

SINOGRAFIN 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: Sinografin.

1. Chemical Name (for active ingredients): Diatrizoate meglumine is 1-deoxy-1-(methylamino)-D-glucitol 3,5-diacetamido-2,4,6-triiodobenzoate (salt). Iodipamide meglumine is 1-deoxy-1-(methylamino)-D-glucitol 3,3'-(adipoyldiimino)bis[2,4,6-triiodobenzoate(2:1)(salt)].
2. Synonyms: Diatrizoate Meglumine and Iodipamide Meglumine Injection.
3. How Supplied: Packages of ten single dose 10 mL vials.
4. Product Use: Diagnostic radiopaque contrast medium for intrauterine use.
5. Chemical Family: Not available.
6. Molecular Formula: For actives- C11H9I3N2O4.C7H17NO5, C20H14I6N2O6.2C7H17NO5.
7. CAS NUMBERS: 131-49-7 (Diatrizoate Meglumine), 3521-84-4 (Iodipamide Meglumine).

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

EMERGENCY OVERVIEW: Aqueous solution. Non-combustible. See Health Effects and Toxicology sections for additional information.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS (>1%)	HAZARDOUS (Y/N)	CONCENTRATION (w/v%)	CAS NUMBER	EXPOSURE GUIDELINE
Diatrizoate meglumine	N	52.7	131-49-7	None
Iodipamide meglumine	N	26.8	3521-84-4	None
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COMPONENTS (>1%)	HAZARDOUS (Y/N)	CONCENTRATION (w/v%)	CAS NUMBER	EXPOSURE GUIDELINE
Water, USP	N	>1	7732-18-5	None

Components present at <1% or used for pH adjustment: sodium citrate; edetate disodium.

SECTION 3: HEALTH HAZARDS IDENTIFICATION

Effects of Overexposure

Routes of Entry:

1. Inhalation: Under normal conditions, 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 is poorly absorbed from the gastrointestinal tract. The extent of systemic absorption of Iodipamide Meglumine after ingestion is not known.

Acute

1. Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.
2. Inhalation: Inhaling small doses of aerosolized material would not be expected to result in symptoms.
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 the formulation, iodides, or other components in the formulation.

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4. Eye Contact: No information.

Chronic

Repeated and prolonged exposure to skin may cause skin irritation.

Exposure Guideline Summary: An exposure guideline has not been established for this material.

Carcinogen Lists IARC: No NTP: No OSHA: No

Target Organs: None known.

Medical Condition Aggravated by Exposure: 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.
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SECTION 5: FIRE FIGHTING MEASURES

1. Flash Point: Not applicable.
2. Auto-ignition Temperature: Not applicable.
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.

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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 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: Single dose 10 mL glass vials.
 3. Storage Conditions: Store at 20-25 degrees C. Protect from light.
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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 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.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

1. Appearance/Physical State/Color: Clear colorless to pale yellow aqueous solution.
2. Boiling Point: Not available.
3. Evaporation Rate: Not available.
4. Flash Point: Not applicable.
5. Freezing point/Melting Point: Not available/Not available.
6. Octanol/Water Partition Coefficient: Not available.
7. Odor (threshold): Not remarkable.

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8. pH: 7.0-7.8.
 9. Solubility in Water: Miscible.
 10. Specific Gravity: 1.43.
 11. Vapor Density: Greater than 1 (heavier than air).
 12. Vapor Pressure: Similar to water at room temperature, <25 mm Hg.
 13. Viscosity: Not available
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SECTION 10: STABILITY AND REACTIVITY

1. Stability: 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.
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SECTION 11: TOXICOLOGICAL INFORMATION - for active ingredients, diatrizoate meglumine, iodipamide meglumine.

1. RTECS # (U.S.): LZ4315000 (diatrizoate meglumine); LZ4297000 (iodipamide meglumine).
2. Acute toxicity data
diatrizoate meglumine:
Acute iv LD50 (rat) = 14565 mg/kg
Acute iv LD50 (mouse) = 21200 mg/kg

iodipamide meglumine:
Acute iv LD50 (rat) = 5000 mg/kg
Acute iv LD50 (mouse) = 3195 mg/kg
Acute iv LD50 (dog) = 1200 mg/kg

Diatrizoate meglumine would be classified as essentially nontoxic after acute intravenous exposure. Iodipamide meglumine is moderately toxic by the acute intravenous route.

3. LC50: Not applicable, exists as a liquid at room temperature.
4. Chronic:
 - a. Carcinogenicity: No information.
 - b. Mutagenicity: No information.
 - 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: Not available.
 2. Chemical Fate Information: Not available.
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SECTION 13: DISOPOSAL 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.
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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.
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SECTION 16: OTHER INFORMATION

May 15, 2001: Updated MSDS for Sinografin was developed by Bracco Diagnostics, Inc.

February 19, 1993: Bristol-Myers Squibb MSDS for Sinografin.

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.

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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.

The information contained in this MSDS was obtained by Bracco Diagnostics from sources believed to be accurate and reliable, and represents information currently on file and known by Bracco. However, Bracco makes no representation, guaranty or warranty, express or implied, with respect to any such information, and specifically disclaims and assumes no liability resulting from the use, misuse or mishandling of either the product or this MSDS.
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