SAFETY DATA SHEET

1. Identification

Product identifier **Ultra-Technekow TM V4 (Technetium Tc 99m Generator)**

Other means of identification

SDS number UTKV4

Recommended use A radioactive source used in the preparation of FDA-approved diagnostic radiopharmaceutical.

The Ultra-Technekow™ V4 generator is a source of sodium pertechnetate Tc 99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic radiopharmaceutical kits. Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for: Thyroid Imaging Salivary Gland Imaging Urinary Bladder Imaging (direct isotopic cystography) for detection of vesico-ureteral reflux Nasolacrimal Drainage System Imaging (dacryoscintigraphy). Sodium Pertechnetate Tc 99m is used IN PEDIATRIC PATIENTS as an agent for: Thyroid Imaging Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

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

Emergency telephone number: 24 Hour Emergency 314-595-3700

Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Sensitization, skin	Category 1
Reproductive toxicity	Effects on or via lactation

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement May cause an allergic skin reaction. May cause harm to breast-fed children.

RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.

Precautionary statement

Prevention Obtain special instructions before use. Do not breathe mist or vapor. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. Wash contaminated clothing before reuse.

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

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations. Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sodium Molybdate MO-99	38848-45-2	50
Sodium Pertechnetate Tc-99m	23288-60-0	50

Composition comments

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

The Ultra-Technekow™ V4 Generator is prepared with fissionproduced molybdenum Mo-99 adsorbed onto alumina in a column shielded by lead, tungsten, or depleted uranium. The column assembly and shielding are encased in a plastic container that is covered with a plastic elution hood. The elution hood has an opening for the column assembly double inlet needles and an opening for the single outlet needle. The needles accommodate the sterile eluant vials and sterile evacuated collection vials. A sterile vial containing a bacteriostat is supplied with the generator for the customer to aseptically seal the outlet needle after each elution. This terminally sterilized generator provides a closed system for the production of sterile metastable technetium Tc-99m, which is produced by the decay of molybdenum Mo-99. Incorporated between the column outlet and the collection vial is a sterile 0.22 micrometer filter. Sterile, non-pyrogenic isotonic solutions of Sodium Pertechnetate Tc 99m can be obtained conveniently by periodic aseptic elution of the generator. These solutions should be clear, colorless, and free from any particulate matter. The Sodium Pertechnetate Tc 99m Injection is suitable for intravenous injection and direct instillation. The carrier-free solution may be used as is, or diluted to the proper concentration. Over the life of the generator, an elution will contain an amount of technetium Tc-99m in direct proportion to the quantity of Mo-99 decay since the previous elution of the generator. The quantity of Tc-99m in the eluate is determined by quantity of Mo-99 on the column, and the elapsed time between elutions. Each eluate of the generator should not contain more than the USP limit of 0.15 kilobecquerel molybdenum Mo-99 per megabecquerel technetium Tc-99m (0.15 microcurie Mo-99 per millicurie Tc-99m) per administered dose at the time of administration and an aluminum ion concentration of not more than 10 micrograms per milliliter of the generator eluate, both of which must be determined by the user before administration.

4. First-aid measures

Inhalation

Call a POISON CENTER or doctor/physician. Notify radiation safety personnel immediately. Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion

Call a POISON CENTER or doctor/physician. Notify radiation safety personnel immediately. Rinse mouth. The amount of material ingested should be assessed and documented.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. May cause an allergic skin reaction. Dermatitis. Rash.

Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

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. Wash contaminated clothing before reuse.

