

SAFETY DATA SHEET

1. Identification

| | |
|---|---|
| Product identifier | Ultratag™ RBC Kit for the preparation of Technetium Tc 99m–Labeled Red Blood Cells |
| Other means of identification | |
| SDS number | URBCK |
| Synonyms | Tc-99m RBC Tagging Kit |
| Recommended use | The content of this kit as sold is non radioactive. Ultratag™ RBC (kit for the preparation of technetium Tc 99m-labeled red blood cells) is a sterile, nonpyrogenic, diagnostic kit for the in vitro preparation of technetium Tc 99m-labeled red blood cells (Not included in this kit). Technetium Tc 99m-labeled red blood cells are used for blood pool imaging, including cardiac first pass and gated equilibrium imaging and for detection of sites of gastrointestinal bleeding. |
| Recommended restrictions | None known. |
| Manufacturer/Importer/Supplier/Distributor information | |
| Supplier | |
| Company name | Curium US LLC |
| Address | 2703 Wagner Place Maryland Heights, MO 63043 United States |
| Telephone number | Customer Service 888-744-1414 |
| E-mail | NuclearMedicine@curiumpharma.com |
| Emergency telephone number: | 24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300 |

2. Hazard(s) identification

| | | |
|------------------------------|--|-------------|
| Physical hazards | Not classified. | |
| Health hazards | Serious eye damage/eye irritation | Category 2A |
| Environmental hazards | Hazardous to the aquatic environment, acute hazard | Category 3 |
| | Hazardous to the aquatic environment, long-term hazard | Category 3 |
| OSHA defined hazards | Not classified. | |
| Label elements | | |



| | |
|--|--|
| Signal word | Warning |
| Hazard statement | Causes serious eye irritation. Harmful to aquatic life with long lasting effects. |
| Precautionary statement | |
| Prevention | Wear eye protection/face protection. Wash thoroughly after handling. Avoid release to the environment. |
| Response | If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. |
| Storage | Store away from incompatible materials. |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | None known. |
| Supplemental information | This safety data sheet covers the content of the kit as sold (non radioactive) prior to reconstitution. |

3. Composition/information on ingredients

Mixtures

| Chemical name | CAS number | % |
|--------------------------|------------|----------------------|
| CITRIC ACID | 77-92-9 | 0.9 (SII) |
| DEXTROSE , ANHYDROUS | 50-99-7 | 59.5 (RV), 1.2 (SII) |
| SODIUM CITRATE DIHYDRATE | 6132-04-3 | 39.7 (RV), 3.3 (SII) |
| SODIUM HYPOCHLORITE | 7681-52-9 | 0.1 (SI) |
| STANNOUS CHLORIDE | 7772-99-8 | 0.8 (RV) |
| Water | 7732-18-5 | 99.9 (SI), 95 (SII) |

RV: Reaction Vial.

SI: Syringe I.

SII: Syringe II.

Composition comments

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Each kit consists of three separate nonradioactive components:

1. A 10 milliliter reaction vial containing: Stannous Chloride, Dihydrate ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 50 ug minimum; Stannous Chloride, Dihydrate ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 96 ug theoretical; Tin Chloride (Stannous and Stannic), Dihydrate (as $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 105 ug maximum; Sodium Citrate, Dihydrate – 3.67 mg; and Dextrose, Anhydrous – 5.50 mg.

Prior to lyophilization, the pH is adjusted to 7.1 to 7.2 with sodium hydroxide. The contents of the vial are lyophilized and stored under argon.

2. Syringe I contains: Sodium Hypochlorite – 0.6 mg in Sterile Water for Injection.

The total volume of this syringe is 0.6 mL. Sodium hydroxide may have been added for pH adjustment. The pH of this solution is 11 to 13. The syringe must be protected from light to prevent degradation of the light-sensitive sodium hypochlorite.

3. Syringe II contains: Citric Acid, Monohydrate – 8.7 mg; Sodium Citrate, Dihydrate – 32.5 mg; and Dextrose, Anhydrous – 12.0 mg in Sterile Water for Injection.

The total volume of this syringe is 1.0 mL. The pH range of this solution is adjusted to 4.5 to 5.5 with sodium citrate or citric acid.

4. First-aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information

IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

| | |
|--|--|
| Specific hazards arising from the chemical | When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid. |
| Special protective equipment and precautions for firefighters | As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Fire fighting equipment/instructions | Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

| | |
|--|--|
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Ensure adequate ventilation. Avoid contact with eyes and prolonged skin contact. Avoid dust formation. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Stop the flow of material, if this is without risk. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

| | |
|--------------------------------------|--|
| Precautions for safe handling | Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with eyes. Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. |
|--------------------------------------|--|

Syringe I should be protected from light if not stored in the kit tray. The drug should be stored at controlled room temperature (20- 25°C) or (68-77°F) 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. Avoid direct handling by using remote manipulation tools, syringe shields and tongs.

| | |
|---|--|
| Conditions for safe storage, including any incompatibilities | Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. The kit should be stored at controlled room temperature 20-25°C (68-77°F). Syringe I should be protected from light if not stored in the kit tray. Store away from incompatible materials (see Section 10 of the SDS). |
|---|--|

Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value |
|--------------------------------------|------|---------------------|
| STANNOUS CHLORIDE (CAS 7772-99-8) | PEL | 2 mg/m ³ |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value |
|--------------------------------------|------|---------------------|
| STANNOUS CHLORIDE (CAS 7772-99-8) | TWA | 2 mg/m ³ |

US. Workplace Environmental Exposure Level (WEEL) Guides

| Components | Type | Value |
|--|------|---------------------|
| SODIUM HYPOCHLORITE (CAS 7681-52-9) | STEL | 2 mg/m ³ |

| | |
|---|--|
| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Appropriate engineering controls | Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Provide eyewash station. |

