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

Product information
Product Name: Gadavist™
MSDS Number: 12200004982

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
Chemetrec: (800) 424-9300

2. HAZARDS IDENTIFICATION

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

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 Aggrevated by Exposure
See product packaging for further information., This is a pharmaceutical material.

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.

Label Ingredients: Water; Gadobutrol; Trometamol; Calciumbutrol; Hydrochloric Acid; Sodium Hydroxide;

Other Ingredients

<table>
<thead>
<tr>
<th>Weight percent</th>
<th>Components</th>
<th>CAS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 - 50%</td>
<td>Gadobutrol</td>
<td>138071-82-6</td>
</tr>
<tr>
<td>0.01 - 0.05%</td>
<td>Calciumbutrol</td>
<td>151878-23-8</td>
</tr>
<tr>
<td>&lt;0.1%</td>
<td>Tris(hydroxymethyl)aminomethane</td>
<td>77-86-1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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.
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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Other protective measures:
Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>liquid</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>no data available</td>
</tr>
<tr>
<td>Density</td>
<td>no data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>no data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>no data available</td>
</tr>
<tr>
<td>Miscibility</td>
<td>no data available</td>
</tr>
<tr>
<td>pH</td>
<td>no data available</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>no data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>no data available</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>not determined</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

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

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

12. ECOLOGICAL INFORMATION

General advice:
No information on ecology is available.

Do not allow to enter surface waters or groundwater.
Toxicity to daphnia and other aquatic invertebrates:
Gadobutrol
static test EC50 > 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 > 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

13. DISPOSAL CONSIDERATIONS
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. 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

16. OTHER INFORMATION

HMIS Rating

<table>
<thead>
<tr>
<th>HMIS Rating</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>1</td>
</tr>
<tr>
<td>Flammability</td>
<td>0</td>
</tr>
<tr>
<td>Physical Hazard</td>
<td>0</td>
</tr>
</tbody>
</table>

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.