



MATERIAL SAFETY DATA SHEET

UltraTag® RBC

Technetium Tc99m Labeled Red Blood Cells

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: UltraTag® RBC
Synonyms: Tc-99m RBC Tagging Kit
Manufacturer:
Mallinckrodt Inc.
2703 Wagner Place
Maryland Heights, MO 63043

Revision Date: January 1, 2003
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314) 654-7860
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Ingredients:

<u>Component</u>	<u>CAS #</u>	<u>Wt %</u>
Reaction Vial:		
Stannous Chloride	7772-99-8	0.8%
Dextrose	50-99-7	59.5%
Sodium Citrate	6132-04-3	39.7%
Syringe I:		
Sodium Hypochlorite	7681-52-9	0.1%
Water	7732-18-5	99.9%
Syringe II:		
Citric Acid	77-92-9	0.9%
Dextrose Anhydrous	50-99-7	1.2%
Sodium Citrate (hydrated form)	6132-04-3	3.3%
Water	7732-18-5	95%
Reconstituted Kit		
Technetium-99m	23288-60-0	

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Read Package Insert prior to use! Promptly remove any contamination from skin, eyes, or clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

The hazardous ingredients found in UltraTag RBC are skin and eye irritants, but due to the small quantities present in each container, no adverse health effects are expected to occur from exposure.

Inhalation:

Not expected to be a health hazard.

Ingestion:

Not expected to be a health hazard.

Skin Contact:

Not expected to be a health hazard.

Eye Contact:

Not expected to be a health hazard.

Chronic Exposure:

Not expected to be a chronic health hazard.

Aggravation of Pre-existing Conditions:

No information found.

SECTION 4. FIRST AID MEASURES

Inhalation:

Not expected to require first aid measures.

Ingestion:

Not expected to require first aid measures.

Skin Exposure:

Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:

Wash thoroughly with running water. Get medical advice if irritation develops.

SECTION 5. FIRE FIGHTING MEASURES

Fire: Not considered to be a fire hazard.

Explosion: Not considered to be an 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 facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Collect non-radioactive spills and dispose of material as non-hazardous waste. **For UltraTag® RBC Reconstituted with Sodium Pertechnetate Tc-99m:** If any loss or release of the radioactive contents occurs, notify your Radiation Safety Department and Mallinckrodt at (314) 654-7860. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations. **After the addition of the blood sample:** Any resulting waste material is considered a biohazard waste and should be handled in accordance with biohazard/medical waste regulations.

SECTION 7. HANDLING AND STORAGE

Protect from light until use (Syringe I). The drug should be stored at or below room temperature (2°C to 25°C) both prior to and following reconstitution with Sodium Pertechnetate Tc-99m, and discarded six (6) hours from the time of preparation. After reconstitution, handling time should be kept to a minimum, and appropriate shielding should be used. Handling devices such as the syringe shields and tongs should be used. Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide, as well as regulations concerning the disposal of medical wastes as appropriate.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:

None established.

Engineering Controls:

Not expected to require any special ventilation.

Respiratory Protection:

Not expected to require personal respirator usage.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye/Face Protection:

Safety glasses.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Small, dry, white crystals clinging to inside of 10 mL glass reaction vial and two (2) syringes partially filled with colorless solution.

Odor: Odorless.

Solubility: Soluble in water.

Boiling Point: ca. 100°C (212°F) reconstituted.

Melting Point: ca. 0°C (32°F) reconstituted.

SECTION 10. STABILITY AND REACTIVITY

Stability: Light sensitive (Syringe I).

Hazardous Decomposition Products: When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.

Hazardous Polymerization: Will not occur.

Incompatibilities: No information found.

SECTION 11. TOXICOLOGICAL INFORMATION

For detailed toxicological information on specific components, write to the address listed in Section 1 - Attn: Regulatory Compliance Department.

SECTION 12. ECOLOGICAL INFORMATION

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

SECTION 13. DISPOSAL CONSIDERATIONS

UltraTag® RBC reconstituted with Sodium Pertechnetate Tc-99m is Radioactive Waste until the activity has decayed to nondetectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

After a blood sample is added to UltraTag RBC, any resulting waste must be handled as a Biohazard and disposed of accordingly.

If not radioactive or a biohazard, waste UltraTag RBC is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

DOT (Department of Transportation): Not Regulated

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:

Tc-99m = 100 Ci (3.7 E 12 Bq); Sodium Hypochlorite = 100 lbs.

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: Acute

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

When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

Australian Hazchem Code: None allocated.

Australian Poison Schedule: None allocated.

WHMIS: 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

MSDS Status: Revised in accordance with ANSI Guideline Z400.1-1998

NFPA Ratings: Health: 1 Flammability: 0 Reactivity: 0

Product Use: Diagnostic imaging agent

Revision Information: No changes.

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