

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Gadobutrol Injection

1.2. Intended Use of the Product

Gadobutrol injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI).

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Jiangsu Hengrui Pharmaceuticals Co., Ltd.
No.7, Kunlunshan Road, Economic & Technological
Development Zone,
Lianyungang, Jiangsu, China222047
Tel +86 0518-81220337
Fax +86-518-85465746
ibd@hengrui.com
www.hengrui.com

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

A safety data sheet is not required for this product. This SDS is intended to facilitate the communication of information.

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	55.5285	Not classified
Gadobutrol	Gadolinium, (10-(2,3-Dihydroxy-1-(hydroxymethyl)propyl)-1,4,7,10-tetraazacyclododecane-1,4,7-triacetato(3-)-N1,N4,N7,N10,O1,O4,O7)-	(CAS-No.) 138071-82-6	46.339	Not classified
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	Trometamol / Tromethamine / Tris(hydroxymethyl)aminomethane / 2-Amino-2-hydroxymethyl-1,3-propanediol / TROMETHAMINE / Tri-(hydroxymethyl)aminomethane / tromethamine / Trisamine / Tris-amino / Tris, free base / Tris(hydroxymethyl)methylamine / Tris-(hydroxymethyl)methanamine / Tris buffer / Tris / Trimethylolamino-methane / Methylamine, 1,1,1-tris(hydroxymethyl)- / Aminotris-(hydroxymethyl)methane / Aminotrimethylolmethane / 2-Amino-2-methylol-1,3-propanediol / 2-Amino-2-(hydroxymethyl)propane-1,3-diol / 2-Amino-2-(hydroxymethyl)-1,3-propanediol	(CAS-No.) 77-86-1	0.092	Comb. Dust

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Calcobutrol	Calciumbutrol, Calcium hydrogen 10-((1RS,2SR)-2,3-dihydroxy-1-(hydroxymethyl)propyl)-1,4,7,10-tetraazacyclododecane-1,4,7-triacetate, 1,4,7,10-TETRAAZACYCLODODECANE-1,4,7-TRIACETIC ACID, 10-(2,3-DIHYDROXY-1-(HYDROXYMETHYL)PROPYL)-, CALCIUM SALT (1:1), (R*,S*)-(+/-)-, Calcium hydrogen 10-((1RS,2SR)-2,3-dihydroxy-1-(hydroxymethyl)propyl)-1,4,7,10-tetraazacyclododecane-1,4,7-triacetate.	(CAS-No.) 151878-23-8	0.0375	Not classified
Sodium hydroxide	SODIUM HYDROXIDE / Sodium hydroxide (Na(OH)) / Caustic soda / LYE	(CAS-No.) 1310-73-2	0.003	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

Other Information: No additional information available.

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5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store at 25 °C (77 °F). Excursions permitted to 15 to 30 °C (59 to 86 °F). Do not freeze.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Gadobutrol injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³

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British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL Ceiling)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Colorless to pale yellow solution.
Odor	: Weak odor.
Odor Threshold	: No data available
pH	: 6.6 – 8
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Density	: 1.305 g/cm ³
Specific Gravity	: No data available
Solubility	: Soluble in water.
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available
Viscosity, Dynamic	: 7.73 – 10.86 mPa·s

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 6.6 – 8

Eye Damage/Irritation: Not classified

pH: 6.6 – 8

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
LD50 Oral Rat	5900 mg/kg
LD50 Dermal Rat	> 5000 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Expected to be readily biodegradable.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

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12.2. Persistence and Degradability

Gadobutrol Injection	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Gadobutrol Injection	
Bioaccumulative Potential	Not expected to bioaccumulate.
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
BCF Fish 1	3 (Estimated using a regression-derived equation)

12.4. Mobility in Soil

Gadobutrol Injection	
Ecology - Soil	Leaches into groundwater.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional Legislation (Waste): Disposal must be done according to official regulations.

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid unintended release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

Sodium hydroxide (1310-73-2)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	

15.3. Canadian Regulations

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Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 02/13/2023

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

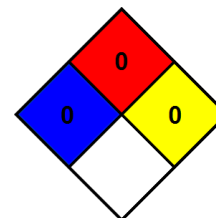
GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H370	Causes damage to organs
H402	Harmful to aquatic life

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Personal protection : B

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.

NA GHS SDS 2015 (Can, US)