

Scientific Documentation

Sodium Propionate, 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



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 Sodium Propionate, NF (S1418)

Item Number	S1418
Item	Sodium Propionate, NF
CAS Number	137-40-6
Molecular Formula	$C_3H_5NaO_2 \cdot xH_2O$
Molecular Weight	96.06 + xH_2O
MDL Number	
Synonyms	Sodium Propanoate ; Propanoic Acid Sodium Salt

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	98.0	102.0 %
ALKALINITY		TO PASS TEST
WATER DETERMINATION		1.0 %
ELEMENTAL IMPURITIES		AS REPORTED
ORGANIC IMPURITIES:		
SODIUM ACETATE		0.3 %
SODIUM ACRYLATE		0.1 %
ANY UNIDENTIFIED INDIVIDUAL IMPURITY		0.1 %
TOTAL IMPURITIES		1.0 %
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR SODIUM	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS		

Spectrum Chemical Mfg Corp

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

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

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300

310.516.8000

Certificate Of Analysis

Item Number	S1418	Lot Number	4MI0061
Item	Sodium Propionate, NF	CAS Number	137-40-6
Molecular Formula	C ₃ H ₅ NaO ₂ •xH ₂ O	Molecular Weight	96.06 + xH ₂ O

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	99.7 %
ALKALINITY		TO PASS TEST	PASSES TEST
WATER DETERMINATION		1.0 %	0.07 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			28-OCT-2024
DATE OF MANUFACTURE			28-OCT-2022
APPEARANCE			WHITE GRANULAR CRYSTALLINE POWDER
RESIDUAL SOLVENTS			NO RESIDUAL SOLVENTS USED

Certificate of Analysis Results Entered By:

MCAMACHO
Matheu Camacho
28-SEP-23 08:57:06

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA
Genaro Herrera
28-SEP-23 10:38:48

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.

SAFETY DATA SHEET

spectrum®



Revision date 24-April-2023

Revision Number 2

1. Identification

Product identifier

Product Name SODIUM PROPIONATE, NF

Other means of identification

Product Code(s) S1418

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

Acute toxicity - Dermal	Category 4
Skin sensitization	Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful in contact with skin
May cause an allergic skin reaction



Appearance Crystalline powder
Granular or Crystals

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wear protective gloves/protective clothing
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing must not be allowed out of the workplace

Precautionary Statements - Response

Specific treatment (see .? on this label)
Specific treatment (see .? on this label)
IF ON SKIN: Wash with plenty of water and soap
Call a POISON CENTER or doctor if you feel unwell
Take off contaminated clothing and wash it before reuse
If skin irritation or rash occurs: Get medical advice/attention

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Sodium Propionate	137-40-6	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 thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the 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 Product is or contains a sensitizer. May cause sensitization by skin contact.

Hazardous combustion products Carbon monoxide. Sodium oxides.

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 Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. Hygroscopic. It absorbs moisture from the air.

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

Wear safety glasses with side shields (or goggles).

Hand protection

Wear suitable gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved 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

Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder Granular or Crystals
Color	Colorless
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	no data available	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
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.51	None known
Water solubility	Easily soluble in cold water Easily soluble in hot water	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	96.06 + xH ₂ O
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	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**

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Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May be absorbed through the skin in harmful amounts. Harmful in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Itching. Rashes. Hives.
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Acute toxicity**Numerical measures of toxicity****Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Propionate 137-40-6	= 5600 mg/kg (Rat)	= 1640 mg/kg (Rabbit) = 500 mg/kg (Rabbit)	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	May cause sensitization by skin contact.
Germ cell mutagenicity	No information available.

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Propionate 137-40-6	-	LC50: 4390 - 5120mg/L (96h, Pimephales promelas)	-	-

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Sodium Propionate 137-40-6	0.33

Other adverse effects	No information available.
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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
IATA	not regulated
IMDG	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDL Complies

EINECS/ELINCS Complies

ENCS This product complies with ENCS:

IECSC This product complies with China:

KECL Complies

PICCS Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

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

DSL/NDL - 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

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

24-April-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
S1418	Sodium Propionate, 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,

