

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Sheets Code: 268

Trade name: Gastrografin

Chemical Name: For active Ingredients: Diatrizoate meglumine and diatrizoate sodium.

Synonyms: Diatrizoate meglumine and diatrizoate sodium solution USP.

How Supplied: 120 mL bottles

1.2 Relevant identified uses of the substance or mixture and uses advised against

We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

Application of the substance / the preparation

Iodinated radiopaque contrast medium for oral or rectal administration.

Chemical Family: Not applicable (pharmacological mixture).

Molecular Formula:

C₁₁H₉I₃N₂O₄.C₇H₁₇NO₅ (diatrizoate meglumine).

C₁₁H₈I₃N₂O₄.Na (diatrizoate sodium).

CAS Number: See Section 3

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

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

Further Information Obtainable from:

B-Lands Consulting
WTC, 5 Place Robert Schuman, BP 1516
38025 Grenoble, FRANCE
Tel: +33 476 295 869
Fax: +33 476 295 870
services@reachteam.eu
www.reachteam.eu

1.4 Emergency telephone number:

EMERGENCY CONTACT:

Health: 1-800-257-5181

U.S. Transport - Chemtrec: 1-800-424-9300

International Transport - 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.

2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of international guidelines.

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Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

Signal word Void

Hazard statements

Safety data sheet available on request.

Effects of Overexposure - Routes of Entry:

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.

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.

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.

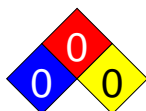
Information pertaining to particular dangers for man and environment:

Negative Effects on the Health: See also Sections 11

Negative Effects on the Environment: See also Section 12

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3: Composition/information on ingredients

3.1 Substances

Active Ingredients:

CAS: 131-49-7	Diatrizoate Meglumine
EINECS: 205-024-7	
RTECS: LZ4315000	

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CAS: 737-31-5 RTECS: DG6125000	Diatrizoate Sodium
Impurities and stabilising additives:	
CAS: 139-33-3 EINECS: 205-358-3	disodium dihydrogenethylenediaminetetraacetate ☒ Xn R22 ⚠ Acute Tox. 4, H302
CAS: 18996-35-5 EINECS: 242-734-6	sodium dihydrogen citrate
CAS: 19872-52-7	Flavor
CAS: 8050-81-5	Simethicone
CAS: 9005-65-6	Polysorbate 80
CAS: 6155-57-3 EINECS: 204-886-1	Saccharin Sodium
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide ☒ C R35 ⚠ Skin Corr. 1A, H314

3.2 Mixtures

Description: Mixture: consisting of the following components.

Dangerous Components		
CAS N°	Description	%
CAS: 139-33-3 EINECS: 205-358-3	disodium dihydrogenethylenediaminetetraacetate ☒ Xn R22 ⚠ Acute Tox. 4, H302	<1%
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide ☒ C R35 ⚠ Skin Corr. 1A, H314	<1%

Not Dangerous Components		
CAS N°	Description	%
CAS: 131-49-7 EINECS: 205-024-7 RTECS: LZ4315000	Diatrizoate Meglumine	66.0%
CAS: 737-31-5 RTECS: DG6125000	Diatrizoate Sodium	10%
CAS: 7732-18-5 EINECS: 231-791-2 RTECS: ZC0110000	Water USP	>1%
CAS: 19872-52-7	Flavor	<1%
CAS: 8050-81-5	Simethicone	<1%
CAS: 9005-65-6	Polysorbate 80	<1%
CAS: 6155-57-3 EINECS: 204-886-1	Saccharin Sodium	<1%

Additional information: For the wording of the listed risk phrases refer to section 16.

4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.

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After 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.

After 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.

After Eye Contact:

Hold eyelids apart and flush with plenty of water for 5 minutes.
Get medical attention if signs of irritation develop.

After Swallowing:

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.

4.2 Most important symptoms and effects, both acute and delayed See also Section 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

No further relevant information available.

Means of Specific and Immediate Treatment to Keep at the Workplace: No special measures required.

Note to physicians: None.

5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or alcohol resistant foam. Fight larger fire with alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Unknown.

5.2 Special hazards arising from the substance or mixture

 See also Section 10.**Hazardous Combustion Products:**

Hydrogen Iodide, Iodine (red-brown gas)
Carbon Dioxide (CO₂)
In the absence of Oxygen: Carbon Monoxide (COx)
Nitrogen Oxides (NxOy)
Iodine Compounds

Additional Information: Not Available

5.3 Advice for Firefighters

Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.

Move container from fire area if you can do it without risk.

Protective Equipment:

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA).

Besides they should wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

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6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment appropriate to the circumstances (see Section 8)

6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning 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.

6.4 Reference to other sections

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protection Equipment.

See Section 13 for Disposal Information.

See Section 12 for Ecological Information.

7: Handling and storage

7.1 Precautions for Safe Handling

Avoid splashing of liquid product.

Avoid skin and eye contact.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for Safe Storage, including any Incompatibilities

Requirements to be Met by Storerooms and Receptacles:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Container Requirements: Store in their original containers.

Storage Conditions: Store at room temperature (20-25 degrees C). Avoid excessive heat. Protect from light.

Information about Storage in one Common Storage Facility: Not required.

Further information about storage conditions:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s) No further relevant information available.

8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Appropriate Technical Controls: Provide adequate aspiration / ventilation in the workplace

Additional information about Design of Technical Facilities: No further data (see Section 7).

Personal protective equipment

General Protective and Hygienic Measures:

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

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Wear protective equipment (PPE) appropriate to the circumstances.



