Material Safety Data Sheet

SECTION 1. IDENTIFICATION	
Common/Trade Name: Divalproex Sodium Delayed Release Tablets USP **Chemical Name:** Sodium hydrogen bis(2-propylvalerate) oligomer / Pentanoic acid, 2-propyl-, sodium salt (2:1). **Synonyms:** Divalproex Sodium **Molecular Formula:** $(C_{16}H_{31}NaO_4)_n$ **Molecular Weight:** Divalproex sodium: 310.41 **CAS No:** 76584-70-8 **Product Group:** Anticonvulsant	
Manufacturer's Name Unichem Laboratories Limited **Address** Unichem Laboratories Limited, Pilerne, Bardez, Goa, INDIA **Marketed by** Unichem Pharmaceuticals (USA), Inc. Rochelle Park, NJ 07662 **Phone Number** 201-226-0240 (Fax : 201-226-0241) **Emergency Phone No.** 1-866-562-4616	
Recommended Use: For management of manic episodes associated with bipolar disorder, complex partial seizures and prophylaxis of migraine headaches.	
Restriction on Use: Prescription Only.	
SECTION 2. HAZARD(s) IDENTIFICATION	
Emergency Overview	**Physical State:** **125 mg:** Orange colored, modified capsule shaped, biconvex enteric coated tablets imprinted with "UL 125" on one side and plain on other side. **250 mg:** Pink colored, oval shaped, biconvex enteric coated tablets imprinted with "UL 250" on one side and plain on other side. **500 mg:** Reddish pink colored, modified capsule shaped, biconvex, enteric coated tablets imprinted with "UL 500" on one side and plain on other side. **Odor:** No data available. **WARNING!** May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.
Primary Route(s) of Entry	Ingestion
Potential Health Effects:	**Eyes** Not expected to be a hazard to the eye in final pharmaceutical form. **Skin** Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. **Inhalation** Not expected to be an inhalation hazard in final pharmaceutical form. **Ingestion** Adverse effects may include unusual tiredness or weakness; facial swelling; vomiting; abdominal pain; nausea; indigestion; diarrhea; constipation; change in weight and/or appetite; trembling; hallucinations; headache; dizziness; confusion; incoordination; involuntary movement of the eyes, hands, or body; vision problems; disturbance in speech or language; hair loss; skin rash or itching; increased sensitivity of skin to light; hearing loss; bone pain; cough; slow heartbeat; fever; low body temperature; behavior, mood, or mental changes; irregular menstruation; unusual bleeding or bruising; breast enlargement; spontaneous flow of breast milk; involuntary urination; and urinary tract infection. Please see Patient Package Insert for further information
Toxicity Data:	See Section 11

Effects of Over Exposure:	Overdosage with valproate may result in somnolence, heart block, and deep coma. Fatalities have been reported; however patients have recovered from valproate levels as high as 2120 µg/mL. In overdose situations, the fraction of drug not bound to protein is high and hemodialysis or tandem hemodialysis plus hemoperfusion may result in significant removal of drug. The benefit of gastric lavage or emesis will vary with the time since ingestion. General supportive measures should be applied with particular attention to the maintenance of adequate urinary output. Naloxone has been reported to reverse the CNS depressant effects of valproate overdosage. Because naloxone could theoretically also reverse the antiepileptic effects of valproate, it should be used with caution in patients with epilepsy.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	**CAS #**	**Quantity**
Divalproex Sodium (active ingredient)	76584-70-8	Equivalent to 125 mg, 250 mg and 500 mg of valproic acid.

REFER to PHYSICIAN'S DESK REFERENCE for common components

Target Organs:	Central nervous system, Liver.

SECTION 4. FIRST-AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Exposure	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

SECTION 5. FIRE-FIGHTING MEASURES

Flammability	Presumed to be a combustible particulate solid.
Flash Point	Not Applicable
Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Special Fire Fighting Procedures	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters. Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. Do NOT use water jet. In the event of fire and/or explosion do not breathe fumes.
Unusual Fire/Explosion Hazards	Not Applicable
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

SECTION 6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED:
Use appropriate personal protective equipment (see Section 8). Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained. Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

SECTION 7. HANDLING AND STORAGE

Precautions General Handling:	Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	Store at 20^0 to 25^0C (68^0 to 77^0F) [See USP Controlled Room Temperature]. Dispense in a tight, light resistant container.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Respiratory Protection	Base respirator selection on a risk assessment.
Personal Protection	**Eye/face Protection** Provide eye protection based on risk assessment. **Skin Protection** Wear nitrile or latex gloves. Wear protective garment. **General Hygiene Considerations** When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday. **Other** Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.
Recommended Facilities	Eye wash, washing facilities

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES					
Appearance	Oval or capsule shaped, biconvex enteric coated tablets	Melting point	Not available	Solubility in water	Not available
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

SECTION 10. STABILITY AND REACTIVITY	
Stability	Stable at room temperature.
Incompatibility	None known
Hazardous Decomposition	None under normal use
Conditions to Avoid	No data available
Hazardous Polymerization	None under normal use.

SECTION 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Divalproex Sodium

Oral Rat : No data available.
Oral Mouse : No data available.
Other Toxicity Data : No data available.
Corrosivity : No data available.

Maximum Tolerated Dose (MTD), Oral

Divalproex Sodium:

Carcinogenicity Valproic acid administered to rats and mice at doses of 80 and 170 mg/kg/day for 2 years resulted in a statistically significant increase in the incidence of subcutaneous fibrosarcomas in high dose male rats and a statistically significant dose-related trend for benign pulmonary adenomas in male mice. Divalproex sodium is comprised of sodium valproate and valproic acid in a 1:1 molar relationship.

Genetic Toxicity Valproate was not mutagenic in an in vitro bacterial assay (Ames test), did not produce dominant lethal effects in mice, and did not increase chromosome aberration frequency in

	an in vivo cytogenic study in rats.
Reproductive Toxicity & Developmental Toxicity	The therapeutic use of valproic acid during the first trimester of pregnancy may cause an increased incidence of neural tube defects (spina bifida) in the fetus. Other birth defects such as craniofacial defects and cardiovascular malformations have also been reported. Valproate has caused birth defects (including neural tube defects, growth retardation, and cardiac or skeletal malformations) in the offspring of mice, rats, rabbits, and rhesus monkeys exposed during pregnancy.
Divalproex Sodium Target Organ(s) of Toxicity	No data available

SECTION 12. ECOLOGICAL INFORMATION

No information is currently available on the environmental impact of this product.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose off in accordance with local and national regulations

SECTION 14. TRANSPORT INFORMATION

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose.

SECTION 15. REGULATORY INFORMATION

DEA: Divalproex sodium is not a controlled substance.

FDA: Divalproex sodium delayed release tablets are approved prescription medication.

SECTION 16. OTHER INFORMATION

ABBEVIATIONS:
N/A – not applicable

Prepared by: Unichem Laboratories Limited

References:
1. Drug Bank
2. PDR – Physicians Desk Reference
3. Divalproex Sodium Delayed Release Tablets USP, Package Insert, Unichem Laboratories Limited

Date: August 11, 2015 - Version: 001

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION