


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	SODIUM VALPROATE, EP
PRODUCT CODE	2780
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Toxic to Reproduction (Category 1A) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Liver, Pancreas) Acute Aquatic toxicity (Category 3)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. Exposure may produce an allergic reaction. May damage fertility or the unborn child. Causes damage to organs (liver, pancreas) through prolonged or repeated exposure. Harmful to aquatic life
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)	Prevention	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Do not breathe dust/fume/gas/mist/ vapors/spray. Avoid release to the environment		
	Response	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice. Get medical help if you feel unwell		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
HMS CLASSIFICATION	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Sodium 2-propylpentanoate
BOTANICAL NAME	Not applicable
SYNONYM	4-Methylmorpholine; 4-Methyl-1oxa-4-azacyclohexane; valproate sodium
CHEMICAL FORMULA	C ₈ H ₁₅ NaO ₂
CHEMICAL FAMILY	Carboxylic acid; derived from valproic acid
CAS NUMBER	1069-66-5
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	166.1945

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
SODIUM VALPROATE	1069-66-5	213-961-8	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES Valproate is a generic term applied to valproic acid and its salts and esters.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.

SYMPTOMS CAUSED BY
EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING
FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION
PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE
EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND
PRECAUTIONS FOR
FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR
CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER
SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE
HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE
STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: SODIUM VALPROATE CAS #: 1069-66-5

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or 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 if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

 USP TWA: 750 micrograms/m³ (as valproic acid).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White or almost white, crystalline, hygroscopic powder.

SOLUBILITY

Very soluble in water, freely soluble in ethanol (96 per cent).

ODOR

Odorless or almost odorless.

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

222 °C (431.6 °F)

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	2.603 (20°C)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	> 300 °C, > 572 °F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	7 - 9.5
RELATIVE DENSITY (WATER = 1)	0.4 -0.6	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants, reducing agents, bases.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur dioxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 670 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.Irritating for eyes and skin.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.Irritating for eyes and skin.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.Exposure may produce an allergic reaction.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.Irritating for eyes and skin. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that thechemical is Sensitizer (moderate reliability)
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Suspected mutagen: The outcome in CTA assay is positive according toSSCTA

CARCINOGENICITY
OSHA SODIUM VALPROATE is not listed.

NTP SODIUM VALPROATE is not listed.

IARC SODIUM VALPROATE is not evaluated.

California Proposition This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: VALPROATE.

Due to lack of data the classification is not possible.

ADDITIONAL CARCINOGENICITY INFORMATION
REPRODUCTIVE TOXICITY

Studies showed a higher frequency of abnormalities (especially neural tube defects) in infants born to women after chronic therapeutic use of Sodium Valproate during pregnancy as an anti-convulsant. The therapeutic chronic use of Sodium Valproate, like some other anti-epileptic drugs, implies an elevated risk of teratogenic effects to the unborn child. The most susceptible period, post conception, is 18 - 60 days.

Chronic exposures usually have a greater potential to cause teratogenic effects than acute exposures at similar doses.

Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability)

Due to lack of data the classification is not possible. May cause local gastric irritation.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Causes damage to organs (liver, pancreas) through prolonged or repeated exposure. Human systemic effects: change in exocrine pancreas, nausea, diarrhea, sleep disturbance, mild to moderate liver enzyme elevations. Rare cases of life threatening pancreatitis have been reported shortly after initial use as therapeutic drug as well as after several years of use. Rare case of serious or fatal hepatotoxicity after use as drug, especially after chronic use by children receiving multiple anticonvulsant therapy.

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS
SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Valproates: Liver injury. Pancreatitis. Blood disorders. Hyperammonemia.

Toxic effects are frequently associated with dose levels over 1800 mg per day (Valproic Acid).

Unconsciousness occurs when 200 mg/kg has been ingested.

Symptoms related to the physical, chemical, and toxicological characteristics of Valproates:

Nausea. Vomiting. Diarrhea. Constipation. Indigestion. Abdominal pain. Loss of appetite. Increased appetite. Weight loss. Weight gain. Dizziness. Tremor. Headache. Weakness. Tiredness. Unsteadiness. Behavior, mood, or mental changes. Blurred vision. Double vision. Uncontrolled eye movements. Ringing in ears. Seizures. Skin rash. Hair loss. Back pain. Flu symptoms. Upper respiratory tract infection. Jaundice.

Medical conditions aggravated by exposure:

Valproates: Active alcoholism. Impaired liver function. Impaired kidney function. Blood disorders. Pancreatitis. Organic brain disease. Urea cycle disorders. Hypoalbuminemia. Porphyrin. Hereditary mitochondrial disease.

POTENTIAL HEALTH EFFECTS
Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion Harmful if swallowed.

Skin May be harmful if absorbed through skin. Causes skin irritation. May cause allergic reaction.

Eyes Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia Magna (mg/L): 73.07* LC50: 96 Hr: Fish: (mg/L): 28.97 - 81.16** EC50: 72 or 96 Hr: Algae: (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Log Pow: 2.603 (20°C). Bioaccumulation not expected.
MOBILITY IN SOIL	Solubility in water: > 300 g/l in water.
OTHER ADVERSE EFFECTS	Not available
NOTES	This product is not intended to be released into the environment *VEGA (Q)SAR platform prediction (moderate reliability) **Fathead Minnow toxicity model (EPA) in VEGA (Q)SAR platform predicts that the chemical has a 96h LC50 of 28.97 mg/L (moderate reliability); Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform predicts that the chemical has a 96h LC50 of 81.16 mg/L (good reliability)

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
AUSTRALIA HAZCHEM	Not applicable
EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
SODIUM VALPROATE 1069-66-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X*

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
SODIUM VALPROATE 1069-66-5	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
SODIUM VALPROATE 1069-66-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES *VALPROIC ACID is listed.

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.