

SECTION 1: Identification

1.1. Identification

Product form	: Mixture
Trade name	: Gadopicleenol solution
Other means of identification	: Solution of gadolinium complex of 2,2',2''-[3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene 3,6,9-triyl] tris (5-[(2,3-dihydroxypropyl)amino]-5-oxopentanoic acid)

1.2. Recommended use and restrictions on use

Use of the substance/mixture	: Drug for MRI use
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1.3. Supplier

GUERBET
P.O. Box BP 57400
Roissy CdG Cedex, 95943
France
T +33 (0) 1 45 91 50 00
fds@guerbet-group.com

1.4. Emergency telephone number

Emergency number	: +33 (0) 1 45 91 50 00
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SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

The classification in hazard categories, in compliance with Regulation 29 CFR 1910.1200, does not apply to drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient

2.2. GHS Label elements, including precautionary statements

Drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling, in compliance with Regulation 29 CFR 1910.1200.

2.3. Other hazards which do not result in classification

Other hazards which do not result in classification	: None to our knowledge.
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2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

Gadopiclenol solution

Product Safety Information Sheet

A safety data sheet is not required for this product. This Product Safety Information Sheet has been created on a voluntary basis

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Gadolinium, [α3,α6,α9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)-κN3,κN6,κN9,κN15,κO3,κO6,κO9]-	CAS-No.: 933983-75-6	48,5	Not classified

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

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after skin contact	: Wash with water and soap as a precaution. If irritation persists, consult a doctor.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes. If irritation persists, consult an eye specialist.
First-aid measures after ingestion	: Induce vomiting. Give nothing to drink. Seek medical advice (show the label where possible).

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects	: No specific effects and/or symptoms are known.
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4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: All extinguishing agents can be used.
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5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO2). Toxic fumes.
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5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Put on breathing apparatus. Complete protective clothing.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin and eyes.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. Concerning personal protective equipment to use, see item 8.
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6.2. Environmental precautions

Do not discharge the product into the environment.

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6.3. Methods and material for containment and cleaning up

For containment	: Take up liquid spill into absorbent material.
Methods for cleaning up	: Clean with water.
Other information	: Collect all waste in suitable and labeled containers and dispose according to local legislation.

6.4. Reference to other sections

For disposal of contaminated materials refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid contact with skin and eyes. Wear recommended personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store tightly closed in a dry, cool and well-ventilated place.
Incompatible products	: Strong acids. Strong bases. Strong oxidizers.
Storage temperature	: ≤ 25 °C Do not freeze

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Gadopiclenol solution
No additional information available
Gadolinium, [α3,α6,α9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)-κN3,κN6,κN9,κN15,κO3,κO6,κO9]- (933983-75-6)
No additional information available

8.2. Appropriate engineering controls

Environmental exposure controls	: Avoid release to the environment.
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8.3. Individual protection measures/Personal protective equipment

Hand protection:
Protective gloves. Breakthrough time : refer to the recommendations of the supplier
Eye protection:
Safety glasses
Skin and body protection:
Suitable protective clothing
Respiratory protection:
No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: colorless to yellow
Odor	: odorless
Odor threshold	: No data available
pH	: 5.5 – 7
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: 1.21 (20°C)
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Not explosive.
Oxidizing properties	: Non oxidizing.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Freezing.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Symptoms/effects : No specific effects and/or symptoms are known.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : To our knowledge, the product does not present any particular risk, under normal conditions of use.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Comply with local regulations for disposal.

Ecology - waste materials : Do not discharge into drains or rivers.

SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

DOT	TDG	IMDG	IATA
14.1. UN number			
Not regulated for transport			
14.2. Proper Shipping Name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	Not applicable

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14.6. Special precautions for user

DOT

No data available

TDG

No data available

IMDG

No data available

IATA

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Commercial status of components according to the United States Environmental Protection Agency's Toxic Substances Control Act (TSCA):

Name	CAS-No.	Listing	Commercial status	Flags
Gadolinium, [α 3, α 6, α 9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)- κ N3, κ N6, κ N9, κ N15, κ O3, κ O6, κ O9]-	933983-75-6	Not present	-	

15.2. International regulations

CANADA

Gadolinium, [α 3, α 6, α 9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)- κ N3, κ N6, κ N9, κ N15, κ O3, κ O6, κ O9]- (933983-75-6)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

EU-Regulations

Gadolinium, [α 3, α 6, α 9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)- κ N3, κ N6, κ N9, κ N15, κ O3, κ O6, κ O9]- (933983-75-6)

Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

A safety data sheet is not required for this product. This Product Safety Information Sheet has been created on a voluntary basis

Data sources

: Supplier Safety Data Sheet.

Other information

: Safety data sheet established by : LISAM TELEGIS

17 rue de la Couture F-60400 Passel

www.lisam-telegis.com.

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Abbreviations and acronyms	
CAS-No.	Chemical Abstract Service number
DOT	Department of Transportation (DOT)
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
TDG	Transportation of Dangerous Goods

Safety Data Sheet (SDS), USA

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.