



SAFETY DATA SHEET

122000005016

Eovist® Injection

Version 2.0

Revision Date 06/30/2010

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: Eovist® Injection
Generic name: Primovist
MSDS Number: 122000005016

Use : Medicinal products

Company

BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals Inc.
6 West Belt
Wayne, NJ 07470
UNITED STATES
1888-84-BAYER

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

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: clear, colourless to yellow **Form:** liquid
This a pharmaceutical product available only with a prescription, for use only as directed.

Hazard Communication (29CFR 1910.1200)

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Other Ingredients	Components	CAS-No.
Weight percent <=30%	Gadoxetate disodium	135326-22-6

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<=1%	Caloctic acid	135306-78-4
<=1%	Tris(hydroxymethyl)aminomethane	77-86-1
<=1%	Hydrochloric acid	7647-01-0
<=1%	Sodium hydroxide	1310-73-2
<=85%	Water	7732-18-5

4. FIRST AID MEASURES

If inhaled: If inhaled, remove to fresh air. Call a physician.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

If swallowed: Rinse mouth with water. Obtain medical attention.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray jet, Foam, Dry powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media: High volume water jet

Specific hazards during fire fighting: Fire may cause evolution of: Carbon dioxide (CO₂) Carbon monoxide

Special protective equipment for fire-fighters: 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: Soak up with inert absorbent material. Flush with plenty of water.

Additional advice: Never return spills in original containers for re-use.

Further Accidental Release Notes Never return spills in original containers for re-use.

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7. HANDLING AND STORAGE**Handling:**

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 and cold. Protect from light, moisture and damage. Store separate from food products. Avoid contact with skin, eyes and clothing. Wash ... thoroughly after handling.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Storage:

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

Storage temperature: 59 - 86 °F (15 - 30 °C)

See expiration date on product container label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Hydrochloric acid (7647-01-0)**

US. ACGIH Threshold Limit Values

Ceiling Limit Value: 2 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Ceiling Limit Value and Time Period (if specified): 5 ppm, 7 mg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Ceiling Limit Value: 5 ppm, 7 mg/m³

Sodium hydroxide (1310-73-2)

US. ACGIH Threshold Limit Values

Ceiling Limit Value: 2 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards

Ceiling Limit Value and Time Period (if specified): 2 mg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

PEL: 2 mg/m³

Respiratory protection:

No personal respiratory protective equipment normally required.

Hand protection:

PVC disposable gloves

Eye protection:

Safety glasses with side-shields

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Skin and body protection:

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures:

Use protective skin cream before handling the product. Keep away from food and drink.

Other protective measures:

Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	clear, colourless to yellow
Boiling point/boiling range:	no data available
Density:	no data available
Vapour pressure:	no data available
Viscosity, dynamic:	no data available
Miscibility with water:	no data available
pH:	6.8 - 8 at (68 °F (20 °C))
Partition coefficient (n-octanol/water):	no data available
Ignition temperature:	not determined

10. STABILITY AND REACTIVITY

Conditions to avoid: None known.

Materials to avoid: Oxidizing agents

Hazardous reactions: Stable

Thermal decomposition:

no data available

Hazardous decomposition products:

Carbon monoxide, Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION**Other information on toxicity:**

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No data is available on the product itself.

Acute oral toxicity:

Gadoxetate disodium

LD50 rat: 18,100 mg/kg

LD50 mouse: 14,500 mg/kg

Acute toxicity (other routes of administration):

Gadoxetate disodium

LD50 intravenous rat: 3,600 - 7,300 mg/kg

LD50 intravenous mouse: 5,400 - 10,900 mg/kg

LD50 intravenous dog: > 2,200 mg/kg

Skin irritation:

Gadoxetate disodium

Result: No skin irritation

Eye irritation:

Gadoxetate disodium

Result: No eye irritation

Sensitisation:

Gadoxetate disodium

Result: According to experience not expected

Pharmaceutic effects:Contrast agent

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Gadoxetate disodium

LC50 > 1,000 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

Gadoxetate disodium

EC50 > 100 mg/l

Test species: Daphnia Duration of test: 48 h

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

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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.

14. TRANSPORT INFORMATION

Land transport (DOT)

Non-Regulated

Inland waterway transport

Non-Regulated

Railway transport

Non-Regulated

Sea transport (IMDG)

Non-Regulated

Air transport (ICAO / IATA cargo aircraft only)

Non-Regulated

Air transport (ICAO / IATA passenger and cargo aircraft)

Non-Regulated

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

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.
60 - 100%	Water	7732-18-5

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight percent	Components	CAS-No.
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0.1 - 1%	hydrochloric acid	7647-01-0
0.1 - 1%	Sodium hydroxide	1310-73-2

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 Not subject to OSHA

16. OTHER INFORMATION**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.