

CHROMITOPE SODIUM MATERIAL SAFETY DATA SHEET

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SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543

Product Identification: Sodium Chromate Cr51 Injection

1. Chemical Name: For active, Cr51: sodium chromate 51.
2. Synonyms: For active, sodium chromate: chromic acid, disodium chromate salt, tetrahydrate (crystalline form).
3. How Supplied: Multidose reaction vials of 1.25 mL or 5 mL.
4. Product Use: Determination of red blood cell volume or mass, study of red blood cell survival time.
5. Chemical Family: Radioisotope of chromium (VI) (hexavalent oxidation state)
6. Molecular Formula: $51\text{CrO}_4 \cdot 2\text{Na}$ (radioisotope)
7. CAS NUMBER: 7775-11-3 (pertains to sodium chromate).

EMERGENCY CONTACTS: (Health) 1-800-257-5181.
(U.S. Transportation) Chemtrec 1-800-424-9300.
(International Transportation) Chemtrec
1-703-527-3887. Nuclear Regulatory
Commission 1-800-368-5642.

EMERGENCY OVERVIEW: Clear, light yellow aqueous solution.
Formulation contains RADIOACTIVE CHROMIUM 51.
As in the use of any radioactive material,
care should be taken to insure minimum
radiation exposure. Personnel who handle
radioactive materials should be trained in
their use and should follow appropriate
precautions for work with these materials.
See Health Effects and Toxicology sections
for additional information.

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SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS (>1%)	HAZARDOUS (Y/N)	CONCENTRATION (w/w%)	CAS NUMBER	EXPOSURE GUIDELINE
Sodium Chromate Cr-51	Y	Not applicable*	7775-11-3**	50 Sv/year, 0.05 mg/m ³ as Cr(TLV TWA)
Water, USP	N	98	7732-18-5	None

*See specifications for radioactivity on package.

**CAS number pertains to sodium chromate.

Components present at <1% or used for pH adjustment: sodium chromate, benzyl alcohol (preservative), sodium chloride, hydrochloric acid, sodium bicarbonate.

SECTION 3: HEALTH HAZARDS IDENTIFICATION

Effects of Overexposure

Routes of Entry:

1. Inhalation: Under normal conditions, this liquid material is handled in closed vials and exposure by inhalation is not expected to occur.
2. Skin Contact: Exposure may occur via skin contact if gloves and protective clothing are not worn. Hexavalent chromium compounds are readily absorbed through damaged skin.
3. 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.

Acute

1. Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms. However, ingestion of substantial amounts may cause kidney damage (acute tubular necrosis). In general, depending on both the dose and duration, exposure to radioactive materials may produce adverse effects. Toxic effects of radiation may include development of cancer, adverse reproductive effects, including adverse effects on the fetus.
2. Inhalation: Formulation contains some materials that are irritants. Inhaling small amounts of liquid aerosol may result in nasal and other respiratory tract irritation. In general, depending on both the dose and duration, exposure to radioactive materials may produce adverse effects.

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Toxic effects of radiation may include development of cancer, adverse reproductive effects, including adverse effects on the fetus.

3. Skin Contact:
 - a. Toxic: Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects. Substantive occupational exposure to hexavalent chromium through damaged skin may produce kidney damage.
 - b. Irritation: This material contains Hexavalent chromium which is an irritant. Sufficient exposure may cause skin ulcers.
 - c. Sensitization: Hexavalent chromium compounds may cause allergic contact dermatitis.
4. Eye Contact: May cause irritation. Goggles should be worn when handling large amounts of this material.

Chronic

Repeated and prolonged exposure to skin may cause skin ulcers.

Exposure Guideline Summary: An exposure guideline of 0.05 mg/cubic meter has been established for water soluble hexavalent chromium by the American Conference of Governmental Industrial Hygienists (ACGIH). OSHA has a ceiling value of 0.1 mg/cubic meter for hexavalent chromium compounds. The occupational guideline for exposure to radioactive materials is an effective dose equivalent to 50 mSv per year.

Carcinogen Lists for hexavalent chromium: IARC: Yes. NTP: Yes. OSHA: Yes.

Target organs for hexavalent chromium: Blood, respiratory system, kidneys, liver, eyes and skin.

Medical Condition Aggravated by Exposure: Renal disease. Skin disorders may be aggravated by exposure to hexavalent chromium compounds.

SECTION 4: FIRST AID MEASURES

1. 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 or experiencing convulsions.
2. Inhalation: Remove exposed person to fresh air. If person is not breathing, give artificial respiration. If breathing is difficult administer oxygen. Get medical attention immediately.
3. Skin Contact: Remove contaminated clothing. Wash skin with plenty of water for 5 minutes. Seek medical attention if

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irritation (redness, itching or swelling) develops or persists.

4. Eye Contact: Hold eyelids apart and flush with plenty of water for 5 minutes. Get medical attention if signs of irritation develop.
5. Note: When transporting an employee for medical assistance, after the employee has had direct contact with a radioactive material, care should be taken to avoid contamination of transport vehicle and medical facility. Skin decontamination and monitoring should be conducted as appropriate.

