

## Safety Data Sheet

### Product information :

Name : Gadoteridol Injection

Issue date : 03/03/2025

### Prepared by :

Cairui Chemical Technology (Shanghai) Co., Ltd.

TEL: +86 21 69110391

E-mail: service@51ghs.com



# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

## 1. Product and Company Identification

**Product name** : Gadoteridol Injection

**Product use** : Use as a paramagnetic contrast agent.

**Manufacturer/ Supplier** : Hainan Poly Pharm Co. Ltd

**Address** : Guilinyang Economic Development Zone, Haikou, Hainan province, 571127 China

**Telephone** : +86 898 65710369

**E-mail** : hnpoly@hnpoly.com

**Emergency telephone number of the company** : +86 898 65710369

## 2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

**GHS classification of the product** : Not classified as hazardous according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Label elements

**Pictogram** : Not applicable.

**Signal word** : Not applicable.

**Hazards not otherwise classified** : Not applicable.

## 3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

| Chemical Name      | CAS-No.     | Concentration |
|--------------------|-------------|---------------|
| Water              | 7732-18-5   | 70-75 %       |
| Gadoteridol        | 120066-54-8 | 25-30 %       |
| Trometamol         | 77-86-1     | 0.1-0.5 %     |
| Calteridol Calcium | 121915-83-1 | 0.01-0.1%     |

## 4. First-Aid Measures

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

## Description of first aid measures

- Inhalation** : Move person to fresh air; If symptoms persist, consult a physician.
- Skin contact** : Flush skin with large amounts of water immediately. If symptoms persist, seek medical advice.
- Eye contact** : If you use contact lenses, remove the lenses first. Wash affected eyes for at least 15 minutes under running water with eyelids held open. If symptoms occur, consult a physician, preferably an ophthalmologist.
- Ingestion** : Rinse your mouth. If you feel uncomfortable, get medical attention and treatment.
- Most important symptoms and effects, both acute and delayed** : Further important symptoms and effects are so far not known.

## Indication of any immediate medical attention and special treatment needed

- Note to physician** : No information available.

## 5 : Fire-Fighting Measures

- Suitable extinguishing media** : Water fog or fine spray. Dry chemical fire extinguishers. Carbon dioxide fire extinguishers.

- Unsuitable extinguishing media** : No information available.

## Special hazards arising from the substance or mixture

- Hazardous combustion products** : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating. Combustion products may include and are not limited to: Nitrogen oxides. Carbon monoxide. Carbon dioxide.

## Advice for firefighters

- Special protective equipment for firefighters** : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

## 6 : Accidental release measures

**Personal precautions, protective equipment and emergency procedures** : Avoid skin contact. Wear personal protective clothing.

**Environmental precautions** : Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

**Methods and materials for containment and cleaning up** : Collect in suitable and properly labeled containers. Then store and dispose of according to local regulations.

## 7 : Handling and storage

**Advice on safe handling** : Avoid contact with the skin, eyes and clothing. Wear safety glasses with side shields.

**Conditions for safe storage, including any incompatibilities** : Keep tightly closed in a dry and well-ventilated place.

## 8 : Exposure Controls/Personal Protection

**Control parameters** : No data available.

### Personal protective equipment

**Respiratory protection** : None required under normal conditions. Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.

**Hand protection** : Use gloves chemically resistant to this material. Examples of acceptable glove barrier materials include: Natural rubber ("latex").

**Eye protection** : Use safety glasses (with side shields).

**Skin and body protection** : Wear protective clothing.

## 9 : Physical and chemical properties

**Form** : liquid

**Colour** : clear to light yellow

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

|  |                     |
|--|---------------------|
| <b>Odour</b>                             | : no data available |
| <b>pH</b>                                | : 6.5-8.0           |
| <b>Melting point</b>                     | : no data available |
| <b>Boiling point</b>                     | : no data available |
| <b>Flash point</b>                       | : no data available |
| <b>Thermal decomposition temperature</b> | : no data available |
| <b>Density</b>                           | : 1.081-1.193g/ml   |
| <b>Water solubility</b>                  | : no data available |
| <b>Viscosity, dynamic</b>                | : no data available |

