



MATERIAL SAFETY DATA SHEET

BAYER HEALTHCARE PHARMACEUTICALS INC.

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NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (888) 842-2937
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Section 1: Product and Company Identification

Product Name: Eovist Injection

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

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

<u>Ingredient Name/ CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Gadoxetate disodium 135326-22-6	OSHA (PEL): ACGIH (TLV):		30%
Caloxetic acid trisodium 153924-80-2	OSHA (PEL): ACGIH (TLV):		1%
TRIS(HYDROXYMETHYL)AMINOMETHANE 77-86-1	OSHA (PEL): ACGIH (TLV):		1%
Hydrochloric Acid, NF 7647-01-0	OSHA (PEL): 5.00 ppm CEIL 7.00 mg/m3 CEIL ACGIH (TLV): 5.00 ppm CEIL 7.50 mg/m3 CEIL		1%

Material Name: Eovist Injection

Sodium hydroxide
1310-73-2

OSHA (PEL):
2.00 mg/m3 TWA
ACGIH (TLV):
2.00 mg/m3 CEIL

1%

Water
7732-18-5

OSHA (PEL):
Not Established
ACGIH (TLV):
Not Established

85%

Section 3: Hazards Identification

EMERGENCY OVERVIEW

Form: Liquid

This a pharmaceutical product available only with a prescription, for use only as directed.

POTENTIAL HEALTH EFFECTS

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush eyes with plenty of water for at least 15 minutes.

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

First Aid for Inhalation: If inhaled, remove to fresh air. Call a physician.

First Aid for Ingestion: If ingested, seek medical attention.

Section 5: Fire Fighting Measures

Flash Point: Not Applicable

Flammable Limits:

Upper Explosion Limit (UEL %): Not Applicable

Lower Explosion Limit (LEL %): Not Applicable

Extinguishing Media:

Suitable: Water spray, Foam, Dry Chemical, Carbon Dioxide

Unsuitable: Water stream

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. Prevent from entering open drains and waterways.

Section 7: Handling and Storage**Storage Temperature:**

Minimum: 59 °F (15 °C)

Maximum: 86 °F (30 °C)

Shelf Life: See expiration date on product container label

Special Sensitivity: Store in a cool dry place, away from oxidizing agents and flammable liquids.

Handling/Storage Precautions: Keep this and all drugs out of the reach of children. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug. Avoid extreme heat. Protect from light. Store separate from food products. Avoid contact with eyes and skin. Wash thoroughly after handling.

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.

Ventilation Requirements: Use local and general exhaust ventilation to control levels of exposure.

Work Practices: Use caution. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.

Additional Protective Measures: Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

Section 9: Physical and Chemical Properties

Physical Form: Liquid

Section 10: Stability and Reactivity

Stability: Stable

Hazardous Polymerization: Will not occur

Conditions to Avoid: None known.

Decomposition Products: Carbon Dioxide, Carbon monoxide

Section 11: Toxicological Information

Toxicity Data for Eovist Injection

Toxicity Note: No data available for this product.

Toxicity Data for Gadoxetate disodium

Toxicity Note: No data available for this component.

Section 12: Ecological Information

Ecological Data for Eovist Injection

Ecological Note: No data available for this product.

Ecological Data for Gadoxetate disodium

Ecological Note: No data available for this component.

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

Material Name: Eovist Injection

Marine Transportation (IMO / IMDG)

Hazard Class Division Non-Regulated

Number:

Air Transportation (ICAO / IATA)

Hazard Class Division Non-Regulated

Number:

Section 15: Regulatory Information**United States Federal Regulations**OSHA Hazcom Standard Not subject to OSHA
Rating: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)

None

Reportable Quantity**SARA Title III****SARA Section 302 Extremely Hazardous Substances:**Component(s)/CAS Number

None

ConcentrationMin.Max.SARA Section 311/312 Hazard Exempt from SARA Section 311/312
Categories:**SARA Section 313 Toxic Chemicals:**Component(s)/CAS Number

None

ReportingThresholdConcentrationMin.Max.**RCRA Status:**

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)

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 InformationComponent(s)/CAS Number

Water

7732-18-5

State Code

PA-N, NJ-N

ConcentrationMin.Max.

60%

100%

The following component(s) are listed under New Jersey Special Hazards:

Hydrochloric Acid, NF	NJ-S	0.1%	1%
7647-01-0			

The following component(s) are listed under Massachusetts Extra-ordinary Hazards:

Hydrochloric Acid, NF	MA-X	0.1%	1%
7647-01-0			

State Code Translation Table

PA-N = Pennsylvania Non-hazardous

NJ-N = New Jersey Other - includes predominant ingredients

NJ-S = New Jersey Special Health Hazardous Substance List

MA-X = Massachusetts Extra-ordinary Hazardous Substance List

Section 16: Other Information

Contact: Product Safety Department

Phone: (888) 84-BAYER

MSDS Number: 000000003391

Version Date: 06/26/2008

MSDS Version: 1.0

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|| Indicates Relevant Change Made.