

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

1 Identification**Product identifier** Sheet Code: 273**Trade name:** Cystografin (30%) and Cystografin Dilute (18%)

Chemical Name: For active, D-Glucitol, 1-deoxy-1-(methylamino)-3,5-diacetamido-2,4,6-triiodobenzoate (salt)

Synonyms: For active, Diatrizoate Meglumine injection USP 30%, Diatrizoate Meglumine injection USP 18%.

Application of the substance / the mixture:

Radiopaque contrast agent.

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.

Cystografin (100mL in 200mL bottle and 300mL in 300mL bottle).

Cystografin Dilute (300mL in 300mL bottle).

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:

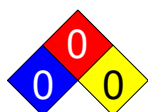
Health: 1-800-257-5181

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]

Printing date 03/04/2019

Version 4

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:** Not applicable.

Information on components		
CAS No.	Name	Qty.
7732-18-5	Water USP	50 – 100 %

Additional information: *Cystografin Dilute **Cystografin**4 First-aid measures****Description of first aid measures****General information:** No special measures required.**After inhalation:** Move patient to fresh air if symptom arise consult a doctor.**After skin contact:**

Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If irritation persists get medical attention.

After swallowing:

Immediately call a doctor.

Induce vomiting in case of ingestion of a significant dose only if the person is conscious and not with convulsion. 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:** Water**Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Carbon dioxide (CO₂)

Carbon monoxide (CO)

Nitrogen oxides (NO_x)

Hydrogen Iodide, Iodine (red-brown gas)

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.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

6 Accidental release measures

Personal precautions, protective equipment, and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material.

Place spilt material in an appropriate container for disposal. The spill area should be ventilated and decontaminated after material is collected.

Reference to other sections

No dangerous substances are released.

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:		
6381-92-6	EDTA, disodium Salt	30 mg/m ³
PAC-2:		
6381-92-6	EDTA, disodium Salt	330 mg/m ³
PAC-3:		
6381-92-6	EDTA, disodium Salt	2,000 mg/m ³

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.

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

Further information about storage conditions:

Container Requirements: 200- and 400-mL containers for 100 and 300 mL quantities of Cystografin, respectively and 300 mL containers for 200 mL quantity of Cystografin Dilute.
Storage Conditions: Store at 20-25 degrees C. Protect from light.

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

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

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:

Not required.

In non-routine exposure conditions, where risk assessment shows air-purifying respirators are appropriate, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Self-contained breathing apparatus should be available for emergency use.

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

Natural rubber, NR Nitrile rubber, NBR

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 cannot 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: Goggles recommended during refilling.

Body protection: Protective work clothing.

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Liquid.
Color: Colorless - Pale Yellow

Odor: Undistinguishable

Odor threshold: Not determined.

pH-value: 7.1 - 7.3

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

Flash point: Not applicable.

Flammability (solid, gaseous): Not applicable.

Decomposition temperature: Not determined.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Flammability Limits:

Lower: Not Determined.

Upper: Not Determined.

Explosion limits:

Lower: Not determined.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Cystografin (30%): 1.162 Cystografin Dilute (18%): 1.009
Vapor density	Not determined.
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:	60.0 %
Solids content:	31.0 %
Other information	No further relevant information available.

10 Stability and reactivity

Reactivity No data 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 ip	44504 mg/kg (Rat)
LD50 iv	21200 mg/kg (Mouse)
	14565 mg/kg (Rat)

Primary irritant effect:

on the skin:

No irritant effect.

Material contains low concentration 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.

on the eye:

No irritating effect.

No irritation effects reported. However, the product should be considered as a potential irritant.

Sensitization:

No sensitizing effects known.

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

Other information (about experimental toxicology):

By Inhalation: Inhaling small doses of aerosolized material would not be expected to result in symptoms.

By Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

symptoms. Ingestion of large quantities of certain meglumine salts may result in mild laxative effects, dehydration, electrolyte disturbances, and occasionally hypersensitivity (allergic) reactions.

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. Medical condition can be aggravated by exposure at this product, for the patients sensitive to Iodine

Carcinogenic categories

IARC (International Agency for Research on Cancer)
None of the ingredients are listed.
NTP (National Toxicology Program)
None of the ingredients are listed.
OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients are listed.

12 Ecological information

Toxicity

Aquatic toxicity: No further relevant information available.

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.

Avoid transfer into the environment.

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's:

Recommendation: Disposal must be made according to official regulations.

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.

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

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.

15 Regulatory information**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 are listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

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 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: 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)

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 03/04/2019

Version 4

Reviewed on 03/05/2022

with these substances.

Contact:

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

Date of preparation / last revision 03/05/2022, 4

Changes: General revision of the entire Safety Data Sheets, changes in Section 3 and Section 9.

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent