



विकिरण एवं आइसोटोप प्रौद्योगिकी बोर्ड

भारत सरकार, परमाणु ऊर्जा विभाग,

BOARD OF RADIATION & ISOTOPE TECHNOLOGY
GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

BRIT-BARC Vashi Complex, Sector 20, Vashi, Navi Mumbai-4000703

Tel +91-22-27887201 Fax +91-22-27887218

Website : www.britatom.gov.in

Package inserts (PI) of ready to use Radiopharmaceuticals

Material safety data sheet (MSDS) of ready to use Radiopharmaceuticals

Package inserts (PI) of ready to use Radiopharmaceuticals:

1. Sodium Chromate [Cr-51] injection (CRM-1)
2. Sodium Iodide [I-131] solution (IOM-1)
3. Sodium Iodide [I-131] diagnostic capsules (IOM-2)
4. Sodium Iodide [I-131] therapeutic capsules (IOM-5)
5. Sodium Iodide [I-131] therapeutic capsules (IOM-5B)
6. Metaiodobenzylguanidine [I-131] injection (IOM-50/IOM-50T)
7. Sodium Orthophosphate [P-32] injection (PHM-3)
8. Colloidal Samarium Phosphate [P-32] injection (PHM-4)
9. Samarium [Sm-153] EDTMP injection (SAM-2)

Material safety data sheet (MSDS) of ready to use Radiopharmaceuticals

- 1. Sodium Chromate [Cr-51] injection (CRM-1)**
- 2. Sodium Iodide [I-131] solution (IOM-1)**
- 3. Sodium Iodide [I-131] therapeutic capsules (IOM-5) and (IOM-5B)
and diagnostic capsules (IOM-2)**
- 4. Metaiodobenzylguanidine [I-131] injection (IOM-50/IOM-50T)**
- 5. Sodium Orthophosphate [P-32] injection (PHM-3)**
- 6. Colloidal Samarium Phosphate [P-32] injection (PHM-4)**
- 7. Samarium [Sm-153] EDTMP injection (SAM-2)**



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Sodium Chromate [Cr-51] injection

(Code: CRM-1)

- ✚ Specifications :

Radioactive concentration	3.7-185 MBq/ml (0.1-5 mCi /ml)
	at calibration date & time
pH	6 - 8
Radiochemical Purity	Not less than 90% Cr-51 as Chromate on the day of determining the Radiochemical purity
Batch No. & Expiry date	As specified on the vial

- ✚ Supply Details :

Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)

- ✚ Storage :

To be stored at temperature 10 °C to 30°C with adequate shielding

- ✚ Package & Instructions :

Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts holding the product glass vial.

- ✚ Recommended Dose & Administration :

925 KBq (25µCi) diagnostic doses for intravenous injection. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.

- ✚ Precautions :

Follow all the AERB Regulations & Guidelines related to handling & administration of radiopharmaceuticals.



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Sodium Iodide [I-131] solution

(Code: IOM-1)

- ✚ Specifications :

Radioactive concentration	370 - 1850 MBq/ml (10 -50 mCi/ml) at calibration date and time
pH	7 - 10
Radiochemical Purity	Not less than 95% on the day of Determining the Radiochemical Purity
Batch No. & Expiry date	As specified on the vial

- ✚ Supply Details :

Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)

- ✚ Storage :

To be stored at temperature 10 °C to 30°C with adequate shielding

- ✚ Package & Instructions :

Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts having a lead pot (of adequate thickness) holding the product glass vial.

- ✚ Recommended Dose & Administration :

370-1850 MBq/ml (10-50 mCi/ml) therapeutic doses for oral administration. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.

- ✚ Precautions :

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Website : www.britatom.gov.in

Sodium Iodide [I-131] diagnostic capsule (Code: IOM-2)

- ✚ Specifications :
- | | |
|---------------------------|--|
| Radioactive concentration | 0.925 & 1.85 MBq (25 & 50 μ Ci) / capsule at calibration date and time |
| pH | 7 - 10 |
| Radiochemical Purity | Not less than 95% on the day of determining the Radiochemical purity |
| Batch No. & Expiry date | As specified on the vial |
- ✚ Supply Details :
- Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)
- ✚ Storage :
- To be stored at temperature 10 °C to 30°C with adequate shielding
- ✚ Package & Instructions :
- Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts holding the product glass vial.
- ✚ Recommended Dose & Administration :
- 0.925 & 1.85 MBq (25 & 50 μ Ci)/ capsule diagnostic doses for oral administration. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.
- ✚ Precautions :
- Follow all the AERB Regulations & Guidelines related to handling & administration of radiopharmaceuticals.



