

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Relistor® (methylnaltrexone bromide) Subcutaneous Injection**
- Product Code** • NDC 64649-552-04; NDC 65649-551-02; NDC 65649-551-03; NDC 65649-551-06; NDC 65649-551-07; NDC 65649-553-05

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; Relistor is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Salix Pharmaceuticals, Inc., a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.

Bridgewater, NJ 08807
United States
salix.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Specific Target Organ Toxicity Single Exposure 2
Acute Toxicity Oral 4

Label elements

UN GHS

WARNING



Hazard statements • Harmful if swallowed

May cause damage to organs - Gastrointestinal system

Precautionary statements

- Prevention** • Do not handle until all safety precautions have been read and understood. Avoid breathing dust, fume, gas, mist, vapours and/or spray. Wash thoroughly after handling.
- Response** • IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
- Storage/Disposal** • Store in a well-ventilated place. Keep container tightly closed. Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
Edetate calcium disodium	CAS:6766-87-6	N/A
Glycine, hydrochloride	CAS:6000-43-7 EINECS:227-841-8	N/A
Naltrexone methobromide	CAS:916055-92-0	2%
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	N/A
Water	CAS:7732-18-5 EINECS:231-791-2	N/A

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation** • Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.
- Skin** • No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.
- Eye** • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get medical attention immediately if symptoms occur.
- Ingestion** • If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • No data available

Hazardous Combustion Products • No data available.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures

- Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F

(excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Do not freeze. Protect from light.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

- Engineering Measures/Controls**
- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Hands

- Wear protective gloves when handling bulk product before closed in final packaging.

Skin/Body

- Avoid contact with skin.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Clear Liquid.
Color	Colorless to pale yellow.	Odor	Not relevant
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Hazardous polymerization will not occur.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze. Protect from light.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information**Information on toxicological effects**

	CAS	
Relistor® (methylnaltrexone bromide) Subcutaneous Injection	NDA	Acute Toxicity: Ingestion/Oral-Dog LD50 • >2000 mg/kg; Ingestion/Oral-Rat LD50 • >5000 mg/kg; Subcutaneous-Rabbit LD50 • >35 mg/kg; Subcutaneous-Rat LD50 • >500 mg/kg

GHS Properties	Classification
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Acute toxicity	UN GHS • Acute Toxicity - Oral 4
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 2
Toxicity for Reproduction	UN GHS • Classification criteria not met

Target Organs

- Gastrointestinal system

Potential Health Effects**Inhalation****Acute (Immediate)**

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available

Skin**Acute (Immediate)**

- Not expected to cause skin irritation.

Chronic (Delayed)

- No data available

Eye

Acute (Immediate) • May cause mild eye irritation with direct contact to eye.

Chronic (Delayed) • No data available

Ingestion

Acute (Immediate) • May be harmful if swallowed. May cause gastrointestinal disturbances including diarrhea, nausea, and vomiting. If unusually severe, persistent, or worsening abdominal pain develop seek medical attention immediately as this may be an indication of gastrointestinal perforation.

Chronic (Delayed) • No data available

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste • Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture**SARA Hazard Classifications** • No data available

Inventory					
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	TSCA
Edetate calcium disodium	6766-87-6	No	No	No	No
Glycine, hydrochloride	6000-43-7	No	Yes	Yes	Yes
Naltrexone methobromide	916055-92-0	No	No	No	No
Sodium chloride	7647-14-5	Yes	No	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Glycine, hydrochloride	6000-43-7	Not Listed
• Naltrexone methobromide	916055-92-0	Not Listed
• Edetate calcium disodium	6766-87-6	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Sodium chloride	7647-14-5	Not Listed
• Glycine, hydrochloride	6000-43-7	Not Listed
• Naltrexone methobromide	916055-92-0	Not Listed
• Edetate calcium disodium	6766-87-6	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Sodium chloride	7647-14-5	Not Listed
• Glycine, hydrochloride	6000-43-7	Not Listed
• Naltrexone methobromide	916055-92-0	Not Listed
• Edetate calcium disodium	6766-87-6	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Sodium chloride	7647-14-5	Not Listed
• Glycine, hydrochloride	6000-43-7	Not Listed
• Naltrexone methobromide	916055-92-0	Not Listed
• Edetate calcium disodium	6766-87-6	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Sodium chloride	7647-14-5	Not Listed
• Glycine, hydrochloride	6000-43-7	Not Listed
• Naltrexone methobromide	916055-92-0	Not Listed
• Edetate calcium disodium	6766-87-6	Not Listed

Section 16 - Other Information

- Revision Date** • 18/December/2015
- Last Revision Date** • 18/December/2015
- Preparation Date** • 18/December/2015
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