

**LIPIODOL  
SAFETY DATA SHEET**Revision date: 03/01/2018

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**1-IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY****1.1 Product Identifier****Product name:** LIPIODOL ULTRA-FLUID**Chemical name:** Ethyl ester of iodized fatty acids of poppy seed oil (drug substance)**Synonym(s):** Ethiodized oil injection, iodized oil fluid injection**CAS number:** 8002-46-8**Formula:** Not applicable**1.2 Product Use**

Medicinal product,

Lipiodol Ultra-Fluid is an oily radiological contrast agent

**1.3 Details of the supplier of the substance****Manufacturer:**

GUERBET

BP 57400

95943 Roissy CdG Cedex.

E-mail contact : fds@guerbet-group.com

**1.4 Emergency Telephone Number: +33 (0)1 45 91 50 00**

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**2-HAZARDS IDENTIFICATION****2.1 Classification of substance:**

The product is not classified according to Regulation (EC) No. 1272/2008 (CLP regulation)

The product is not classified as dangerous according to Directive 67/548/EEC.

**2.2 Label elements**

Labelling according to regulation (EC) N° 1272/2008: none

Labelling according to Directive 1999/45/EC: none

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**3-COMPOSITION / INFORMATIONS ON INGREDIENTS**

Classification of components according to Regulation (EC) N° 1272/2008: No known specific risks

| Product  | Classification | Concentration (%) |
|--|----------------|-------------------|
| Ethyl ester of iodized fatty acids of poppy seed oil | 8002-46-8      | 100               |

This medical product does not contain any excipients.

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#### 4-FIRST AID MEASURES

**Eye contact:** Wash with water for at least 15 minutes. Call a physician if irritation develops.

**Skin contact:** Wash with soap and water. Call a physician if irritation develops.

**Ingestion:** If large amounts are ingested, get medical advice. Unexpected allergic reactions may occur in certain highly susceptible persons.

**Inhalation:** No adverse effects expected, which would require first aid or medical assistance.

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#### 5-FIRE FIGHTING MEASURES

**Suitable extinguishing media:** Water, foam, dry powder, carbon dioxide.

**Special hazards arising from substance or mixture:**

Carbon oxides,

Hydrogen iodine, Iodine (red-brown gas)

**Advice for fire-fighters:** As in any fire, wear normal protective equipment and positive-pressure self-contained breathing apparatus.

**Environmental protection measures:** Prevent fire extinguishing water from contaminating surface or ground water.

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#### 6-ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Avoid contact with skin and eyes, wear safety shoes to avoid slipping

**Environmental precautions:** Do not release in drains. Containerize the product.

**Methods for clean up:** Spread sodium carbonate and wait until the product is fully absorbed before discarding

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#### 7-HANDLING AND STORAGE

**Precautions for safe handling:**

Avoid contact with eye, skin and clothing

**Conditions for safe storage:**

Protect from light and heat (to avoid product degradation)

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#### 8-EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Occupational Exposure Limits:**

The product is considered not to be hazardous and has no occupational exposure limits established for it.

**8.2 Exposure parameters:** Not applicable

**8.3 Exposure Controls:** Not applicable

**8.3.1 Occupational Exposure Controls:**

No further relevant information available (see section 5 and 7)

**8.3.2 Environmental Exposure Controls:** Not applicable

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## 9-PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 General Information

**Appearance:** Oily liquid

**Colour:** Pale yellow to amber

**Odour:** Vegetable oil

### 9.2 Important Information for Health, Safety, and Environment

**pH:** Not applicable

**Initial Boiling Point and Boiling Range:** 125°C (8mmHg)

**Initial Melting Point and Melting Range:** Not available

**Flash Point:** 177°C (closed container)

**Flammability (solid/gas):** Not applicable

**Upper/lower Flammability:** Not available

**Explosion Limits:** Not available

**Vapour Pressure:** Not available

**Density:** 1.28 g/cm<sup>3</sup> at 20°C

**Water Solubility:** Insoluble

**Other Information:**

**Viscosity:** 34-70mPa.s at 20°C

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## 10-STABILITY AND REACTIVITY

**Conditions to avoid:**

Air, light and heat: risk of product degradation and release of iodine into the oil

**Incompatible Materials:** Natural or synthetic rubber

**Possibility of Hazardous Reactions:** No data available

**Hazardous Decomposition Products:** Iodine vapors are released above 173°C

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## 11-TOXICOLOGICAL INFORMATION

**Acute Toxicity:**

LD50 (intraperitoneal route in mice) > 30 ml/kg

LD50 (intravenous route in mice) = 1.8 ml/kg

LD50 (intravenous route in dogs) = 1.58 ml/kg

Oral route in mice: no reaction at 2 ml/kg dose level

**Chronic and Long Term Toxicity:**

No data available.

**Systemic Effects:**

**CMR Effects** (Carcinogenicity, Mutagenicity and toxicity for Reproduction) :

Carcinogenicity: no data available.

Mutagenicity: Not mutagenic in the Ames test, in an *in vitro* Mouse Lymphoma Assay (MLA and in an *in vivo* micronucleus test in rats (intravenous route).

Toxicity to reproduction: Not embryotoxic or teratogenic in rats and rabbits (oral route).

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## 12-ECOLOGICAL INFORMATION

**Ecotoxicity information:** No data available

**Mobility:** No data available

**Persistence and degradability:** No data available

**Bioaccumulative Potential:** No data available

**Result of the PBT and vPvB assessment:** Not applicable

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## 13-DISPOSAL CONSIDERATIONS

Refer to local regulation

Do not release in drains.

Eliminate by incineration.

Eliminate in compliance with local and national regulations.

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## 14-TRANSPORT INFORMATION

Outside the EU, refer to local or national regulations

**Land transport (ADR/RID/DOT):** Non-Regulated

**Inland waterway transport:** Non-Regulated

**Sea transport (IMO/IMDG):** Non-Regulated

**Air Transport (ICAO/IATA):** Non-Regulated

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## 15-REGULATORY INFORMATION

Outside the EU, refer to local or national regulations

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## 16-OTHER INFORMATION

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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