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Sodium Iodide [I-131] therapeutic capsule (Code: IOM-5)

- ✚ Specifications :

Radioactive concentration	111 - 370 MBq (3-10 mCi)/ capsule) at calibration date & time
pH	7 - 10
Radiochemical Purity	Not less than 95% on the day of determining the Radiochemical Purity
Batch No. & Expiry date	As specified on the vial

- ✚ Supply Details :

Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)

- ✚ Storage :

To be stored at temperature 10 °C to 30°C with adequate shielding

- ✚ Package & Instructions :

Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts having a lead pot (of adequate thickness) holding the product glass vial.

- ✚ Recommended Dose & Administration :

111-370 MBq (3-10 mCi)/ capsule therapeutic doses for oral administration. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.

- ✚ Precautions :

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Sodium Iodide [I-131] therapeutic capsule (Code: IOM-5B)

- ✚ Specifications :

Radioactive concentration	0.925 - 3.7 GBq (25 - 100mCi)/capsule) at calibration date & time
pH	7 - 10
Radiochemical Purity	Not less than 95% on the day of determining the Radiochemical Purity
Batch No. & Expiry date	As specified on the vial

- ✚ Supply Details :

Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)

- ✚ Storage :

To be stored at temperature 10 °C to 30°C with adequate shielding

- ✚ Package & Instructions :

Shipped in AERB approved “Type-A” package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts having a lead pot (of adequate thickness) holding the product glass vial.

- ✚ Recommended Dose & Administration :

0.925-3.70 GBq (25-100 mCi) /capsule therapeutic doses for oral administration. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.

- ✚ Precautions :

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Website : www.britatom.gov.in

Metaiodobenzylguanidine [I-131] injection

(Code: IOM-50/IOM-50T)

✚ Specifications :	Radioactive concentration	185 - 555 MBq/ml (5 - 15 mCi/ml) at calibration date and time
	Specific activity	Not less than 370 MBq/mg (10 mCi/mg)
	pH	5 - 8
	Radiochemical Purity	Not less than 95% at expiry
	Batch No. & Expiry date	As specified on the vial

✚ Supply Details : Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)

✚ Storage : To be stored frozen at a temperature below -20°C in a deep freezer with adequate shielding

✚ Package & Instructions :

- ❖ Shipped in AERB approved "Type-A" package. Package consists of a sealed tin container having a lead pot (of adequate thickness) holding the product glass vial, which is placed in to the thermacole box with adequate dry ice all around.
- ❖ Avoid sudden temperature changes for the drug vial.
- ❖ Prior to the use thaw the drug vial in the shielding to room temperature gradually for around 30-40 minutes and use suitably diluted with normal saline, before slow i.v. administration.

✚ Recommended Dose & Administration:

- ❖ 18.5 MBq (0.5 mCi) diagnostic doses per patient. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.
- ❖ 3.3- 4.1 GBq (90-110 mCi) therapeutic doses per patient. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.

✚ Precautions :

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Sodium Orthophosphate [P-32] injection (Code: PHM-3)

- ✚ Specifications :
- | | |
|---------------------------|--|
| Radioactive concentration | 74 - 370 MBq/ml (2 - 10 mCi/ml) at calibration date and time |
| pH | 6-8 |
| Radiochemical Purity | Not less than 95% on the day of determining the radiochemical purity |
| Batch No. & Expiry date | As specified on the vial |
- ✚ Supply Details :
- Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)
- ✚ Storage :
- To be stored at temperature 10 °C to 30°C with adequate shielding
- ✚ Package & Instructions :
- Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts holding the product glass vial.
- ✚ Recommended Dose & Administration:
- 222 - 444 MBq (6 - 12 mCi) therapeutic doses for intravenous injection. The actual dose to be decided by the clinician. Follow permitted clinical protocol only.
- ✚ Precautions :
- Follow all the AERB Regulations & Guidelines related to handling & administration of radiopharmaceuticals.



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Website : www.britatom.gov.in

Samarium [Sm-153] EDTMP injection
(Code: SAM-2)

- ✚ Specifications :
- | | |
|---------------------------|---|
| Radioactive concentration | 0.29 - 1.85 GBq/ml (8 - 50 mCi/ml)
at calibration date & time |
| pH | 7 - 8 |
| Radiochemical Purity | Not less than 95% on the day of determining
the Radiochemical purity |
| Batch No. & Expiry date | As specified on the vial |
- ✚ Supply Details :
- Please see the product label and packing note
(Each Consignment is meant for single patient use only)
(View the product vial label strictly through a lead glass window only)
- ✚ Storage :
- To be stored at 0°C / 2-8 °C with adequate shielding
- ✚ Package & Instructions :
- Shipped in AERB approved "Type-A" package. Package consists of a sealed plastic HDPE container with suitable thermacole inserts having a lead pot (of adequate thickness) holding the product glass vial.
- ✚ Recommended Dose & Administration :
- 111 - 222 MBq (3 - 6 mCi)/Kg of patient weight. The actual dose to be decided by the clinician.
Follow permitted clinical protocol only.
- ✚ Precautions :
- Follow all the AERB Regulations & Guidelines related to handling & administration of radiopharmaceuticals.



