



MATERIAL SAFETY DATA SHEET

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VALPROATE SODIUM INJECTION, USP

SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Valproate Sodium Injection, USP
Supplier: West-Ward Pharmaceuticals
401 Industrial Way West,
Eatontown, NJ 07724
Phone (732 542 1191)
Fax (732 720 6220)

Technical Phone: (800 631 2174)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

DESCRIPTION	CAS	% (BY WEIGHT)
Valproic Acid	99-66-1	100mg/mL
Edetate Sodium	139-33-3	0.40mg/mL
Hydrochloric Acid Concentrated (35-39 w/w)	7647-01-0	QS
Sodium Hydroxide	1310-73-2	QS
Water for Injection, USP	7732-18-5	QS

Category: Anti-convulsant

SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, ingestion, or absorption through the skin or eyes.

Health Hazard (Acute & Chronic): Valproate affects the digestive and central nervous system as well as the liver and kidneys. Short-term contact may cause dermal, eye, gastrointestinal tract, and respiratory irritation. Ingestion may result in nausea, vomiting, abdominal cramps, and diarrhea. Possible allergic reaction if inhaled, ingested, or contact with the skin.

Chemical List as Carcinogen:

NTP: No
IARC: No
OSHA: No



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SECTION 4. FIRST AID MEASURES

- Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin: Wash skin with cool, soapy water for 15 minutes. Seek medical attention if pain, redness, or swelling persists.
- Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
- Ingestion: If ingested, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

SECTION 5. FIRE AND EXPLOSION DATA

Fire and explosion Data

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| Flash Point: | Non-flammable |
| Extinguishing Media: | Use water or type ABC multi-purpose extinguisher as appropriate for surrounding area. |
| Fire Fighting Instructions | Evacuate personnel to safe area. |
| Fire Fighting Equipment: | Firefighters should wear self-contained breathing apparatus to avoid smoke inhalation. Product is aqueous based and is not expected to present a fire hazard. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

Leak and Spill Procedures: Wear recommended protective equipment. Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water. Dispose according with local, state, and federal guidelines.

SECTION 7. HANDLING AND STORAGE

General Handling: Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated. When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapours associated with the product.

Storage Conditions: Store between 20-25°C (68-77°F). [See USP controlled room temperature]



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment:

Respiratory Protection: Under normal use, respiratory protection is not required.
Ventilation: Handle product in a well ventilated area.
Hand Protection: Latex or nitrile gloves
Eye protection: Safety glasses with side-shields, or goggles.
Skin Protection: Labcoat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Liquid, clear, colorless to pale yellow solution, odorless.
Boiling Point/ Boiling Range: Approx to Water.
Melting Point/ Melting Range: N/A.
Freezing Point: 0°C/32°F
Vapor Pressure: Approx to Water.
Relative Vapor Density: Approx to Water.
Percent Volatiles: N/A.
pH: 7.0-9.0
Solvent Solubility: Soluble in water

SECTION 10. STABILITY AND REACTIVITY DATA.

Stability: Stable under most conditions. Decomposition products of this compound may include potentially hazardous byproducts, acid, and toxic fumes.
Conditions to Avoid: Storage near water reactive materials.
Hazardous Polymerization: Will not occur.
Hazardous Decomposition or By-products: None known based on information supplied.

SECTION 11. TOXICOLOGICAL INFORMATION

Chemical Name	LD ₅₀ Oral	LD ₅₀ Dermal	LDL ₀
Valproic Acid	670 mg/kg (rat) 1098 mg/kg (mouse)	860 mg/kg (mouse) 470 mg/kg (mouse)	100 mg/kg (Woman)

Long term exposure may result in hair loss, trembling hands and arms, mood or mental changed, tiredness and weakness, swelling of face, yellow eyes or skin, vision disturbances or uncontrolled eye movement, unusual bleeding or bruising, clumsiness, or unsteadiness, dizziness, headaches, skin rash and unusual excitement, restlessness or irritability.

Teratogenic effect such as neural tube defects (e.g. spina bifida) have been associated with therapeutic valproate therapy. Accordingly, the use of valproate products in women of childbearing potential requires that the benefits of its use be weighed against the risk of injury to the fetus.



SECTION 12. ECOLOGICAL INFORMATION

Not available.

SECTION 13. DISPOSAL CONSIDERATIONS

Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14. TRANSPORT INFORMATION

US DOT Hazard Class: Not regulated

SECTION 15. REGULATORY INFORMATION

U.S. Regulatory Information: Not regulated

SECTION 16. OTHER INFORMATION

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Use of this product should be through or under the direction of a physician.

This MSDS does not address therapeutic use of this material.

Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.