

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

1 Identification

Product identifier

Sheet Code: 277

Trade name: Sinografin

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).

Synonyms: Diatrizoate Meglumine and Iodipamide Meglumine Injection.

How Supplied: Packages of ten single dose 10 mL vials.

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.

Chemical Family: Not available.

Molecular Formula:

For actives:

Diatrizoate-Meglumine: C₁₁H₉I₃N₂O₄•C₇H₁₇NO₅,

Iodipamide-Meglumine: C₂₀H₁₄I₆N₂O₆•2C₇H₁₇NO₅.

CAS Number:

Diatrizoate Meglumine: 131-49-7

Iodipamide Meglumine: 3521-84-4

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

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

Emergency Overview:

Aqueous solution. Non-combustible.

See Health Effects and Toxicology sections for additional information.

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 1)

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 Void

Hazard pictograms Void

Signal word Void

Hazard statements Void

Effects of Overexposure - Routes of Entry:

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.

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 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.

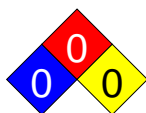
Additional Information:

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

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



HEALTH 0 Health = 0
FIRE 0 Fire = 0
REACTIVITY 0 Reactivity = 0

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Substances

Active Ingredient:

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

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 2)

CAS: 3521-84-4 RTECS: LZ 4297000	Iodipamide-Meglumine	
Impurities and stabilising additives:		
CAS: 139-33-3 EINECS: 205-358-3	disodium dihydrogenethylenediaminetetraacetate	⚠ Acute Tox. 3, H301
CAS: 68-04-2 EINECS: 200-675-3 RTECS: GE8300000	Sodium citrate	

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components:

CAS: 139-33-3 EINECS: 205-358-3	disodium dihydrogenethylenediaminetetraacetate ⚠ Acute Tox. 3, H301	<1%
------------------------------------	--	-----

Non-Hazardous Components:

CAS: 131-49-7 EINECS: 205-024-7 RTECS: LZ4315000	Diatrizoate Meglumine	52.7%
CAS: 3521-84-4 RTECS: LZ 4297000	Iodipamide-Meglumine	26.8%
CAS: 7732-18-5 EINECS: 231-791-2 RTECS: ZC0110000	Water USP	10-25%
CAS: 68-04-2 EINECS: 200-675-3 RTECS: GE8300000	Sodium citrate	<1%

4 First-aid measures

Description of first aid measures

General information: No special measures required.

After Inhalation: Supply fresh air. If required, provide artificial respiration.

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:

Wash with running water for several minutes holding the eyelids open.

If any symptoms of irritation develop and / or persist, consult your doctor.

After Swallowing:

Get medical attention immediately.

Vomiting may be induced only 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.

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

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.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin**Note to physicians:** None.

(Contd. of page 3)

* 5 Fire-fighting measures

Extinguishing media**Suitable extinguishing agents:** In case of fire, flood with Water**For safety reasons unsuitable extinguishing agents:** Unknown.**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 (CO)

Nitrogen Oxides (N_xO_y)

Iodine Compounds

Additional Information: Not Available**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).

Wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

* 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures²Wear protective equipment appropriate to the circumstances (see Section 8)**Environmental precautions:** No special measures required.**Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, vermiculite) or other non combustible absorbent 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

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

Precautions for Safe Handling

Avoid splashing of liquid product.

Avoid skin and eye contact.

Conditions for Safe Storage, including any Incompatibilities**Requirements to be met by Storerooms and Receptacles:**

Store in a cool, dry place in tightly closed receptacles.

Container Requirements: Single dose 10 mL glass vials.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 4)

Storage Conditions: Store at 20-25 degrees C. Protect from light.
Information about Storage in one Common Storage Facility: Not required.
Further information about storage conditions: None.
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.

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

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.

Wear protective equipment (PPE) appropriate to the circumstances.



Do not eat, drink, smoke while working.

Provide appropriate ventilation.