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	May emit radioactive fumes containing Mo-99 and Tc-99m when heated to decomposition.
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. Follow all guidances provided by NRC or equivalent authority. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Wear appropriate personal protective equipment. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust. Local authorities should be advised if significant spillages cannot be contained. 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. Dike far ahead of spill for later disposal. Minimize dust generation and accumulation. Collect in containers and seal securely. Clean contaminated surface thoroughly. 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	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs. Minimize dust generation and accumulation. Do not use in areas without adequate ventilation. Do not breathe dust. Do not get in eyes and avoid contact with skin and clothing. Avoid contact during pregnancy/while nursing. When using, do not eat, drink or smoke. Avoid prolonged exposure. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority.
Conditions for safe storage, including any incompatibilities	Store at controlled room temperature at 20–25 ºC (68-77ºF). Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Storage 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	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	The specific gamma ray constant for Mo-99 : 1 E-6 µCi/mL of air. The specific gamma ray constant for Tc-99m : 6 E-5 µCi/mL of air.

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.

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	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Consult with your facility's Radiation Safety Personnel or Health Physics staff for use of appropriate respiratory equipment.
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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	The V4 generator column consists of a glass column packed with Aluminum Oxide, Silicar and Glass wool. The columns are stoppered on each end and needles inserted into the stoppers. The columns are conditioned prior to being loaded with a radioactive Mo-99 solution. The Mo-99 is allowed to bind to the aluminum oxide substrate prior to loading into the V4 generator system. In order to elute the Tc-99m from the generator a sodium chloride solution is passed over the column and the eluate collected containing the radioactive Tc-99m leaving the Mo-99 bound to the aluminum oxide substrate.
Color	White.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
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)	Not available.
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. Molybdenum-99 (Mo-99) is a beta and gamma emitter with maximum energies of 1.214 MeV and 0.778 MeV, respectively. Mo-99 has a gamma ray constant of 1.8 R/hr per mCi at 1 cm. Technetium-99m (Tc-99m) is a gamma emitter with a maximum energy of 0.140 MeV. Tc-99m has a gamma ray constant of 0.63 R/hr per mCi at 1 cm. The physical half-lives of Mo-99 and Tc-99m are 65.94 hours and 6.02 hours, respectively.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	May emit radioactive fumes containing Mo-99 and Tc-99m when heated to decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Exposure to radioactive materials may produce adverse effects. Sodium Molybdate Mo-99 and Sodium Pertechnetate Tc-99m do not easily become airborne.
Skin contact	May cause an allergic skin reaction.
Eye contact	May be irritating to eyes.
Ingestion	Exposure to radioactive materials may produce adverse effects. May cause asymptomatic physiological uptake by specific target organs or tissues.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. May cause an allergic skin reaction. Dermatitis. Rash. Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

Information on toxicological effects

Acute toxicity	May cause asymptomatic physiological uptake by specific target organs or tissues.
Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	May be irritating to eyes.

Respiratory or skin sensitization

Respiratory sensitization	Not available.
Skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is a potential mutagen to human.
Carcinogenicity	No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is carcinogenic to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity	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. No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. In animal reproductive studies, Sodium Pertechnetate Tc 99m (as free pertechnetate) has been shown to cross the placental barrier. It is not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Ideally, examinations using radiopharmaceutical drug products - especially those elective in nature - of women of childbearing capability should be performed during the first ten days following the onset of menses.
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	The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

12. Ecological information

Ecotoxicity	This product has not been tested.
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.
Bioaccumulative potential	No data available.
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	The Ultra-Technekow™ V4 (Technetium Tc 99m Generator) is Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC 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. If not radioactive or a biohazard, a spent Ultra-TechneKow ® DTE (Technetium Tc 99m Generator) may still be considered special waste due to the lead shielding inside the unit. 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

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	8
Label(s)	7
Packing group	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	A56, W7, W8
Packaging exceptions	None
Packaging non bulk	415, 418, 419
Packaging bulk	415, 418, 419

IATA

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7

Subsidiary risk	8
Label(s)	7
Packing group	Not available.
Environmental hazards	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	8
Label(s)	7
Packing group	Not available.
Environmental hazards	
Marine pollutant	No.
EmS	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulations Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

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	Respiratory or skin sensitization Reproductive toxicity

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) Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California 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.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
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 06-December-2018

Revision date -

Version # 01

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