

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Omnipaque®

Synonyms: Omnipaque® 140 mg I/ml, 180 mg I/ml, 210 mg I/ml, 240 mg I/ml, 300mg/ml and 350 mg I/ml Injection

Applications: Radiodiagnostic

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>
Iohexol*	66108-95-0	> 25.0
Water	7732-18-5	> 25.0

* - Sterling Health Protection Guide:
5mg/m³ 8-hr TWA, 10mg/m³ STEL

3. HAZARDS IDENTIFICATION

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

An aqueous solution. Presents little or no hazard if spilled or in fire.

WARNING: This is a pharmaceutical material available only with a prescription - use only as directed. Persons allergic to shellfish or iodine may be allergic to iohexol.

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 immediate medical attention or contact the Poison Control Center for further 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. Ventilate area - free flame may rupture container and decompose product to form toxic and irritating iodine vapors.

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: Store away from heat and light - these conditions may produce iodine vapors. 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: Exposure to flame or temperatures above 300 °F.

Materials to Avoid: None known

Hazardous Decomposition

Products: Iodine vapors

Hazardous

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

Subchronic (Target

Organ Effects): The following adverse reactions have been reported:

Central Nervous System: Vertigo (including dizziness and lightheadedness), pain, vision abnormalities (including blurred vision and photomas), headache, and taste perversion. Other including anxiety, fever, motor and speech dysfunction, convulsion, paresthesia, somnolence, stiff neck, hemiparesis, syncope, shivering, transient ischemic attack, cerebral infarction, and nystagmus were reported.

Gastrointestinal System: Nausea and vomiting. Others including diarrhea, dyspepsia, cramp, and dry mouth were reported.

Cardiovascular System: Arrhythmias including PVCs and PACs, angina/chest, pain and hypotension. Others including cardiac failure, asystole, bradycardia, tachycardia, and vasovagal reaction were reported. In controlled clinical trials, involving 1485 patients, one fatality occurred. A cause and effect relationship between this death and iohexol has not been established.

Respiratory System: Dyspnea, rhinitis, coughing, and laryngitis.

Skin and Appendages: Urticaria, purpura, abscess, and pruritus.

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

12. ECOLOGICAL INFORMATION

No data available

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 deminimus 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. Omnipaque® Package Insert
2. Omnipaque® 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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