MATERIAL SAFETY DATA SHEET

Bayer HealthCare Pharmaceuticals Inc
6 West Belt
Wayne, NJ 07470

TRANSPORTATION EMERGENCY
CALL CHEMTREC..... : (800) 424-9300

INTERNATIONAL ..... : (703) 527-3887

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (888) 84-BAYER
BAYER INFORMATION PHONE: (888) 84-BAYER

Section 1: Product and Company Identification

Product Name: Magnevist® Injection
Material Number: PH003259

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Ingredient Name/ CAS Number	Exposure Limits	Concentration Min.	Concentration Max.
Gadopentate dimeglumine	**OSHA (PEL):** **ACGIH (TLV):**		38.8%
Meglumine 6284-40-8	**OSHA (PEL):** Not Established **ACGIH (TLV):** Not Established		0.08%
Diethylenetriamine pentaacetic acid 67-43-6	**OSHA (PEL):** **ACGIH (TLV):**		0.03%
Water 7732-18-5	**OSHA (PEL):** Not Established **ACGIH (TLV):** Not Established		61.09%

Section 3: Hazards Identification

EMERGENCY OVERVIEW

CAUTION! **Color:** Clear, Colorless to light yellow **Form:** Liquid **Odor:** Odorless
This a pharmaceutical product available only with a prescription, for use only as directed.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Accidental:, Injection, Skin Contact, Appropriate route of entry:, Intravenous

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Human Health Effects Postnote: This a pharmaceutical product available only with a prescription, for use only as directed.

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush with copious amounts of water for at least 15 minutes. Use fingers to ensure that eyelids are separated and that the eye is being irrigated. Get medical attention if irritation develops or persists.

First Aid for Skin: In case of skin contact, wash affected areas with soap and water.

First Aid for Inhalation: Not an expected entry route.

First Aid for Ingestion: Not an expected entry route.

Section 5: Fire Fighting Measures

Flash Point: Not Applicable

Flammable Limits:

Upper Explosion Limit (UEL %): Not Applicable

Lower Explosion Limit (LEL %): Not Applicable

Auto-ignition Temperature: Not Applicable

Extinguishing Media:

Suitable: Carbon Dioxide, Foam, Dry Chemical, as appropriate for the source

of the fire.

Section 6: Accidental Release Measures

Spill or Leak Procedures: Use appropriate personal protective equipment during clean up. Absorb material and place in appropriate containers for disposal. Wash spill area with soap and water.

Section 7: Handling and Storage

Storage Temperature:
Minimum: 59 °F (15 °C)
Maximum: 86 °F (30 °C)

Handling/Storage Precautions: Protect from light. Keep container tightly closed.

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment
Eye Protection Requirements: None for normal use.

Skin Protection Requirements: No special skin protection requirements during normal handling and use., Wear gloves during clean-up.

Ventilation Requirements: Under normal conditions of use, special ventilation is not required.

Respirator Requirements: Under normal conditions of use, respiratory protection is not required.

Section 9: Physical and Chemical Properties

Physical Form: Liquid
Color: Clear, Colorless to light yellow
Odor: Odorless
pH: 6.5 - 8
Boiling Point: 99 °C
Solubility in Water: Soluble

Section 10: Stability and Reactivity

Stability: Stable

Hazardous Polymerization: Will not occur

Substances to Avoid: Strong oxidizing agents

Decomposition Products: None known.

Section 11: Toxicological Information

Toxicity Data for Magnevist® Injection

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.

Acute inhalation toxicity: Not tested.

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 of application only.

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.

Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of gadopentetate dimeglumine. This compound is not listed by IARC, 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.

Developmental Toxicity/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. Fetal mortality and delayed ossification were observed in progeny of pregnant rats given maternally toxic intravenous doses of gadopentetate dimeglumine daily during organogenesis.

Toxicity to Reproduction/Fertility: 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.

Section 12: Ecological Information

Ecological Data for Magnevist® Injection

Biodegradation: Not readily biodegradable

Ecological Note: No data available for this product., Expected to enter aquatic compartments., Photodegradable

Section 13: Disposal Considerations

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

Section 14: Transportation Information

Technical shipping name: Pharmaceutical

Domestic Surface Transportation (DOT)

Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)

Hazard Class Division Number: Non-Regulated

Air Transportation (ICAO / IATA)

Hazard Class Division Number: Non-Regulated

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Rating: Not subject to OSHA

Non-Hazardous

TSCA Inventory List: **This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.**

CERCLA Hazardous Substance:

Component(s)	Reportable Quantity
None	

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

Component(s)/ CAS Number	Concentration Min.	Concentration Max.
None		

SARA Section 313 Toxic Chemicals:

Component(s)/ CAS Number	Reporting Threshold	Concentration Min.	Concentration Max.
None			

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

Component(s)/ CAS Number	**State Code**	**Concentration Min.**	**Concentration Max.**
Water 7732-18-5	PA-N, NJ-N	40%	70%

State Code Translation Table

PA-N = Pennsylvania Non-hazardous
NJ-N = New Jersey Other - includes predominant ingredients

Section 16: Other Information

Contact: Product Safety Department
Phone: (888) 84-BAYER
MSDS Number: 000000003259
Version Date: 04/10/2008
MSDS Version: 1.0

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Bayer HealthCare Pharmaceuticals Inc. The data on this sheet relates only to the specific material designated herein. Bayer HealthCare Pharmaceuticals Inc assumes no legal responsibility for use or reliance upon these data.

Indicates Relevant Change Made.