

# **Scientific Documentation**

# **Divalproex Sodium, USP**

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





# **Table of Contents**

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label



# Specification for Divalproex Sodium, USP (D2044)

Item Number	D2044
Item	Divalproex Sodium, USP
CAS Number	76584-70-8
Molecular Formula	(C <sub>16</sub> H <sub>31</sub> NaO <sub>4</sub> ) <sub>n</sub>
Molecular Weight	(310.41)N
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY (OF AVAILABLE VALPROIC ACID)	98.10	102.0 %	
WATER DETERMINATION		1.0 %	
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
RETEST DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	TO PASS TEST		

# Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



# **Certificate Of Analysis**

Item Number	D2044	Lot Number	4MH0011
Item	Divalproex Sodium, USP	Manufacturer Lot	SC0100042
CAS Number	76584-70-8	Manufacturer Code	9855
Molecular Formula	$(C_{16}H_{31}NaO_4)_n$	Molecular Weight	(310.41)N

TECT	SPECIFI	CATION	DECLUT
TEST	MIN	MAX	RESULT
ASSAY (OF AVAILABLE VALPROIC ACID)	98.10	102.0 %	98.9 %
WATER DETERMINATION		1.0 %	0.04 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			01-DEC-2027
DATE OF MANUFACTURE			01-JAN-2023
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 15-NOV-23 12:07:27

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO Matheu Camacho 15-NOV-23 12:15:02

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by HARMAN FINOCHEM LIMITED at A-100, A-100/1, A-100/2 & D-1, M.I.D.C Industrial Area, Shendra,, Aurangabad, Maharashtra 431007, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.





Revision date 26-June-2023 Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name Divalproex Sodium, USP

Other means of identification

Product Code(s) D2044

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

**Supplier Address** 

Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

# 2. Hazard(s) identification

#### Classification

Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 1B
Specific target organ toxicity (repeated exposure)	Category 2

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Danger

#### Hazard statements

Causes serious eye irritation May damage fertility or the unborn child

May cause damage to organs through prolonged or repeated exposure



Appearance Crystalline powder Physical state Solid Odor Odorless

#### **Precautionary Statements - Prevention**

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 Wash face, hands and any exposed skin thoroughly after handling

Do not breathe dust/fume/gas/mist/vapors/spray

#### **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention

#### **Precautionary Statements - Storage**

Store locked up.

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Other information

May be harmful if swallowed.

# 3. Composition/information on ingredients

#### **Substance**

Chemical name	CAS No	Weight-%
Divalproex Sodium	76584-70-8	100

#### 4. First-aid measures

#### **Description of first aid measures**

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

**Skin contact** Wash skin with soap and water.

Ingestion Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

#### Most important symptoms and effects, both acute and delayed

**Symptoms** May cause redness and tearing of the eyes. Burning sensation.

#### Indication of any immediate medical attention and special treatment needed

# 5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge none

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

## 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

**Other information** Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## 7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes. Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

# 8. Exposure controls/personal protection

Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

#### **Appropriate engineering controls**

Engineering controls Showers

Eyewash stations Ventilation systems.

#### Individual protection measures, such as personal protective equipment

**Eye/face protection** If splashes are likely to occur, wear safety glasses with side-shields.

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear

None known

suitable gloves and eye/face protection.

## 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Crystalline powder

Color White Odor Odorless

Odor threshold No information available

Property	<u>Values</u>	Remarks • Method
рН	no data available	None known

Melting point / freezing point 99 - 101 °C / 210.2 - 213.8 °F None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known None known Flammability Limit in Air

Upper flammability or explosive

limits

No data available

Lower flammability or explosive

limits

No data available

No data available Vapor pressure None known Vapor density no data available None known Relative density no data available None known Water solubility No data available None known Solubility(ies) Soluble in Methanol None known No data available **Partition coefficient** None known **Autoignition temperature** no data available None known **Decomposition temperature** None known Kinematic viscosity no data available None known

No data available

Dynamic viscosity

Other information

Explosive properties
Oxidizing properties
No information available
No information available
No information available

Molecular weight 310.41

VOC Content (%)
Liquid Density
No information available
No information available
No information available

# 10. Stability and reactivity

**Reactivity** No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

**Incompatible materials**None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

# 11. Toxicological information

#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. May cause irritation.