## 10 : Stability and Reactivity

|   |  |
|---|--|
| <b>Reactivity</b>                         | : No hazardous reactions if stored and handled as prescribed/indicated.              |
| <b>Chemical stability</b>                 | : The product is stable if stored and handled as prescribed/indicated.               |
| <b>Possibility of hazardous reactions</b> | : This material is considered stable.  |
| <b>Conditions to avoid</b>                | : No information available.  |
| <b>Incompatible materials</b>             | : Avoid contact with: Strong acids.Strong bases.Strong oxidizers.                    |
| <b>Hazardous decomposition products</b>   | : No hazardous decomposition products if stored and handled as prescribed/indicated. |

## 11 : Toxicological information

*Toxicological information appears in this section when such data are available.*

### Information on likely routes of exposure

Eye contact, Skin contact, Inhalation, Ingestion.

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

---

## **Acute toxicity**

### **Acute Toxicity Endpoints:**

#### **Acute oral toxicity**

##### **Information for the Product:**

Shall not be classified as acutely toxic (oral).

As product: Single dose oral LD50 has not been determined.

Based on information for component(s): LD50, > 2 000 mg/kg Estimated.

##### **Information for components:**

Gadoteridol

LD50, rat, > 2000 mg/kg bw, estimated

Trometamol

LD50, rat, > 5 000 mg/kg bw

#### **Acute dermal toxicity**

##### **Information for the Product:**

Shall not be classified as acutely toxic (dermal).

As product: The dermal LD50 has not been determined.

Based on information for component(s): LD50, > 2 000 mg/kg Estimated.

##### **Information for components:**

Gadoteridol

LD50, rabbit, >2000 mg/kg bw, estimated

Trometamol

LD50, rat, > 5 000 mg/kg bw

#### **Acute inhalation toxicity**

##### **Information for the Product:**

Shall not be classified as acutely toxic (inhalation).

As product: The LC50 has not been determined.

Based on information for component(s): LC50, rat, >20 mg/L air, estimated

Information for components:

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

---

Gadoteridol  
LC50, rat, >5.0 mg/L air, estimated

Trometamol  
LC50, rat, >5.0 mg/L air, estimated

## **Skin corrosion/irritation**

### **Information for the Product:**

Shall not be classified as corrosive/irritant to skin.

### **Information for components:**

Gadoteridol  
Shall not be classified as corrosive/irritant to skin

Trometamol  
Shall not be classified as corrosive/irritant to skin

## **Serious eye damage/eye irritation**

### **Information for the Product:**

Shall not be classified as irritant to eye.

### **Information for components:**

Gadoteridol  
Shall not be classified as irritant to eye

Trometamol  
Shall not be classified as irritant to eye

## **Respiratory or skin sensitisation**

### **Information for the Product:**

Shall not be classified as a respiratory or skin sensitiser.

### **Information for components:**

Gadoteridol  
For skin sensitization:  
Shall not be classified as a skin sensitiser  
For respiratory sensitization:  
Shall not be classified as a respiratory sensitiser.

Trometamol  
For skin sensitization:  
Shall not be classified as a skin sensitiser

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

---

For respiratory sensitization:  
Shall not be classified as a respiratory sensitiser.

## **Germ cell mutagenicity**

### **Information for the Product:**

Shall not be classified as germ cell mutagenic.

### **Information for components:**

Gadoteridol  
Shall not be classified as germ cell mutagenic

Trometamol  
Shall not be classified as germ cell mutagenic

## **Carcinogenicity**

### **Information for the Product:**

Shall not be classified as carcinogenic.

### **Information for components:**

Gadoteridol  
Shall not be classified as carcinogenic

Trometamol  
Shall not be classified as carcinogenic

## **Reproductive toxicity**

### **Information for the Product:**

Shall not be classified as a reproductive toxicant.

