Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

1 Identification

Product identifier: Sheet code 268

Trade name: Gastrografin.

Chemical Name: For active ingredients: Diatrizoate meglumine and diatrizoate sodium.
Synonyms: Diatrizoate meglumine and diatrizoate sodium solution USP

Application of the substance / the mixture:
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.
Supplied: 120 mL bottles

Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ
08543
Phone number: 1-800-257-5181
Email: HSE@bracco.com (responsible for the SDS)

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

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

2 Hazard(s) identification

Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

Label elements

GHS label elements: Not applicable

Hazard pictograms: Not applicable

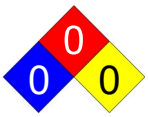
Signal word: Not applicable

Hazard statements: Not applicable

Additional Information

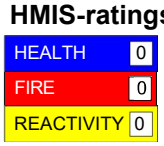
Classification system:

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

Other hazards: No further relevant information available

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components			
CAS No.	**Name**	**Classification**	**Qty.**
139-33-3	disodium dihydrogen ethylenediaminetetraacetate	Acute Tox. 3, H301	< 5 %

Information on components		
CAS No.	**Name**	**Qty.**
131-4-7	Diatrizoate Meglumine	50 -100 %

4 First-aid measures

Description of first aid measures

After inhalation:
Move patient to fresh air, if symptom arise consult a doctor.
Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

After skin contact:
Immediately wash with water and soap and rinse
thoroughly. If symptoms persist, consult a doctor.

After eye contact:
Rinse immediately with plenty of water, also under the eyelids, for at least 15
minutes. Get medical attention.

After swallowing:
Immediately call a doctor.
Vomiting may be induced if person is conscious and not experiencing
convulsions. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents:
CO2, Extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing agents:
Not applicable.

Special hazards arising from the substance or mixture

In case of fire, the following can be released:
Hydrogen Iodide, Iodine (red-brown gas) Carbon Dioxide (CO2)
In the absence of Oxygen: Carbon Monoxide (CO)
Nitrogen Oxides (NxOy)
Iodine Compounds

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

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).
In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep away from ignition sources
Wear protective equipment. Keep unprotected persons away.

Environmental precautions:

Do not allow to enter sewers/ surface or ground
water. Dilute with plenty of water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material.
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.

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.

Protective Action Criteria for Chemicals

PAC-1:		
139-33-3	disodium dihydrogenethylenediaminetetraacetate	11 mg/m³
18996-35-5	sodium dihydrogen citrate	4 mg/m³
1310-73-2	sodium hydroxide	0.5 mg/m³
PAC-2:		
139-33-3	disodium dihydrogenethylenediaminetetraacetate	120 mg/m³
18996-35-5	sodium dihydrogen citrate	44 mg/m³
1310-73-2	sodium hydroxide	5 mg/m³
PAC-3:		
139-33-3	disodium dihydrogenethylenediaminetetraacetate	730 mg/m³
18996-35-5	sodium dihydrogen citrate	270 mg/m³
1310-73-2	sodium hydroxide	50 mg/m³

7 Handling and storage

Precautions for safe handling

Avoid splashes or spray in enclosed areas.
Avoid contact with the eyes and skin.

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

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:
Store in a cool, dry place in well-sealed receptacles. Store only in the original receptacle.

Information about storage in one common storage facility: Not required.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

Further information about storage conditions:
Store in cool, dry conditions in well-sealed receptacles. Protect from heat and direct sunlight.
Store at room temperature (20-25 degrees C).

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

8 Exposure controls/personal protection

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.

Exposure controls

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.
Ensure good ventilation/exhaustion at the workplace.

Do not eat, drink and smoke while working.

Breathing equipment:

Use suitable respiratory protective device in case of insufficient ventilation.

Protection of hands:

Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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:

Safety glasses

Body protection:

Protective work clothing.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information:

Appearance

Form:	Liquid
Color:	Light Yellow to Dark Amber
Odor:	Lemony
Odor threshold:	Not determined
pH – Value:	6.0 – 7.6
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
Flash point:	Not determined
Flammability (Solid, Gaseous):	Not applicable
Ignition temperature:	Not determined
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
Oxidizing properties:	Not determined
Vapor pressure:	Not determined
Density:	Not determined
Relativity density at 20 °C (68 °F):	1.08 g/cm³ (9.0126 lbs/gal) (9.013 lbs/gal)
Vapor Density at 20 °C (68 °F):	> 1.0 g/cm³ (>8.345 lbs/gal) (heavier than Air = 1.0)
Evaporation rate:	Not determined
Solubility in / Miscibility with	
Water:	Fully miscible
Partition coefficient (n-octanol/water):	Not determined
Viscosity:	
Dynamic:	Not determined
Kinematic:	Not determined
Water:	15.0 %
VOC Content:	0.0 %
Solid content:	0.0 %

Other Information

No further relevant information available

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

10 Stability and Reactivity

Reactivity
No data available
No further information available.

Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No further relevant information available.

Incompatible materials

No further relevant information available.

Hazardous decomposition products

No dangerous decomposition products known.

11 Toxicological Information

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:		
131-49-7 Diatrizoate Meglumine		
	LD50 iv	21,200 mg/kg (Mouse)
		14,565 mg/kg (Rat)
	LD50 ip	44,504 mg/Kg (Rat)
737-31-5 Diatrizoate Sodium		
	LD50 iv	11,300 mg/kg (Cat)
		13,200 mg/kg (Dog)
		14,000 mg/kg (Mouse)
		11,400 mg/kg (Rat)
		12,200 mg/kg (Rabbit)
	LD50 im	20,349 mg/Kg (Mouse)
9005-65-6 Polysorbate 80		
Oral	LD50	42,200 mg/kg (Rat) (External SDS)
6155-57-3 Saccharin Sodium dihydrate		
Oral	LD50	>14,200 mg/kg (Rat) (anydrous substance - RTEC)
1310-73-2 sodium hydroxide		
Oral	LD50	2,000 mg/kg (Rat)

Primary irritant effect:

on the skin: No irritating effect

on the eye: No irritating effect.

Sensitization:

No sensitizing effects known.

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.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

Other information (about experimental toxicology):
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.

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.

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:
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
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.

Carcinogenic categories

IARC (International Agency for Research on Cancer)		
6155-57-3	Saccharin Sodium dihydrate	Yes: Carc. 3
NTP (National Toxicology Program)		
6155-57-3	Saccharin Sodium dihydrate	YES
OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients are listed.		

12 Ecological information

Toxicity

Aquatic toxicity:	
9005-65-6 Polysorbate 80	
LC50/96h	471 mg/L (Oncorhynchus Mykiss) (External SDS)
EC0	>10,000 mg/L (Pseudomonas Putida) (External SDS)
1310-73-2 sodium hydroxide	
LC50	180 mg/L (Fish)

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

Persistence and degradability

No further relevant information available.

Bio accumulative potential

No further relevant information available.

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.

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects

No further relevant information available.

13 Disposal considerations

Waste treatment methods

Recommendation:
Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilize if possible or contact a waste processor for recycling or safe disposal.

Uncleaned packaging:

Recommendation:
Disposal must be made according to official regulations.
Packaging that cannot be cleansed are to be disposed of in the same manner as the product.
Recommended cleansing agent:
Water, if necessary, with cleansing agents.

14 Transport information

UN-Number
DOT, ADR, ADN, IMDG, IATA Not applicable.

UN proper shipping name
DOT, ADR, ADN, IMDG, IATA Not applicable.

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA
Class Not applicable.

Packing group
DOT, ADR, IMDG, IATA Not applicable.

Environmental hazards:
Marine pollutant: No

Special precautions for user Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

15 Regulatory Information

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

Sara

Section 355 (extremely hazardous substances):
None of the ingredients are listed.
Section 313 (Specific toxic chemical listings):
None of the ingredients are listed.

Proposition 65

Chemicals known to cause cancer:
None of the ingredients are listed.
Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed.
Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.
Chemicals known to cause developmental toxicity:
None of the ingredients are listed.

Carcinogenic categories

EPA (Environmental Protection Agency)
None of the ingredients are listed.
TLV (Threshold Limit Value established by ACGIH)
None of the ingredients are listed.
NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients are listed.

GHS label elements: Not applicable
Hazard pictograms: Not applicable
Signal word: Not applicable
Hazard statements: Not applicable

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.
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.

Contact:

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

Date of preparation / last revision: 03/05/2022, revision 4
Changes: General revision of the entire Safety DataSheet, changes in section 3, section 5 and section 8.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Version 4

Printing date: 02/22/2019 Reviewed on: 03/05/2022

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists EINECS:
European Inventory of Existing Commercial Chemical Substances ELINCS:
European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent LD50:
Lethal dose, 50 percent
Acute Tox. 3: Acute toxicity – Category 3