



Scientific Documentation

P1729, Procainamide Hydrochloride, 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

Ver4.03 8.January.2018



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", with a large, sweeping flourish at the end.

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com

8.January.2018

P1729, Procainamide Hydrochloride, USP

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spectrum[®]
CHEMICAL MFG CORP



Specification for Procainamide Hydrochloride, USP (P1729)

Item Number	P1729
Item	Procainamide Hydrochloride, USP
CAS Number	614-39-1
Molecular Formula	$C_{13}H_{21}N_3O.HCl$
Molecular Weight	271.79
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0 - 102.0 %	
MELTING RANGE	165 - 169 C	
LOSS ON DRYING		0.3 %
RESIDUE ON IGNITION		0.1 %
HEAVY METALS		0.002 %
FREE p-AMINOBENZOIC ACID		0.1 %
ORDINARY IMPURITIES		TO PASS TEST
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
RESIDUAL SOLVENTS		TO PASS TEST

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

SAFETY DATA SHEET

Preparation Date: 3/24/2016

Revision Date: Not Applicable

Revision Number: Not Applicable

1. IDENTIFICATION

Product identifier

Product code: P1729
Product Name: PROCAINAMIDE HYDROCHLORIDE, USP

Other means of identification

Synonyms: Amidoprocain
 p-Amino-N-(2-(diethylamino)ethyl)benzamide hydrochloride
 4-Amino-N-(2-(diethylamino)ethyl)benzamide monohydrochloride
 Novocamid hydrochloride
 Procainamide hydrochloride
 Procaine amide hydrochloride
 Procan-SR hydrochloride
 Procapan hydrochloride
 Procardyl hydrochloride
 Promide hydrochloride
 Pronestyl hydrochloride
 Supicane amide hydrochloride

CAS #: 614-39-1
RTECS # CV2295000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
Uses advised against No information available

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

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2

Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Label elements

Warning

Hazard statements
 Harmful if swallowed
 Causes skin irritation
 Causes serious eye irritation
 May cause respiratory irritation



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Wear protective gloves
 Wear eye/face protection
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

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.
 IF ON SKIN: Wash with plenty of water
 If skin irritation occurs: Get medical advice/attention
 Take off contaminated clothing and wash it before reuse
 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
 Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name: Procainamide Hydrochloride

Components	CAS-No.	Weight %
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Procainamide Hydrochloride 614-39-1	614-39-1	100
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4. FIRST AID MEASURES

First aid measures

General Advice:

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms

Irritating to eyes and skin. Irritating to respiratory system. Ingestion may cause nausea, vomiting, and diarrhea. Bitter taste in mouth. May cause loss of appetite. Joint pain. Weakness. May cause decreased urination. May affect the cardiovascular system. Weak, rapid pulse or rapid heart rate (Tachycardia). Cardiac arrhythmias. It may affect the blood. It may cause blood disorders such as leukopenia, thrombocytopenia, and agranulocytosis. Central nervous system depression. Central nervous system effects.

Indication of any immediate medical attention and special treatment needed

Notes to Physician:

Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:

Dry chemical. Carbon dioxide (CO₂). Water spray mist or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products:

Carbon monoxide; Carbon dioxide; nitrogen oxides; hydrogen chloride gas

Specific hazards:

May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods:

No information available.

Special Protective Equipment for Firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Use personal protective equipment. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Procainamide Hydrochloride 614-39-1	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Procainamide Hydrochloride 614-39-1	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Procainamide Hydrochloride 614-39-1	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles

Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent. .

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: White to tan.
Odor: No information available	Taste No information available	Formula: C ₁₃ H ₂₁ N ₃ O•HCl
Molecular/Formula weight: 271.79	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	pH: 5 - 6.5 (10% in water)	Melting point/range(°C/°F): 157 - 170 °C (315 - 338 °F)
Decomposition temperature(°C/°F): >400 °C	Boiling point/range(°C/°F): No information available	Bulk density: No information available
Density (g/cm³): No information available	Specific gravity: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water Slightly soluble in alcohol Insoluble in Acetone Insoluble in Petroleum ether	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with strong oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Strong oxidizing agents.

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Nitrogen oxides (NO_x). Hydrogen chloride gas.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product code: P1729

Product name: PROCAINAMIDE
HYDROCHLORIDE, USP

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Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Procainamide Hydrochloride - 614-39-1

LD50/oral/rat = 1509 mg/kg Oral LD50 Rat

LD50/oral/mouse = 1110 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 1509mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 1110mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:

Causes skin irritation. Moderately irritating to the skin.

Eye Contact:

Causes eye irritation. Moderately irritating to the eyes. Causes conjunctival irritation.

Inhalation

Irritating to respiratory system

Ingestion

Harmful if swallowed. May cause digestive (gastrointestinal) tract irritation. Ingestion may cause nausea, vomiting, diarrhea. May cause loss of appetite. May cause weakness. May affect behavior/central nervous system (somnolence, tremor, hallucinations). May affect behavior/central nervous system (convulsions). May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (ataxia). May cause fainting. It may affect the joints. May affect the blood (thrombocytopenia). May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (cardiac arrhythmias).