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Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEET

Date Published : July 2014

Date Revised: Original

Revision : Original

Section 1 : Product and Manufacturer's Identification

Product Name	:	Sodium Chromate [Cr-51] injection
Manufacturer	:	Board of Radiation and Isotope Technology DAE, BRIT- BARC Vashi Complex, Sector 20 Vashi, Navi Mumbai - 400703, India Tel +91-22-27887201 Fax +91-22-27887218
In Emergency contact	:	+91-22-27887254 / +91-9869454120
Synonyms and Trade names	:	Sodium chromate [Cr-51] injection
Category	:	Diagnostic Radiopharmaceutical
Product code	:	CRM-1

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Sodium Chromate [Cr-51] injection contains Radioactivity.

Eye Contact: May cause eye irritation

Skin Contact: Exposure may occur via skin contact. Hexavalent chromium compounds are readily absorbed through damaged skin.

Ingestion: Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if the material contacts hands and hands are not washed prior to eating, drinking or smoking. Hexavalent chromium is readily absorbed after ingestion.

Inhalation: May cause respiratory tract irritation. May be harmful if inhaled.

CARCINOGENICITY

Hexavalent chromium is a known human carcinogen

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
Chromium	7440-47-3	< .02
Sodium Chloride	7647-14-5	0.9
Water for injection	7732-18-5	99.08

- Appearance: Clear, colorless or faint yellow solution

* Radioactive concentration : Not more than 5 mCi (185MBq)/ml

Maximum gama energy: 320 KeV

Half-life: 27.7 days.

Atomic Energy Regulatory Board (AERB), India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

The AERB Annual Limit on Intake (ALI) for Cr -51 is 5.3×10^8 Bq (approximately 1400 μ Ci) by ingestion and 6.7×10^8 Bq (approximately 18000 μ Ci) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

Skin Exposure: Wash exposed area with soap and plenty of water. Avoid skin abrasion. Remove contaminated clothing and shoes. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. If breathing is difficult, give oxygen. Consult a physician. Consult with radiation safety officer.

Ingestion: Get medical attention immediately. Vomiting may be induced if a person is conscious and if ingestion has occurred within the past three hours. Never induce vomiting in a person who is unconscious and experiencing convulsions. Flush mouth out with water. Consult with radiation safety officer.

Section 5: Fire Fighting Measures

Fire Extinguishing Media: In case of fire, flood with water. Use any means suitable for extinguishing surrounding fire.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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 other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Use HEPA filtered vacuum or wet mop. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material.

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area.

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove radioactive Cr-51 is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Clear, Colorless or faint yellow solution

Odour : Odorless.

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: Sodium Chromate[Na₂⁵¹CrO₄]

Physical Half-life (⁵¹Cr) : 27.7 days.

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage. This formulation contain sodium chromate (Cr-51). The Cr-51 radioactively decays with a half life of 27.7 days.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, radioactive chromium- 51 compounds.

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Not known.

Section 11: Toxicological Information

Harmful if ingested. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Diagnostic radiopharmaceutical (injection)

MSDS Status : Published in July 2014

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

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MATERIAL SAFETY DATA SHEET

Date Published: August 2014

Date Revised : July 2014

Revision : 1st

Section 1 : Product and Manufacturer's Identification

- Product Name** : Sodium Iodide [I-131] solution
- Manufacturer** : Board of Radiation and Isotope Technology
DAE, BRIT- BARC Vashi Complex, Sector 20
Vashi, Navi Mumbai - 400703, India
Tel +91-22-27887201 Fax +91-22-27887218
- In Emergency contact** : +91-22-27887254 / +91-9869454120
- Synonyms and Trade names** : Sodium Iodide [I-131] solution, Na¹³¹I, ¹³¹I, I-131
- Category** : Therapeutic Radiopharmaceutical
- Product code** : IOM-1

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Sodium Iodide ¹³¹I solution, contains radioactivity.

Eye Contact: Significant radiation dose is possible; wash eyes immediately on contact.

Skin Contact: Significant radiation dose is possible; wash skin immediately on contact.

Inhalation: Respiration and inhalation of vaporous ¹³¹I can result in a significant thyroid radiation dose. No respiratory symptoms.

Ingestion: Ingestion of ¹³¹I can result in significant thyroid radiation dose.

