

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 12/12/2018

Version 3

Reviewed on 12/12/2018

1 Identification

Product identifier Sheet Code: 266

Trade name: Iopamiron - Isovue 128, 200, 250, 300, 370 solutions

Application of the substance / the mixture:

Intravascular diagnostic contrast media.

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 as Glass vials/bottles. Depending on the container, the volume of liquid can range from 10 to 500 mL

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.

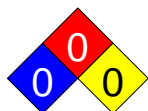
Hazard statements Not applicable.

Additional information: No records about adverses caused by exposition in handling the product.

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

Other hazards No further relevant information available.

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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:

60166-93-0	(S)-N,N'-BIS[2-hydroxy-1-(hydroxymethyl)ethyl]-5-[(2-hydroxy-1-oxopropyl)amino]-2,4,6-triiodoisophthaldiamide	76%
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4 First-aid measures

Description of first aid measures

After inhalation:

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Remove and rinse contaminated clothing immediately with water. Seek medical attention if skin irritation, swelling or redness develops and persists.

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 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

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:

Hydrogen Iodide, Iodine (red-brown gas)

Carbon Dioxide (CO₂)

In the absence of Oxygen:

Carbon Monoxide (CO)

Nitrogen Oxides (N_xO_y)

Hydrogen Chloride (HCl)

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.

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6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep away from ignition sources

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.
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.

Protective Action Criteria for Chemicals

PAC-1:		
1310-73-2	sodium hydroxide	0.5 mg/m ³
PAC-2:		
1310-73-2	sodium hydroxide	5 mg/m ³
PAC-3:		
1310-73-2	sodium hydroxide	50 mg/m ³

7 Handling and storage

Precautions for safe handling

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

Information about protection against explosions and fires: The product is not flammable.

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:

Container Requirements:

Glass vials/bottles or plastic prefilled syringes. Depending on the container, the volume of liquid can range from range 10 to 500 ml.

Storage Conditions: Store at 20-25 degrees C. Protect from light.

Further information about storage conditions: None.

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.

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Exposure controls

Personal protective equipment

General protective and hygienic measures:

Wash hands before breaks and at the end of work.



Do not eat, drink and smoke while working.

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).

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 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

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Liquid.
Color: Colorless.

Odor: Undistinguishable
Odor threshold: Not determined.

pH-value: 6.5 - 7.5

Melting point/Melting range: < 0 °C

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Boiling point/Boiling range:	Not determined.
Flash point:	Not determined.
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	Not determined.
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.
Oxidizing properties	Not determined.
Vapor pressure at 20 °C (68 °F):	<25 hPa (<18.8 mm Hg) (similar to water)
Density:	Not determined.
Relative density	Isovue 128 = 1.15 Isovue 370 = 1.405
Vapor density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Variable depending on Iopamidol concentration: Isovue 128: $\eta = 2.1$ mPas at 20°C, $\eta = 1.4$ mPas at 37°C; Isovue 370: $\eta = 9.4$ mPas at 20°C, $\eta = 20.9$ mPas at 37°C.
Kinematic:	Not determined.
Water:	20.0 %
VOC content:	0.00 %
Solids content:	0.0 %
Other information	No further relevant information available.

10 Stability and reactivity**Reactivity** No data available.**Chemical stability**

Stable under normal conditions.

Shelf-life indicated on individual containers.

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known.

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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:

60166-93-0 (S)-N,N'-BIS[2-hydroxy-1-(hydroxymethyl)ethyl]-5-[(2-hydroxy-1-oxopropyl)amino]-2,4,6-triiodoisophthaldiamide

Oral	LD50	>49,000 mg/kg (Mouse) >49,000 mg/kg (Rat)
	LD50 ip	40,825 mg/Kg (Mouse)
LD50 iv		17 g (Iodine) / Kg (Dog) (referred to amount of Iodine)
		21.8 g (Iodine) / Kg (Mouse) (referred to amount of Iodine)
		13.8 g (Iodine) / Kg (Rat) (referred to amount of Iodine)
		9.6 g (Iodine) / Kg (Rabbit) (referred to amount of Iodine)
		35,000 mg/kg (Dog)
LD50 iv		33,000 mg/kg (Mouse)
		20,000 mg/kg (Rabbit)
		28.2 g/kg (Rat)
MNLD iv		2,750 mg/kg (Dog)

62-33-9 sodium calcium edetate

Oral	LD50	12,000 mg/kg (Rat)
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1310-73-2 sodium hydroxide

Oral	LD50	2,000 mg/kg (Rat)
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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.

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 symptoms.

Germ Cell Mutagenicity: In studies to determine mutagenic activity, Iopamidol did not cause any increase in mutation rates.

Reproductive Toxicity: No teratogenic / reproductive effects attributable to Iopamidol have been observed in teratology studies performed in animals. In animal reproduction studies performed on rats, intravenously administered Iopamidol did not induce adverse effects on fertility or general reproductive performance.

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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.

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:
1310-73-2 sodium hydroxide
LC50 180 mg/L (Fish)

Persistence and degradability No further relevant information available.

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

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations.

Packagings 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.

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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****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

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drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

Date of preparation / last revision 12/12/2018 / 2**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