

Scientific Documentation

Propionic Acid, NF

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



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Specification for Propionic Acid, NF (P1464)

Item Number	P1464
Item	Propionic Acid, NF
CAS Number	79-09-4
Molecular Formula	C ₃ H ₆ O ₂
Molecular Weight	74.08
MDL Number	
Synonyms	Propanoic Acid

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY	97.0	102.0 %
SPECIFIC GRAVITY @ 25°C	0.988	0.993
DISTILLING RANGE	138.5°	142.5°C
NONVOLATILE RESIDUE		2.0 mg
ELEMENTAL IMPURITIES:		
LEAD (Pb)	AS REPORTED	
READILY OXIDIZABLE SUBSTANCES		2.2 mL
ALDEHYDE		1.75 mL
ORGANIC IMPURITIES	TO PASS TEST	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters: *West Coast Facility:*
769 Jersey Ave. 14422 S. San Pedro St.

Spectrum Chemical Mfg Corp

Corporate Headquarters: ***West Coast Facility:***

New Brunswick, NJ 08901 Gardena, CA 90248

732.214.1300

310.516.8000

Certificate Of Analysis

Item Number	P1464	Lot Number	1ML0062
Item	Propionic Acid, NF	CAS Number	79-09-4
Molecular Formula	C ₃ H ₆ O ₂	Molecular Weight	74.08

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			CLEAR COLORLESS LIQUID
ASSAY	97.0	102.0 %	99.9 %
SPECIFIC GRAVITY @ 25°C	0.988	0.993	0.989
DISTILLING RANGE	138.5°	142.5°C	138.5° - 142.5°
NONVOLATILE RESIDUE		2.0 mg	< 2.0 mg
ELEMENTAL IMPURITIES:			.
LEAD (Pb)	AS REPORTED		< 0.5 ug/g
READILY OXIDIZABLE SUBSTANCES		2.2 mL	< 2.2 mL
ALDEHYDE		1.75 mL	< 1.75 mL
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			15-NOV-2025
DATE OF MANUFACTURE			15-NOV-2023
MONOGRAPH EDITION			(USP-NF)2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT

Certificate of Analysis Results Entered By:

AMENDEZ
Ana Mendez
18-DEC-23 15:37:07

Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
02-JAN-24 12:26:06

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA



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.



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
P1464	Propionic Acid, NF

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 qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

P1464, Propionic Acid, NF

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

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 24 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
- Bisphenol A (BPA)
- Pesticides
- Phthalates



RE: Elemental Impurities - Propionic Acid, NF (P1464)

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:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	
Lead	Pb	1	<0.5 ppm
Arsenic	As	1	
Mercury	Hg	1	
Cobalt	Co	2A	
Vanadium	V	2A	
Nickel	Ni	2A	
Thallium	Tl	2B	
Gold	Au	2B	
Palladium	Pd	2B	
Iridium	Ir	2B	
Osmium	Os	2B	
Rhodium	Rh	2B	
Ruthenium	Ru	2B	
Selenium	Se	2B	
Silver	Ag	2B	
Platinum	Pt	2B	
Lithium	Li	3	
Antimony	Sb	3	
Barium	Ba	3	
Molybdenum	Mo	3	
Copper	Cu	3	
Tin	Sn	3	
Chromium	Cr	3	

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

* Lead is present below the limit of 10 ppm under the specification Lead as required by the USP monograph.

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



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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Propionic Acid, NF (Cat# P1464)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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
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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.

Retest Date: 00-00-0000



* 4 9 4 5 2 P 1 4 6 4 *

DANGER

• Causes severe skin burns and eye damage •
Flammable liquid and vapor • Toxic in contact with skin • May be harmful if swallowed.

• Keep away from heat, sparks, open flames, hot surfaces
 • No smoking • Ground container and receiving equipment
 • Use explosion-proof equipment • Use only non-sparking tools • Take precautionary measures against static discharge • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe mist or vapors
 • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

KEEP FROM CHILDREN

P1464

SIZ SY

Propionic Acid

NF

CAS 79-09-4

CAUTION: For manufacturing, processing or repacking.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN3463, Propionic acid, 8 (3), PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_3H_6O_2$ F.W. 74.08

Assay 99.5-100.5%
 Specific Gravity @ 25°C 0.988-0.993
 Distilling Range 138.5°-142.5°C

MAXIMUM LIMITS

Nonvolatile Residue To pass test
 Elemental Impurities As reported
 Readily Oxidizable Substance To pass test
 Aldehydes To pass test
 Residual Solvents To pass test

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

W 10/J9GHS ? Lot No. XQ####

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