

<u>Acute</u>

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 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.

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential Germ cell mutagenicity

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.

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic Carcinogenicity

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, leukemia, 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.

IARC Monographs. Overall Evaluation of Carcinogenicity

NTP Report on Carcinogens

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

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 -

Not classified.

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure **Aspiration hazard**

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

The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and **Chronic effects**

teratogenic effects) are believed to involve levels of radiation exposure which are much higher

than those permitted occupationally.

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic **Further information**

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 (C	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 LC50 Fathead minnow (Pimephales promelas) 6020 - 7070 mg/l, 96 hours

SODIUM CITRATE DIHYDRATE (CAS 6132-04-3)

Aquatic

EC50 Water flea (Ceriodaphnia dubia) Crustacea 655 - 825.9 mg/l, 48 hours

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL (CAS 100-51-6) 1.1

No data available. Mobility in soil 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.

Dispose in accordance with all applicable regulations. Local disposal 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

Label(s)

DOT

UN2915 **UN** number

UN proper shipping name Transport hazard class(es) Radioactive material, Type A package

Class 7 Subsidiary risk

Not available. Packing group

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

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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)

7 Class Subsidiary risk 7 Label(s)

Packing group Not available.

No. **Environmental hazards**

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

IMDG

UN number UN2915

UN proper shipping name Transport hazard class(es)

Radioactive material, Type A package

Class 7 Subsidiary risk 7 Label(s)

Packing group Not available.

Environmental hazards

Marine pollutant Nο

Not available. **EmS**

Special precautions for user Read safety instructions, SDS and emergency procedures before handling. Transport in bulk according to This substance/mixture is not intended to be transported in bulk.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations

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

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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 1910.1001-1053)

Not regulated.

Toxic Substances Control

One or more components of the mixture are not on the TSCA 8(b) inventory or are designated

Act (TSCA) "inactive"

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

Reproductive toxicity

categories

SARA 313 (TRI reporting)

Not regulated.

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

Not regulated.

(SDWA)

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.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No

Country(s) or region Inventory name On inventory (yes/no)*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

*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, including date of preparation or last revision

Issue date25-January-2019Revision date04-February-2019

Version # 03

Disclaimer Curium US LLC cannot anticipate all conditions under which this information and its product, or the

products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the

sheet was written based on the best knowledge and experience currently available.