



MATERIAL SAFETY DATA SHEET

OptiMARK®

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: OptiMARK®
Synonyms: Gadoversetamide injection

Manufacturer: Mallinckrodt Inc.
P. O. Box 5840
St. Louis, MO 63134

Revision Date: January 1, 2003
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314) 654-1600
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

<u>Component</u>	<u>CAS #</u>	<u>Percent</u>
Gadoversetamide	131069-91-5	33%
Versetamide	129009-83-2	2.5%
Water	7732-18-5	64.5%

SECTION 3. HAZARDS IDENTIFICATION

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 procedure, avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

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

Ingestion:
Excessive oral doses may cause gastrointestinal disturbances.

Skin Contact:
No adverse effects expected but may cause minor skin irritation.

Eye Contact: No adverse health effects expected, but splashes may cause irritation.

Chronic Exposure:
No adverse health effects expected.

Aggravation of Pre-existing Conditions:
No information found.

OptiMARK®

SECTION 4. FIRST AID MEASURES

Inhalation:

Not expected to require first aid measures.

Ingestion:

If large amounts were swallowed, give water to drink and get medical advice.

Skin Contact:

Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

SECTION 5. FIRE FIGHTING MEASURES

Fire: Not considered to be a fire hazard.

Explosion Hazards: Not considered to be an explosion hazard.

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

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Small spills may be mopped up or flushed to sewer. Large spills may be collected for disposal or absorbed with an inert material and containerized for disposal. Flush any residue with copious amounts of water.

SECTION 7. HANDLING AND STORAGE

OptiMARK® Injection should be stored at controlled room temperature, 20°C to 25°C (68°F to 77°F) and protected from light and freezing.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:

None established.

Ventilation Systems:

Not expected to require any special ventilation.

Personal Respirators (NIOSH Approved):

Not expected to require personal respirator usage.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless to slightly yellow solution.

Odor: Odorless.

Specific Gravity: 1.16 g/ml at 25° C.

ph: 5.5 - 6.8

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.

Hazardous Polymerization: Will not occur.

Incompatibilities: No information found.

SECTION 11. TOXICOLOGICAL INFORMATION

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

For detailed toxicological information on specific components, write to the address listed in Section 1 - Attn: Professional Services Department.

SECTION 12. ECOLOGICAL INFORMATION

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

Collected spills may be flushed to sewer with large amounts of water. Containerized material may be disposed in an approved waste facility.

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 OptiMARK® is considered non-hazardous.

Dispose of container and unused contents in accordance with federal, state and local requirements.

SECTION 14. TRANSPORT INFORMATION

Not regulated as a Hazardous Material by the Department of Transportation.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:None

SARA Title III

302 Extremely Hazardous Substances: None

311/312 Hazard Categories: None

313 Toxic substances subject to annual release reporting requirements: None

RCRA Hazardous Waste Status

Non-hazardous (See Section 13 for additional details.)

California Proposition 65 Warning:

Not Applicable.

Australian Hazchem Code: None allocated.

Australian Poison Schedule: None allocated.

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.

SECTION 16. OTHER INFORMATION

MSDS Status: Prepared in accordance with ANSI Guideline Z400.1-1998.

NFPA Ratings: Health: 0 Flammability: 0 Reactivity: 0

Product Use: MRI imaging agent.

Revision Information: No changes.

Mallinckrodt provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER

EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

tyco / Healthcare

MALLINCKRODT