Ingestion: May also cause other blood disorders such as leukopenia, and agranulocytosis.
May also cause decreased urination.
May also cause bitter taste in mouth

Aspiration hazard No information available

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

Chronic Toxicity Prolonged or repeated skin contact may cause dermatitis, and dryness and cracking of the skin.

Sensitization: May cause sensitization by skin contact

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Procainamide Hydrochloride	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Procainamide Hydrochloride	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: None
ERG No: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

14. TRANSPORT INFORMATION

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Procainamide Hydrochloride</i>	Present	Not present	Not present	Not present	Not present	Present	Present 210-381-7

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Procainamide Hydrochloride</i>	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
<i>Procainamide Hydrochloride</i>	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Procainamide Hydrochloride</i>	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D2B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Procainamide Hydrochloride	Not Listed	Present

Components	CEPA Schedule I - Toxic Substances
Procainamide Hydrochloride	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Procainamide Hydrochloride	Not listed

EU Classification**R-phrase(s)**

R22 - Harmful if swallowed.

R36/37/38 - Irritating to eyes, respiratory system and skin.

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 - Wear suitable gloves.

S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	Classification	Concentration Limits:	Safety Phrases
Procainamide Hydrochloride		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xi - Irritant.

Xn - Harmful.

Xi



Xn

**16. OTHER INFORMATION**

16. OTHER INFORMATION

Preparation Date: 3/24/2016
Revision Date: Not Applicable
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Manufacturer

Product Covered: P1729, Procainamide Hydrochloride, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com

8.January.2018

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248,
USA,

Additional sites: 13915 South Main Street, Los Angeles, California,
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the
requirements of:

ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine
chemicals, solutions, equipment, supplies and products for the
laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance,
biotechnology, environmental and process industries.

Certificate Number:

94-316m-03

Initial Certification Date:

27 December 1994

Certificate Issue Date:

31 July 2017

Certificate Expiry Date:

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

Authorized Signature

Calin Moldovean

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
900 Chelmsford Street, Lowell, MA, USA



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018



Authorised Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



014



The certificate remains the property of Intertek, to whom it must be returned upon request.



March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston
Quality Assurance Specialist

January 8, 2018

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
P1729	Procainamide Hydrochloride, 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
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,



Oralia Chavez
Quality Assurance Specialist



July 27, 2016

Re: Procainamide Hydrochloride, USP- P1729

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Procainamide Hydrochloride, USP- P1729

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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



July 27, 2016

Re: Procainamide Hydrochloride, USP- P1729

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Procainamide Hydrochloride, USP- P1729

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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



July 27, 2016

Re: Procainamide Hydrochloride, USP- P1729

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Procainamide Hydrochloride, USP- P1729

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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

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.

SPECTRUM[®]

P1729 **25 G**

Procainamide Hydrochloride
U.S.P.

CAS 614-39-1

WARNING: Harmful if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.

Do not eat, drink or smoke when using this product • Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. 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 ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

C₁₃H₂₁N₃O•HCl F.W. 271.79

Assay (Dried Basis).....98.0-102.0%
Melting Range.....165°-169°C

MAXIMUM LIMITS

Loss on Drying.....0.3%
Residue on Ignition.....0.1%
Heavy Metals.....0.002%
Free *p*-Aminobenzoic Acid.....0.1%
Ordinary Impurities.....To pass test
Residual solvents.....To pass test

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

LIGHT SENSITIVE, HYGROSCOPIC: Keep tightly closed in light-resistant containers.

G 4/E12GHS A **Lot No. 062233**

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|---|--|---|
| A Bar Code | F Size/Quantity | K Empirical Formula, Formula Weight and Technical Specifications Panel |
| B GHS Hazard Pictograms | G Chemical Abstracts Service (CAS) Registry Number | L Expiration Information |
| C Warning, Safety Data and Precautionary Information | H Caution Information | M Lot Number |
| D Product Catalog Number | I DOT Shipping Information | N Kosher Certified by Kosher Supervision of America (KSA). |
| E Item Name, Form, Grade | J Toll-Free 24-Hour Chemical Emergency Telephone Number | |
| O Storage Color Band | | |

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248

310.516.8000

Item Number	P1729	Lot Number	2FD0009
Item	Procainamide Hydrochloride, USP		
CAS Number	614-39-1		
Molecular Formula	C ₁₃ H ₂₁ N ₃ O.HCl	Molecular Weight	271.79

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 102.0 %		99.95 %
MELTING RANGE	165 - 169 C		166 - 168.5 C
LOSS ON DRYING		0.3 %	0.22 %
RESIDUE ON IGNITION		0.1 %	0.031 %
HEAVY METALS		0.002 %	0.0005 %
FREE p-AMINOBENZOIC ACID		0.1 %	0.05 %
ORDINARY IMPURITIES		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			02-JUN-2018
RESIDUAL SOLVENTS		TO PASS TEST	.
CLASS 3 (solvent) / ETHANOL			<5000 ppm
APPEARANCE			OFF-WHITE POWDER
DATE OF MANUFACTURE			03-JUN-2015

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:




Mulbah F. Dwanah
Laboratory Supervisor
Spectrum Chemicals & Laboratory Products

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

January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,



Michael Dang
Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: P1729, Procainamide Hydrochloride, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, P1729, Procainamide Hydrochloride, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605