SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition UNITED NATIONS New York and Geneva, 2023

DIVALPROEX SODIUM DELAYED RELEASE CAPSULES USP 125 MG

1. IDENTIFICATION

GHS Product identifier: Divalproex Sodium Delayed Release Capsules USP 125 mg

Product code:#
Chemical Description: sodium;2-propylpentanoate;2-propylpentanoic acid
Other means of identification:
Recommended use of the chemical: Pharmaceutical use -- For treatment and management of seizure disorders, mania, and prophylactic treatment of migraine headache.
Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Acute toxicity	4	Oral
Skin Irritation	2	Dermal
Eye irritation	2	
Reproductive toxicity	1A	Oral
STOT (RE)	2	-
Carcinogenicity	2	Oral
Mutagenicity	2	Oral

Labeling
Globally Harmonized System, UN (GHS)

Signal Word	Danger
Hazard Statements:	H302: Harmful when swallowed H360: May damage fertility or the unborn child H316: Causes mild skin irritation H315: Causes skin irritation

	H319: Causes serious eye irritation H373: May cause damage to organs through prolonged and repeated exposure H341: Suspected of causing genetic defects H351: Suspected of causing cancer
Precautionary Statements:	P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves / eye protection / face protection. P301+P312 If swallowed: Call a poison center/doctor if you feel unwell P330 Rinse mouth. P302+P352 If on skin: Wash with plenty of water. P304+P340 If inhaled: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 If skin irritation occurs: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse. P337+P313 If eye irritation persists: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Divalproex Sodium

Hazardous ingredients	CAS	Content
Divalproex Sodium	76584-70-8	54.79%
Ethylcellulose	9004-57-3	<100%
Methylene Chloride	75-09-2	<100%
Triethyl citrate	77-93-0	<100%
Hydroxypropylmethyl cellulose	9004-65-3	<100%
Magnesium Stearate	557-04-0	<100%
Isopropyl Alcohol	67-63-0	<100%

4. FIRST-AID MEASURES

Occupational exposure to divalproex sodium may occur through inhalation and dermal contact with this compound at workplaces where this drug is produced or used. No limits for exposure have been established.

Inhalation

In case of irritation of the respiratory system or mucous membranes, seek medical attention. Move to fresh air. Seek medical attention if you feel unwell or if exposure prolonged.

Skin contact

Remove contaminated clothing. Wash affected skin with soap and plenty of water. If skin irritation or dermatitis commences or persists seek medical attention. Cover skin burns with dry sterile dressings after decontamination.

Eye contact

Immediately flush contaminated eyes with gently flowing water.

Ingestion

In case of acute oral exposure, administer charcoal as a slurry. Consider gastric lavage after ingestion of a potentially life-threatening amount of the compound if it can be performed soon after ingestion (generally within 1 hour).

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Water spray, Foam, Carbon dioxide (CO_2), Dry powder.

Fire/explosion hazard

No data available

Specific hazards arising from the chemical

Thermal decomposition can lead to release of irritating gases and vapors. Keep product and empty container away fromheat andsources of ignition.

Hazardous combustion products

Carbon monoxide (CO). Carbon dioxide (CO2). Phosgene. Hydrogen chloride gas.

Personal protection

Self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Handling- Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.

Fire precautions

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed. Store at 20° to 25°C.

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS	Name	TWA	STEL	Source
76584-70-8	Divalproex sodium	Not established	-	-
75-09-2	Methylene chloride	25 ppm	125 ppm	OSHA
67-63-0	Isopropyl Alcohol	200 ppm	400 ppm	ACGIH
557-04-0	Magnesium stearate	10 mg/m^3 (eye, skin, & URT irr)	-	ACGIH

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Hand protection

Protective gloves.

Eye protection

Goggles.

Skin and body protection

Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid
Form: Capsule
Colour: Light Blue Transperant cap, White Opaque body
Odour: N.A.
pH: not tested
Melting point: not tested
Boiling point: not applicable
Flash point: not applicable
Flammability (solid): not tested
Vapour pressure: not tested
Auto-ignition temperature: not applicable
Decomposition temperature: not tested
Density: not tested
Solubility in water: Insoluble in water

Solubility in solvents: Not tested
n-Octanol/Water Partition Coefficient: Not known
Viscosity: Not applicable
Oxidizing properties: not tested
Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid

Avoid moisture, light and heat.

Materials to avoid

Stable under normal ambient and anticipated storage and handling conditions.

Hazardous decomposition products

No data available for mixture.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Divalproex sodium-
Oral, mouse: LD_{50} = 1098 mg/kg; Oral, rat: LD_{50} = 670 mg/kg.

Oral TDLO 135.7 ml/kg/2h (man)
Substance is classified as Category 4.

Methylene chloride

LC_{50} inhalation - 53 mg/L (Rat) 6 h, 76000 mg/m^3 (Rat) 4 h

Based on additivity formula, mixture is classified as category 4.

Primary Irritation

Divalproex sodium on the skin: Irritant to skin and mucous membranes.
on the eye: Irritating effect.

- Skin Irritation.: category 2
- Eye Irritation.: category 2

Magnesium stearate
Skin - category 2
Eye Irritation - category 2

Isopropyl Alcohol
Eye irritation - Category 2

GHS Classification of the mixture for skin irritation and eye irritation category 2.

Respiratory or Skin sensitization

- Respiratory: Not tested

GHS Classification is not possible.

CMR consideration:

Germ cell mutagenicity:
Methylene chloride - Category 2
GHS Classification of mixture – category 2 mutagen (if this substance is present at ≥1%

Carcinogenicity
Methylene chloride – category 2

·IARC (International Agency for Research on Cancer) Substance is listed.
· NTP (National Toxicology Program) Substance is listed.
· OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

Mixture is classified as Category 2

Reproductive toxicity

- Divalproex sodium – category 1A

GHS classification for mixture is category 1A since substance is present at >0.1 %.

Specific target organ toxicity single exposure

Methylene chloride – category 3
Isopropyl alcohol – category 3

Mixture is not classified.

Specific target organ toxicity repeated exposure

Methylene chloride – category 2

Mixture is classified as category 2 (if concentration exceeds >1%)

Aspiration hazard:
Due to lack of data GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity data for divalproex sodium is not available.

SLS and Magnesium stearate are classified as chronic 3 and chronic 4 respectively. Based on the GHS classification for environmental hazards, the mixture has been classified as chronic 4.

Methylene chloride
Freshwater algae - EC50:>660 mg/L/96h
Freshwater fish - Pimephales promelas: LC50:193 mg/L/96h
Microtox - EC50: 1 mg/L/24 h EC50: 2.88 mg/L/15 min
Water flea - EC50: 140 mg/L/48h
A measured BCF range of 2-40 suggests bioconcentration in aquatic organisms is low to moderate.

GHS Classification is not applicable for the mixture.

Persistence and degradability
Data not available. GHS Classification is not possible.

Behaviour in treatment plants
Data not available. GHS Classification is not possible.

Additional information
Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Product disposal
Incinerate in approved facility. Observe specific national regulation.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

The substance is not considered to be a dangerous good according to transport regulations

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING
Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2023 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019

16. OTHER INFORMATION

Recommended restrictions on use
This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

Prepared on 05-05-2025