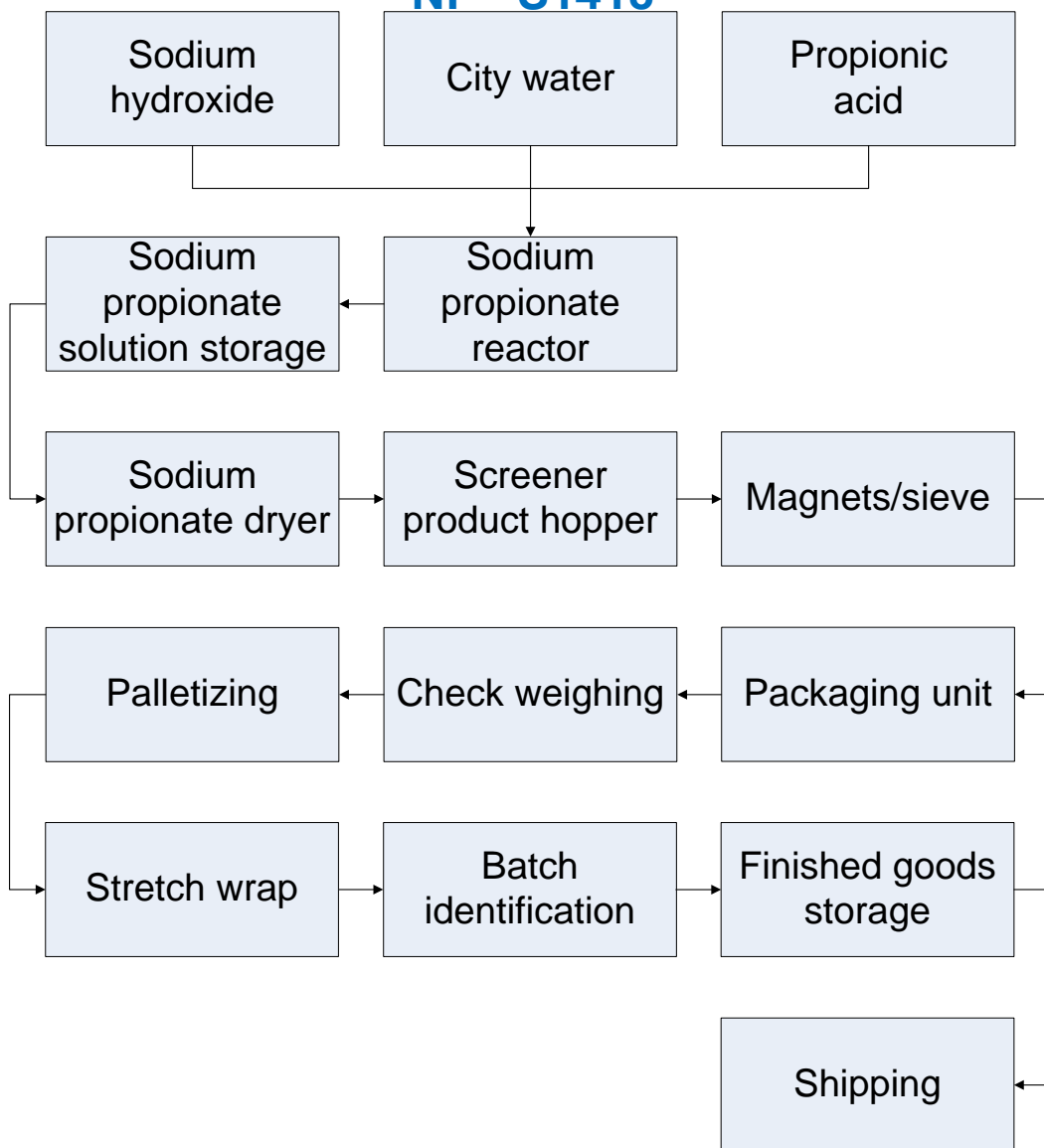
A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process

Flowchart - Sodium Propionate,

NF - S1418



Spectrum Chemical Mfg Corp

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769 Jersey Ave.
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732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

S1418, Sodium Propionate, 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:

- Bisphenol A (BPA)
- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Sodium Propionate, NF (Cat# S1418)

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
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 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 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



RE: Residual Solvents - Sodium Propionate, NF (Cat# S1418)

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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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.

s1418 03/12/2018 gh ghs

Retest Date: 00-00-0000



WARNING

- Harmful in contact with skin
- May cause an allergic skin reaction.
- Avoid breathing dust • Wear protective gloves, protective clothing
- Contaminated work clothing must not be allowed out of the workplace.

FIRST AID: IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. Call a POISON CENTER or physician if you feel unwell.



KEEP FROM CHILDREN

S1418 SIZ SY Sodium Propionate (Propanoic Acid Sodium Salt)

NF

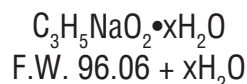
CAS 6700-17-0

CAUTION: For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com



Assay (Dried Basis)..... 99.0-100.5%
MAXIMUM LIMITS

Alkalinity To pass test
Water Determination 1.0%
Elemental Impurities As reported
Residual Solvents To pass test

HYGROSCOPIC: Keep tightly closed.

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

G 8/H3GHS

?

Lot No. XQ####

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