



Product name: Gadoterate Meglumine Injection

Issue date: 07/04/24

SDS

Safety Data Sheet

SDS No. : 24868980704301



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1. Product and Company Identification

Product name : Gadoterate Meglumine Injection

Product use : As a gadolinium-based contrast agent

Manufacturer/ Supplier : Hainan Poly Pharm Co. Ltd

Address : Guilinyang Economic Development Zone,Haikou,Hainan,571127 China.

Telephone : +86 898 65710369

E-mail : hncpsw@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 : Eye damage/irritation category 2
Specific target organ toxicity (single exposure) category 3

Label elements

Pictogram



Signal word : Warning

Hazard statement : Causes serious eye irritation
May cause respiratory irritation

Precautionary statements

Prevention : Wash exposed skin thoroughly after handling.
Wear protective gloves / protective clothing / eye protection / face protection.
Avoid breathing dust/fume/gas/mist/ vapours/spray.
Use only outdoors or in a well-ventilated area.

Response : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Call a POISON CENTER/doctor if you feel unwell.

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Storage	:	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	:	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazards not otherwise classified	:	No specific dangers known, if the regulations/notes for storage and handling are considered.

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	60-65%
Meglumine gadopentate	92943-93-6	35-40%
Tetraxetan	60239-18-1	0.01-0.05%

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.
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5 : Fire-Fighting Measures

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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 firefighter : 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 : Use latex, nitrile, or rubber gloves. Wear lab coat, gown, or smock as appropriate for procedure. Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

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 and protect from light.

8 : Exposure Controls/Personal Protection

Control parameters : No data available.

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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 latex, nitrile, or rubber gloves.
- Eye protection** : Use safety glasses (with side shields). Depending on conditions of use, a face shield may be necessary.
- Skin and body protection** : Wear protective clothing.

9 : Physical and chemical properties

- Form** : liquid
- Colour** : clear to yellow
- Odour** : odorless
- 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** : no data available
- 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.

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Conditions to avoid : No information available.

Incompatible materials : Avoid contact with: Strong acids.Strong bases.Strong oxidizers.

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

11 : Toxicological information

Information on likely routes of exposure

Inhalation, Eye contact, Skin contact, Ingestion.

Acute toxicity

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

Causes serious eye irritation.

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

May cause respiratory irritation.

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

Toxicity

No data available.

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Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No data 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 regulated as dangerous goods

UN proper shipping name : Not regulated as dangerous goods

Transport hazard class(es) : Not regulated as dangerous goods

Packing group : Not regulated as dangerous goods

Sea transport

IMDG

UN number : Not regulated as dangerous goods

UN proper shipping name : Not regulated as dangerous goods

Transport hazard class(es) : Not regulated as dangerous goods

Packing group : Not regulated as dangerous goods

Air transport

IATA/ICAO

UN number : Not regulated as dangerous goods

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UN proper shipping name : Not regulated as dangerous goods
Transport hazard class(es) : Not regulated as dangerous goods
Packing group : Not regulated as dangerous goods

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

SDS Prepared by:

Cairui Chemical Technology (Shanghai) CO.,LTD

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NFPA Hazard codes:

Health : 2 Fire: 0 Reactivity: 0 Special:

HMIS III rating

Health: 2 Flammability: 0 Physical hazard: 0

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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.
