

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/05/2011

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

### 1.1 Product identifier

**Sheets Code:** 274

**Trade name:** Cholografin Meglumine (52%), Cholografin Meglumine for Infusion (10.3%)

**Chemical Name:**

For active, iodipamide meglumine injection USP 52%, iodipamide meglumine injection USP 10.3%.

**Synonyms:**

For active, D-Glucitol, 1-deoxy-1-(methylamino)-,3,3'-(adipoyldiimino)bis(2,4,6-triodobenzoate) (2:1) (salt)

**How Supplied:** Single dose vials of 20 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** Radiopaque contrast agent.

**Chemical Family:** None provided.

**Molecular Formula:** C<sub>20</sub>H<sub>14</sub>I<sub>6</sub>N<sub>2</sub>O<sub>6</sub>.2C<sub>7</sub>H<sub>17</sub>NO<sub>5</sub>

**CAS Number:** Iodipamide meglumine: 3521-84-4

### 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 does not have 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.

(Contd. on page 2)

USA

# Material Safety Data Sheet

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**Trade name:** Cholografin Meglumine (52%), Cholografin Meglumine for Infusion (10.3%)

(Contd. of page 1)

## 2.2 Label elements

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

**Hazard pictograms** Void

**Signal word** Void

**Hazard statements** Void

### 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.

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

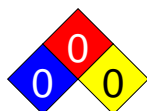
### Information pertaining to particular dangers for man and environment:

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

Fire = 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: 3521-84-4	Iodipamide-Meglumine
RTECS: LZ 4297000	

(Contd. on page 3)

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

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**Trade name:** Cholografín Meglumine (52%), Cholografín Meglumine for Infusion (10.3%)

(Contd. of page 2)

### Impurities and stabilising additives:

CAS: 6381-92-6 EINECS: 205-358-3	EDTA, disodium Salt Xn R22 Acute Tox. 4, H302
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

### 3.2 Mixtures

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

#### Dangerous Components

CAS N°	Description	%
CAS: 6381-92-6 EINECS: 205-358-3	EDTA, disodium Salt Xn R22 Acute Tox. 4, H302	<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%

#### Not Dangerous Components

CAS N°	Description	%
CAS: 3521-84-4 RTECS: LZ 4297000	Iodipamide-Meglumine	10.3-52%
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.

#### After Eye Contact:

Wash with running water for several minutes holding the eyelids open.  
If any symptoms of irritation develop and / or persist, consult your doctor.

#### 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.

(Contd. on page 4)

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/05/2011

**Trade name:** Cholografin Meglumine (52%), Cholografin Meglumine for Infusion (10.3%)

(Contd. of page 3)

**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** 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 (COx)

Nitrogen Oxides (NxOy)

Iodine Compounds

**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.

See Section 13 for Disposal Information.

See Section 12 for Ecological Information.

## \* 7: Handling and storage

### 7.1 Precautions for Safe Handling

Avoid splashing of liquid product.

(Contd. on page 5)

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/05/2011

**Trade name:** Cholografin Meglumine (52%), Cholografin Meglumine for Infusion (10.3%)

(Contd. of page 4)

Avoid skin and eye contact.

**Information about protection against explosions and fires:** No special measures required.

## 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:** Single-use 20 mL vials

**Storage Conditions:** Store at room temperature (20-25 degrees C). Protect from light.

**Information about Storage in one Common Storage Facility:** Not required.

**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.

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.

(Contd. on page 6)

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

Version 1

Reviewed on 11/05/2011

**Trade name:** Cholografín Meglumine (52%), Cholografín Meglumine for Infusion (10.3%)

(Contd. of page 5)

**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:**

<b>Form:</b>	Liquid
<b>Color:</b>	Colorless to Light Amber
<b>Odor:</b>	Undistinguishable
<b>Odour threshold:</b>	Not determined.

<b>pH-value:</b>	6.5 - 7.7
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	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:**

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

**Explosion limits:**

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

**Vapor pressure:** Not determined.

**Density at 20°C:** 1.295 g/cm<sup>3</sup>

**Relative density** Not determined.

**Vapour density** Not determined.

**Evaporation rate** Not determined.

**Solubility in / Miscibility with**

**Water:** Fully miscible.

**Segregation coefficient (n-octanol/water):** Not determined.

(Contd. on page 7)

# Material Safety Data Sheet

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Version 1

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(Contd. of page 6)

**Viscosity:**

**Dynamic:** Not determined.

**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.

**Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications

**10.3 Possibility of hazardous reactions:** No dangerous reactions known.

**10.4 Conditions to avoid:**

Simultaneous presence of air and dust ignition sources: the dusts suspended in air and in the presence of primers of sufficient energy are a potential danger of explosion.  
Lower Explosive Limit and Ignition Energy are not 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:**

**3521-84-4 Iodipamide-Meglumine**

LD50 ip	1921 mg/kg (rat)
	1446 mg/kg (rabbit)
LD50 iv	1200 mg/kg (dog)
	3195 mg/kg (mouse)
	5000 mg/kg (rat)

**68-04-2 Sodium Citrate, anhydrous**

LD50 ip	1364 mg/kg (mouse)
	1548 mg/kg (rat)
LD50 iv	170 mg/kg (mouse)
	449 mg/kg (rabbit)

**6381-92-6 EDTA, disodium Salt**

Oral	LD50	2000 mg/kg (rat)
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**Toxicological Information for Active Ingredients:**

Iodipamide meglumine would be classified as moderately toxic after acute intravenous injection. \*  
No information is available for ingestion.

(Contd. on page 8)

## Material Safety Data Sheet

*acc. to ISO/DIS 11014*

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Version 1

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(Contd. of page 7)

**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:** No further relevant information available

**Carcinogenicity:** Not Available.

**Reproductive Toxicity:** 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

**Additional toxicological information:**

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

Medical condition can be aggravated by exposure at the Cholografin Meglumine, for the patients sensitive to Iodine

**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:**

**6381-92-6 EDTA, disodium Salt**

LC50/96 h	152 mg/l (fish)
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**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.

Avoid transfer into the environment.

**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.

USA

(Contd. on page 9)





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Version 1

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(Contd. of page 9)

***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.

***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***

H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H335 May cause respiratory irritation.

R22 Harmful if swallowed.  
R34 Causes burns.  
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:***

B-Lands Consulting  
WTC, 5 Place Robert Schuman, BP 1516  
38025 Grenoble, FRANCE  
Tel: +33 476 295 869  
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(Contd. on page 11)

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/07/2011

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**Trade name:** Cholografin Meglumine (52%), Cholografin Meglumine for Infusion (10.3%)

(Contd. of page 10)

**Contact:**

HSE Department - Bracco Group  
hse@bracco.com

**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.**

- data updating on the basis of the latest amendments.

- adaptation of the form according to Regulation 1907/2006/CE.