### **Information for components:**

Gadoteridol  
Shall not be classified as a reproductive toxicant

Trometamol  
Shall not be classified as a reproductive toxicant

## **STOT-single exposure**

### **Information for the Product:**

Shall not be classified as a specific target organ toxicant (single exposure).



# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

---

## Information for components:

Gadoteridol

Shall not be classified as a specific target organ toxicant (single exposure)

Trometamol

Shall not be classified as a specific target organ toxicant (single exposure)

## STOT-repeated exposure

### Information for the Product:

Shall not be classified as a specific target organ toxicant (repeated exposure).

## Information for components:

Gadoteridol

Shall not be classified as a specific target organ toxicant (repeated exposure)

Trometamol

Shall not be classified as a specific target organ toxicant (repeated exposure)

## Aspiration Hazard

### Information for the Product:

Shall not be classified as presenting an aspiration hazard.

## Information for components:

Gadoteridol

Shall not be classified as presenting an aspiration hazard

Trometamol

Shall not be classified as presenting an aspiration hazard

## 12 : Ecological information

### Toxicity

Trometamol

Short-term toxicity to aquatic invertebrates

EC50, 48h, Daphnia magna, > 980 mg/L, OECD guideline 202

Toxicity to aquatic algae and cyanobacteria

ErC50, 72h, Pseudokirchneriella subcapitata, 397 mg/L, OECD guideline 201

NOEC, 72h, 100 mg/L

Toxicity to microorganisms

EC50, activated sludge, > 1000 mg/L, OECD guideline 209

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

## Persistence and degradability

Trometamol  
Readily biodegradable  
Biodegradation: 100%  
Exposure time: 28d  
Method: OECD Guideline 301 F

## Bioaccumulative potential

Trometamol  
No significant bioaccumulation expected (log Kow = -2.31)

## Mobility in soil

Trometamol  
Koc, 75(20 °C)

## Other adverse effects

Gadoteridol  
This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

Trometamol  
This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

## 13 : Disposal considerations

|                               |  |
|-------------------------------|--|
| <b>Product</b>                | : Observe national and local legal requirements.   |
| <b>Contaminated packaging</b> | : Packs that cannot be cleaned should be disposed of in the same manner as the contents. |

## 14 : Transport Information

### Land transport

#### DOT

|                                     |                  |
|-------------------------------------|------------------|
| <b>UN number</b>                    | : not applicable |
| <b>UN proper shipping name :</b>    | : not applicable |
| <b>Transport hazard class(es) :</b> | : not applicable |
| <b>Packing group</b>                | : not applicable |

### Sea transport

#### IMDG

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

**UN number** : not applicable  
**UN proper shipping name** : not applicable  
**Transport hazard class(es)** : not applicable  
**Packing group** : not applicable

## Air transport

### IATA/ICAO

**UN number** : not applicable  
**UN proper shipping name** : not applicable  
**Transport hazard class(es)** : not applicable  
**Packing group** : not applicable

## 15 : Regulatory information

### Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### SARA 311/312 Hazard Categories

No SARA Hazards.

### Pennsylvania Right To Know Components

No components are subject to the Pennsylvania Right to Know Act.

### California Proposition 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### United States TSCA Inventory (TSCA)

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

## 16 : Other information

NFPA Hazard codes:

Health: 1      Fire: 0      Reactivity: 0      Special:

HMIS III rating

Health: 1      Flammability: 0      Physical hazard: 0

# SAFETY DATA SHEET

Version 1.0

Issue Date: 03/03/25

Revision Date: 03/03/25

---

**SDS Prepared by:**

Cairui Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 03/03/25

The information herein is provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. The information presented here pertains only to the product as shipped. Since conditions for use of the product are not under the control of the manufacturer, it is the buyer's/user's duty to determine the conditions necessary for the safe use of this product. Due to the proliferation of sources for information such as manufacturer specific SDSs, we are not and cannot be responsible for SDSs obtained from any source other than ourselves. If you have obtained an SDS from another source or if you are not sure that the SDS you have is current, please contact us for the most current version.

---