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|  | MATERIAL SAFETY DATA SHEET | | | |
| | MSDS NO: | 001.00 | Date of Publish | 2015, March |
| | | | Date of Revision | - |
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| MOLTEK FDG (¹⁸ F) SOLUTION FOR INJECTION MATERIAL SAFETY DATA SHEET | | | | |

This form is created upon the reference of “Zararlı Maddeler ve Karışımlara İlişkin Güvenlik Bilgi Formları Hakkında Yönetmelik” which is published on Turkish Gazette vol. 29204 at December 13, 2014.

1. TANITIMI INTRODUCTION OF MATERIAL / PRODUCT AND COMPANY / BUSINESS MAN

1.1. Introduction Of Material / Product

Commercial Name Of the Product : Moltek FDG (¹⁸F) Solution For Injection
is a trademark of Moltek Moleküler Teknoloji Araştırma San. Tic. A.Ş.

Therapeutic Group of the Product : Diagnostic Radiopharmaceutical

Use Of The Product : Only Applicable in Nuclear Medicine Centers


1.2. Producer Company

Producer Company : Moltek Moleküler Teknoloji Araştırma San. Tic. A.Ş.
Production Address : Gebze Organize Sanayi Bölgesi Şahabettin Bilgisu Caddesi No:611/1 Gebze Kocaeli TURKEY
Emergency Call : Tel : +90 262 677 11 60
Fax : +90 262 677 11 66
E-Mail Address : info@moltek.com.tr; cemile.yanic@moltek.com.tr

2. INTRODUCTION OF THE HARMFULNESS

2.1. Classification In Terms Of Risk And Security

Description Of Risk : H312 It is harmful in case of dermal exposure.
H302 It is harmful in case of swallow.
Description Of Security : P201 Read the prospectus prior to use.
P262 Do not exposure to eyes, skin and clothing.
P280 Use protective gloves / protective clothing /

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goggles / protective mask

2.2. Determination of the Danger

No undesirable effect is observed after use of fludeoxyglucose (¹⁸F) in clinic. The quantity of the used material is quite low; so the main risk is the emitted radiation. Being exposed to ionizing radiation may cause stochastic and deterministic effects on human body. However; due to the exposed radiation dose is lower than 20 mSv on nuclear medicine applications, the probability of observing stochastic and deterministic effects is too low.

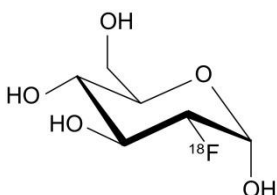
Effect to Eyes : It may irritate.

Effect to Skin : It may irritate.

Effect in Case of Swallow : It may cause to nausea, vomiting and diarrhea.

3. INFORMATION ABOUT COMPOUND / CONTENT

3.1. Structural Formula



Structural Formula : 2- [¹⁸F] fluoro-2-deoxy-D-glucose, (Fludeoxyglucose ¹⁸F)


Molecular Formula : C₆H₁₁¹⁸FO₅

Molecular Weight : 181,15 g/mol

Synonymous : 2-[¹⁸F] fluoro-2-deoxy-D-glucose,
Fludeoxyglucose ¹⁸F
FDG - ¹⁸F

4. FIRST AID PRECAUTIONS

Due to the product is radioactive, in the all cases described below which require emergency help; the radiation safety officer must be informed immediately and all the work must be done under instructions given by the radiation safety officer.

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4.1. General Suggestion

Consult to a doctor. Show this Material Safety Datasheet to the doctor.

4.2. In Case of Dermal Exposure

Wash the contaminated area with radioactive material decontamination solution and rinse with plenty of water. If your clothing or shoes are contaminated, undress them and keep them in a safe area until the radiation level on the clothing is lowered below 0,5 µSv/hr. Consult to a doctor.

4.3. In Case of Exposure to Eyes

Wash your eyes with plenty of water. Consult a doctor.

4.4. In Case Of Swallow

Gargle with plenty of water. If the person who swallowed the product is unconscious, do not give anything oral and immediately consult a doctor.

5. FIRE FIGHTING PRECAUTIONS

5.1. Appropriate Fire Fighting Materials

Water, foam, dry chemical or carbon-dioxide can be used.

