

1. Product and company Identification

Product names: Visipaque®, In concentrations ranging from 270 to 320 mg I/ml
Synonyms: Iodixanol Injection
Application: Diagnostic imaging agent for injection
Supplier: GE Healthcare, Nycoveien 1-2, P.O. Box 4220, Torshov, N-0401 OSLO, Norway
Emergency Number: +47-23185050. Fax: +47-23186000

2. Composition/information on ingredients

Composition:	Main ingredients:	CAS No.:	Content:	Hazard classification
	Iodixanol	92339-11-2	30-75 %	None
	Purified water	7732-18-5	25-70 %	None

Primary packaging: Glass vials and bottles, Soft pack, Soft bottles, Flexi bags, Pre filled syringes

3. Hazards identification

Emergency overview: A clear colourless to pale yellow aqueous solution. Presents little hazard if spilled or in case of a fire

Potential adverse health effects: Regarded as having very low health hazard. May cause hypersensitivity ("allergy-like") reactions in susceptible people. People with allergies may also have a lower threshold to such stimuli, particularly if recently exposed to agents they are allergic to (e.g. pollen in the pollen season).

4. First-aid measures

Skin contact: Wash skin with soap and water.

Inhalation: Not applicable

Eyes: Flush eyes with water. If persistent irritation occurs, seek medical advice.

Ingestion: Drink water to dilute the swallowed solution. Seek medical advice if large quantity (more than 1litre) has been consumed.

5. Fire-fighting measures

Flammability: Non flammable. Water-based formulation.

Decomposition and Explosion Hazards: In a fire the solid product will decompose and release irritating iodine vapour

6. Accidental release measures

Clean up procedures: Small spills: Clean up with a moist cloth or paper towel. Larger spills: Collect with absorbent material. If appropriate, flush down the drain, using cold water. Contaminated area should be washed with soap and water. Take appropriate precautions when broken glass is present

7. Handling and storage

Storage conditions: Store in original container at ambient temperature (below 30° C). Protect from light, sunlight, localised heating sources. Do not freeze

8. Exposure controls/personal protection

Ventilation:	None required.	Protective gloves:	None required.
Eye protection:	None required.	Protective clothing:	None required.

9. Physical and chemical properties

Appearance, colour: A clear aqueous solution. Colourless to pale yellow.

Odour: None

Specific gravity: 1.2 – 1.4 g/ml at 37°C (dependent on concentration)

Melting point, °C: Not applicable

Boiling point, °C: Not applicable

Decomposition temperature: The active ingredient, in a solid form, decomposes at temperatures above 170°C (338°F)

Decomposition products: Iodine gas, Carbon dioxide

Solubility: Readily soluble in water

pH: 6.8 – 7.6

10. Stability and reactivity

Stability:	Stable under normal and anticipated storage and handling conditions
Reactivity:	Avoid high temperatures.
Conditions or materials to avoid	Avoid contact with reactive substances or strong oxidising agents

11. Toxicological information

LD ₅₀ :	see Acute effects		
Acute Effects:	The intravenous LD ₅₀ of the final dosage form in mice is 44,4 g/kg, and in rat is 24.4 g/kg. The oral and intraperitoneal LD ₅₀ values of the final dosage form in mice is greater than 39.9 g/kg.		
Local Effects:	Not applicable	Inhalation Effects:	Not applicable
Sensitisation:	Not applicable	Other Effects:	Not teratogenic.

12. Ecological information

Environmental Fate:	The preparation is easily soluble in water
Environmental Toxicity	The active ingredient is rated not toxic to fish, Daphnia, or algae
Biodegradability:	Not readily biodegradable

13. Disposal consideration

Clean-up procedure:	Clean up with moist cloth or paper towel. Take care if in a glass bottle
Waste disposal method:	Normal waste route for a regulated waste according to EU Commission Directive 91/689/EC, regulated as it is a pharmaceutical. If incinerated, the incineration facility must be notified that the product contains iodine and that appropriate controls are necessary. For complete boxes the material can be returned to GE Healthcare for recycling.

14. Transport information

Hazard classification:	Non Hazardous for all modes of transport.
Transport conditions:	An outer shipping carton must always be used. The sales pack must never be used as the only distribution/transportation pack. The product must never be split down to units smaller than the sales pack. Containers might be fragile, handle with care. Extra cushioning might be required. Transport the product at ambient temperature (between 2° and 30° C). Protect from light and localised heating sources. The product must not be frozen.

15. Regulatory information

Health Hazard Classification:	Not applicable	Fire an Explosion Hazard Classification:	Not applicable
Environmental Hazard Classification:	Not applicable		
R-phrases:	Not applicable	S-phrases:	Not applicable

16. Other information

Disclaimer:	Although reasonable care has been taken in the preparation of this document. We extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).
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