Renografin-60 MATERIAL SAFETY DATA SHEET

The author of this Material Safety Data Sheet (MSDS) is Bracco Diagnostics Inc. This MSDS is generated and/or distributed by the Bristol-Myers Squibb Company on behalf of Bracco Diagnostics Inc. Please carefully review all of the information disclosed in this MSDS prior to handling or using the product referenced below.

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

Product Identification: Renografin-60.

1. Chemical Name: For active (diatrizoate meglumine) D-Glucitol, 1-deoxy-1-(methylamino)-3,5-diacetamido-2,4,6-triiodobenzoate (salt).
   For active (diatrizoate sodium) 3,5-Diacetamido-2,4,6-triiodobenzoic acid, sodium salt.
2. Synonyms: Diatrizoate meglumine and Diatrizoate sodium injection.
3. How Supplied: Ten 10 mL single dose vials, twenty-five 50 mL single dose vials, ten 100 mL single dose bottles.
4. Product Use: Iodinated radiopaque contrast agent.
5. Chemical Family: Not applicable (pharmacological mixture).
6. Molecular Formula: $C_{11}H_9I_3N_2O_4.C_7H_{17}NO_5$ (Diatrizoate meglumine)
   $C_{11}H_8I_3N_2O_4.Na$ (Diatrizoate sodium)
7. CAS NUMBER: Diatrizoate meglumine (131-49-7).
   Diatrizoate sodium (737-31-5).

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

EMERGENCY OVERVIEW: Colorless to pale yellow sterile aqueous solution. Non-combustible. See Health Effects and Toxicology sections for additional information.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS	HAZARDOUS (Y/N)	CONCENTRATION %(w/v)	CAS NUMBER	EXPOSURE GUIDELINE
> 1%				
Diatrizoate Meglumine	N	52	131-49-7	None
Diatrizoate sodium	N	8	737-31-5	None
Water	N	>1	7732-18-5	None

Components present at < 1% or used for pH adjustment: edetate disodium, sodium citrate, and sodium hydroxide.
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SECTION 3: HEALTH HAZARDS IDENTIFICATION

Effects of Overexposure

Routes of Entry:

1. Inhalation: Under normal conditions, this material is handled in closed vials and exposure to this material by inhalation is not expected to occur. However, in a situation where the liquid would be aerosolized, there may be potential for inhalation. The extent of systemic absorption of the material after inhalation is not known.
2. Skin Contact: Exposure may occur via skin contact if gloves and protective clothing are not worn. The extent of systemic absorption of the material after skin contact is not known.
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. Diatrizoate meglumine and diatrizoate sodium are very poorly absorbed from the gastrointestinal tract.

Acute

1. Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms. Ingestion of large quantities of certain meglumine salts may result in mild laxative effects, dehydration, electrolyte disturbances, and occasionally hypersensitivity (allergic) reactions.
2. Inhalation: Inhaling trace amounts of aerosolized material would not be expected to result in symptoms, although a hypersensitivity (allergic) reaction may (occasionally) occur. Inhalation of large amounts of material may result in inflammation and/or edema of the lungs.
3. Skin Contact:
   a. Toxic: Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.
   b. Irritation: Material contains low concentrations of components that are mild irritants or possible irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.
   c. Sensitization: This material may act as a sensitizer (allergen) for those persons who are allergic to these formulations, iodine, or other components in the formulation.
4. Eye Contact: No information.

Chronic

Repeated and prolonged exposure to skin may cause skin irritation. Renografin is not intended for chronic use and there is no information on the possible adverse effects associated with chronic exposure.

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Carcinogen Lists IARC: No. NTP: No. OSHA: No.

Target Organs: None known.

Medical Condition Aggravated by Exposure: Significant doses to patients with multiple myeloma, pheochromocytoma or sickle cell disease may aggravate conditions. Sensitivity to iodine.

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 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 to physicians: None.

SECTION 5: FIRE FIGHTING MEASURES

1. Flash Point: Not applicable.
2. Auto-ignition Temperature: Not available.
3. Flammability Limits:
   a. LEL: Not applicable.
   b. UEL: Not applicable.
4. Combustibility of Dusts: Not applicable, material exists as a liquid.
5. Extinguishing Media: In case of fire, flood with water.
6. 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.
7. Hazardous Combustion Products: carbon monoxide, carbon dioxide, hydrogen iodide, iodine, nitrogen oxides.
8. Unusual Hazards: None.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Lab coat, impermeable gloves (latex, latex/nitrile or nitrile) and eye protection should be worn as a minimum precaution. Absorb spill with inert material, e.g. sand, vermiculite or other non-combustible absorbent materials, and place into a closed container for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up.

