

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 10.02.2011

Sheet n° 34

Revision: 09.02.2011

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

- **1.1 Product identifier**
- **Trade name:** *Iomeprol*
- **Chemical name:**
N,N'-Bis(2,3-dihydroxypropyl)-5-[(hydroxyacetyl)methylamino]-2,4,6-triiodo-1,3-benzenedicarboxamide
- **Article number:** 02073A; 02074B; 094441; 094452; B16880
- **Molecular weight** 777,09
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Pharmaceutical preparation
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Spin S.p.A.
Via dei Bossi, 4
20121 Milano
tel. sito Torviscosa (UD): +39 (0)43 19761
- **Further information obtainable from:** hse@bracco.com
- **Emergency telephone number:**
Emergency contact:
Antivenoms Center: +39(0)266101029
Ospedale Niguarda Ca' Granda - Milano
In case of need, call 118 or any other emergency telephone number available.

2 Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) N. 1272/2008 and subsequent amendments:**
The substance is not classified according to the CLP regulation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
The product is not under an obligation to be classified according to Directive 67/548/CEE and subsequent amendments.
Void
- **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.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard-determining components of labelling:** Void
- **Hazard statements** Void
- **2.3 Other hazards** Not applicable.

3 Composition/information on ingredients

- **3.1 Chemical characterization: Substances**
N,N'-Bis(2,3-dihydroxypropyl)-5-[(hydroxyacetyl)methylamino]-2,4,6-triiodo-1,3-benzenedicarboxamide
- **CAS No. Description**
78649-41-9 Iomeprol
- **Identification number(s)** EINECS number not available

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4 First aid measures

- **4.1 Description of 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:**
Wash with water and rinse thoroughly.
Remove contaminated clothing.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms of irritation persist, consult a doctor.
- **After swallowing:**
Rinse out mouth with water.
Seek immediate medical advice.

5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO₂, powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents:** Unknown.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
See also Section 10.
- **5.3 Advice for firefighters**
Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus). See also Section 8.
- **Additional information**
Cool endangered receptacles with water spray.
Raccogliere l'acqua contaminata usata per lo spegnimento, non convogliarla assolutamente nel sistema fognario.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
See also Section 8.
- **6.2 Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically. Send for recovery or disposal in suitable receptacles. Clean the affected area carefully; suitable cleaners are: warm water.
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully; suitable cleaners are:
Warm water
- **6.4 Reference to other sections**
.
See Section 8 for information on personal protection equipment.
See Section 10 for information on stability and reactivity.

7 Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.

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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.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Requirements to be met by storerooms and receptacles:** Store in a cool location.

· **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. Keep container tightly sealed. Protect from heat and direct sunlight.

Keep container tightly sealed.

Protect from heat and direct sunlight.

* 8 Exposure controls/personal protection

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:** Not required.

· **8.2 Exposure controls**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals. Be sure to clean skin thoroughly after work and before breaks. Keep away from foodstuffs, bevarages and feed. Keep away from tobacco products.

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Keep away from foodstuffs, beverages and feed.

Keep away from tobacco products.

· **Personal protective equipment:**

· **Respiratory protection:**

Suitable respiratory protective device recommended.

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Short term filter device:

Filter P2

Self-contained breathing apparatus for emergency use (for instance: large fire).

Filter P2

Self-contained breathing apparatus for emergency use (for instance: large fires).

· **Protection of hands:**



Protective gloves

· **Material of gloves**

Rubber gloves

PVC or PE gloves

Rubber 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

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- **Body protection:**
Normal working clothes.
Disposable light overall

9 Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· Appearance:

- **Colour:** White
- **Odour:** Odourless
- **Melting point/Melting range:** 295°C
- **Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Product is not flammable.

- **Ignition temperature:** Auto-ignition temperature; flame effect, non-explosive.
No effects in cloud.

- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· Density:

- **Bulk density:** 300 kg/m³

· Solubility in / Miscibility with:

- **water:** Soluble.
- **alcohols:** Partly soluble.
(methanol)
- **ketones:** Insoluble.
(acetone)
- **chlorohydrocarbons:** Insoluble.
(chloroform)

10 Stability and reactivity

- **10.5 Incompatible materials:** Oxidants.
- **10.6 Hazardous decomposition products:**
Carbon monoxide
Nitrogen oxides (NOx)
Iodine compounds

11 Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity:

· 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.

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The substance is not subject to classification according to the latest version of the EU lists.

12 Ecological information· **12.1 Toxicity**· **Acquatic toxicity:**

EC50 >1000 mg/l (daphnia)

· **12.2 Persistence and degradability** Not easily biodegradable· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.**13 Disposal considerations**· **13.1 Waste treatment methods**· **Product:**

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.

14 Transport information· **Special precautions for user** Not applicable.· **Transport/Additional information:**

Not reported as dangerous in a matter of transportation, according to dangerous goods transport regulations.

15 Regulatory information· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**· **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· **Abbreviations and acronyms:**

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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

· **Sources**

- BRACCO Report RF 206

- RBM Report 1953

- RBM Reports M659, M660, M661, M662

- EISAI Report 907407

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- BRACCO Report RF 479
- BRACCO RF 1430
- RBM REPORT EXP. N°940742
- RBM REPORT EXP. N°940741
- RBM REPORT EXP. N°940743
- REDOX - CMR/L/00/0177 (07/08/2000)
- *** Data compared to the previous version altered.**
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