

MATERIAL SAFETY DATA SHEET
DOTAREM®

SECTION 1. IDENTIFICATION

Product Name: Dotarem®
Chemical Name: Gadoterate Meglumine (active ingredient)

Manufactured for and Distributed By:

Guerbet LLC
120 W 7th Street, Suite 108
Bloomington, IN 47404 USA
812-333-0059

Information Telephone Number: 877-729-6679

American Association of Poison Control Centers:
800-222-1222

Product Use: Diagnostic contrast agent

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of substance

The product is not classified according to regulation.

2.2 Label elements

Labelling according to regulation.

EMERGENCY OVERVIEW

Read Package Insert prior to use.

Ensure prompt removal from skin, eyes and clothing. As part of good laboratory and personal hygiene and safety and safety procedure, avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Inhalation: Not expected to be a health hazard via inhalation.

Ingestion: Do not drink and do not induce vomiting, seek medical advice.

Skin Contact: Rinse with water and soap.

Eye Contact: Rinse immediately with abundant water and continue to rinse for 15 min. Seek advice from an ophthalmologist if irritation persists.

Chronic Exposure: See section 11

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Component</u>	<u>CAS #</u>	<u>Wt %</u>
Gadoterate Meglumine	92943-93-6	37.7%
Proprietary Components	-	62.3%

Synonyms: Gd-DOTA, Gadoteric Acid

SECTION 4. FIRST AID MEASURES

Inhalation: Not expected to require first aid measures.

Skin Exposure: Wash exposed area with water. Get medical advice if irritation develops.

Ingestion: Do not give water to drink, do not induce vomiting and seek medical advice.

Eye Exposure: In case of contact, immediately flush and rinse eyes with plenty of water for at least 15 minutes. Seek medical advice if irritation develops.

SECTION 5. FIRE FIGHTING MEASURES

Flammability: Not a flammable material.

Fire/Explosion Hazards: Not considered to be a fire or explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions:

- As in any fire, fire-fighters should wear normal protective equipment and positive-pressure self-contained breathing apparatus.
- Prevent fire extinguishing water from contaminating surface or ground water

SECTION 6. ACCIDENTAL RELEASE MEASURES

Clean up with water. Avoid contact with skin and eyes. Clean-up personnel may require protective clothing. Do not release in drains. Containerize unusable material for disposal in an approved waste facility. Ensure compliance with local, state and federal regulations.

SECTION 7. HANDLING AND STORAGE

Keep in a closed container, stored in a dry, ventilated area, at room temperature (25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)). Protect against physical damage.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits: None established. The product is considered not to be hazardous and has no occupational exposure limits established for it.

Engineering Controls: Use ventilation.

Respiratory Protection: (NIOSH Approved) Not expected to require personal respiratory usage.

Eye/Face Protection: Wear glasses.

Skin Protection: Wear protective gloves, lab coat or special protective garment

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless to yellow solution.

Odor: Odorless.

Solubility: Water-miscible.

Boiling Point: No information found.

Melting Point: No information found.

Density: 1.1753 g/cm³ at 20°C

Vapor Density (Air=1): No information found.

Vapor Pressure (mm Hg): No information found.

Evaporation Rate: No information found.

pH: 6.5 to 8.0

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary condition of usage and storage.

Hazardous Decomposition Products: None.

Hazardous Polymerization: None.

Incompatibilities: None.

NFPA Ratings: Health: 0 Fire: 0 Reactivity: 0

SECTION 11. TOXICOLOGICAL INFORMATION

No LD50/LC50 information found relating to normal routes of occupational exposure.

LD50 mice intravenous = 11.4 mmol/kg. LD50 mice oral route > 25.3 mmol/kg. LD50 rat intravenous > 14.5 mmol/kg.

CMR effects:

- Carcinogenicity: no data available.
- Mutagenicity: not mutagenic in the in vitro Ames test, in an in vivo gene mutation assay (V79 Chinese hamster cells), in an in vitro chromos aberration test on Chinese hamster ovary (CHO) cells and in an in vivo micronucleus test in mice (intravenous route). Reproductive and Developmental Toxicity: no effect on fertility and reproductive performance in rats (intravenous route). Not embryotoxic or teratogenic in rats and rabbits (intravenous route).

For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Compliance Department. Read Package Insert.

SECTION 12. ECOLOGICAL INFORMATION

No risk to aquatic organisms in the water column. No risks to microorganisms in water sewage plants. No risk to sediment-dwelling organisms. Not readily biodegradable. No bioaccumulative potential (logKow=2.23 at pH 7.0). Not PBT or vBvB.

SECTION 13. DISPOSAL CONSIDERATIONS

If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly.

If not a biohazard, waste Dotarem[®] is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

Not regulated as a Hazardous Material by the Department of Transportation. Outside the EU, refer to local or national regulations.

SECTION 15. REGULATORY INFORMATION

SARA Title III

302 Extremely Hazardous Substances: None.

313 Toxic substances subject to annual release reporting requirements: None.

WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

CERCLA Reportable Quantities: Not applicable.

Australian Poison Schedule: None allocated.

California Proposition 65 Warning: Not applicable.

Australian Hazchem Code: None allocated.

RCRA Hazardous Waste Status

Non-hazardous (See Section 13 for details).

SECTION 16. OTHER INFORMATION

Revision Date: May 28, 2015

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.