SECTION 7: HANDLING AND STORAGE

1. Handling Precautions: Avoid splashing of liquid product. Avoid skin and eye contact.
2. Container Requirements: 10 mL single dose vials, 50 mL single dose vials, 100 mL single dose bottles.
3. Storage Conditions: Store at 20-25 degrees C. Protect from light.

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 exposure potential. Self-contained breathing apparatus should be available for emergency use.
3. Eye Protection: Wear safety glasses (ANSI Z87.1).
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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

1. Appearance/Physical State/Color: Colorless to pale yellow sterile aqueous solution.
2. Boiling Point: Not available.
3. Evaporation Rate: Not available.
4. Flash Point: Not applicable.
5. Freezing point/Melting Point: Not available.
6. Octanol/Water Partition Coefficient: Not available.
7. Odor (threshold): Practically odorless.
8. pH: 6.0-7.7.
9. Solubility in Water: Miscible.
10. Specific Gravity: 1.334.
11. Vapor Density: Not available.
12. Vapor Pressure: Not available.
13. Viscosity: 6.2 cps at 25 degrees C

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SECTION 10: STABILITY AND REACTIVITY

1. Stability: Filled containers are stable under normal conditions.
2. Incompatibilities: None known.
3. Conditions of Reactivity: No information.
4. Hazardous Decomposition Products: carbon monoxide, carbon dioxide, hydrogen iodide, iodine, nitrogen oxides.
5. Hazardous Polymerization: None.
6. Explosion data relative to mechanical impact: No information.
7. Explosion data relative to static discharge: No information.

SECTION 11: TOXICOLOGICAL INFORMATION – for active ingredients, diatrizoate meglumine and diatrizoate sodium.

1. RTECS # (U.S.): LZ4315000 (diatrizoate meglumine)
   DG6125000 (diatrizoate sodium)
2. For diatrizoate meglumine:
   Acute iv LD50 (rat)= 14,565 mg/kg
   Acute iv LD50 (mouse)= 21,200 mg/kg
   Acute ip LD50 (rat)= 44,504 mg/m=kg

   For diatrizoate meglumine:
   Acute iv LD50 (rat)= 11,400 mg/kg
   Acute iv LD50 (mouse)= 14,000 mg/kg
   Acute iv LD50 (dog)= 13,200 mg/kg
   Acute iv LD50 (cat)= 11,300 mg/kg
   Acute iv LD50 (rabbit)= 12,200 mg/kg
   Acute im LD50 (mouse)= 20,349 mg/kg

   Diatrizoate meglumine and diatrizoate sodium would be classified as essentially nontoxic after acute intravenous injection.
3. LC50: Not applicable, exists as a liquid at room temperature.
4. Chronic
   a. Carcinogenicity: No information.
   b. Mutagenicity: No information.
   c. Teratogenicity: When administered intravenously, diatrizoate salts cross the placenta and are evenly distributed in fetal tissues. No teratogenic effects attributable to diatrizoate meglumine or diatrizoate sodium have been observed in teratology studies performed in animals. There are, however, no adequate and well-controlled studies in pregnant women.
   d. Reproductive Effects: It is not known whether this product can affect reproductive capacity. Diatrizoate meglumine is excreted in breast milk following intravascular exposure.
   e. Toxicological Synergistic Products: None known.
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SECTION 12: ECOLOGICAL INFORMATION

1. Ecotoxicological Information: Not available.
2. Chemical Fate Information: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national, state, local or applicable country regulations.

SECTION 14: TRANSPORT INFORMATION

1. Domestic
   a. Proper Shipping Name: Not classified.
   b. Hazard Class, UN Number, Packing Group: Not classified.
   c. Label Requirements: Not applicable.
   d. Placard Requirements: Not applicable.
2. International
   a. Proper Shipping Name: Not classified.
   b. Hazard Class, UN Number, Packing Group: Not classified.
   c. Label Requirements: Not applicable.
   d. Placard Requirements: Not applicable.

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

NOTE: Not meant to be all-inclusive.

1. U.S. Federal: None noted.
2. International: None noted.
3. EC Labeling: Not applicable.

SECTION 16: OTHER INFORMATION

September 20, 2001: New MSDS for Renografin-60 was developed by Bracco Diagnostics Inc. and supercedes the previous version.

February 19, 1993: MSDS for Renografin-60 developed by Bristol-Myers Squibb.

Diagnostic agents are intended for use under direction of a physician and only 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.
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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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