



DaTSCAN™
(loflupane I-123 Injection)

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: DaTSCAN™

Product Code: 2010

Synonyms: loflupane I-123

Manufacturer/Distributor: GE Healthcare
Medi-Physics, Inc.
3350 North Ridge Avenue
Arlington Heights, 60004

Technical Information No.: (800) 654-0118

CHEMTREC Emergency No.: (800) 424-9300 for US / (708) 527-3887 outside US

2. COMPOSITION/INFORMATION ON INGREDIENTS

| <u>Ingredient :</u> | <u>CAS No.</u> | <u>% V</u> |
|---------------------|----------------|------------|
| loflupane (I-123) | 155797-99-2 | 0.01% |
| Acetic Acid | 64-19-7 | 0.57% |
| Sodium Acetate | 127-09-3 | 0.78% |
| Ethyl Alcohol | 64-17-5 | 5.0% |
| Water | 7732-18-5 | 93.64% |

3. HAZARD IDENTIFICATION

Emergency Overview: Read package insert prior to use. DaTSCAN™ is a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to clinical personnel and patients. Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose training and experience has been approved by the appropriate government agency authorized to license the use of radionuclides.

Physical & Chemical Hazard Ratings (0 = no hazard)

NFPA: Health 1 Flammability 0 Stability 0
HMIS: Health 1 Flammability 0 Stability 0

Potential Health Effects:

Inhalation: Small fraction of Iodine-123 may volatilize which may result asymptomatic physiological uptake by thyroid gland or other tissues.

Ingestion: May cause symptomatic physiological uptake by thyroid gland or other tissues.

Skin Contact: Not considered an acute health hazard.

Eye Contact: Not considered an acute health hazard, but benzyl alcohol may cause irritation.

Chronic Exposure: Data on biological effects of ionizing radiation are based on exposures much higher than those permitted occupationally. No effects are expected from exposures received as a result of normal use.

Aggravation of Pre-existing Conditions: May cause allergic reaction in individuals sensitive to iodine.

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| 4. FIRST AID MEASURES |
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Eyes: In case of eye contact, immediately flush eyes with water for at least 15 minutes. Notify Radiation Safety Officer immediately. Call a physician if irritation develops.

Skin: Wash exposed area with soap and water or other approved decontamination media. Notify Radiation Safety Officer immediately. Call a physician if irritation develops.

Ingestion: Notify Radiation Safety Officer immediately. The amount of I-123 in the thyroid gland and other tissues should be assessed and documented. A thyroid blocking agent may need to be administered at the discretion of a physician.

Inhalation: Notify Radiation Safety Officer immediately. The amount of I-123 inhaled should be assessed and documented.

Note to Physician: Treat symptomatically

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| 5. FIRE FIGHTING MEASURES |
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Flammable Properties: Not flammable

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous Combustion products: Carbon oxides, Nitrogen oxides, volatilized I-123

Explosion Data: None

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.

6. ACCIDENT RELEASE MEASURES

Any cleanup of spilled radioactive material should be conducted under the direction of site radiation safety personnel. Any packages received with leaking internal components should be reported to GE Healthcare Technical Services at (800) 654-0118. Any packages delivered in damaged condition should be reported to Chemtrec at (800) 424-9300.

7. HANDLING AND STORAGE

Handling: Always observe good health physics and hygiene practices when handling radioactive material.

Storage: Store at 15 - 30° C. Do not freeze or expose to heat. Material should be shielded when not in use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Limit (I-123):

NRC Occupational Concentration Limit: $(3 \times 10^{-6} \mu\text{Ci/ml})$

Ioflupane:

Airborne Exposure Limits Not Established

Acetic Acid:

-OSHA Permissible Exposure Limit (PEL): 10 ppm (TWA).

-ACGIH Threshold Limit Value (TLV): 10 ppm (TWA); 15 ppm (STEL).

Sodium Acetate:

Airborne Exposure Limits Not Established

Ethyl Alcohol:

-OSHA Permissible Exposure Limit (PEL): 1000 ppm (TWA).

-ACGIH Threshold Limit Value (TLV): 1000 ppm (TWA)

Engineering Measures: Eyewash station and good general room ventilation

Eye/Face Protection: Avoid contact with eyes & face, use eye protection

Skin & Body Protection: Disposable latex or nitrile gloves examination glove, lab coat

Respiratory Protection: Not required under normal conditions of use.

Hygiene Measures: No smoking, eating, drinking or application of cosmetics should be allowed in area where radioactive materials are handled or stored.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid

Autoignition Temperature: None

Appearance: Clear Liquid

Flammable Limits: None

Odor: Faint alcohol odor

Boiling Point: 100°C

Solubility: Soluble in water

Melting Point: 0°C

Specific Gravity: No data available

Vapor Pressure (mm Hg): No data available

Viscosity: No data available

Evaporation Rate: Not data available

pH: No data available

Vapor Density: No data available

Flash Point: None

Radioactivity: 5 mCi (370 MBq) at time of calibration

Specific Activity: 2 mCi/ml (74 MBq/ml) at time of calibration

Half-Life: 13.2 hours

10. STABILITY AND REACTIVITY

Stability: Stable under specified conditions of use and storage.

Conditions to Avoid: None known

Incompatible Products: None known

Hazardous Decomposition Products: Carbon oxides, Nitrogen oxides, volatilized I-123

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: May result in slight to total thyroid dysfunction.

Carcinogenicity: Sufficient exposure to ionizing radiation may cause harmful biological effects such as cancer.

Reproductive Toxicity: See section 15 California Proposition 65.

Target Organ Effects: May result in slight to total thyroid dysfunction.

Endocrine Disruptor Information: Radioactive forms of iodine will act as an endocrine disruptor at sufficient dosages.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

13. DISPOSAL CONSIDERATIONS

DaTSCAN™ is considered radioactive waste until the activity has decayed to nondetectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Program. Ioflupane is listed as a Schedule II Compound by DEA. Consult local, state and federal regulations for proper disposal.

14. TRANSPORT INFORMATION

DOT:

Proper Shipping Name: Radioactive Material, n.o.s.

Hazard Class: 7

Identification Number: UN2982

15. REGULATORY INFORMATION

OSHA Hazard Communication: This product is a pharmaceutical, it is not regulated under the OSHA Hazard Communication Standard (29 CFR 1910.1200) guidelines.

CERCLA Reportable Quantities: I-123 = 10 Ci (370 GBq), CAS# 64-19-7 (5,000 lb.)

Releases to the environment which exceed the Reportable Quantity (RQ) must be reported to the National Response Center at (800) 424-8802.

SARA Title III:

302 Extremely Hazardous Substances: None

311/312 Hazardous Categories: Acute, Chronic

313 Toxic Substances subject to annual reporting requirements: None

CWA: Not regulated

RCRA hazardous Waste Status: Non-hazardous (See Section 12 for details)

STATE:

CAS# 64-17-5 can be found on the following state right to know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California Proposition 65: This product contains a substance (radioactive material) known to the State of California to cause reproductive toxicity.

Canada: This MSDS contains all of the information required by the Controlled Products Regulations (CPR).

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| 16. OTHER INFORMATION |
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Revision Date: July 30, 2012

Disclaimer:

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End of MSDS