

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## 1 Identification

**Product identifier** Sheet Code: 280

**Trade name:** Isovue-M200, Isovue-M300 solutions  
**Chemical Name:** For active ingredient: Iopamidol Injection

### 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.  
 Single dose vials, Isovue-M 200 in 10 mL and 20 mL vials, Isovue-M 300 in 15 mL vials

### 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.

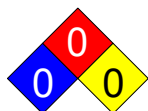
**Hazard statements** Not applicable.

**Additional information:** No records about adverse 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.

#### Results of PBT and vPvB assessment

**PBT:** Not applicable.  
**vPvB:** Not applicable.

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## 3 Composition/information on ingredients

**Chemical characterization: Mixtures**

**Description:** Mixture: consisting of the following components.

Hazardous Components			
CAS No.	Name	Classification	Qty.
1310-73-2	Sodium Hydroxide	Skin Corr. 1A, H314; Acute Tox. 4, H302	< 2.5 %

Non-Hazardous 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		76.0 %
7732-18-5	Water USP		10 – 25 %

## 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. Give oxygen or artificial respiration if needed Call a doctor immediately.

**After skin contact:**

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

**After eye contact:**

Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes. If irritation persists get medical attention.

**After swallowing:**

Immediately call a doctor. Do not induce vomiting.

### 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 (CO<sub>2</sub>)  
 Carbon monoxide (CO)  
 Nitrogen oxides (NO<sub>x</sub>)  
 Hydrogen chloride (HCl)  
 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 05/24/2019

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.  
Avoid inhaling dust and fumes.

### 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.

## 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:** 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 location in well-sealed receptacles.

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

#### Further information about storage conditions:

Container Requirements: Single-use 10-, 15- or 20-mL vials. 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 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.

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## 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

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.

**Odor:** Undistinguishable  
**Odor threshold:** Not determined.

**pH-value:** 6.5 - 7.5

**Boiling point/Boiling range:** Not determined.

**Flash point:** Not applicable.

**Flammability (solid, gaseous):** Not applicable.

**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.

**Vapor pressure:** Not determined.

**Density:** Not determined.

**Relative density**  
Isovue-M 200 = 1.216  
Isovue-M 300 = 1.328

**Vapor density** Not determined.

**Evaporation rate** Not determined.

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## Solubility in / Miscibility with

**Water:** Fully miscible.

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

## Viscosity:

**Dynamic:** Variable depending on Iopamidol concentration:

Isovue-M 200:  
 $\eta = 3.3$  cP at 20°C,  
 $\eta = 2.0$  cP at 37°C;

Isovue-M 300:  
 $\eta = 8.8$  cP at 20°C,  
 $\eta = 4.7$  cP at 37°C.

**Kinematic:** Not determined.

**Water:** 20.0 %

## 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:

#### 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)
	MNLD iv	2,750 mg/kg (Dog)

#### hydrochloric acid

Oral LD50 900 mg/kg (Rabbit)

#### 62-33-9 sodium calcium edetate

Oral LD50 12,000 mg/kg (Rat)

#### 1310-73-2 sodium hydroxide

Oral LD50 2,000 mg/kg (Rat)

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## 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.

## 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.

Medical condition can be aggravated by exposure at this product, for the patients sensitive to Iodine Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

## Carcinogenic categories

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

## 12 Ecological information

### Toxicity

<b>Aquatic toxicity:</b>
<b>1310-73-2 sodium hydroxide</b>
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.

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.

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

## 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.

**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.

## 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.

# Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

**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.

**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.**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



**Safety Data Sheet**  
*According to OSHA HazCom Standard [2012]*

Printing date 05/24/2019

Version 4

Reviewed on 03/05/2022

**Trade name:** Isovue 128, 200, 250, 300, 370 solutions  
Chemical Name: For active ingredient: Iopamidol Injection

LD50: Lethal dose, 50 percent  
Acute Tox. 4: Acute toxicity – Category 4  
Skin Corr. 1A: Skin corrosion/irritation – Category 1A