5.2. Special Equipments Required For Extinguishers

Extinguishers must use protective mask for healthy respiration and wear protective / fireproof clothing. Other people must be kept away from fire.

6. PRECAUTIONS AGAINST ACCIDENTLY SPREAD


Due to the material is radioactive, in such a case, radiation safety officer must be informed and radiation safety procedures must be applied. For cleaning / decontamination process, decontamination procedure must be applied.

6.1. Personal Precautions

Use protective equipment such as gloves, clothing and goggles. Do not touch or breathe the waste. Supply adequate ventilation.

6.2. Environmental Precautions

Prevent the product to blend to sewage and residential waste.

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6.3. Cleaning Methods

Put an absorber material on the contaminated area to absorb the contaminant. By wiping from outside to inside, prevent the material to spread. By applying the decontamination procedure, clean the contaminated area and ventilate the environment. Throw all the contaminated cleaning materials to the radioactive waste bin and inform radiation safety officer.

7. USAGE AND STORAGE

Due to the material is radioactive, radiation safety procedures are applied.

7.1. Usage

Avoid exposure to skin and eyes. Use protective gloves, clothing and goggles, if necessary. In case of touching or contamination, wash your hand with decontamination solution and rinse with plenty of water.

7.2. Storage

Due to the materials radioactive half-life is 110 minutes; it is not convenient for storage. Transportation of the material must be done in the way suitable to national and international regulations.

The material must be kept in its package under room temperature. The precautions against fire must be taken.

8. CONTROLS AGAINST EXPOSURE / PERSONAL PROTECTION

8.1. Technical Precautions

While working with the material, radiation safety procedure must be applied.


8.2. Personal Protective Equipment

While working the material, one must use protective goggles and lead chest shield. Against to contamination risk, it is mandatory to use protective gloves, apron and bonnet. All the work with the material must be done under radiation safety regulations.

9. PHYSICAL AND CHEMICAL SPECIFICATIONS

pH : 4,5 – 8,5

Physical State (at room temperature) : Liquid (Solution)

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Color : Clear, colorless / Soft Yellow

10. STABILITY AND REACTION

10.1. Chemical Stability

The material is stable at storage conditions.

10.2. The Other Materials That Cannot Kept Together

There is no known material that is objectionable to keep together.

10.3. Decay / Fragmentation

The F-18 in the material decays to O-18 radioactively. The radioactive half-life is 110 minutes.

11. TOXICOLOGICAL INFORMATION

There is no toxicity finding observed on the prior-clinic acute toxicity tests with fifty times of regular radiation dose for human on dogs and thousand times of radiation does for human on mice.

There is no experiment made on carcinogenicity mutagenicity of the material and its effect on fertility.

12. ECOLOGIC INFORMATION

There is no ecologic information about the material.

13. DISPOSAL INFORMATION

The waste of the material must be disposed under national and international regulations. For disposal process, radiation safety officer must be informed and related procedures must be followed.


14. TRANSPORTATION INFORMATION

Class Label : Radioactive Material, Type A Packaging

Danger Class : 7

UN Number : 2915

Transportation of the material must be done according to related national and international regulations.

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14.1. Transportation Via Highway

Transportation of the material via highway must be done according to national and international radioactive transportation regulations and ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road) regulations.

14.2. Transportation Via Skyway

Transportation of the material via skyway is done according to ICAO (International Civil Aviation Organization) and IATA (International Air Transport Association).

15. REGULATIONS INFORMATION

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards *by IAEA*

Regulations for the Safe Transport of Radioactive Material *by IAEA*

Disposal of Radioactive Waste *by IAEA*

Upon its known specification, this drug is not determined as dangerous in national and international regulations.

Prior to use, label and prospectus must be read carefully and the drug must be used according to the given instructions.

16. OTHER INFORMATION

Material Safety Data Sheet – Standard Information

The information given above is known in the Moltek Molecular Technology Research Inc. and it is believed to be true but it is not expected that all the information about the material is given. This document's scope is only being a guide. Due to the information given in this document can be used out of Moltek Molecular Technology Research Inc.'s control, any result may depend on usage of the material is out of the Moltek Molecular Technology Research Inc.'s responsibility.