Prolonged contact may cause redness and irritation.

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** May cause redness and tearing of the eyes.

**Acute toxicity** 

#### **Numerical measures of toxicity**

No information available

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** May cause skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May damage fertility or the unborn child.

**STOT - single exposure** No information available.

**STOT - repeated exposure** May cause damage to organs through prolonged or repeated exposure.

**Aspiration hazard** No information available.

Other adverse effects No information available.

Interactive effects No information available.

# 12. Ecological information

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

Persistence and degradability

No information available.

Bioaccumulation

Inherently biodegradable.

Other adverse effects No information available.

## 13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# 14. Transport information

**DOT** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

# 15. Regulatory information

#### International Inventories

TSCA Not listed

Note \*Contact supplier for details. One or more substances in this product are either not listed

on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise

#### exempted from inventory listing requirements

DSL/NDSL Does not Comply EINECS/ELINCS Does not Comply

**ENCS IECSC**This product complies with ENCS:
This product does not comply with china:

**KECL** Does not Comply **PICCS** Does not Comply

AICS This product does not comply with AICS

#### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances
 IECSC - China Inventory of Existing Chemical Substances
 KECL - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

## SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

## 16. Other information

#### NFPA

Health hazards 2 Flammability 0 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 2 \*
Flammability 0
Physical hazards 0
Personal protection X

Chronic Hazard Star Legend

\* = Chronic Health Hazard

#### Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 26-June-2023

**Revision Note** No information available.

**Disclaimer** 

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet** 



### Certification of Compliance with current Good Manufacturing Practices

#### Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
D2044	Divalproex Sodium, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632 Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

**Divalproex Sodium, USP (Cat# D2044)** 

#### Stage I: Synthesis of Di-n-propyl malonic acid (DIPMA)

### Stage II: Synthesis of n-propyl pentanoic acid (Valproic acid)

#### Stage III: Synthesis of Divalproex Sodium & batch formation:

# CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

Divalproex Sodium

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



# D2044, Divalproex Sodium, USP

## **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

## **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

# **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

# **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

#### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

## **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

# **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

# **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



# RE: Elemental Impurities - Divalproex Sodium, USP (Cat# D2044)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

<b>Elemental Impurity</b>		Class	Expected Concentration
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Nickel	Ni	2A	< 20 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



# RE: Residual Solvents - Divalproex Sodium, USP (Cat# D2044)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Ethanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



# **Label Information**

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



#### **DANGER**

Date: 00-00-0000

 Causes serious eye irritation
 May damage fertility or the unborn child • May cause damage to organs through prolonged or repeated exposure • May be harmful if swallowed.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product . Wear protective gloves, protective clothing, eye protection, face protection . Do not breathe dust . Wash face, hands and any exposed skin

thoroughly after handling.
FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. If exposed or concerned: Get medical

**KEEP FROM CHILDREN** 

# SIZ SY D2044 **Divalproex** Sodium

**USP** 

CAS 76584-70-8



**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $(C_{16}H_{31}NaO_4)_n$  F.W.  $(310.41)_n$ 

Manufacturer/Supplier Code ..... Manufacturer Lot Number..... Assay (of available Valproic Acid) .... 98.0-102.0% MAXIMUM LIMITS Water Determination ...... 1.0% Elemental Impurities ...... As reported Residual Solvents ......To pass test

WARNING: Cancerwww.P65Warnings.ca.gov

Repackaged by Spectrum as:

Lot No. XO#### G 4/I7GHS-A

# Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

New Brunswick, NJ 08901

West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300