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October 10, 2001

Gastrografin Material Safety Data Sheet NDC 0270-0445-40

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.

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08540

Product Identification: Gastrografin.

1. Chemical Names (for active ingredients): Diatrizoate meglumine and diatrizoate sodium.
2. Synonym: Diatrizoate meglumine and diatrizoate sodium solution USP.
3. How Supplied: 120 mL bottles.
4. Product Use: Iodinated radiopaque contrast medium for oral or rectal administration.
5. Chemical Family: Not applicable (pharmacological mixture).
6. Molecular Formula: C₁₁H₉I₃N₂O₄.C₇H₁₇N₅ (diatrizoate meglumine).
C₁₁H₈I₃N₂O₄.Na (diatrizoate sodium).
7. CAS NUMBER: See Section 2.

EMERGENCY CONTACTS: (Health) 1-800-257-5181 (M-F, daytime).
(U.S. Transportation) Chemtrec 1-800-424-9300.
(International Transportation) Chemtrec 1-703-527-3887.
EMERGENCY OVERVIEW: Light yellow to dark amber aqueous liquid. May burn if involved in a fire. 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
diatrizoate meglumine	N	66.0	131-49-7	none
diatrizoate sodium	N	10	737-31-5	none
water, USP	N	> 1	7732-18-5	none

Present at < 1%:

edetate disodium; sodium citrate; sodium hydroxide; saccharin sodium;
polysorbate 80; flavor; simethicone.

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37% organically bound iodine

lot 24026 (civ 1335)

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SECTION 3: HEALTH HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE

Routes of Entry:

1. Inhalation: Under normal conditions exposure to this material by inhalation would not be 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, if inhalation were to occur, is unknown.
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 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 liquid would not be expected to result in symptoms. At therapeutic doses, most adverse effects associated with ingestion of this formulation are mild and transitory. However, nausea, vomiting and/or diarrhea, urticaria with erythema, hypoxia, acute dyspnea, tachyarrhythmia, and anaphylaxis have occurred following ingestion of the contrast medium, particularly after the administration of high concentrations or large volumes of solution. Electrolyte disturbances may also occur. Severe changes in serum osmolarity and electrolyte concentrations may produce shock-like states. Cases of hyperthyroidism have been reported with the use of iodine-containing oral contrast media.
2. Inhalation: There is no information concerning the potential of this material to produce symptoms after inhalation of small amounts of aerosol. In general, inhalation of large amounts of liquid may result in pneumonia or pulmonary edema.
3. Skin Contact:
 - a. Toxic: Skin contact with small quantities of material for short periods is not expected to produce symptoms.
 - b. Irritation: The irritant potential of this material of its components has not been evaluated.
 - c. Sensitization: The potential of this material to act as a sensitizer (allergen) has not been evaluated.
4. Eye Contact: Material has not been tested for eye irritation potential. In the absence of this information, the material should be handled as a potential eye irritant.

Chronic

Gastrografin is not intended for chronic use and there is no information on the possible adverse effects associated with chronic exposure. Chronic oral exposure may produce the same range of adverse effects associated with acute ingestion (see above).

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Exposure Guideline Summary: None.

Carcinogen Lists IARC: Yes NTP: Yes OSHA: No
Saccharin is listed by IARC as a Class 2B carcinogen (inadequate evidence for carcinogenicity to humans). This product contains 0.3 wt % saccharin sodium, which is considered a possible carcinogen based on development of bladder tumors in rodents that ingested very high doses for prolonged periods.

Target Organs: No specific target organs identified.

Medical Conditions Aggravated by Exposure: Therapeutic or excessive doses may aggravate gastrointestinal disorders, electrolyte disturbances, allergies to iodine, hyperthyroidism and euthyroid goiter.

Medical Surveillance Recommendation: None.

SECTION 4: FIRST AID MEASURES

1. Ingestion: Seek medical attention immediately. Vomiting may be induced if person is conscious and not experiencing convulsions. Never give anything by mouth to an unconscious person.
 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.
 3. Skin Contact: Remove contaminated clothing. Wash skin with plenty of water for 5 minutes. Get 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.
 5. Note to physicians: None.
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SECTION 5: FIRE FIGHTING MEASURES

1. Flash point: Not determined.
 2. Auto-ignition Temperature: Not determined.
 3. Flammability limits
 - a. LEL: Not determined.
 - b. UEL: Not determined.
 4. Combustibility of Dusts: Not applicable.
 5. Extinguishing Media: Use dry chemical, carbon dioxide (CO₂), or "alcohol" foam.
 6. Fire-fighting Instructions: Firefighters should wear self-contained breathing apparatus (SCBA), flame and chemical resistant clothing, boots and gloves. Evacuate personnel to upwind direction, remove unneeded material. Cool container(s) with water from maximum distance. Fight fire from a maximum distance or use an unmanned monitor. Move container from fire area if you can do it without risk.
 7. Hazardous Combustion Products: carbon monoxide, carbon dioxide, hydrogen iodide, iodine (reddish-brown gas), nitrogen oxides.
 8. Unusual Hazards: None known.
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SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: 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. Flush residual spill area with water to process sewer if allowable under national, state, or local permits and regulations.