Individual protection measures, such as personal protective equipment

| | |
|----------------------------|---|
| Eye/face protection | If contact is likely, safety glasses with side shields are recommended. |
|----------------------------|---|

| | |
|---------------------------------------|---|
| Skin protection | |
| Hand protection | Chemical resistant gloves. Suitable gloves can be recommended by the glove supplier. |
| Skin protection | |
| Other | Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. |
| Respiratory protection | No personal respiratory protective equipment normally required. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| General hygiene considerations | When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. |

9. Physical and chemical properties

| | |
|---|---|
| Appearance | Small, dry white crystals clinging to inside of 10 mL glass vial and 2 syringes partially filled with colorless solution. |
| Physical state | Solid, Liquid. |
| Form | Crystals. Solution. |
| Color | White. |
| Odor | Odorless. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | 32 °F (0 °C) reconstituted. |
| Initial boiling point and boiling range | 212 °F (100 °C) reconstituted. |
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not available. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Soluble. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Explosive properties | Not explosive. |
| Oxidizing properties | Not oxidizing. |

10. Stability and reactivity

| | |
|---|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. Syringe I is sensitive to light. |
| Possibility of hazardous reactions | Will not occur. |
| Conditions to avoid | Light. Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |

Hazardous decomposition products Carbon oxides. Hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation May be harmful if inhaled. Inhalation of dusts may cause respiratory irritation.

Skin contact May be harmful in contact with skin. May be irritating to the skin.

Eye contact Causes serious eye irritation.

Ingestion May be harmful if swallowed. May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity May be harmful if swallowed. May be harmful if absorbed through skin. May be harmful if inhaled. Causes eye irritation.

| Components | Species | Test Results |
|-------------------------------------|---------|--------------|
| CITRIC ACID (CAS 77-92-9) | | |
| <u>Acute</u> | | |
| Oral | | |
| LD50 | Rat | 6730 mg/kg |
| DEXTROSE , ANHYDROUS (CAS 50-99-7) | | |
| <u>Acute</u> | | |
| Other | | |
| LD | Rabbit | 35000 mg/kg |
| SODIUM HYPOCHLORITE (CAS 7681-52-9) | | |
| <u>Acute</u> | | |
| Oral | | |
| LD50 | Mouse | 5800 mg/kg |
| | Rat | 9 g/kg |
| STANNOUS CHLORIDE (CAS 7772-99-8) | | |
| <u>Acute</u> | | |
| Oral | | |
| LD50 | Mouse | 1200 mg/kg |
| | Rat | 700 mg/kg |

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization None known.

Germ cell mutagenicity For the content of kit as sold prior to reconstitution (non radioactive): No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity For the content of kit as sold prior to reconstitution (non radioactive): This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

SODIUM HYPOCHLORITE (CAS 7681-52-9) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

| | |
|---|--|
| Reproductive toxicity | For the content of kit as sold prior to reconstitution (non radioactive): Due to lack of data the classification is not possible. For UltraTag® RBC reconstituted with Sodium Pertechnetate Tc-99m: May cause harm to breastfed babies. Technetium Tc-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings. |
| Specific target organ toxicity - single exposure | Due to partial or complete lack of data the classification is not possible. |
| Specific target organ toxicity - repeated exposure | Due to partial or complete lack of data the classification is not possible. |
| Aspiration hazard | Due to partial or complete lack of data the classification is not possible. |
| Chronic effects | For the content of kit as sold prior to reconstitution (non radioactive): Prolonged inhalation may be harmful. |

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

| Components | Species | Test Results |
|--|--|------------------------------|
| SODIUM CITRATE DIHYDRATE (CAS 6132-04-3) | | |
| Aquatic | | |
| Crustacea | EC50 Water flea (Ceriodaphnia dubia) | 655 - 825.9 mg/l, 48 hours |
| SODIUM HYPOCHLORITE (CAS 7681-52-9) | | |
| Aquatic | | |
| Fish | LC50 Chinook salmon (Oncorhynchus tshawytscha) | 0.038 - 0.065 mg/l, 96 hours |

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)
 DEXTROSE , ANHYDROUS (CAS 50-99-7) -3.24

Mobility in soil No data available.

Other adverse effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal considerations

Disposal instructions For the content of kit as sold prior to reconstitution (non radioactive): Dispose in accordance with all 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. If not a biohazard, consult local, state and federal regulations for proper disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

SODIUM HYPOCHLORITE (CAS 7681-52-9) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Toxic Substances Control Act (TSCA)

One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Serious eye damage or eye irritation**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

SODIUM HYPOCHLORITE (CAS 7681-52-9)

STANNOUS CHLORIDE (CAS 7772-99-8)

US. New Jersey Worker and Community Right-to-Know Act

SODIUM HYPOCHLORITE (CAS 7681-52-9)

STANNOUS CHLORIDE (CAS 7772-99-8)

US. Pennsylvania Worker and Community Right-to-Know Law

SODIUM HYPOCHLORITE (CAS 7681-52-9)

US. Rhode Island RTK

Not regulated.

California Proposition 65California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

STANNOUS CHLORIDE (CAS 7772-99-8)

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | Yes |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | Yes |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | Yes |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 07-August-2019

Revision date -

Version # 01

List of abbreviations
TWA: Time Weighted Average Value.
Ceiling: Short Term Exposure Limit Ceiling value.
STEL: Short-Term Exposure Limit.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
EC50: Effective Concentration 50%.
LD50: Lethal Dose, 50%.
LC50: Lethal Concentration 50%.

Disclaimer
Curium provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the 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. CURIUM 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 THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, CURIUM WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.