



## 1. Product and company Identification

Product names: Clariscan  
 Synonyms: Gadoterate  
 Application: Diagnostic imaging agent for injection  
 Supplier: GE Healthcare AS, Nycoveien 1, P.O. Box 4220Nydalén, N-0401, OSLO, Norway.  
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## 2. 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

## 3. Composition/information on ingredients

Composition:	Main ingredients:	CAS No.:	Content:	Hazard classification
	Gadoterate	72573-82-1	~30%	None
	Purified water	7732-18-5	~70%	None
	DOTA (tetraxetan)	60239-18-1	~1%	None

Primary packaging: in plastic and glass bottles/containers and prefilled syringes

## 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: Not applicable

## 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 temperatures below 30° C. Protect from light, sunlight, localised heating sources. Do not freeze.

## 8. Exposure controls/personal protection

None required.

## 9. Physical and chemical properties

Appearance, colour: A clear aqueous solution. Colourless to pale yellow.  
 Odour: None Specific gravity: 1.1759 at 25°C  
 Decomposition temperature, °C: Not applicable  
 Decomposition products: Not applicable  
 Solubility: Readily soluble in water pH: 6.9 – 7.8

## 10. Stability and reactivity

Stability: Stable under normal and anticipated storage and handling conditions



Reactivity: Not applicable

Conditions or materials to avoid: Not applicable

### 11. Toxicological information

Acute Effects: The intravenous LD50 of the final dosage form in mice is 10.6 mmol/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

Bio-accumulation potential: Not applicable

### 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 routes. Not a regulated waste according to EU Commission Directive 2008/98/EC and Waste list Decision 2000/532/EC and US EPA Toxic Release Inventory (TRI) -Listed Chemicals. Dispose as non-hazardous liquid/dry waste.

### 14. Transport information

Hazard classification: Non Hazardous for all modes of transport.

Transport conditions: Shipping container must always be used. The product must never be split down to smaller units than the sales pack. The sales pack must never be used as the only distribution/transportation pack. Containers might be fragile, handle with care. Extra cushioning might be required/necessary.  
For product integrity: transport at temperatures between 0°C and 32°C for up to one week.  
Protect from light, 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

Hazard statements: Not applicable Precautionary statements: Not applicable

Other regulatory info:

US Federal Regulations: This product does not contain any ingredients which are regulated on the EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under Section 313 of EPCRA.

### 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).

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

Status: Clariscan Version 1.2

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