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 non 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)

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 Harmonizes System (GHS).

Label elements
GHS label elements: Not applicable.

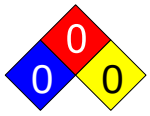
Hazard pictograms: Not applicable.

Signal word: Not applicable.

Hazard statements: Not applicable.

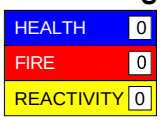
Additional Information

Classification system:
NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

Other hazards:
Results of PBT and vPvB assessment

PBT: Not classified
vPvB: Not classified

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture consisting of the following components.

Information on components		
CAS No.	**Name**	**Qty.**
60166-93-0	(S)-N,N'-BIS[2-hydroxy-1-(hydroxymethyl)ethyl]-5-[(2-hydroxy-1-oxopropyl)amino]- 2,4,6-triiodoisophthaldiamide	76 %

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 (NxOy)
- 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.

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 split 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, 8 and 13.

Protective Action Criteria for Chemicals

PAC-1:		
1310-73-2	Sodium Hydroxide	0.5 mg/m3

PAC-2:		
1310-73-2	Sodium Hydroxide	5 mg/m3

PAC-3:		
1310-73-2	Sodium Hydroxide	50 mg/m3

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

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 respiratory 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 oof 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 – 7.0
Melting point/Melting range:	< 0 °C
Boiling point/Boiling range:	Not determined
Flash Point:	Not determined
Flammability (Solid, Gaseous)	Not applicable
Ignition temperature:	Not determined
Danger of explosion:	Not determined
Flammability Limits	
Lower:	Not determined
Upper:	Not determined
Explosion Limits	
Lower:	Not determined
Upper:	Not determined
Oxidizing properties:	Not determined
Vapor pressure:	< 25 hPa (< 18.8 mm Hg)
Density	Not determined
Relativity Density at 20° C (68° F):	Isovue 128 = 1.15 Isovue 370 = 1.405
Vapor Density at 20° C (68° F):	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: n = 2.1 mPas at 20° C n = 1.4 mPas at 37 ° C Isouve 370: η = 9.4 mPas at 20°C, η = 20.9 mPas at 37°C.
Kinematic:	Not determined

Water:	20.0 %
VOC Content:	0.0 %
Solid Content:	0.0 %
Other Information:	No further relevant information available

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

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)
	LD50 iv	35,000 mg/kg (Dog)
		33,000 mg/kg (Mouse)

		20,000 mg/kg (Rabbit)
	LD50 iv	28.2 g/kg (Rat)
	MNDL iv	2,750 mg/kg (Dog)
62-33-9	**Sodium Calcium edetate**	
Oral	LD50	12,00 mg/kg (Rat)
1310-73-2	**Sodium Hydroxide**	
Oral	LD50	2,000 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.

Sensitization: No sensitizing effects known.

This material may act as sensitizer (allergen) for those person 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.

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

Acquatic Toxicity	
1310-73-2	**Sodium Hydroxide**
LC50	180 mg/l (Fish)

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 if 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 MARPOL 73/78 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 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.

Warning:
Diagnostics 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, personell 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
HSE@Bracco.com
Date of preparation / last revision: 01/01/2023, Version 05
Changes: General revision.

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