Bayer HealthCare

SAFETY DATA SHEET 122000004992

Magnevist®

Version 5.0 Revision Date 07/02/2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information

Product Name: Magnevist®
MSDS Number: 122000004992

Use : Medical Product

Company
BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
USA
1888-84-BAYER

In case of emergency: 1888-84-BAYER
Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: Colorless to light yellow **Form:** liquid **Odour:** odourless.
This a pharmaceutical product available only with a prescription, for use only as directed. Appropriate route of entry: intravenous Accidental: Injection Skin contact

GHS Classification:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

GHS Label element:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Hazard Communication (29CFR 1910.1200)

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Label Ingredients: Water; Gadopentate dimeglumine salt; Octadecanoic acid; Meglumine;

Other Ingredients

Weight percent	Components	CAS-No.
25 - 50%	Gadopentate dimeglumine salt	92923-57-4
0.05 - 0.1%	Meglumine	6284-40-8

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO2)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Cover spilt product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labelled, closable containers.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

Handling:
Avoid formation of aerosol. Avoid contact with skin, eyes and clothing.

Containers should be kept tightly closed to prevent contamination.

Storage:
Do not expose to light.

Storage temperature: 59 - 86 ℉ (15 - 30 ℃)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:
Recommended Filter type: Organic vapor with prefilter

Hand protection:
Chemically resistant gloves.

Eye protection:
Safety glasses

Other protective measures:
Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	Colorless to light yellow
Odour:	odourless
Odour Threshold:	No applicable information is available

Melting point:	No applicable information is available
Boiling point/boiling range:	99 ℃
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available
Water solubility:	soluble
pH:	6.5 - 8
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	soluble
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.
strong oxidization agents

Thermal decomposition:

no data available

Hazardous decomposition products:
Carbon monoxide (CO), Carbon dioxide (CO2)

Oxidizing properties:

No statements available.

Impact Sensitivity:
no data available

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity:
Oral doses of 40 mL/kg (male rats) and 50 mL/kg (male and female mice)were not lethal and were well tolerated. In dogs, repeated ingestion of 10 mL/kg/day for 30 consecutive days was well tolerated, with only mild gastrointestinal effects.

Skin irritation:
May be irritating., Paravenous, intramuscular, or subcutaneous administration of gadopentetate dimeglumine (0.5 mol/L) caused some reversible, slight to moderate, local irritation in tissues surrounding the injection sites., Gadopentetate dimeglumine did not induce delayed hypersensitivity in the guinea pig maximization test.

Eye irritation:
May be irritating. A single application of a 33% solution of gadopentetate dimeglumine into the conjunctival sac of the rabbit eye caused transient local irritation on the day ofapplication only.

Pharmaceutic effects:
Contrast agent

CMR classification:
Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of gadopentetate dimeglumine. This compound is not listed byIARC, NTP, or OSHA as a carcinogen.
Mutagenicity: Gadopentetate dimeglumine was not mutagenic in invitro (Ames, Chinese hamster lung gene mutation tests) or in vivo (micronucleus tests in mice and dogs after intravenous administration)., In addition, gadopentetate dimeglumine did not induce unscheduled DNA repair in rat hepatocytes or cause cellular transformation of mouse embryo fibroblasts., However, the drug did show some evidence of mutagenic potential in vivo in the mouse dominant lethal assay at doses of 6 mmol/kg, but did not show any such potential in the mouse and dog micronucleus tests at intravenous doses of 9mmol/kg and 2.5 mmol/kg, respectively.
Teratogenicity: Gadopentetate dimeglumine was not teratogenic in pregnant rats or pregnant rabbits given daily intravenous injections of 4.5 mmol Gd/kg (rats) or 3 mmol Gd/kg (rabbits)during organogenesis., Gadopentetate dimeglumine retarded fetal development slightly when given intravenously for 10 consecutive days to pregnant rats at daily doses of 0.25, 0.75, and 1.25 mmol/kg (2.5, 7.5 and 12.5 times the human dose respectively, based on body weight) but not at daily doses of 0.25mmol/kg., No congenital anomalies were noted in rats or rabbits., Fetal mortality and delayed ossification were observed in progeny of pregnant rats given maternally toxic intravenous doses of gadopentetate dimeglumine daily during organogenesis., Adequate and well controlled studies were not conducted in pregnant women.
Reproductive toxicity: Repeated daily intravenous injections of high doses (45 to 50 times the human dose) of gadopentetate dimeglumine to adult rats caused spermatogenic atrophy and maternal toxicity., When administered intra-peritoneally to and female rats daily prior to mating, during mating and during embryonic development for up to 74 days (males) or 35 days (females), gadopentetate caused a decrease in number of corpora lutea at the 0.1 mmol/kg dose level., After daily dosing with 2.5 mmol/kg suppression of food consumption and body weight gain (males and females) and a decrease in the weights of testes and epididymis were also observed., In a separate experiment in rats, daily injections of gadopentetate dimeglumine over 16 days caused spermatogenic cell atrophy at a dose level of 5 mmol/kg but not at a dose level of 2.5mmol/kg., This atrophy was not reversed within a 16-day observation period following the discontinuation of the drug.

Carcinogenicity:
No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:
no data available

STOT - repeated exposure:
no data available

12. ECOLOGICAL INFORMATION

General advice:
No data available for this component. Expected to enter aquatic compartments. Photodegradable

Toxicity to fish:
Gadopentate dimeglumine salt
LC50 > 1,000 mg/l
Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:
Gadopentate dimeglumine salt
EC50 > 100 mg/l
Test species: Daphnia Duration of test: 48 h

Toxicity to bacteria:
Gadopentate dimeglumine salt
EC50 > 1,000 mg/l
tested on: Pseudomonas putida
Duration of test: 16 h

Biodegradability:
Not readily biodegradable.

13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

Contaminated, empty containers are to be treated in the same way as the contents.

14. TRANSPORT INFORMATION

Land transport (CFR)
Non-Regulated

US Sea transport (IMDG)
Non-Regulated

US Air transport (ICAO / IATA cargo aircraft only)
Non-Regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)
Non-Regulated

International IATA	- -
IMDG	- -

15. REGULATORY INFORMATION

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components
None

SARA Section 311/312 Hazard Categories Non-hazardous under Section 311/312

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components
None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
40 - 70%	Water	7732-18-5

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Non-Hazardous

16. OTHER INFORMATION

NFPA 704M Rating

Health	0

Flammability	1
Reactivity	0
Other	

0=Insignificant 1=Slight 2=Moderate 3=High 4=Extreme

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.