

SAFETY DATA SHEET
according to 1907/2006/EC, Article 31

Printing date 06.07.2010

Sheet n° 125

Revision: 06.07.2010

* **1 Identification of the substance/preparation and of the company/undertaking**

· **Product details**

· **Trade name:** *Iopamidol*

· **Article number:** 014650; 014843

· **Application of the substance / the preparation** Pharmaceutical preparation

· **Manufacturer/Supplier:**

Bracco Imaging S.p.A.

Via E. Folli, 50

20134 Milano

tel. +39 (0)2 21771

· **Further information obtainable from:** hse@bracco.com

· **Information in case of emergency:**

Emergency contact:

Ospedale Niguarda Ca' Granda - Milano

Antivenoms Centre: +39 (0)2 66101029

In case of need, call any emergency telephone number available.

2 Hazards identification

· **Hazard description:** Not applicable.

· **Information concerning particular hazards for human and environment:**

Mechanical irritation of upper respiratory tract is possible after high exposure to dusts.

See also Sections 11 and 12.

· **GHS label elements** Void

* **3 Composition/information on ingredients**

· **Chemical characterization:**

· **CAS No. Description**

60166-93-0 Iopamidol

· **Identification number(s)**

· **EINECS Number:** 262-093-6

4 First aid measures

· **General information:** See also Sections 2 and 11.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:**

Rinse out mouth with water.

If symptoms persist consult a doctor.

5 Fire-fighting measures

· **Suitable extinguishing agents:** CO₂, powder or water spray. Fight larger fires with water spray.

· **For safety reasons unsuitable extinguishing agents:** Unknown.

· **Protective equipment:**

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus).

See also Section 8.

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Wear a self-contained breathing apparatus.

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6 Accidental release measures

- **Person-related safety precautions:**
Wear protective equipment. Keep unprotected persons away.
See also Section 8.
- **Measures for environmental protection:**
Prevent, as much as possible, generation and diffusion of dusts.
Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully; suitable cleaners are:
Warm water

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Operations must be carried on in closed systems or, alternatively, in facilities fitted with exhaust hoods or equivalent dust capturing devices.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
Store receptacle in a well ventilated area.
Protect from heat and direct sunlight.

8 Exposure controls/personal protection

- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Valid data and limit values in date of revision were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Short term filter device:
Filter P2

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· Protection of hands:

Protective gloves

· Material of gloves

PVC or PE 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.

· 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:

Tightly sealed goggles

· Body protection:

Normal working clothes.

In case of emergency:

Protective work clothing

· Limitation and supervision of exposure into the environment See also Section 7.1

9 Physical and chemical properties

· General Information

Form:	Solid Crystalline powder
Colour:	White
Odour:	Odourless

· Change in condition

Melting point/Melting range:	circa 320 °C
Boiling point/Boiling range:	Undetermined.

· Flash point: Not applicable.**· Flammability (solid, gaseous):** Product is not flammable.**· Danger of explosion:** Product does not present an explosion hazard.**· Explosion limits:****Oxidizing properties:** Non combustive agent.**· Density:** 3 g/cm³**· Solubility in / Miscibility with**

water:	Easily soluble.
alcohols:	Slightly soluble.
ketones:	Insoluble.
chlorohydrocarbons:	Insoluble.

· pH-value: 6,5 - 7,5

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10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Materials to be avoided:** Oxidants.
- **Dangerous reactions**
Self igniting at raised temperature.
Reacts with strong oxidizing agents.
- **Dangerous decomposition products:**
Carbon monoxide
Nitrogen oxides (NOx)
Iodine compounds

11 Toxicological information

- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

Oral	LD50	>49000 mg/kg (mouse)
		>49000 mg/kg (rat)

- **Primary irritant effect:**
- *on the skin:* No irritating effect.
- *on the eye:* No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.

13 Disposal considerations

- **Product:**
- **Recommendation**
Product's surplus or waste resulting from use must be handled according to precautions and individual protective measures as indicated under Sections 7 and 8.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **Transport/Additional information:**
Not reported as dangerous in a matter of transportation, according to the above mentioned regulations.

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15 Regulatory information**· Labelling according to EU guidelines:**

The substance is not subject to classification according to EU lists and other sources of literature known to us.

· National regulations: D.lgs. n°152/2006 and subsequent amendments.**16 Other information**

This information is based on our present knowledge; it is believed to be accurate and represent the best available set of data at the date of revision. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This sheet voids and takes over any other MSDS' previous release concerning this product.

· 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.

· Department issuing MSDS: HSE Department - Bracco Group**· Contact:** Ing. Daniela Arnoldi**· Abbreviations and acronyms:**

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· * 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.

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