

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Omniscan®
Synonyms: WIN 50678 Injection
Applications: Magnetic Resonance Imaging Agent
Emergency Number: In an emergency, call 1-800-654-0118
Manufacturer: Amersham Health
101 Carnegie Center
Princeton, NJ 08540-9998
609-514-6000 or 1-800-654-0118

2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient Name</u>	<u>CAS No.</u>	<u>Percent by Weight</u>
Water	7732-18-5	> 25.0
Gadodiamide*	122795-43-1	> 25.0
Caldiamide Sodium	12260-91-2	1.0 to 5.0

* - Sterling Health Protection Guide
TWA: 5mg/m³, STEL: 10mg/m³

3. HAZARDS IDENTIFICATION

***** EMERGENCY OVERVIEW *****

A colorless to pale yellow aqueous solution. Presents little or no hazard if spilled or in a fire.

WARNING: This is a pharmaceutical material available only with a prescription - use only as directed.

4. FIRST AID MEASURES

Eyes: In case of eye contact, flush eyes with plenty of water for at least 15 minutes.
Seek medical attention if irritation develops.

Skin: Wash thoroughly with soap and water.

Ingestion: In case of overdosage, seek medical attention or contact the Poison Control Center for further information or instructions.

Inhalation: Not an expected route of entry.

5. FIRE FIGHTING MEASURES

Flammable Properties: Nonflammable. This is an aqueous-based formulation.

Extinguishing Media: Use any extinguishing agent which is suitable for the surrounding fire.

Fire Fighting Procedures: Use normal fire fighting gear.

Unusual Fire and Explosion Hazards: None known

6. ACCIDENTAL RELEASE MEASURES

Spills: Contain the spill by placing paper towels or a suitable absorbent material around the edges of the spill and work inward. Carefully scoop up into a properly labeled waste container for disposal. Wash area of spill to remove from surfaces.

7. HANDLING AND STORAGE

Handling and Storage Precautions: Keep this and all drugs out of the reach of children.

Work/Hygienic Practices: Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Normal ventilation.

Eye/Face Protection: None normally required. Avoid eye contact.

Skin Protection: None normally required. Gloves should be worn to clean up spills.

Respiratory Protection: None normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear liquid

Color: Colorless to pale yellow

Solubility in Water: Soluble

Specific Gravity: Not applicable

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Materials to Avoid: None known

**Hazardous
Decomposition
Products:** None known

**Hazardous
Polymerization:** Will not occur

11. TOXICOLOGICAL INFORMATION

Subchronic (Target Organ Effects): General adverse reactions in human and animal studies were mild to moderate. These reactions included nausea, vomiting, cardiovascular effects, dizziness, headache, and kidney effects. Only kidney effects are thought to be due to the drug itself. Headaches, lightheadedness, dizziness, drowsiness, and nausea are likely related to the hypertonic properties of the formulation administered via the intravenous route. These effects are not expected to be observed in the occupational setting.

Carcinogenicity: NTP: No, IARC: No, OSHA: No

Test	Species	Result
Oral LD ₅₀	Mice	19.7g/kg
Min. lethal dose	Rat	11.5g/kg
Skin Sensitization	Guinea pig	Negative
Antigenicity (in-vitro)	Human serum complement factors	Negative
Mutagenicity	S. typhimurium E. coli	Negative at all dosage levels with and without S-9 activation.
Genotoxicity	CHO Mouse micronucleus	Negative

12. ECOLOGICAL INFORMATION

Microbial Growth Inhibition (EC₅₀): >1000 mg/l

Aerobic Biodegradation (t_{1/2}): 121 hrs. - A. Niger microbe

Acute Aquatic Toxicity

Daphnia (EC₅₀): >1000 mg/l

No negative impact projected on wastewater pretreatment, biotreatment, or elementary neutralization facilities during normal operations.

13. DISPOSAL CONSIDERATIONS

Disposal Methods: As of the MSDS revision date, this product does not meet the United States EPA definition of a hazardous waste. Dispose in accordance with local, state and federal regulations.

14. TRANSPORT INFORMATION

Proper Shipping Name: Non-regulated

15. REGULATORY INFORMATION

U. S. Federal Regulations:

This product does **not** contain any ingredients which are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372) above the de minimus threshold, and is therefore not subject to release reporting under Section 313 of EPCRA.

16. OTHER INFORMATION

Revision Date: April 2003 (company name and emergency number)

Reference

Documentation: Primary references used in the preparation of this document:

1. OMNISCAN® Package Insert
2. OMNISCAN® MSDS (Sterling Winthrop).
3. ACGIH Guide to Occupational Exposure Values - 1991
4. Sterling Winthrop Corporate Quality Pharmaceutical File - 2/10/89

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