

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Visipaque®
Synonyms: Visipaque® (iodixanol) Injection 270 mg l/ml and 320 mg l/ml
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>
Iodixanol	92339-11-2	>25%
Water	7732-18-5	>25%

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. May cause allergic reaction. Persons allergic to shellfish or iodine may be allergic to Iodixanol.

4. FIRST AID MEASURES

Eyes: Flush eyes with water for at least 15 minutes. Seek medical attention if irritation develops.

Skin: Wash thoroughly with soap and water.

Ingestion: If ingested, 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 that is suitable for the surrounding fire.

**Fire Fighting
Procedures:**

Use normal fire fighting gear. Ventilate areas -- free flame may rupture containers 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 toward center. 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 contact with eyes.

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

Respiratory Protection: None normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Colorless to pale yellow liquid

Specific Gravity: 1.341/1.396 (270 mg l/320 mg l)

Solubility in Water: Soluble

pH: 6.8 to 7.7

10. STABILITY AND REACTIVITY

Stability: Stable.

Conditions to Avoid: Exposure to flame or temperature above 300°F.

Materials to Avoid: None known.

**Hazardous
 Decomposition**

Products: Iodine vapors.

Hazardous

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Data

<u>Acute Toxicity Data</u>	<u>Species</u>	<u>Result</u>
Intravenous LD ₅₀	Mouse	15-20 g l/kg
Intravenous LD ₅₀	Rat	19-20 g l/kg
Intravenous lethal dose	Monkey	>3.0 g l/kg
Skin irritation	Rabbit	None
Eye irritation	Rabbit	None (Draize 0)

Effects of

Chronic Exposure: Not determined.

Reproductive Toxicity: Not expected to be a reproductive toxin; negative in reproductive and developmental toxicity studies.

Mutagenicity:

Not expected to be mutagenic; negative in mutagenicity assays with or without metabolic activation.

Carcinogenicity:

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

Other Toxicity Data

<u>Other Toxicity Data</u>	<u>Species</u>	<u>Result</u>
Mutagenicity/Genotoxicity data		Negative
Segment I Fertility	Rat	No effects
Segment II Teratology	Rat	No significant effects
Teratology	Rabbit	No effects
Segment II Peri-/Postnatal	Rat	No significant effects

12. ECOLOGICAL INFORMATION

Microbial Inhibition

Toxicity: Threshold inhibition concentration > 150 mg/L.

Biodegradation: Does not biodegrade.

Acute Aquatic Toxicity Daphnia: EC₅₀ >1,000 mg/L.

Wastewater Treatment

Effects: No negative impact project on wastewater treatment facilities during normal operations.

13. DISPOSAL CONSIDERATIONS

Disposal Methods: As of the MSDS revision date, this produce 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

US Federal Regulations: This product does **not** contain any ingredients that are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372), 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 reference used in the preparation of this document:

1. VISIPAQUE® Package Insert
2. Iodixanol MSDS (Nycomed)
3. ACGIH Guide to Occupational Exposure Values - 1991
4. Nycomed Corporate Quality Pharmaceutical File - 2/10/89
5. Nycomed Protection Guide - 10/16/92

Disclaimer: This information is furnished without warranty, representation, or license of any kind, except that it is accurate to the best of Amersham Health knowledge or obtained from sources believed to be accurate. Amersham Health does not assume any legal responsibility for use or reliance upon same. Customers are encouraged to conduct their own tests. Before using any product, read its label.