



SAFETY DATA SHEET

122000004982

Gadavist®

Version 3.0

Revision Date 07/02/2014

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
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
USA
1888-84-BAYER

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

2. HAZARDS IDENTIFICATION**Emergency Overview**

WARNING! Colour: clear, colourless, to, yellowish **Form:** liquid
Appropriate route of entry: Injection May cause skin irritation. May cause eye irritation.

GHS Classification:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

GHS Label element:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Hazard Communication (29CFR 1910.1200)

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

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Medical Conditions Aggravated by Exposure

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

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

| Weight percent | Components | CAS-No. |
|-----------------------|---------------------------------|----------------|
| 50% | Gadobutrol | 770691-21-9 |
| 0.09% | Tris(hydroxymethyl)aminomethane | 77-86-1 |

4. FIRST AID MEASURES

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon dioxide (CO₂) Carbon monoxide (CO)

Special protective equipment for firefighters: 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.

No special protective measures against fire required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|------------------------------|--|
| Form: | liquid |
| Colour: | clear, colourless, to, yellowish |
| Odour: | No applicable information is available |
| Odour Threshold: | No applicable information is available |
| Melting point: | No applicable information is available |
| Boiling point/boiling range: | No applicable information is available |
| Density: | 1.3 g/cm ³ at 68 °F (20 °C) |
| Bulk density: | No applicable information is available |
| Vapour pressure: | No applicable information is available |
| Viscosity, dynamic: | 8.86 mPa.s at 68 °F (20 °C) 4.96 mPa.s at 98.6 °F (37 °C) |
| Viscosity, kinematic: | No applicable information is available |
| Flow time: | No applicable information is available |
| Surface tension: | No applicable information is available |
| Miscibility with water: | No applicable information is available |
| Water solubility: | Product is highly soluble. |
| pH: | 6.6 - 8.0 |
| Relative density: | No applicable information is available |
| Partition coefficient: | No applicable information is available |

| | |
|----------------------------|--|
| Solubility(ies): | No applicable information is available |
| Flash point: | no data available |
| Flammability (solid, gas): | No applicable information is available |
| Ignition temperature: | No applicable information is available |
| Explosion limits: | No applicable information is available |

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 (CO), Carbon dioxide (CO₂)

Oxidizing properties:

No statements available.

Impact Sensitivity:

no data available

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

The substance or mixture has no acute oral toxicity

Acute toxicity (other routes of administration):

Gadobutrol

LD50 intravenous rat: > 9,000 mg/kg

Tris(hydroxymethyl)aminomethane

LD50 intravenous rat: 1,800 mg/kg

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LD50 intravenous mouse: 1,210 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: Severe eye irritation

Danger of corneal opacity.

Sensitisation:

Gadobutrol

According to experience not expected

Genotoxicity in vitro:

Gadobutrol

Ames test Salmonella typhimurium

Result: negative

Tris(hydroxymethyl)aminomethane

In vitro tests did not show mutagenic effects

Pharmaceutic effects:

Contrast agent

Carcinogenicity:

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

STOT - single exposure:

no data available

STOT - repeated exposure:

no data available

12. ECOLOGICAL INFORMATION**General advice:**

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

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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:

Gadobutrol

44 %, 29 d not rapidly biodegradable

Not toxic to the microbes of activated sludge.

Tris(hydroxymethyl)aminomethane

89 %, 28 d rapidly biodegradable

Bioaccumulation:

Tris(hydroxymethyl)aminomethane

Bioaccumulation is unlikely.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION**Land transport (CFR)**

Non-Regulated

US Sea transport (IMDG)

Non-Regulated

US Air transport (ICAO / IATA cargo aircraft only)

Non-Regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

Non-Regulated

International IATA

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IMDG

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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

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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 Non-Hazardous

16. OTHER INFORMATION**HMIS Rating**

| | |
|------------------------|---|
| Health | 1 |
| Flammability | 0 |
| Physical Hazard | 0 |

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

* = Chronic Health Hazard

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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.