SECTION 5: FIRE FIGHTING MEASURES

1. Flash Point: Not available.
 2. Auto-ignition Temperature: Not available.
 3. Flammability Limits:
 - a. LEL: Not applicable.
 - b. UEL: Not applicable.
 4. Combustibility of Dusts: Not applicable, product exists as a liquid.
 5. Extinguishing Media: In case of fire, flood with water.
Fire-fighting Instructions: Firefighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.
 6. Hazardous Combustion Products: Carbon monoxide, carbon dioxide, radioactive chromate.
- Unusual Hazards: Material is radioactive.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Radioactive shielding if appropriate to minimize exposure, lab coat, impermeable gloves (latex, latex/ nitrile or nitrile) and chemical safety goggles. Absorb liquid onto appropriate absorbent material and place into an appropriate container for disposal. The spill area should be ventilated and decontaminated after material has been picked up. Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

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SECTION 7: HANDLING AND STORAGE

1. Handling Precautions: Avoid skin and eye contact.
 2. Container Requirements: Lead vial shield and lead cover must remain in place on the reaction vial. Chromitope Sodium is available in multiple dose 1.25 mL vials containing 9.25 megabecquerels (250 microcuries) and multiple dose 5.0 mL vials containing 37 megabecquerels (1.0 millicurie).
 3. Storage Conditions: Store at 20-25 degrees C.
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SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

1. Ventilation Requirements: None beyond good room ventilation.
 2. Respiratory Protection: Not anticipated for normal clinical environment. Non-routine exposure conditions may require NIOSH approved respiratory protection appropriate for potential exposure to radionuclides. Self-contained breathing apparatus should be available for emergency use.
 3. Eye Protection: Wear safety glasses (ANSI Z87.1). In the event of a spill wear chemical safety goggles.
 4. Protective Gloves: Wear impervious gloves (latex, latex/nitrile, or nitrile) if the potential exists for dermal contact.
 5. Special Clothing: None.
 6. Hygiene: Wash hands after handling product and before eating, smoking, using lavatory and at the end of the day.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

1. Appearance/Physical State/Color: Clear, light yellow, aqueous solution.
 2. Boiling Point: Not available.
 3. Evaporation Rate: Not available.
 4. Flash Point: Not available.
 5. Freezing point/Melting Point: Not available.
 6. Octanol/Water Partition Coefficient: Water soluble.
 7. Odor (threshold): Not available.
 8. pH: 7.5 to 8.5.
 9. Solubility in Water: Soluble.
 10. Specific Gravity: Not available.
 11. Vapor Density: Not available.
 12. Vapor Pressure: Not available.
 13. Viscosity (cP): Similar to water (98% water).
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SECTION 10: STABILITY AND REACTIVITY

1. Stability: This formulation contains sodium chromate (Cr51). The Cr51 radioactively decays with a half-life of 27.7 days.
 2. Incompatibilities: None known.
 3. Conditions of Reactivity: None known.
 4. Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, radioactive chromium 51 compounds.
 5. Hazardous Polymerization: None.
 6. Explosion data relative to mechanical impact: No information.
 7. Explosion data relative to static discharge: No information.
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SECTION 11: TOXICOLOGICAL INFORMATION - for active ingredient, sodium chromate, unless indicated differently.

RTECS # (U.S.): GB2955000

1. Acute toxicity data:
 - Acute ip LD50(mouse)= 32 mg/kg;
 - Acute ip LD50(rat)= 57 mg/kg.
 - Acute iv LD50 (cat)= 164 mg/kg.

Chronic: Biological effects from exposure to radioactive materials are based on exposures higher than those permitted in an occupational setting. No harmful effects are expected from Chromitope Sodium under normal use conditions.

- a. Carcinogenicity: Hexavalent chromium is a known human carcinogen
 - b. Mutagenicity: DNA damage occurred in chicken embryos when exposed to sodium chromate at a concentration of 2500 nmol/l.
 - c. Teratogenicity: No information.
 - d. Reproductive Effects: No information.
 - e. Toxicological Synergistic Products: No information.
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SECTION 12: ECOLOGICAL INFORMATION

1. Ecotoxicological Information for sodium chromate:
 - LC50 (rotifers)= 3.1 ppm/96 hours;
 - LC50 (fathead minnow)= 3 ppm/96 hours.
 2. Chemical Fate Information: Not available.
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SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

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SECTION 14: TRANSPORT INFORMATION

1. Domestic

DOT shipping classification: Radioactive material- see US regulations regarding shipment of radioactive materials.

2. International

DOT shipping classification: Radioactive material- see US and other nations' regulations on shipment of radioactive materials.

SECTION 15: REGULATORY/STATUTORY INFORMATION (limited to health, safety, environmental)

NOTE: Not meant to be all-inclusive.

1. U.S. Federal: Radioactive material.
 2. International: Radioactive material.
 3. EC Labeling: Radioactive material.
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SECTION 16: OTHER INFORMATION

March 20, 2001: New MSDS for CHROMITOPE Sodium was developed by Bracco Diagnostics, Inc.

March 6, 1992: Bristol-Myers Squibb MSDS for CHROMITOPE Sodium.

CHROMITOPE Sodium vial is a sterile, pyrogen-free liquid containing radioactive Chromium 51.

When transporting an employee for medical assistance, after the employee has had direct contact with a radioactive material, care should be taken to avoid contamination of transport vehicle and medical facility. Skin decontamination and monitoring should be conducted as appropriate.

If ingestion of Chromitope Sodium (containing radioactive chromium 51) inadvertently occurs, the individual may be treated by water hydration or diuresis to facilitate elimination of the radioactive material.

Radioactive materials may pose significant health risks if not properly handled. Personnel who handle radioactive materials should be trained in their use and should follow appropriate precautions for work with these materials.

Chromium 51 decays by electron capture and gamma emission with a physical half-life of 27.7 days. The specific gamma ray constant \$\$\$

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for Chromium 51 is 0.19 R/hour-millicurie at 1 cm. The first half value layer is 0.2 mm of lead (Pb).

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides) and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

Diagnostic agents are intended for use under direction of a physician and under the conditions of use described on the label and in the product's package insert. As a general precaution, personnel who handle these products should avoid contact (ingestion, inhalation, skin and eye contact) with them.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities and it does not address the diagnostic use of this material. Information concerning the use of this diagnostic agent should be obtained from the product package insert and other appropriate references.

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