

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/07/2011

1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Sheets Code: 266

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

Chemical Name: For active ingredient: Iopamidol Injection

How Supplied:

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

1.2 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.

Application of the substance / the preparation Intravascular diagnostic contrast media.

Chemical Family: None provided.

Molecular Formula: C₁₇H₂₂I₃N₃O₈

CAS Number: 60166-93-0

1.3 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
Tel: +33 476 295 869
Fax: +33 476 295 870
services@reachteam.eu
www.reachteam.eu

1.4 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: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of international guidelines.

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

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, 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. The extent of systemic absorption of the material after ingestion is not known.

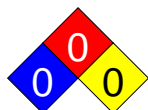
Information pertaining to particular dangers for man and environment:

Negative Effects on the Health: See also Sections 11

Negative Effects on the Environment: See also Section 12

Classification system:

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

3.1 Substances

Active Ingredients:

| | |
|-------------------|-----------|
| CAS: 60166-93-0 | Iopamidol |
| EINECS: 262-093-6 | |
| RTECS: CZ223500 | |

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Impurities and stabilising additives:

| | |
|--|--|
| CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6 | sodium hydroxide C R35 Skin Corr. 1A, H314 |
| EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000 | hydrochloric acid C R34; Xi R37 Skin Corr. 1B, H314; STOT SE 3, H335 |
| CAS: 83147-39-1 | Tromethamine |
| CAS: 62-33-9 EINECS: 200-529-9 | sodium calcium edetate Xi R36/37/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 |

3.2 Mixtures

Description: Mixture: consisting of the following components.

Dangerous Components

| CAS N° | Description | % |
|--|--|------|
| CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6 | sodium hydroxide C R35 Skin Corr. 1A, H314 | < 1% |
| EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000 | hydrochloric acid C R34; Xi R37 Skin Corr. 1B, H314; STOT SE 3, H335 | < 1% |
| CAS: 62-33-9 EINECS: 200-529-9 | sodium calcium edetate Xi R36/37/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | < 1% |

Not Dangerous Components

| CAS N° | Description | % |
|---|-------------|--------------|
| CAS: 60166-93-0 EINECS: 262-093-6 RTECS: CZ223500 | Iopamidol | 23-54 26-76% |
| CAS: 7732-18-5 EINECS: 231-791-2 RTECS: ZC0110000 | Water USP | >1% |

Additional information: For the wording of the listed risk phrases refer to section 16.

4: First aid measures

4.1 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.

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.

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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.

4.2 Most important symptoms and effects, both acute and delayed See also Section 2 and 11.**4.3 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: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents:** In case of fire, flood with Water**For safety reasons unsuitable extinguishing agents:** Unknown.**5.2 Special hazards arising from the substance or mixture****Hazardous Combustion Products:**

Hydrogen Iodide, Iodine (red-brown gas)

Carbon Dioxide (CO₂)

In the absence of Oxygen: Carbon Monoxide (COx)

Nitrogen Oxides (NxOy)

Hydrogen Chloride (HCl)

Additional Information: Not Available**5.3 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).

Besides they should wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment appropriate to the circumstances (see Section 8)

6.2 Environmental precautions: No special measures required.**6.3 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.

6.4 Reference to other sections

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protection Equipment.

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See Section 13 for Disposal Information.
See Section 12 for Ecological Information.

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* 7: Handling and storage

7.1 Precautions for Safe Handling

Avoid splashing of liquid product.
Avoid skin and eye contact.

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

7.2 Conditions for Safe Storage, including any Incompatibilities

Requirements to be Met by Storerooms and Receptacles:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

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.

7.3 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.

8.1 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.

8.2 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.

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.

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Protection of Hands:



Wear impervious gloves if the potential exists for dermal contact.

Material of 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.

Latex, Latex / Nitrile or Nitrile Gloves.

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

9.1 Information on basic physical and chemical properties

General Information

Appearance:

| | |
|-------------------------|-------------------|
| Form: | Liquid |
| Color: | Colorless |
| Odor: | Undistinguishable |
| Odour threshold: | Not Available |

| | |
|-------------------------------------|---------------|
| pH-value: | 6.5 - 7.5 |
| Melting point/Melting range: | < 0 °C |
| Boiling point/Boiling range: | Undetermined. |

Flash point: Not applicable.

Flammability (solid, gaseous): Not applicable.

Ignition temperature:

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. |

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Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapor pressure at 20°C: < 25 mmHg (similar to water)

Density: Not determined.

Relative density
Isovue 128 = 1.15
Isovue 370 = 1.405

Vapour density Not determined.

Evaporation rate Not determined.

Solubility in / Miscibility with Water: Fully miscible.

Segregation 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.

9.2 Other information No further relevant information available.

10: Stability and reactivity

10.1 Reactivity:

There are not particular dangerous reactions with other substances in normal conditions of use

10.2 Chemical stability:

Stable under normal conditions.

Shelf-life indicated on individual containers.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No further relevant information available (See Section 5)

11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:

60166-93-0 Iopamidol

| | | |
|------|------|-----------------------|
| Oral | LD50 | > 49000 mg/kg (mouse) |
|------|------|-----------------------|

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| | | |
|---------------------------------------|----------|-----------------------------|
| | | > 49000 mg/kg (rat) |
| | LD50 ipn | 40825 mg/kg (mouse) |
| | LD50 ivn | 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) |
| | | 13.8 g (Iodine) /kg (rqt) |
| | MNLD ivn | 2750 mg/kg (dog) |
| hydrochloric acid | | |
| Oral | LD50 | 900 mg/kg (rabbit) |
| 62-33-9 sodium calcium edetate | | |
| Oral | LD50 | 12000 mg/kg (rat) |
| 1310-73-2 sodium hydroxide | | |
| Oral | LD50 | 2000 mg/kg (rat) |

Toxicological Information for Active Ingredients:

Iopamidol would be classified as essentially nontoxic after acute intravenous exposure.

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.

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:

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

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

Subacute to Chronic Toxicity: No further relevant information available

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.

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Any Eventual Delayed Effect after Prolonged Exposure:

Repeated and prolonged exposure to skin may cause skin irritation

12: Ecological information

12.1 Toxicity

Aquatic toxicity:

1310-73-2 sodium hydroxide

LC50 180 mg/l (fish)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

Additional Information: Use according to good working practice.

13: Disposal considerations

13.1 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

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class

Void

14.4 Packing group

DOT, ADR, IMDG, IATA

Void

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14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

UN "Model Regulation": -

15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

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.

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

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.

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OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

R34 Causes burns.

R35 Causes severe burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R37 Irritating to respiratory system.

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 MSDS:

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

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

*** Data compared to the previous version altered.**