Regulix

SDS No. : 25868980303302

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

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.

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

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

10： Stability and Reactivity

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

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:

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

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).

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

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

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

14： Transport Information

Land transport

DOT

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

Sea transport

IMDG

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

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 manufacturerspecific 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.