Aggravation of Pre-existing Conditions : No information found

CARCINOGENICITY

Compounds containing radioactive ¹³¹I emit ionizing radiation. High doses of ionizing radiation increase the risk of cancer to those who are exposed; however radiological health effects have not been demonstrated for doses of less than 10 rem (100 mSv) delivered at high dose rates.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
*Sodium Iodide I-131	7790-26-3	< 0.001 %
Sodium Thiosulfate	10102-17-7	>0.25%
NaOH	1310-73-2	>0.03%
Water	7732-18-5	>99.7%

- Appearance: Clear, colourless solution
- * Radioactive ingredient : Between $0.925 \pm 10\%$ GBq to $22.2 \pm 10\%$ GBq ($25 \text{ mCi} \pm 10\%$ to $600 \text{ mCi} \pm 10\%$) per vial of therapeutic solution

High energy gamma emitter

Half-life : 8.04 days.

Atomic Energy Regulatory Board (AERB) , India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

Iodine -131 has an effective clearance half-life of less than 10 days. The AERB Annual Limit on Intake (ALI) for Iodine-131 is 9 E+05 Bq (approximately 24 μ Ci) by ingestion and 1 E+06 Bq (approximately 27 μ Ci) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes. Get medical advice for external radiation exposure or if irritation develops.

Skin Exposure: Wash exposed area with soap and water. Avoid skin abrasion. Remove contaminated clothing. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake.

Ingestion: Wash out mouth with water; call physician if necessary. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake

Section 5: Fire Fighting Measures

Fire: Presents no combustion hazard. No flash point or auto combustion temperature.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, water spray, fog or foam on large fires; do not use a water stream.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

Special Instructions: In the event of a fire, the principal hazard will be from volatile ^{131}I . Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Soak up the solution with vermiculite or charcoal. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove volatile ^{131}I is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Clear, Colorless solution

Odour : Odorless.

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: Na^{131}I ,

Physical Half-life (^{131}I) : 8.04 days

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: When heated to decomposition, substance will emit gaseous ^{131}I .

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Acids will cause the release of gaseous ^{131}I

Section 11: Toxicological Information

Harmful if ingested. Ingestion of ^{131}I in all forms can result in a significant thyroid radiation dose. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic or diagnostic oral radiopharmaceutical

MSDS Status : Published in October 2013

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

Board of Radiation Isotope Technology, India provides the information contained herein in good faith but makes no representation as to its comprehensiveness. This document is intended only as a guide to the appropriate precautionary handling of the radioactive material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. BOARD OF RADIATION ISOTOPE TECHNOLOGY MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, BOARD OF RADIATION ISOTOPE TECHNOLOGY WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.



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भारत सरकार, परमाणु ऊर्जा विभाग,

BOARD OF RADIATION & ISOTOPE TECHNOLOGY

GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEE

Date Published : August 2014

Date Revised : July 2014

Revision : 1st Revision

Section 1 : Product and Manufacturer's Identification

Product Name	:	Sodium Iodide [I-131] therapeutic capsules Sodium Iodide [I-131] diagnostic capsules
Manufacturer	:	Board of Radiation and Isotope Technology DAE, BRIT- BARC Vashi Complex, Sector 20 Vashi, Navi Mumbai - 400703, India Tel +91-22-27887201 Fax +91-22-27887218
In Emergency Contact	:	+91-22-27887254 / +91-9869454120
Synonyms and Trade names	:	Sodium Iodide I-131capsules, Na ¹³¹ I, ¹³¹ I, I-131
Category	:	Therapeutic and Diagnostic Radiopharmaceutical
Product code	:	IOM-5, IOM-5B IOM-2

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Sodium Iodide ¹³¹I capsule (therapeutic / diagnostic) contains radioactivity.

Eye Contact: Significant radiation dose is possible; wash eyes immediately on contact.

Skin Contact: Significant radiation dose is possible; wash skin immediately on contact.

Inhalation: Respiration and inhalation of vaporous ¹³¹I can result in a significant thyroid radiation dose. No respiratory symptoms.

Ingestion: Ingestion of ¹³¹I can result in significant thyroid radiation dose.

Aggravation of Pre-existing Conditions : No information found

CARCINOGENICITY

Compounds containing radioactive ¹³¹I emit ionizing radiation. High doses of ionizing radiation increase the risk of cancer to those who are exposed; however radiological health effects have not been demonstrated for doses of less than 10 rem (100 mSv) delivered at high dose rates.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
*Sodium Iodide I-131	7790-26-3	< 0.001 %
Sodium sulphate anhydrous	7747-82-6	> 80%
Hard Gelatine Capsule	N/A	< 20 %
Sodium Thiosulfate	10102-17-7	< 1 %

- Appearance: Coloured hard gelatin capsules
- The capsule is odourless

* Radioactive ingredient : Between $111 \pm 10\%$ MBq to $5550 \pm 10\%$ MBq ($3 \text{ mCi} \pm 10\%$ to $150 \text{ mCi} \pm 10\%$) per therapeutic capsule and 0.925 MBq to 1.850 MBq ($25 \text{ } \mu\text{Ci}$ to $50 \text{ } \mu\text{Ci}$) per diagnostic capsule at the time of calibration

High energy gamma emitter: Half-life : 8.04 days.

