Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date: **12/04/2023** Reviewed on: **12/04/2023** Version **05**

1 Identification

Product identifier: Sheet code 280

Trade name: Isovue-M200, Isovue-M300 solutions
Chemical Name: Iopamidol injection (related to Active Pharmaceutical Ingredient)

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)

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

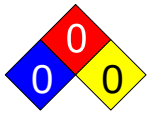
Signal word: Not applicable

Hazard statements: Not applicable

Additional Information

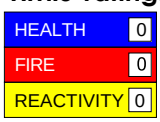
Classification system:

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: The product is not classified as PBT
vPvB: The product is not classified as vPvB

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 (Iopamidol)	76.0 %
7732-18-5	Water USP	10 – 25 %

Additional information: No additional information available.

4 First-aid measures

Description of first aid measures

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 no 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

Unsuitable extinguishing agents: None in particular

Special hazards arising from the substance or mixture

In case of fire, the following can be released:

- Carbon Dioxide (CO2)
- Carbon Monoxide (CO)
- Nitrogen Oxides (NOx)
- 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.

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 products 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.

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 cannot 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
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
Flash Point:	Not applicable
Flammability (Solid, Gaseous)	Not flammable
Ignition temperature:	Not determined
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:	Not determined
Density	Not determined
Relativity Density at 20° C (68° F):	Isovue-M 200 = 1.216 Isovue-M 300 = 1.328
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-M 200:** η = 3.3 cP at 20°C, η = 2.0 cP at 37°C; **Isovue-M 300:** η = 8.8 cP at 20°C, η = 4.7 cP at 37°C.

Kinematic:	Not determined
Water:	20.0 %
VOC Content:	Not determined
Solid Content:	Not determined
Other Information:	No further relevant information available

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 according to specifications.

Possibility of hazardous reactions
No dangerous reaction 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 (Iopamidol)		
Oral	LD50	> 49,000 mg/kg (Mouse) > 49,000 mg/kg (Rat)
	LD50 ip LD50 iv	40,825 mg/Kg (Mouse) 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 MNLD iv	28.2 g/kg (Rat) 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)

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

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

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 it to reach ground water, water course or sewage system. Avoid transfer into the environment

Results of PBT and vPvB assessment

PBT: Not classified
vPvB: Not classified

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 packaging:

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:	Not applicable
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.

Contact:
Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543
Date of preparation / last revision: 12/04/2024, Revision 5
Changes: General revision of the entire Safety Data Sheet.

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