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
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
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

USES:
Anticonvulsant; antiepileptic

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)

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.

AUSTRALIA-ONLY HAZARDS:
Not Applicable.

PRECAUTIONARY STATEMENT(S):
Prevention:
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye protection, face protection.
Do not breathe dust/fume/gas/mist/ vapors/spray.

Response:
IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

Storage:
Store locked up.

Disposal:
Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION:
Health Hazard: 2
Flammability: 0
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>Sodium 2-propylpentanoate</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOTANICAL NAME</td>
<td>Not applicable</td>
</tr>
<tr>
<td>SYNONYM</td>
<td>4-Methylmorpholine; 4-Methyl-1oxa-4-azacyclohexane; valproate sodium</td>
</tr>
<tr>
<td>CHEMICAL FORMULA</td>
<td>C₈H₁₅NaO₂</td>
</tr>
<tr>
<td>CAS NUMBER</td>
<td>1069-66-5</td>
</tr>
<tr>
<td>ALTERNATE CAS NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT</td>
<td>166.1945</td>
</tr>
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<td>COMPOSITION</td>
<td></td>
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<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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</thead>
<tbody>
<tr>
<td>SODIUM VALPROATE</td>
<td>1069-66-5</td>
<td>100</td>
</tr>
</tbody>
</table>

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.

Chemical family: Carboxylic acid; derived from valproic acid.
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
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.

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.
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.

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.

STORAGE CONDITIONS

- Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: SODIUM VALPROATE  CAS #: 1069-66-5

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
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<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>N/L</td>
<td>-</td>
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<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

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

NOTES

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- **PHYSICAL STATE:** Solid
## SAFETY DATA SHEET

### 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Odor threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower flammable/explosive limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor density (air = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>Not available</td>
</tr>
<tr>
<td>Upper flammable/explosive limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting point</td>
<td>&gt; 300 °C, &gt; 572 °F</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Log P (octanol-water)</td>
<td>2.603 (20°C)</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

**Reactivity**
Not established

**Stability**
Stable under recommended storage conditions

**Materials to Avoid**
Strong oxidants, reducing agents, bases.

**Hazardous Decomposition Products**
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides 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: LD50: (mg/L/4hr): Not available

**Skin Corrosion/Irritation**
Irritating for eyes and skin.
Due to lack of data the classification is not possible.

**Serious Eye Damage/Eye Irritation**
Irritating for eyes and skin.
Due to lack of data the classification is not possible.

**Respiratory or Skin Sensitization**
Due to lack of data the classification is not possible.
Exposure may produce an allergic reaction.

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SAFETY DATA SHEET

GERM CELL MUTAGENICITY
Due to lack of data the classification is not possible.

CARCINOGENICITY

<table>
<thead>
<tr>
<th>Agency</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>SODIUM VALPROATE is not listed.</td>
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<tr>
<td>NTP</td>
<td>SODIUM VALPROATE is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>SODIUM VALPROATE is not evaluated.</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: VALPROATE.</td>
</tr>
</tbody>
</table>

ADDITIONAL CARCINOGENICITY INFORMATION
Not available

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 then acute exposures at similar doses.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

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.

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

SIGNS AND SYMPTOMS OF EXPOSURE

Toxic effects are frequently associated with dose levels over 1800 mg per day (Valproic Acid). Unconsciousness occurs when 200 mg/kg has been ingested.


POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. Causes skin irritation.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes serious eye irritation.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

<table>
<thead>
<tr>
<th>Test</th>
<th>EC50 (mg/L)</th>
<th>LC50 (mg/L)</th>
<th>IC50 (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish</td>
<td>48 Hr: 596</td>
<td>96 Hr: Not available</td>
<td>72 Hr: Not available</td>
</tr>
<tr>
<td>Daphnia magna</td>
<td>48 Hr: 596</td>
<td>LC50: Not available</td>
<td>IC50: Not available</td>
</tr>
</tbody>
</table>

PERSISTENCE AND DEGRADABILITY

<table>
<thead>
<tr>
<th>Test</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish</td>
<td>2.603</td>
</tr>
</tbody>
</table>

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
This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
Not dangerous good

UN PROPER SHIPPING NAME
Not applicable

UN NUMBER
Not applicable

CLASS
Not applicable

PACKING GROUP
Not applicable

AUSTRALIA
Not dangerous good

UN PROPER SHIPPING NAME
Not applicable

UN NUMBER
Not applicable

CLASS
Not applicable

PACKING GROUP
Not applicable

HAZCHEM
Not applicable

ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
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<tbody>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X*</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>SODIUM VALPROATE 1069-66-5</td>
<td>Not Listed</td>
<td>Listed as Schedule 4*</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

NOTES
*VALPROIC ACID is listed.
SAFETY DATA SHEET

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH – American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL – Recommended Exposure Limit

LAST REVISION
02/2016

SUPERSEDES
12/2013

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.