Do not eat, drink, smoke while working.

Provide appropriate ventilation

Breathing Equipment:

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.

Protection of Hands:



Wear impervious gloves if the potential exists for dermal contact.

Material of Gloves:

Latex, Latex / Nitrile or Nitrile Gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

Penetration Time of Glove Material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye Protection:



Wear safety glasses (ANSI Z87.1)

Body Protection:

If the risk assessment deems it necessary, wear protective coveralls to prevent contact with the body, due to the splashing and spraying of liquid.

Limitation and Supervision of Exposure into the Environment: See also Section 7.

Additional Information about Design of Technical Systems: No further data; see Section 7.

9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Liquid
Color:	Light Yellow to Dark Amber
Odour threshold:	Lemon

pH-value:	6.0 - 7.6
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

Flash point:	Not applicable.
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Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Flammability Limits:	
Lower:	Not Determined.
Upper:	Not Determined.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density at 20°C	1.08 g/cm ³ (9.013 lbs/gal)
Vapour density at 20°C	> 1.0 g/cm ³ (heavier than Air = 1.0)
Evaporation rate	Not determined.
Solubility in / Miscibility with Water:	Fully miscible.
Segregation coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
9.2 Other information	No further relevant information available.

10: Stability and reactivity

10.1 Reactivity:

There are not particular dangerous reactions with other substances in normal conditions of use

10.2 Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No further relevant information available (See Section 5)

11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:

131-49-7 Diatrizoate Meglumine

LD50 ipr	44504 mg/kg (rat)
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	LD50 ivn	21200 mg/kg (mouse) 14565 mg/kg (rat)
737-31-5 Diatrizoate Sodium		
	LD50 ims	20349 mg/kg (mouse)
	LD50 ivn	11300 mg/kg (gatto) 13200 mg/kg (dog) 14000 mg/kg (mouse) 11400 mg/kg (rat) 12200 mg/kg (rabbit)
1310-73-2 sodium hydroxide		
Oral	LD50	2000 mg/kg (rat)

Toxicological Information for Active Ingredients:

Diatrizoate Meglumine and Diatrizoate Sodium would be classified as essentially nontoxic after acute intravenous injection.

Primary irritant effect:

By 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.

By 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.

on the skin: The irritant properties have not been evaluated on the basis of experimental data.

on the eyes:

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.

Sensitization:

The potential of this material to act as a sensitizer (allergen) has not been evaluated.

This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.

This material may act as sensitizer (allergen) for those persons who are allergic to these formulations, Iodides, or other components in the formulation.

Germ Cell Mutagenicity: No further relevant information available

Carcinogenicity:

Saccharin is listed by IARC as a Class 2B carcinogen (inadequate evidence for carcinogenicity to humans).

Gastrografin contains 0.3 wt % of saccharin sodium, which is considered a possible carcinogen based on development of bladder tumors in rodents that ingested very high doses for prolonged periods.

Reproductive Toxicity:

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.

It is not known whether Gastrografin can affect reproductive capacity. Diatrizoate meglumine is excreted in human breast milk following intravascular exposure.

Specific Target Organ Toxicity

Single Exposure (STOT - SE): No specific target organs identified.

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Repeated Exposure (STOT - RE): No specific target organs identified.

Aspiration Hazard: No further relevant information available

Subacute to Chronic Toxicity:

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).

Additional toxicological information:

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

Therapeutic or excessive doses may aggravate gastrointestinal disorders, electrolyte disturbances, allergies to iodine, hyperthyroidism and euthyroid goiter.

There are not known products which results in toxicological synergistic effects with Gastrografin.

Any Eventual Delayed Effect after Prolonged Exposure: No evidence reported in working practice.

* **12: Ecological information**

12.1 Toxicity

Aquatic toxicity:

1310-73-2 sodium hydroxide

LC50 | 180 mg/l (fish)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information

General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Avoid transfer into the environment.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

Additional Information: Use according to good working practice.

* **13: Disposal considerations**

13.1 Waste treatment methods:

Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Reutilise if possible or contact a waste processors for recycling or safe disposal.

Uncleaned packagings:

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

Recommended cleansing agent: Water, if necessary with cleansing agents.

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14: Transport information

14.1 UN-Number DOT, ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class	Void
14.4 Packing group DOT, ADR, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	-

15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Sara

Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

7732-18-5	Water USP
139-33-3	disodium dihydrogenethylenediaminetetraacetate
18996-35-5	sodium dihydrogen citrate
19872-52-7	Flavor
9005-65-6	Polysorbate 80
1310-73-2	sodium hydroxide

Proposition 65

Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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Carcinogenic categories

EPA (Environmental Protection Agency)

None of the ingredients is listed.

IARC (International Agency for Research on Cancer)

6155-57-3	Saccharin Sodium	Yes: Carc. 2B
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NTP (National Toxicology Program)

6155-57-3	Saccharin Sodium	YES
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TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Significant Dangers:

Relevant phrases

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

R22 Harmful if swallowed.

R35 Causes severe burns.

Training Hints:

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

WARNINGS:

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.

Department issuing MSDS:

B-Lands Consulting
WTC, 5 Place Robert Schuman, BP 1516
38025 Grenoble, FRANCE
Tel: +33 476 295 869
Fax: +33 476 295 870
services@reachteam.eu
www.reachteam.eu

Contact:

HSE Department - Bracco Group
hse@bracco.com

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods

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IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

*** Data compared to the previous version altered.**

- data updating on the basis of the latest amendments.
- adaptation of the form according to Regulation 1907/2006/CE.

USA