



## SAFETY DATA SHEET

122000004982

**Gadavist™**

Version 1.0

Revision Date 03/15/2011

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

**Product Name:** Gadavist™  
**MSDS Number:** 122000004982

**Use** : Medical Product

**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

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**2. HAZARDS IDENTIFICATION****Emergency Overview**

**WARNING! Form:** liquid  
Appropriate route of entry: Injection May cause skin irritation. May cause eye irritation.

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**Hazard Communication (29CFR 1910.1200)**

This product is not covered under the OSHA Hazard Communication Standard.

**Acute Effects of Exposure** Acute overexposure to this product may cause: Nausea  
Vomiting

**Medical Conditions Aggravated by Exposure** See product packaging for further information., This is a pharmaceutical material.

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

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### 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; Gadobutrol; Trometamol; Calciumbutrol; Hydrochloric Acid; Sodium Hydroxide;

**Other Ingredients**

<b>Weight percent</b>	<b>Components</b>	<b>CAS-No.</b>
40 - 50%	Gadobutrol	138071-82-6
0.01 - 0.05%	Calciumbutrol	151878-23-8
<0.1%	Tris(hydroxymethyl)aminomethane	77-86-1

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### 4. FIRST AID MEASURES

**Contact Number:** Use the Bayer Emergency Number in Section 1

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### 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:** Water spray jet, Foam, Dry powder, Carbon dioxide (CO<sub>2</sub>)

**Unsuitable extinguishing media:** High volume water jet

**Specific hazards during fire fighting:** Fire may cause evolution of: Carbon dioxide (CO<sub>2</sub>)  
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.

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### 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:**

Avoid contact with skin, eyes and clothing.

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

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Other protective measures:**

Wear suitable protective equipment.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Boiling point/boiling range:	no data available
Density:	no data available
Vapour pressure:	no data available
Viscosity, dynamic:	no data available
Miscibility:	no data available
pH:	no data available
Partition coefficient (n-octanol/water):	no data available
Flash point:	no data available
Ignition temperature:	not determined

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## 10. STABILITY AND REACTIVITY

**Conditions to avoid:** no data available

**Materials to avoid:** Oxidizing agents

**Hazardous reactions:** None known.

**Thermal decomposition:**

no data available

**Hazardous decomposition products:**

Carbon monoxide, Carbon dioxide (CO<sub>2</sub>)

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

No data is available on the product itself.

**Acute oral toxicity:**

Gadobutrol

LD50 rat: > 12,000 mg/kg

Tris(hydroxymethyl)aminomethane

LD50 rat: 5,900 mg/kg

**Acute toxicity (other routes of administration):**

Gadobutrol

LD50 intravenous rat: > 9,000 mg/kg

**Skin irritation:**

Gadobutrol

Result: No skin irritation

Tris(hydroxymethyl)aminomethane

Result: Moderate skin irritation

May cause skin irritation and/or dermatitis.

**Eye irritation:**

Tris(hydroxymethyl)aminomethane

Result: Moderate eye irritation

Danger of corneal opacity.

**Sensitisation:**

Gadobutrol

Result: According to experience not expected

**Pharmaceutic effects:**

Contrast agent

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**12. ECOLOGICAL INFORMATION****General advice:**

No information on ecology is available.

Do not allow to enter surface waters or groundwater.

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**Toxicity to daphnia and other aquatic invertebrates.:**

Gadobutrol

static test EC50 &gt; 100 mg/l

Test species: Daphnia Duration of test: 48 h

Method: OECD Test Guideline 202

NOEC 10,000 mg/l

**Toxicity to algae:**

Gadobutrol

EC50 &gt; 100 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Method: OECD Test Guideline 201

**Biodegradability:**

Tris(hydroxymethyl)aminomethane

98 %, 28 d Readily biodegradable

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**13. DISPOSAL CONSIDERATIONS**

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

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**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

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**15. REGULATORY INFORMATION**

**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

**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**      Hazardous

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**16. OTHER INFORMATION****HMIS Rating**

<b>Health</b>	1
<b>Flammability</b>	0
<b>Physical Hazard</b>	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

\* = Chronic Health Hazard

The personal protective equipment of chapter 8 is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

**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.