Atomic Energy Regulatory Board (AERB) , India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

Iodine 131 has an effective biological half-life of less than 10 days. The AERB Annual Limit on Intake (ALI) for Iodine-131 is $9 \text{ E}+05 \text{ Bq}$ (approximately $24 \text{ } \mu\text{Ci}$) by ingestion and $1 \text{ E}+06 \text{ Bq}$ (approximately $27 \text{ } \mu\text{Ci}$) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes. Get medical advice for external radiation exposure or if irritation develops.

Skin Exposure: Wash exposed area with soap and water. Avoid skin abrasion. Remove contaminated clothing. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake.

Ingestion: Wash out mouth with water; call physician if necessary. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake

Section 5: Fire Fighting Measures

Fire: Presents no combustion hazard. No flash point or auto combustion temperature.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, water spray, fog or foam on large fires; do not use a water stream.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

Special Instructions: In the event of a fire, the principal hazard will be from volatile ^{131}I . Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Soak up the solution with vermiculite or charcoal. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove volatile ^{131}I is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Coloured Hard gelatin capsules

Odour : Odourless.

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: Na^{131}I , Carrier: Na_2SO_4

Physical Half-life (^{131}I): 8.04 days

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: When heated to decomposition, substance will emit gaseous ^{131}I .

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Acids will cause the release of gaseous ^{131}I

Section 11: Toxicological Information

Harmful if ingested. Ingestion of ^{131}I in all forms can result in a significant thyroid radiation dose. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have “RQ” marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic or diagnostic oral radiopharmaceutical

MSDS Status : Published in October 2013

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

Board of Radiation Isotope Technology, India provides the information contained herein in good faith but makes no representation as to its comprehensiveness. This document is intended only as a guide to the appropriate precautionary handling of the radioactive material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. BOARD OF RADIATION ISOTOPE TECHNOLOGY MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, BOARD OF RADIATION ISOTOPE TECHNOLOGY WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.



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BOARD OF RADIATION & ISOTOPE TECHNOLOGY

GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEET

Date Published: July 2014

Date Revised : Original

Revision : Original

Section 1 : Product and Manufacturer's Identification

Product Name	:	Metaiodobenzylguanidine [I-131] injection
Manufacturer	:	Board of Radiation and Isotope Technology DAE,BRIT- BARC Vashi Complex, Sector 20 Vashi, Navi Mumbai - 400703, India Tel +91-22-27887201 Fax +91-22-27887218
In Emergency contact	:	+91-22-27887254 / +91-9869454120
Synonyms and Trade names	:	I-131 mIBG injection, Iobenguane Sulphate [I-131]
Category	:	Diagnostic and Therapeutic Radiopharmaceutical
Product code	:	IOM-50 / IOM-50 [T]

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology [I-131] IMIBG injection contains radioactivity.

Eye Contact: Significant radiation dose is possible; wash eyes immediately on contact.

Skin Contact: Significant radiation dose is possible; wash skin immediately on contact.

Inhalation: Respiration and inhalation can result in a significant thyroid radiation dose.

Ingestion: Ingestion can result in significant thyroid radiation dose.

Aggravation of Pre-existing Conditions : No information found

CARCINOGENICITY

Compounds containing radioactive ¹³¹I emit ionizing radiation. High doses of ionizing radiation increase the risk of cancer to those who are exposed; however radiological health effects have not been demonstrated for doses of less than 10 rem (100 mSv) delivered at high dose rates.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
*Sodium Iodide I-131	7790-26-3	< 5.6x10 ⁻⁶
mIBG Sulphate	87862-25-7	< .07
Benzyl Alcohol	100-51-6	0.9
Sodium Chloride Solution	7647-14-5	0.9
Sodium Acetate	127-09-3	0.2
Water	7732-18-5	> 97.93

- Appearance: Clear, colourless solution
- * Radioactive ingredient : 18.5 MBq \pm 10% (0.5 mCi \pm 10%) per vial of diagnostic injection
3.3-4.1 GBq \pm 10% (90-110 mCi \pm 10%) of therapeutic injection

High energy gamma emitter

Half-life : 8.04 days.

