



Product name: Gadobutrol Injection

Issue date: 05/29/23

# SDS

## Safety Data Sheet

SDS No. : 23868980529203



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## 1. Product and Company Identification

**Product name** : Gadobutrol Injection

**Product use** : Used in diagnostic magnetic resonance imaging (MRI) in adults and children.

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

**Address** : No.2 Xingyang Road, Guilinyang Economic Development Area, Haikou, Hainan 571127, P.R.China

**Telephone** : +86 898-36389016

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

**Emergency telephone number of the company** : +86 898-36389016

## 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
Gadobutrol monohydrate	198637-52-4	60-65%
Calcobutrol sodium	/	0.01-0.10%
Glycerol tristearate	68334-00-9	0.1-0.5%

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Water

7732-18-5

35-40%

## 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

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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).

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Skin and body protection : Wear protective clothing.

## 9 : Physical and chemical properties

Form : liquid

Colour : clear to light yellow

Odour : none

pH : 6.6-8.0

Melting point : no data available

Boiling point : no data available

Flash point : no data available

Thermal decomposition : no data available  
temperature

Density : 1.25~1.35 g/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.

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Hazardous decomposition products : Carbon monoxide. Carbon dioxide. Nitrogen oxides.

## 11 : Toxicological information

### Information on toxicological effects

#### Acute toxicity

Shall not be classified as acutely toxic.

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Shall not be classified as irritant to eye.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

## 12 : Ecological information

#### Ecotoxicity

No information available

#### Persistence and degradability

No information available

#### Bioaccumulative potential

No information available

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Mobility in soil  
No information available

Other adverse effects  
No information available

## 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

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## 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.

NFPA Hazard codes:

Health : 1      Fire: 0      Reactivity: 0      Special:

HMIS III rating

Health: 1      Flammability: 0      Physical hazard: 0

## 16 : Other information

SDS Prepared by:

Cairui Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 05/29/23

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