

# 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:** 280

**Trade name:** Isovue-M 200, Isovue-M 300 solutions.

**Chemical Name:** For active ingredient: Iopamidol Injection

**Synonyms:** For active, none.

**How Supplied:** Single dose vials, Isovue-M 200 in 10 mL and 20 mL vials, Isovue-M 300 in 15 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:** None provided.

**Molecular Formula:** C<sub>17</sub>H<sub>22</sub>I<sub>3</sub>N<sub>3</sub>

**CAS Number:** 60166-93-0

### **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

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Fax: +33 476 295 870

services@reachteam.eu

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#### **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.

## 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

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**Trade name:** Isovue-M 200, Isovue-M 300 solutions.

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**Signal word** Void

**Hazard statements** Void

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

**Effects of Overexposure - Routes of Entry:**

**Inhalation:**

Under normal conditions, this material is handled in closed vials and 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

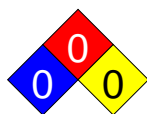
**Additional Information:**

**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: 60166-93-0	(S)-N,N'-BIS[2-hydroxy-1-(hydroxymethyl)ethyl]-5-[(2-hydroxy-1-oxopropyl)amino]-
EINECS: 262-093-6	2,4,6-triiodoisophthaldiamide
RTECS: CZ223500	

**Impurities and stabilising additives:**

CAS: 1310-73-2	sodium hydroxide
EINECS: 215-185-5	⚠ Skin Corr. 1A, H314
Index number: 011-002-00-6	
EINECS: 231-595-7	hydrochloric acid
Index number: 017-002-01-X	⚠ Skin Corr. 1B, H314; ⚠ STOT SE 3, H335
RTECS: MW 9620000	
CAS: 83147-39-1	Tromethamine

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**Trade name:** Isovue-M 200, Isovue-M 300 solutions.

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CAS: 62-33-9  
EINECS: 200-529-9

sodium calcium edetate  
⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335

**Chemical characterization: Mixtures**

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

**Hazardous Components:**

CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide ⚠ Skin Corr. 1A, H314	< 1%
EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000	hydrochloric acid ⚠ Skin Corr. 1B, H314; ⚠ STOT SE 3, H335	< 1%
CAS: 62-33-9 EINECS: 200-529-9	sodium calcium edetate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	< 1%

**Non-Hazardous Components:**

CAS: 60166-93-0 EINECS: 262-093-6 RTECS: CZ223500	(S)-N,N'-BIS[2-hydroxy-1-(hydroxymethyl)ethyl]-5-[(2-hydroxy-1-oxopropyl)amino]-2,4,6-triiodoisophthaldiamide	34 - 61%
CAS: 7732-18-5 EINECS: 231-791-2 RTECS: ZC0110000	Water USP	> 1%
CAS: 83147-39-1	Tromethamine	< 1%

## 4 First-aid measures

**Description of first aid measures**

**General information:** No special measures required.

**After Inhalation:**

Remove exposed person to fresh air.  
If person is not breathing, give artificial respiration.  
If breathing is difficult administer oxygen.  
Get medical attention immediately.  
Remove exposed person to fresh air.  
If person is not breathing, give artificial respiration.  
If breathing is difficult administer oxygen.  
Get medical attention immediately.

**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:**

Hold eyelids apart and flush with plenty of water for 5 minutes.  
Get medical attention if signs of irritation develop.

**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.  
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.

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**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.

**Note to physicians:** None.

## \* 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 (CO<sub>2</sub>)

In the absence of Oxygen: Carbon Monoxide (CO)

Nitrogen Oxides (NxO<sub>y</sub>)

Hydrogen Chloride (HCl)

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 procedures**

<sup>2</sup>Wear 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.

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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-use 10, 15 or 20 mL vials.

**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.

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**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:**



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:**

<b>Form:</b>	Liquid
<b>Color:</b>	Colorless

<b>Odor:</b>	Undistinguishable
<b>Odour threshold:</b>	Not determined. Not Available

<b>pH-value:</b>	6.5 - 7.5
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<b>Flash point:</b>	Not applicable.
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<b>Flammability (solid, gaseous):</b>	Not applicable.
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**Ignition temperature:**

<b>Decomposition temperature:</b>	Not determined.
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<b>Auto igniting:</b>	Product is not selfigniting.
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<b>Danger of explosion:</b>	Product does not present an explosion hazard.
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**Flammability Limits:**

<b>Lower:</b>	Not Determined.
<b>Upper:</b>	Not Determined.

<b>Density:</b>	Not determined.
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<b>Relative density</b>	Isovue-M 200 = 1.216 Isovue-M 300 = 1.328
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<b>Vapour density</b>	Not determined.
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**Solubility in / Miscibility with**

<b>Water:</b>	Fully miscible.
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<b>Partition coefficient (n-octanol/water):</b>	Not determined.
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**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:** There are not particular dangerous reactions with other substances in normal conditions of use.

**Chemical stability:** Stable under normal conditions.

**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:**

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

Oral	LD50	> 49000 mg/kg (Mouse)
		> 49000 mg/kg (rat)
	LD50 ip	40825 mg/kg (Mouse)
LD50 iv		17 g (Iodine) /kg (Dog)
		35000 mg/kg (Dog)
		21.8 g (Iodine) /kg (Mouse)
		33000 mg/kg (Mouse)
		28.2 g/kg (rat)
		9.6 g (Iodine) /kg (Rabbit)
		20000 mg/kg (Rabbit)
MNLD iv		13.8 g (Iodine) /kg (rqt)
		2750 mg/kg (Dog)

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<b>hydrochloric acid</b>		
Oral	LD50	900 mg/kg (Rabbit)
<b>62-33-9 sodium calcium edetate</b>		
Oral	LD50	12000 mg/kg (rat)
<b>1310-73-2 sodium hydroxide</b>		
Oral	LD50	2000 mg/kg (rat)

**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 (carcinogenicity, 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 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.

**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:**

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.

**Any Eventual Delayed Effect after Prolonged Exposure:**

Repeated and prolonged exposure to skin may cause skin irritation

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### 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.

**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.

**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.

### 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.

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**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

62-33-9 sodium calcium edetate

1310-73-2 sodium hydroxide

**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.

**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**

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

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H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

**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:**

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**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  
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A  
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B  
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2  
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A  
STOT SE 3: Specific target organ toxicity - Single exposure, 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.