

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Gadoterate Meglumine Injection

**Synonyms:** D-glucitol,1-deoxy-1-(methylamino)-,[1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraaceto(4-)-.kappa.N1, .kappa.N4, .kappa.N7, .kappa.N10, .kappa.O1, .kappa.O4, .kappa.O7, .kappa.O10]gadolate(1-)(1:1) (Gd-DOTA)

### 1.2. Intended Use of the Product

Gadoterate Meglumine Injection is a gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

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

#### 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/>

#### Manufacturer

Jiangsu Hengrui Pharmaceuticals Co., Ltd.

7 Kunlunshan Road, Economic and Technological Development Zone

222047 Lianyungang - China

T +86-518-85473511 - F +86-518-85465746

[ibd@hengrui.com](mailto:ibd@hengrui.com) - [www.hengrui.com](http://www.hengrui.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : ChemTel LLC  
(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

Skin Irrit. 2 H315

Eye Irrit. 2A H319

Full text of hazard classes and H-statements : see section 16

### 2.2. Label Elements

#### GHS-US/CA Labeling

#### Hazard Pictograms (GHS-US/CA)



GHS07

#### Signal Word (GHS-US/CA)

: Warning

#### Hazard Statements (GHS-US/CA)

: H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

#### Precautionary Statements (GHS-US/CA)

: P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 - Specific treatment (see section 4 on this SDS).

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other Hazards

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

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### 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	AQUA / water	(CAS-No.) 7732-18-5	67.93	Not classified
D-Glucitol, 1-deoxy-1-(methylamino)-, [1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetato(4-)-.kappa.N1,.kappa.N4,.kappa.N7,.kappa.N10,.kappa.O1,.kappa.O4,.kappa.O7,.kappa.O10]gadolate(1-) (1:1)	Gadoterate meglumine	(CAS-No.) 92943-93-6	32.05	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
1,4,7,10-Tetraazacyclododecane-1,4,7,10-tetraacetic acid	1,4,7,10-Tetra(carboxymethyl)-1,4,7,10-tetraazacyclododecane / tetraxetan	(CAS-No.) 60239-18-1	0.02	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

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).

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

**Skin Contact:** Remove contaminated clothing. Obtain medical attention if irritation develops or persists. Immediately drench affected area with water for at least 15 minutes.

**Eye Contact:** Immediately rinse with water for at least 15 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:** Causes skin irritation. Causes serious eye irritation.

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

**Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** The chronic effects of this substance are unknown.

### 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 (CO<sub>2</sub>), 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.

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**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:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Nitrous fumes. Gadolinium oxides.

### 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 breathing (vapor, mist, spray). Avoid all contact with skin, eyes, or clothing.

#### 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:** 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. Ventilate area.

### 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. Transfer spilled material to a suitable container for disposal. 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

**Precautions for Safe Handling:** Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray.

**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.

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

### 7.3. Specific End Use(s)

Gadoterate Meglumine Injection is a gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

## 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.

### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Emergency eye wash fountains and safety showers should be available in the immediate 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.



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**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical safety goggles.

**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 yellow
Odor	: Odorless
Odor Threshold	: No data available
pH	: 6.5 – 8.0
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	: 1.176 g/cm <sup>3</sup>
Specific Gravity	: No data available
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available
Viscosity, Dynamic	: 2.4 mPa·s at 37 °C (98.6 °F)

## 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. Light.

### 10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Nitrous fumes. Gadolinium oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

**Acute Toxicity (Oral):** Not classified

**Acute Toxicity (Dermal):** Not classified

**Acute Toxicity (Inhalation):** Not classified

**LD50 and LC50 Data:**

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No additional information available

**Skin Corrosion/Irritation:** Causes skin irritation.

**pH:** 6.5 – 8.0

**Eye Damage/Irritation:** Causes serious eye irritation.

**pH:** 6.5 – 8.0

**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:** Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

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

**Chronic Symptoms:** The chronic effects of this substance are unknown.

### 11.2. Information on Toxicological Effects - Ingredient(s)

**LD50 and LC50 Data:**

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General:** Not classified.

### 12.2. Persistence and Degradability

Gadoterate Meglumine Injection	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

Gadoterate Meglumine Injection	
Bioaccumulative Potential	Not established.

### 12.4. Mobility in Soil

No additional information available

### 12.5. Other Adverse Effects

**Other Information:** Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

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

**Ecology - Waste Materials:** Avoid 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

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<b>SARA Section 311/312 Hazard Classes</b>	Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation
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<b>Water (7732-18-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

### 15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

### 15.3. Canadian Regulations

<b>Water (7732-18-5)</b>
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** : 02/08/2022

### 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.

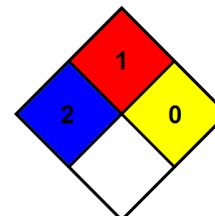
### GHS Full Text Phrases:

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

**NFPA Health Hazard** : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

**NFPA Fire Hazard** : 1 - Materials that must be preheated before ignition can occur.

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



### HMIS III Rating

**Health** : 2 Moderate Hazard

**Flammability** : 1 Slight Hazard

**Physical** : 0 Minimal Hazard

*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)