SECTION 7: HANDLING AND STORAGE

1. Handling Precautions: No special requirements.
 2. Container Requirements: Store in the container provided.
 3. Storage Conditions: Store at room temperature (20-25 degrees C). Avoid excessive heat. Protect from light.
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SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

1. Ventilation Requirements: None beyond good room ventilation normally required; local exhaust ventilation is recommended if significant dust concentrations are generated.
 2. Respiratory Protection: When engineering controls are not sufficient to control exposure, wear 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 (i.e., latex, latex/nitrile, or nitrile) if the potential exists for dermal contact.
 5. Special Clothing: Wear protective coveralls, whenever the potential for splashing or spraying liquids exists.
 6. Hygiene: Wash hands after handling compound 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: 120 mL bottles containing light yellow to dark amber aqueous liquid.
 2. Boiling point: Not available.
 3. Evaporation rate: Not available.
 4. Flash point: Not available.
 5. Freezing point: Not available.
 6. Melting point: Not available.
 7. Octanol/water partition coefficient: Not available.
 8. Odor (threshold): Lemon.
 9. pH: 6.0 - 7.6.
 10. Solubility in water: Miscible.
 11. Specific gravity: 1.08.
 12. Vapor density (Air = 1): Greater than 1, heavier than air.
 13. Vapor Pressure: Not available.
 14. 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: Not determined.
 4. Hazardous Decomposition Products: carbon monoxide, carbon dioxide, hydrogen iodide, iodine (reddish-brown gas), nitrogen oxides.
 5. Hazardous Polymerization: Will not occur.
 6. Explosion data relative to mechanical impact: Not available.
 7. Explosion data relative to static discharge: Not available.
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SECTION 11: TOXICOLOGICAL INFORMATION - for active ingredients

1. RTECS NUMBER (U.S.):
 - LZ4315000 (diatrizoate meglumine)
 - DG6125000 (diatrizoate sodium)
 2. ACUTE
 - a. LD50 (diatrizoate meglumine):
 - Acute iv LD50 (rat) = 14,565 mg/kg;
 - Acute iv LD50 (mouse) = 21,200 mg/kg.
 - b. LD50 (diatrizoate sodium):
 - 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.
 3. LC50: Not applicable, exists as a liquid at room temperature.
 4. Diatrizoate meglumine and diatrizoate sodium would be classified as essentially nontoxic after acute intravenous injection.
 5. CHRONIC
 - a. Carcinogenicity: See Section 3.
 - 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 Gastrografin can affect reproductive capacity. Diatrizoate meglumine is excreted in human breast milk following intravascular exposure.
 6. Toxicological synergistic products: None known.
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SECTION 12: ECOLOGICAL INFORMATION

1. Ecotoxicological Information: No information
 2. Chemical Fate Information: No information.
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SECTION 13: DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with national, state, local and applicable country regulations.

SECTION 14: TRANSPORT INFORMATION

1. DOMESTIC

- a. Hazard Class (UN NUMBER): Not D.O.T. regulated.
- b. Proper shipping name: Not applicable.
- c. Label requirements: Not applicable.
- d. Placard requirements: Not applicable.
- e. Limited Quantity Exemption: Not applicable.

2. INTERNATIONAL

- a. Hazard Class (UN NUMBER or PIN NUMBER): Not regulated.
 - b. Proper shipping name: Not applicable.
 - c. Label requirements: Not applicable.
 - d. Placard requirements: Not applicable.
 - e. Limited Quantity Exemption: Not applicable.
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SECTION 15: REGULATORY/STATUTORY INFORMATION - not meant to be all inclusive

- 1. U.S. Federal: None noted.
 - 2. International: None noted.
 - 3. EC Labeling: None noted.
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SECTION 16: OTHER INFORMATION

October 10, 2001: New MSDS for Gastrografin was developed, and supercedes the previous MSDS.

Persons allergic to diatrizoate salts, iodides, or other components of this formulation should avoid contact to this substance.

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

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

The information contained in this MSDS is believed to be accurate and represents the best information available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.
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