Atomic Energy Regulatory Board (AERB), India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

The AERB Annual Limit on Intake (ALI) for Iodine-131 is 9 E+05 Bq (approximately 24 μ Ci) by ingestion and 1 E+06 Bq (approximately 27 μ Ci) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes. Get medical advice for external radiation exposure or if irritation develops.

Skin Exposure: Wash exposed area with soap and water. Avoid skin abrasion. Remove contaminated clothing. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake.

Ingestion: Wash out mouth with water; call physician if necessary. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake

Section 5: Fire Fighting Measures

Fire: Presents no combustion hazard. No flash point or auto combustion temperature.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, water spray, fog or foam on large fires; do not use a water stream.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

Special Instructions: In the event of a fire, the principal hazard will be from volatile ¹³¹I. Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Soak up the solution with vermiculite or charcoal. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove volatile I-131 is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Clear, Colorless solution

Odour : Odorless.

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: I-131 mIBG

Physical Half-life (¹³¹I mIBG) : 8.04 days.

Section 10: Stability and Reactivity

Stability: Stable at a temperature below -20° C

Hazardous Decomposition Products: When heated to decomposition, substance gets deteriorated and will emit gaseous ¹³¹I.

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Acids will cause the release of gaseous ¹³¹I

Section 11: Toxicological Information

Harmful if ingested. Ingestion of Metaiodobenzylguanidine ¹³¹I in all forms can result in a significant thyroid radiation dose. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic or diagnostic injectable radiopharmaceutical

MSDS Status : Published in July 2014

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

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BOARD OF RADIATION & ISOTOPE TECHNOLOGY

GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEET

Date Published : July 2014

Date Revised: Original

Revision : Original

Section 1 : Product and Manufacturer's Identification

Product Name	:	Sodium Orthophosphate [P-32] injection
Manufacturer	:	Board of Radiation and Isotope Technology DAE, BRIT- BARC Vashi Complex, Sector 20 Vashi, Navi Mumbai - 400703, India Tel +91-22-27887201 Fax +91-22-27887218
In Emergency contact	:	+91-22-27887254 / +91-9869454120
Synonyms and Trade names	:	Sodium orthophosphate P-32 injection
Category	:	Therapeutic Radiopharmaceutical
Product code	:	PHM-3

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Sodium Orthophosphate [P-32] injection contains radioactivity.

Eye Contact: May cause eye irritation

Skin Contact: May cause skin irritation. May be harmful if absorbed through the skin.

Ingestion: May cause irritation of the digestive tract. May be harmful if swallowed.

Inhalation: May cause respiratory tract irritation. May be harmful if inhaled.

CARCINOGENICITY

This product does not contain any carcinogens or potential carcinogens as listed by IARC, NTP or OSHA.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
Sodium Phosphate [mono basic] [dibasic]	7558-80-7 7558-79-4	1.0
Sodium Chloride	7647-14-5	0.8
Water for injection	7732-18-5	98.2

- Appearance: Clear, colorless solution

* Radioactive concentration : Not more than 15 mCi (555MBq)/ml

Maximum beta energy: 1.71 MeV

Half-life : 14.3 days.

Atomic Energy Regulatory Board (AERB), India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

Sodium orthophosphate P-32 has an effective biological half life of 10 days. The AERB Annual Limit on Intake (ALI) for P-32 is 8×10^6 Bq (approximately 216 μ Ci) by ingestion and 1×10^7 Bq (approximately 270 μ Ci) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

Skin Exposure: Wash exposed area with soap and plenty of water. Avoid skin abrasion. Remove contaminated clothing and shoes. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. If breathing is difficult, give oxygen. Consult a physician. Consult with radiation safety officer.

Ingestion: Flush mouth out with water. Consult with radiation safety officer.

Section 5: Fire Fighting Measures

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, CO₂ water spray, fog or foam on large fires; do not use a water stream. **Caution:** CO₂ will displace air in confined space and may cause an Oxygen deficient atmosphere.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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 other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Use HEPA filtered vacuum or wet mop. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove Radioactive P-32 is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Clear, Colorless solution

Odour : Odorless.

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: Sodium orthophosphate P-32

Physical Half-life (³²p) : 14.3 days.

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: Oxides of Phosphorous and sodium may be released by thermal decomposition

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Reactive with strong acids and oxidizers

Section 11: Toxicological Information

Harmful if ingested. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic radiopharmaceutical (injection)

MSDS Status : Published in July 2014

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

Board of Radiation Isotope Technology, India provides the information contained herein in good faith but makes no representation as to its comprehensiveness. This document is intended only as a guide to the appropriate precautionary handling of the radioactive material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. BOARD OF RADIATION ISOTOPE TECHNOLOGY MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, BOARD OF RADIATION ISOTOPE TECHNOLOGY WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.



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भारत सरकार, परमाणु ऊर्जा विभाग,

BOARD OF RADIATION & ISOTOPE TECHNOLOGY

GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEET

Date Published : July 2014

Date Revised: Original

Revision : Original

Section 1 : Product and Manufacturer's Identification

Product Name : Colloidal Samarium Phosphate [P-32] injection

Manufacturer : Board of Radiation and Isotope Technology
DAE, BRIT - BARC Vashi Complex, Sector 20
Vashi, Navi Mumbai - 400703, India
Tel +91-22-27887201 Fax +91-22-27887218

In Emergency contact : +91-22-27887254 / +91-9869454120

Synonyms and Trade names : Colloidal Samarium phosphate P-32 injection

Category : Therapeutic Radiopharmaceutical

Product code : PHM-4

Section 2: Hazards Identification

EMERGENCY OVERVIEW

**CAUTION – RADIOACTIVE MATERIAL
HANDLE ACCORDING TO AERB AND OTHER
REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL**

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Colloidal Samarium phosphate [P-32] injection contains radioactivity.

Eye Contact: May cause eye irritation

Skin Contact: May cause skin irritation. May be harmful if absorbed through the skin.

Ingestion: May cause irritation of the digestive tract. May be harmful if swallowed.

Inhalation: May cause respiratory tract irritation. May be harmful if inhaled.

CARCINOGENICITY

This product does not contain any carcinogens or potential carcinogens as listed by IARC, NTP or OSHA.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
Samarium Phosphate	13465-57-1	0.2
Sodium Chloride	7647-14-5	0.9
Polygeline (Haemaccel)	9015-56-9	3.5
Water for injection	7732-18-5	95.4

- Appearance: white colloidal suspension

* Radioactive concentration : Not more than 5 mCi (185 MBq)/ml

Maximum beta energy: 1.71 MeV

Half-life:

14.3 days.

Atomic Energy Regulatory Board (AERB), India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

The AERB Annual Limit on Intake (ALI) for P-32 is $8 \text{ E} + 06 \text{ Bq}$ (approximately 216 μCi) by ingestion and $1 \text{ E}+07 \text{ Bq}$ (approximately 270 μCi) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

Skin Exposure: Wash exposed area with soap and plenty of water. Avoid skin abrasion. Remove contaminated clothing and shoes. Get medical advice for external radiation exposure or if irritation develops.

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. If breathing is difficult, give oxygen. Consult a physician. Consult with radiation safety officer.

Ingestion: Flush mouth out with water. Consult with radiation safety officer.

Section 5: Fire Fighting Measures

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, CO_2 water spray, fog or foam on large fires; do not use a water stream. **Caution:** CO_2 will displace air in confined space and may cause an oxygen deficient atmosphere.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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 other positive pressure mode.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Use HEPA filtered vacuum or wet mop. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Adequate ventilation to remove Radioactive P³² is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : white colloidal suspension

Odour : Odorless.

Solubility : N/A

Melting Point : N/A

Molecular formula : Active ingredient: Samarium phosphate P-32

Physical Half-life (³²p) : 14.3 days.

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: Oxides of Phosphorous and Samarium may be released by thermal decomposition

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Reactive with strong acids and oxidizers

Section 11: Toxicological Information

Harmful if ingested. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic radiopharmaceutical (injection)

MSDS Status : Published in July 2014

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

Board of Radiation Isotope Technology, India provides the information contained herein in good faith but makes no representation as to its comprehensiveness. This document is intended only as a guide to the appropriate precautionary handling of the radioactive material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. BOARD OF RADIATION ISOTOPE TECHNOLOGY MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, BOARD OF RADIATION ISOTOPE TECHNOLOGY WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.



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भारत सरकार, परमाणु ऊर्जा विभाग,

BOARD OF RADIATION & ISOTOPE TECHNOLOGY

GOVERNMENT OF INDIA, DEPARTMENT OF ATOMIC ENERGY

Website : www.britatom.gov.in

MATERIAL SAFETY DATA SHEET

Date Published : July 2014

Date Revised : Original

Revision : Original

Section 1 : Product and Manufacturer's Identification

Product Name : Samarium [Sm-153] EDTMP injection
Manufacturer : Board of Radiation and Isotope Technology
DAE, BRIT- BARC Vashi Complex, Sector 20
Vashi, Navi Mumbai - 400703, India
Tel +91-22-27887201 Fax +91-22-27887218

In Emergency contact : +91-22-27887254 / +91-9869454120

Synonyms and Trade names : Samarium [Sm-153] EDTMP injection, Quadramet
Samarium [Sm-153] lexicidronam, pentasodium