Breathing Equipment:

Not anticipated for normal clinical environment.

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:



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.

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 5)

Eye Protection:



Wear safety glasses (ANSI Z87.1)

Body Protection: Normal working clothes.

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

Information on basic physical and chemical properties

General Information

Appearance:

Form:	Liquid
Color:	Colorless - Pale Yellow
Odour threshold:	Not remarkable

pH-value: 7.0 - 7.8

Flash point: Not applicable.

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.

Density at 20 °C: 1.43 g/cm³

Relative density Not determined.

Vapour density (heavier than Air) > 1.0

Solubility in / Miscibility with

Water: Fully miscible.

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.
Water:	15.0 %

Other information No further relevant information available.

10 Stability and reactivity

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

Chemical stability: Stable under normal conditions.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 6)

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.
Avoid contact of product with hot surfaces and ignition sources (i.e. open flames, sparks).

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 further relevant information available (See Section 5)

11 Toxicological information

Information on toxicological effects

Acute toxicity:

Toxicological Information for Active Ingredients:

LD/LC50 values that are relevant for classification:

131-49-7 Diatrizoate Meglumine

LD50 ipr	44504 mg/kg (rat)
LD50 ivn	21200 mg/kg (Mouse)
	14565 mg/kg (rat)

3521-84-4 Iodipamide-Meglumine

LD50 ipr	1921 mg/kg (rat)
	1446 mg/kg (Rabbit)
LD50 ivn	1200 mg/kg (Dog)
	3195 mg/kg (Mouse)
	5000 mg/kg (rat)

68-04-2 Sodium citrate

LD50 ipr	1364 mg/kg (Mouse)
	1548 mg/kg (rat)
LD50 ivn	170 mg/kg (Mouse)
	449 mg/kg (Rabbit)

Primary irritant effect:

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 symptoms.

on the skin:

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 eyes: Not Available.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

Sensitization:

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: Not Available.

Reproductive Toxicity: No further relevant information available

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 7)

Specific Target Organ Toxicity

Single Exposure (STOT - SE): No further relevant information available

Repeated Exposure (STOT - RE): No further relevant information available

Aspiration Hazard: No further relevant information available

Other information (about experimental toxicology): No further relevant information available

Subacute to Chronic Toxicity: No further relevant information available

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

Additional toxicological information:

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

Any Eventual Delayed Effect after Prolonged Exposure:

Repeated and prolonged exposure to skin may cause skin irritation

*** 12 Ecological information**

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability No further relevant information available.

Bioaccumulative potential No further relevant information available.

Mobility in soil: No further relevant information available.

General notes: 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.

Additional Information: Use according to good working practice.

*** 13 Disposal considerations**

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.

USA

(Contd. on page 9)

Safety Data Sheet
acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 8)

14 Transport information

UN-Number
DOT, ADR, ADN, IMDG, IATA Void

UN proper shipping name
DOT, ADR, ADN, IMDG, IATA Void

Transport hazard class(es)
ADR, ADN, IMDG, IATA
Class Void

Packing group
DOT, ADR, IMDG, IATA Void

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.

UN "Model Regulation": -

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 is listed.

Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

7732-18-5	Water USP
68-04-2	Sodium citrate
139-33-3	disodium dihydrogenethylenediaminetetraacetate

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.

Carcinogenic categories

EPA (Environmental Protection Agency)
None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH)
None of the ingredients is listed.

(Contd. on page 10)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2015

Version 2

Reviewed on 12/05/2015

Trade name: Sinografin

(Contd. of page 9)

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

None of the ingredients is listed.

GHS label elements Void**Hazard pictograms** Void**Signal word** Void**Hazard statements** Void**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**

H301 Toxic if swallowed.

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) with these substances.

Department issuing SDS:

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

Date of preparation / last revision 10/13/2014 / -**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

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

Acute Tox. 3: Acute toxicity, Hazard Category 3

*** 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.