



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Fluorodeoxyglucose-F18

Version 2.1 11/4/2015

Synonyms: FDG, (18F)FDG Fluorodeoxyglucose Injection

Product uses: This material is used as a medical imaging agent.

COMPANY IDENTIFICATION: **Lantheus Medical Imaging**
331 Treble Cove Road
Billerica, MA 01862
United States of America
1-800-362-2668

EMERGENCY PHONE: **CHEMTREC 1-800-424-9300.**
For International Transportation Emergencies Call
CHEMTREC @ 1-703-527-3887.
Collect Calls are accepted

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from 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 or syringe 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.

SECTION 2: Hazards Identification Continued

Potential Health Effects

Inhalation:

FDG does not easily become airborne. Not expected to be a health hazard via inhalation.

Ingestion:

May cause asymptomatic physiological uptake by specific target organs or tissues.

Skin Contact:



Not expected to produce any acute adverse health effects.

Eye Contact:

No adverse effect expected, but may cause mechanical irritation.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

COMPONENTS	CONCENTRATION	CAS NO.
2-Fluoro-2-deoxy-D-glucose	<0.001%	29702-43-0
Sodium Chloride	0.9%	7647-14-5
Water	~99%	7732-18-5

SECTION 4: FIRST AID MEASURES

Inhalation:

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

Ingestion:

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

Skin Exposure:

If skin contact occurs, wash the affected area thoroughly with soap and water until no more radioactivity can be removed. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye Exposure:

If a splash occurs, wash eyes with water for at least 15 minutes or until no more radioactivity can be removed. Notify radiation safety personnel.

SECTION 5: FIRE-FIGHTING MEASURES

Flammability: Not a flammable material.

Fire/Explosion Hazards: Not considered to be a fire or explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full-face piece operated in the pressure demand or positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions

Refer to protective measures listed in Sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves.



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.
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc. as appropriate for chemically and pharmacologically similar materials.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Handling time should be kept to a minimum and appropriate Shielding should be used such as syringe shields and tongs. <i>For a complete discussion of Handling and Storage information, please consult the full prescribing information.</i>
Storage Conditions	Store at room temperature. Storage and disposal of products should be controlled in a manner, which is in compliance with appropriate regulations of federal or state government agency authorized to license the use of this radionuclide.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls and Ventilation	Properly sealed containers are not expected to require and special ventilation.
Respiratory Protection	Not expected to require personal respirator usage.
Eye Protection	Follow good chemical hygiene practices when using clinical or consumer presentations. Glasses or goggles are recommended if eye contact is possible.
Hand Protection	Follow good chemical hygiene practices when using clinical or consumer presentations. Wear gloves when working this product.



Skin and Body Protection

Follow good chemical hygiene practices when using clinical or consumer presentations. A laboratory coat must be worn when handling this product.

Hygiene

Wash hands and face before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear colorless solution
Color	Colorless
Odor	Odorless
Solubility:	Soluble in water.

Physical and Chemical Properties

Boiling point:	100 ° Celsius (212°F)
Melting point:	0° Celsius (32°F)
Flashpoint	>200F
Radioactivity:	0.005 to 10 Ci of F18 on calibration date and time.
Concentration:	0.005 to 660 mCi/mL of F-18 on calibration date and time.
Specific Activity:	>100 mCi/ug of F-18 on the calibration date and time.
Half Life:	109.3 minutes
Vapor Density	(Air = 1): No information found
Vapor Pressure	(mm Hg): No information found

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: May emit radioactive fumes containing F-18 when heated to decomposition.

Hazardous Polymerization: Will not occur.

Incompatibilities: No information found.

Section 11 TOXICOLOGICAL INFORMATION

It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia, and genetic and teratogenic effects. FDG is a glucose analogue, acting like sugar, which concentrates in cells that rely upon glucose as a primary energy source. In clinical trials, possible adverse reactions from this sugar might be transient hypotension, hypo- or hyperglycemia or transient increase in alkaline phosphatase.

SECTION 12: ECOLOGICAL INFORMATION

Because this product is intended for use by hospital of clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13: DISPOSAL CONSIDERATIONS

Advice on Disposal and Packaging

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.

SECTION 14: TRANSPORT INFORMATION

DOT (Department of Transportation):
Domestic US Ground Shipments

IATA and ICAO:
Commercial Air or International

Proper Shipping Name:
Radioactive Material, Type A Package

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Radioactive Material, Type A Package

Hazard Class: 7

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Identification Number: UN2915

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SECTION 15: REGULATORY INFORMATION**OSHA Hazard Communication:**

This product is considered hazardous under OSHA Hazard Communication Standard (29 CFR 1910-1200)

CERCLA Reportable Quantities:

F-18 FDG = 10,000 Ci (3.7×10^{14} Bq)

Releases to air, land or water of these hazardous substances, 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 Hazard Categories: Chronic

313 Toxic substances subject to annual release reporting requirements: None

RCRA Hazardous Waste Status

Non-hazardous (See Section 13 for additional details)

California Proposition 65 Warning

This product contains a substance known to the State of California to cause cancer.

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by: Environment, Health and Safety 1-978-671-8673
Prepared on: November 4, 2015

This information contained in this SDS 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 use of it.