



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 AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, N-0401 OSLO, Norway
Contact:	+47-23185050. Fax: +47-23186000. http:// www.gehealthcare.com
Emergency Phone No:	Giftinformasjonssentralen: +47 23591300 (Norway)

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, Polypropylene bottles			

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

LD₅₀: see Acute effects

Acute Effects: The intravenous LD₅₀ of the final dosage form in mice is 44,4 g/kg, and in rat is 43 g/kg. The oral and intraperitoneal LD₅₀ 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. Unopened containers 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. For product integrity: transport between 0-32° C, for up to one week. Protect from light and localised heating sources. The product must not be frozen.

15. Regulatory information

Health Hazard Classification: Not applicable Fire and 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 purposes(s).

A safety data sheet is not required for this product under Article 31 of REACH

Status: Visipaque Version 1.5

Revision date: December 2014