

SAFETY DATA SHEET

Version 8.3 Revision Date 12/20/2024 Print Date 12/21/2024

SECTION 1. IDENTIFICATION

1.1 Product identifiers

Product name : Gadoterate Meglumine

Product Number : 1287620

Brand : US Pharmacopeia CAS-No. : 92943-93-6

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Synthesis of substances

Uses advised against : The product is being supplied under the TSCA R&D Exemption

(40 CFR Section 720.36). It is the recipient's responsibility to comply with the requirements of the R&D exemption. The product may not be used for a non-exempt commercial purpose under TSCA unless appropriate consent is granted in writing by

MilliporeSigma.

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Inc.

3050 SPRUCE ST ST. LOUIS MO 63103 UNITED STATES

Telephone : +1 314 771-5765 Fax : +1 800 325-5052

1.4 Emergency telephone

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-

527-3887 CHEMTREC (International) 24

Hours/day; 7 Days/week

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

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Other hazards

Caution: Physiologically highly active, therapeutically usable substance. The substance must be handled with the care required for hazardous materials.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : After inhalation: fresh air. Consult doctor if feeling

unwell.

In case of skin contact : In case of skin contact: Take off immediately all con-

taminated clothing. Rinse skin with water/ shower.

: The most important known symptoms and effects are

Consult a physician.

In case of eye contact : After eye contact: rinse out with plenty of water.

Remove contact lenses.

If swallowed : After swallowing: immediately make victim drink wa-

ter (two glasses at most).

Consult a physician.

Most important symptoms and effects, both acute and delayed

described in the labelling (see section 2.2) and/or in

section 11

Protection of first-aiders : For personal protection see section 8.

Notes to physician : No data available

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing

media

: Water Foam

Carbon dioxide (CO2)

Dry powder

Unsuitable extinguishing

media

: For this substance/mixture no limitations of extin-

guishing agents are given.

Specific hazards during

fire fighting

: Combustible.

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Development of hazardous combustion gases or vapours possible in the event of fire.

Hazardous combustion products

: Carbon oxides

Nitrogen oxides (NOx)

gadolinium oxides

Specific extinguishing

methods

: No data available

Further information : Suppress (knock down) gases/vapors/mists with a

water spray jet.

Prevent fire extinguishing water from contaminating

surface water or the ground water system.

ment for fire-fighters

Special protective equip- : Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

: Advice for non-emergency personnel:

Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation.

Evacuate the danger area, observe emergency proce-

dures, consult an expert.

Advice for emergency responders: For personal protection see section 8.

Environmental precautions

: Do not let product enter drains.

Methods and materials for containment and cleaning up

: Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7

and 10).

Take up dry. Dispose of properly. Clean up affected

area. Avoid generation of dusts.

SECTION 7. HANDLING AND STORAGE

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For precautions see section 2.2.

Further information on : Tightly closed.

storage conditions

Dry.

: 11, Combustible Solids Storage class

temperature

Recommended storage : 59 - 77 °F / 15 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : required when dusts are generated.

> Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter

type:

: Filter type P3

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Hand protection

: Nitrile rubber Material Break through time : 480 min Glove thickness : 0.11 mm

Protective index : Full contact

Manufacturer : KCL 741 Dec

: KCL 741 Dermatril® L Manufacturer

Material : Nitrile rubber Break through time : 480 min Glove thickness : 0.11 mm Protective index : Splash contact

: KCL 741 Dermatril® L Manufacturer

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Remarks : Handle with impervious gloves.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-

36124 Eichenzell, Internet: www.kcl.de).

Eye protection : Use equipment for eye protection tested and ap-

proved under appropriate government standards such

as NIOSH (US) or EN 166(EU).

Safety glasses

Skin and body protection : protective clothing

Hygiene measures : Change contaminated clothing. Preventive skin pro-

tection recommended. Wash hands after working

with substance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Color : No data available

Odor : No data available

Odor Threshold : No data available pH : No data available

Freezing point : No data available

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Flammability (liquids) : No data available

Burning rate : No data available

Upper explosion limit / Upper flammability limit

: No data available



Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : slightly soluble

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition tempera-

ture

: No data available

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Flow time : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

Molecular weight : 753.86 g/mol

Particle characteristics

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : The following applies in general to flammable organic

substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential $% \left(1\right) =\left(1\right) \left(1\right) \left($

may generally be assumed.

Chemical stability : The product is chemically stable under standard ambi-

ent conditions (room temperature).

Possibility of hazardous

reactions

the US and Canada

: No data available

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The life science business of Merck operates as MilliporeSigma in

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Conditions to avoid : no information available

: Strong oxidizing agents Incompatible materials

Hazardous decomposition : In the event of fire: see section 5

products

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available Inhalation: No data available Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No ingredient of this product present at levels greater than or equal to

0.1% is identified as probable, possible or confirmed human carcinogen

by IARC.

NTP: No ingredient of this product present at levels greater than or equal to

0.1% is identified as a known or anticipated carcinogen by NTP.

No component of this product present at levels greater than or equal to OSHA:

0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues

: Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National regulation

49 CFR Road

Not regulated as a dangerous good

Poison Inhalation Hazard : No

Special precautions for user

Remarks : Not classified as dangerous in the meaning of

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SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : This material does not contain any chemical compo-

nents with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by

SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

TSCA : Product contains substance(s) not listed on TSCA in-

ventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

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AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT -Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA -Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale. Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

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information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.

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