

 <b>Pharmaceutical Division</b>	<b>Valproate Sodium Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 05OCT2022	SDS No.: <b>SDS054</b>	Revision No: <b>01</b>	Page <b>1 of 9</b>

### Section 1 - Identification


- (a) **Product Identifier:** Valproate Sodium Injection, USP
- (b) **Product Code:** 70860-784
- Common/Trade Name:** Valproate Sodium
- Chemical Name:** sodium 2-propylpentanoate
- Chemical Family:** Antiepileptic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

<b>Classification:</b>	Serious Eye Damage. Category 1. Skin corrosion. Category 1. Respiratory sensitization. Category 1. Reproductive toxicity. Category 1A. Skin Sensitization. Category 1. Reproductive toxicity. Effects on or via lactation.
<b>Signal Word:</b>	Danger
<b>Hazard Statement</b>	Causes serious eye damage, Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage fertility or the unborn child. May cause an allergic skin reaction. May cause harm to breastfed children.
<b>Symbols</b>	

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<b>Precautionary Statement(s)</b>	<p>Obtain special instructions before use.</p> <p>Do not handle until all safety precautions have been read and understood.</p> <p>Do not breathe dust/fume/gas/mist/vapors/spray.</p> <p>Avoid breathing dust/fume/gas/mist/vapors/spray.</p> <p>Avoid contact during pregnancy and while nursing.</p> <p>Wash hands thoroughly after handling.</p> <p>Do not eat, drink or smoke when using this product.</p> <p>Contaminated work clothing should not be allowed out of the workplace.</p> <p>Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>In case of inadequate ventilation wear respiratory protection.</p> <p>If swallowed: Rinse mouth. Do not induce vomiting.</p> <p>If on skin: Wash with plenty of water.</p> <p>If on skin (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower.</p> <p>If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>If exposed or concerned: Get medical advice/attention.</p> <p>If experiencing respiratory symptoms: Call a Poison Center or doctor/physician.</p> <p>Take off contaminated clothing and wash it before reuse.</p> <p>Store locked up.</p> <p>Dispose of contents/container in accordance with local, state, and federal regulations.</p>
<b>Emergency Overview</b>	<p>This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.</p>
<b>Unknown Acute Toxicity</b>	<p>N/A</p>

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### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Valproic Acid	Valproic Acid	100 mg/mL	1069-66-5	N/A
Edetate Disodium	Edetate Disodium	0.40 mg/mL	6381-92-6	N/A
Sodium Hydroxide	Sodium Hydroxide	26.33 mg/mL	1310-73-2	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s. to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s. to pH	7647-01-0	N/A

### Section 4 – First Aid Measures

- Eye Contact:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Skin Contact:** Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
- Ingestion:** If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
- Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

### Section 5 – Fire-fighting Measures

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- (a) **Extinguishing Media** Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- (b) **Hazardous Decomposition Products:** Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.
- (c) **Special Protective Equipment / Precautions:** Fire-fighters should wear a self-contained breathing apparatus (SCBA) with full protective gear.

### Section 6 - Accidental Release Measures

- Spill:** **Cleanup:** Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.  
**Containment:** Contain spills with an inert absorbent material such as soil, sand, or oil dry.
- Personnel Precautions:** Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists.
- Release to Water:** Avoid runoff into storm sewers, ditches, and waterways.

### Section 7 - Handling and Storage

- General Handling:** **Protective Measures:** When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.  
**Occupational Hygiene:** Facilities storing or utilizing this material should be equipped with an eyewash station and a safety shower. Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.
- Storage Conditions:** Store vials at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.]