Category : Therapeutic Radiopharmaceutical

Product code : SAM-2

Section 2: Hazards Identification

EMERGENCY OVERVIEW

CAUTION – RADIOACTIVE MATERIAL HANDLE ACCORDING TO AERB AND OTHER REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Board of Radiation and Isotope Technology Samarium [Sm-153] EDTMP injection contains radioactivity. The primary occupational hazard associated with Samarium [Sm-153] EDTMP injection is related to the presence of Sm-153, a moderate beta and low gamma and X- ray radiation emitter. Hence, Samarium [Sm-153] EDTMP injection should be handled and used only by physicians and other professionals who are qualified and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Hazards of non-radioactive chemical component of Samarium [Sm-153] EDTMP injection, namely Ethylendiaminetetramethylenephosphonic acid salt (EDTMP), have not been fully evaluated in humans, although animal data are available. Animal studies suggest that EDTMP is an eye irritant. In lifetime oral studies in rats, high dose of EDTMP produced tumors in the pancreas and bone.

Individuals with preexisting conditions of the bone marrow and/or increased bleeding time may be aggravated by exposure to Samarium [Sm-153] EDTMP injection.

CARCINOGENICITY

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Section 3: Composition/Information on Ingredients

Ingredients	CAS #	Wt %
*153 Samarium EDTMP (max. beta energy, 805 KeV)	160369-78-8	1.5
Water	7732-18-5	98.5

- Appearance: Clear, colourless solution

* Radioactive ingredient: 2.775 GBq \pm 10% (75 mCi \pm 10%) per vial of therapeutic solution

Maximum beta emitter: 0.805 MeV

Half-life: 46.3 Hours.

Atomic Energy Regulatory Board (AERB) , India Permitted Exposures are 20 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

The AERB Annual Limit on Intake (ALI) for SAM-2 is 2.7 E + 07 Bq (approximately 729 μ Ci) by ingestion and 2.9 E+07 Bq (approximately 780 μ Ci) by inhalation.

Section 4: First Aid Measures

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Inhalation: Shift to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. If breathing is difficult, give oxygen. Call a physician. Consult with radiation safety officer.

Eye Exposure: Wash open eyes thoroughly with running water for at least 15 minutes. Call a physician.

Ingestion: Ingestion is not considered a potential route of exposure. Consult with radiation safety officer.

Skin Exposure: Immediately wash exposed area with soap and plenty of water. Dispose of contaminated clothing. Consult with radiation safety officer.

Section 5: Fire Fighting Measures

Fire: Presents no combustion hazard. No flash point or auto combustion temperatures

Explosion: Not considered to be an explosion hazard

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, CO₂, water spray, fog or foam on large fires; do not use a water stream.

Fire Fighting Instructions: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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 other positive pressure mode. Contaminated clothing should be removed and discarded.

Section 6: Accidental Release Measures

ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS.
NOTIFY THE LOCAL RADIATION SAFETY OFFICER AND ASK FOR ASSISTANCE

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Use HEPA filtered vacuum or wet mop. Prevent entry of spilled material into sewer system. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. If on site, follow the site license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license issued by AERB, India or the regulations governing the use of radioactive material.

The material should be stored (2-8°C) in a tightly-closed shielding container stored in a dry, ventilated area.

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Section 8: Exposure controls/ Personnel Protection

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Use procedures to maintain isolation and containment of this material during handling procedures. A safety shower and eyewash should be immediately accessible. Keep solution behind lead glass windows whenever possible.

Respiratory Protection: Use a personal respirator with a combination of radionuclide cartridge or SCBA where a spill has occurred.

Section 9: Physical and Chemical Properties

Appearance : Clear, Colorless solution

Odour : Odourless

Solubility : Soluble in water.

Melting Point : N/A

Molecular formula : Active ingredient: [Sm-153] EDTMP

Physical Half-life (^{153}Sm) : 46 hours

Section 10: Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: Decomposition will not occur if handled and stored properly

Hazardous Polymerization: Will not occur.

Incompatibilities with other Materials: Incompatible or can react with strong oxidizers

Section 11: Toxicological Information

Information on the adverse effects of this material in animal studies by inhalation, oral, dermal or ocular route(s) of exposure is not available. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Radiopharmaceuticals

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available

Section 13: Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by Radiation Safety Officer, AERB (India) 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.

Section 14: Transportation Information

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

RQ: Shipments of 10 mCi or more per package must have “RQ” marked on the package exterior and on the shipping papers.

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

Section 15: Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR

Section 16: Other Information

Product Use : Therapeutic radiopharmaceutical

MSDS Status : Published in July 2014

Revision Information: Original

For additional information, refer to the AERB Web site at **[http:// www.aerb.gov.in](http://www.aerb.gov.in)**

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