

OXILAN[®]
(loxilan Injection)

Product Name: Oxilan[®]
Generic Name: loxilan Injection
USAN Name: loxilan

Manufacturer: Guerbet LLC
120 W. 7th Street, Suite 108
Bloomington, IN 47404 USA
(812) 333-0059

IUPAC Name: N-(2,3-dihydroxypropyl)-N'-(2-hydroxyethyl)-5-[N-(2,3-dihydroxypropyl) acetamido]-2,4,6-triiodoisophthal-amide

Formula: C₁₈H₂₄I₃N₃O₈

CAS No.: 107793-72-6

Appearance, Odor, Clarity: Oxilan[®] is a clear, odorless, colorless to slightly yellow solution.

Composition:

Strength	300 mg/ml*	350 mg/ml*
Edetate Calcium Disodium	0.1 mg/ml	0.1 mg/ml
PH	5.5 – 7.5	5.5 – 7.5
loxilan Content	623 mg/ml	727 mg/ml
Tromethamine	1.0 mg/ml	1.0 mg/ml
Sodium Chloride	0.5 mg/ml	0.5 mg/ml
Sodium	0.2 mg/ml	0.2 mg/ml

*mg/ml is milligrams of Iodine

Toxicological Data:

LD₅₀>2000mg loxilan/Kg body weight (oral rat) – active bulk drug substance

Acute intravenous toxicity – Mice:	LD ₅₀ (male)	19.5g Iodine/Kg b.wt.
	LD ₅₀ (female)	19.1g Iodine/Kg b.wt.
Acute intravenous toxicity – Rats:	LD ₅₀ (male)	>30.0g Iodine/Kg b.wt.
	LD ₅₀ (female)	>22.8g Iodine/Kg b.wt.

First Aid:

Eye Contact: Rinse immediately with plenty of water. Seek medical advice if irritation continues.
Skin Contact: Rinse with water.
Ingestion: Rinse mouth immediately with water.
General: Ordinary first aid.
Overdosage: Refer to Oxilan[®] Package Insert.

Protective Measures:

Protective Equipment: Wear suitable clothing. Wear gloves when necessary.
Respiratory Protection: No protection required. Oxilan[®] is non-volatile.
Eye Protection: Wear safety glasses in case of splashing.
Storage: Protect from light. Store at room temperature not exceeding 30°C (86°F).

Reactivity and Special Precautions:

Unreactive
Does not readily polymerize

Waste Disposal:

Dispose of in sanitary sewer system.

Emergency Action by Spill or Leakage:

Wash area with soap and hot water and dispose in municipal waste.

Fire and Explosion Hazard:

Extinguishing Media: No particular methods reported. Oxilan[®] is non-flammable.
Special Fire Hazards: Decomposes and evolves iodine vapors when exposed to heat.

Labeling:

Hazard Category: Non-Hazardous
Health: Biologically Inert, Non-Toxic
Fire: Non-Flammable

See Oxilan[®] Package Insert for additional medical information.