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**Section 8 - Exposure Controls / Personal Protection**

- (a) **Exposure Limits:** None
- (b) **Engineering Controls**


**Ventilation:** General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering controls such as process enclosures, local exhaust ventilation, or other controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

**(c) Individual Protection Measures**

<b>Respiratory Protection:</b>	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e., an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting.
<b>Eye Protection:</b>	Chemical splash goggles. Wear a face shield when splash hazard exists.
<b>Skin Protection:</b>	Protective laboratory coat, apron, or disposable garment recommended. Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Additional Exposure Precautions:</b>	In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	Clear, colorless solution.
<b>(b) Odor</b>	Odorless
<b>(c) Odor Threshold</b>	Not available
<b>(d) pH</b>	7.0 – 9.0
<b>(e) Melting Point:</b>	Not available

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<b>(f)</b>	<b>Initial Boiling Point:</b>	Not available
<b>(g)</b>	<b>Flash Point</b>	Not available
<b>(h)</b>	<b>Evaporation Rate:</b>	Not available
<b>(i)</b>	<b>Flammability</b>	Not available
<b>(j)</b>	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k)</b>	<b>Vapor Pressure:</b>	Not available
<b>(l)</b>	<b>Vapor Density:</b>	Not available
<b>(m)</b>	<b>Relative Density</b>	Not available
<b>(n)</b>	<b>Solubility(ies)</b>	Soluble in water
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	Not available
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

**Section 10 - Stability and Reactivity**

<b>Chemical Stability</b>	Stable at normal temperatures and pressures
<b>Special Decomposition Products</b>	Decomposition products of this compound may include potentially hazardous byproducts, acrid, and toxic fumes.
<b>Incompatible Materials</b>	Avoid storage near oxidizers and water reactive materials.
<b>Hazardous Polymerization</b>	Not reported.

**Section 11 - Toxicological Information**

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Ingestion, inhalation, or eye or dermal contact.
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<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	<p><b>Eye Contact:</b> No known significant effects or critical hazards</p> <p><b>Inhalation:</b> Adverse symptoms may include the following:</p> <ul style="list-style-type: none"> <li>• reduced fetal weight</li> <li>• increase in fetal deaths</li> <li>• skeletal malformations</li> </ul> <p><b>Skin Contact:</b> Adverse symptoms may include the following:</p> <ul style="list-style-type: none"> <li>• reduced fetal weight</li> <li>• increase in fetal deaths</li> <li>• skeletal malformations</li> </ul> <p><b>Ingestion:</b> Adverse symptoms may include the following:</p> <ul style="list-style-type: none"> <li>• reduced fetal weight</li> <li>• increase in fetal deaths</li> <li>• skeletal malformations</li> </ul>
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short- and long-term exposure</b>	<p>No known significant effects or critical hazards from short or long-term exposure.</p> <p><b>Potential chronic health effects:</b>  <i>Teratogenicity:</i> May damage the unborn child.  <i>Fertility effects:</i> May damage fertility.</p>

**(d) Acute Toxicity**


Component	Type	Route	Species	Dosage
Valproic Acid	LD <sub>50</sub>	Intraperitoneal	Mouse	470 mg/kg
		Subcutaneous	Mouse	860 mg/kg
		Oral	Rat	670 mg/kg (behavioral)
		Oral	Mouse	1098 mg/kg
		Oral	Rat	675 mg/kg

**Section 12 - Ecological Information**

<b>Ecotoxicity</b>	<b>Valproate Sodium:</b> No ecotoxicity data was determined for product.
<b>Environmental Stability</b>	Not determined for product.

**Section 13 - Disposal Considerations**

**Waste Disposal:** To avoid accidental exposure due to waste handling, place waste residue in a segregated, sealed plastic container. Used syringes, needles, and sharps should not be crushed,

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clipped, or recapped, but placed directly into an approved sharps container. Dispose of any cleanup materials and waste residue per all applicable laws and regulations, e.g., secure chemical landfill disposal.

**Section 14 - Transport Information**

**Not regulated for transport under USDOT, IATA, or IMDG regulations.**

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 313 - Not on this list

**Section 16 - Other Information**

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


For additional information contact:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230  
 Schaumburg, IL 60173  
 847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute



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CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System