

Scientific Documentation

Butyl Alcohol, 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 Butyl Alcohol, NF (B1197)

Item Number	B1197
Item	Butyl Alcohol, NF
CAS Number	71-36-3
Molecular Formula	C ₄ H ₁₀ O
Molecular Weight	74.12
MDL Number	
Synonyms	1-Butanol ; n-Butyl Alcohol

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (GC-FID)	99.5 %	
ACIDITY		2.5 ml
WATER DETERMINATION		0.1 %
NONVOLATILE RESIDUE		0.004 %
BUTARALDEHYDE		0.1 %
2-BUTANOL		0.1 %
ISOBUTYL ALCOHOL (2-METHYL-1-PROPANOL)		0.1 %
BUTYL ETHER		0.2 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
RESIDUAL SOLVENTS		AS REPORTED
CLASS 3 (solvent) / ETHANOL	.	
CLASS 3 (solvent) / 1-PROPANOL	.	
CLASS 3 (solvent) / 2-PROPANOL	.	
MONOGRAPH EDITION		
RETEST DATE		
DATE OF MANUFACTURE		

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	B1197	Lot Number	2NC0004
Item	Butyl Alcohol, NF	CAS Number	71-36-3
Molecular Formula	C ₄ H ₁₀ O	Molecular Weight	74.12

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			CLEAR, COLORLESS LIQUID
ASSAY (GC-FID)	99.5 %		99.95 %
ACIDITY		2.5 ml	0.7 ml
WATER DETERMINATION		0.1 %	0.04 %
NONVOLATILE RESIDUE		0.004 %	0.000 %
BUTARALDEHYDE		0.1 %	<0.1 %
2-BUTANOL		0.1 %	<0.1 %
ISOBUTYL ALCOHOL (2-METHYL-1-PROPANOL)		0.1 %	0.05 %
BUTYL ETHER		0.2 %	0.00 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 3 (solvent) / ETHANOL	.		<5000 ppm
CLASS 3 (solvent) / 1-PROPANOL	.		<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL	.		<5000 ppm
MONOGRAPH EDITION			NF 2023
RETEST DATE			11-APR-2027
DATE OF MANUFACTURE			12-APR-2022

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
05-MAR-24 12:34:49

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
05-MAR-24 12:57:58

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



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 30-December-2021

Revision Number 2

1. Identification

Product identifier

Product Name BUTYL ALCOHOL, NF

Other means of identification

Product Code(s) B1197

UN/ID no UN1120

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 - Oral	Category 4
Acute toxicity - Inhalation (Gases)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 1
Flammable liquids	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful if swallowed
Harmful if inhaled
Causes skin irritation
Causes serious eye irritation
Causes damage to organs through prolonged or repeated exposure
May cause respiratory irritation. May cause drowsiness or dizziness
Flammable liquid and vapor



Appearance clear

Physical state Liquid

Odor Strong and Characteristic

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Use only outdoors or in a well-ventilated area
Do not breathe dust/fume/gas/mist/vapors/spray
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof electrical/ ventilating / lighting / .? / equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Wear protective gloves/eye protection/face protection

Precautionary Statements - Response

Specific treatment (see .? on this label)
Get medical advice/attention 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 advice/attention
If skin irritation occurs: Get medical advice/attention
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower
Wash contaminated clothing before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor if you feel unwell
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth
In case of fire: Use CO2, dry chemical, or foam to extinguish

Precautionary Statements - Storage

Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful in contact with skin.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Butyl Alcohol	71-36-3	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

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. Get medical attention immediately if symptoms occur. If symptoms persist, call a physician. If breathing has stopped, give artificial respiration. Get medical attention immediately.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.
Self-protection of the first aider	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Avoid breathing vapors or mists.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause redness and tearing of the eyes. Burning sensation. Coughing and/ or wheezing. Difficulty in breathing.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO ₂). water spray. Alcohol resistant foam. 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	risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	yes.
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	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate
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ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Avoid breathing vapors or mists.

Other information

Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment

Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up

Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. 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. Take off contaminated clothing and wash before reuse. In case of insufficient ventilation, wear suitable respiratory equipment.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Butyl Alcohol 71-36-3	No data available	100 ppm TWA 300 mg/m ³ TWA	-

Appropriate engineering controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection

Tight sealing safety goggles.

Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.
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. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	clear
Color	Colorless
Odor	Strong and Characteristic
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	-89.8 °C / -129.6 °F	None known
Boiling point / boiling range	117 °C / 242.6 °F	None known
Flash point	37 °C / 98.6 °F	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	11.2 %	
Lower flammability or explosive limits	1.4 %	
Vapor pressure	No data available	None known
Vapor density	2.6	None known
Relative density	0.8	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Miscible with Ethanol Miscible with Ether Miscible with many organic solvents	None known
Partition coefficient	0.88	None known
Autoignition temperature	343 °C / 649.4 °F	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	74.12
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 Heat, flames and sparks. Excessive heat.

Incompatible materials Strong acids. Strong bases. Strong oxidizing agents.

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. Harmful by inhalation. (based on components).

Eye contact Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes. Coughing and/ or wheezing.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Butyl Alcohol 71-36-3	= 700 mg/kg (Rat)	= 3400 mg/kg (Rabbit)	> 8000 ppm (Rat) 4 h > 17.7mg.L (Rat) 4 h

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

Skin corrosion/irritation Classification based on data available for ingredients. Irritating to skin.

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.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure.

Target organ effects respiratory system, Eyes, Skin, central nervous system.

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
Butyl Alcohol 71-36-3	EC50: >500mg/L (72h, <i>Desmodesmus subspicatus</i>) EC50: >500mg/L (96h, <i>Desmodesmus subspicatus</i>)	LC50: 100000 - 500000µg/L (96h, <i>Lepomis macrochirus</i>) LC50: 1730 - 1910mg/L (96h, <i>Pimephales promelas</i>) LC50: =1740mg/L (96h, <i>Pimephales promelas</i>) LC50: =1910000µg/L (96h, <i>Pimephales promelas</i>)	-	EC50: 1897 - 2072mg/L (48h, <i>Daphnia magna</i>) EC50: =1983mg/L (48h, <i>Daphnia magna</i>)

Persistence and degradability No information available.
Bioaccumulation Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Butyl Alcohol 71-36-3	0.785

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. Transport information

DOT

UN/ID no UN1120
Proper Shipping Name: Butanols
Hazard class 3
Packing group: III
Special Provisions B1, IB3, T2, TP1
Marine Pollutant Severe Marine Pollutant
Description: UN1120, Butanols, 3, III
Emergency Response Guide Number 129

TDG

UN-No: UN1120
Proper Shipping Name: Butanols
Hazard class 3
Packing Group: III
Description: UN1120, Butanols, 3, III

MEX

UN-No UN1120
Proper Shipping Name Butanols

Hazard class	3
Special Provisions	223
Packing Group	III
Description	UN1120, Butanols, 3, III

ICAO (air)

UN-No:	UN1120
Proper Shipping Name:	Butanols
Hazard class	3
Packing Group:	III
Special Provisions	A3
Description:	UN1120, Butanols, 3, III

IATA

UN number	UN1120
Proper Shipping Name:	Butanols
Transport hazard class(es)	3
Packing group	III
Description:	UN1120, Butanols, 3, III

IMDG

UN number	UN1120
Proper shipping name	Butanols
Transport hazard class(es)	3
Packing group	III
EmS-No	F-E, S-D
Special Provisions	223
Marine pollutant	NP1
Description	UN1120, Butanols, 3, III, (37°C c.c.)

RID

UN number	UN1120
Proper Shipping Name:	Butanols
Transport hazard class(es)	3
Packing group	III
Classification code	F1
Description:	UN1120, Butanols, 3, III
Labels	3

ADR

UN number	1120
Proper Shipping Name:	Butanols
Transport hazard class(es)	3
Packing group	III
Classification code	F1
Tunnel restriction code	(D/E)
Description:	1120, Butanols, 3, III, (D/E)
Labels	3

ADN

UN/ID No	UN1120
Proper shipping name	Butanols
Transport hazard class(es)	3
Packing Group	III
Classification code	F1
Description	UN1120, Butanols, 3, III
Hazard label(s)	3
Limited quantity (LQ)	5 L
ventilation	VE01
Equipment Requirements	PP, EX, A

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL 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/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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Butyl Alcohol - 71-36-3	1.0

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Butyl Alcohol 71-36-3	5000 lb final RQ 2270 kg final RQ	-

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 3

Flammability 3

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2 *

Flammability 3

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 30-December-2021

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
B1197	Butyl Alcohol, 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

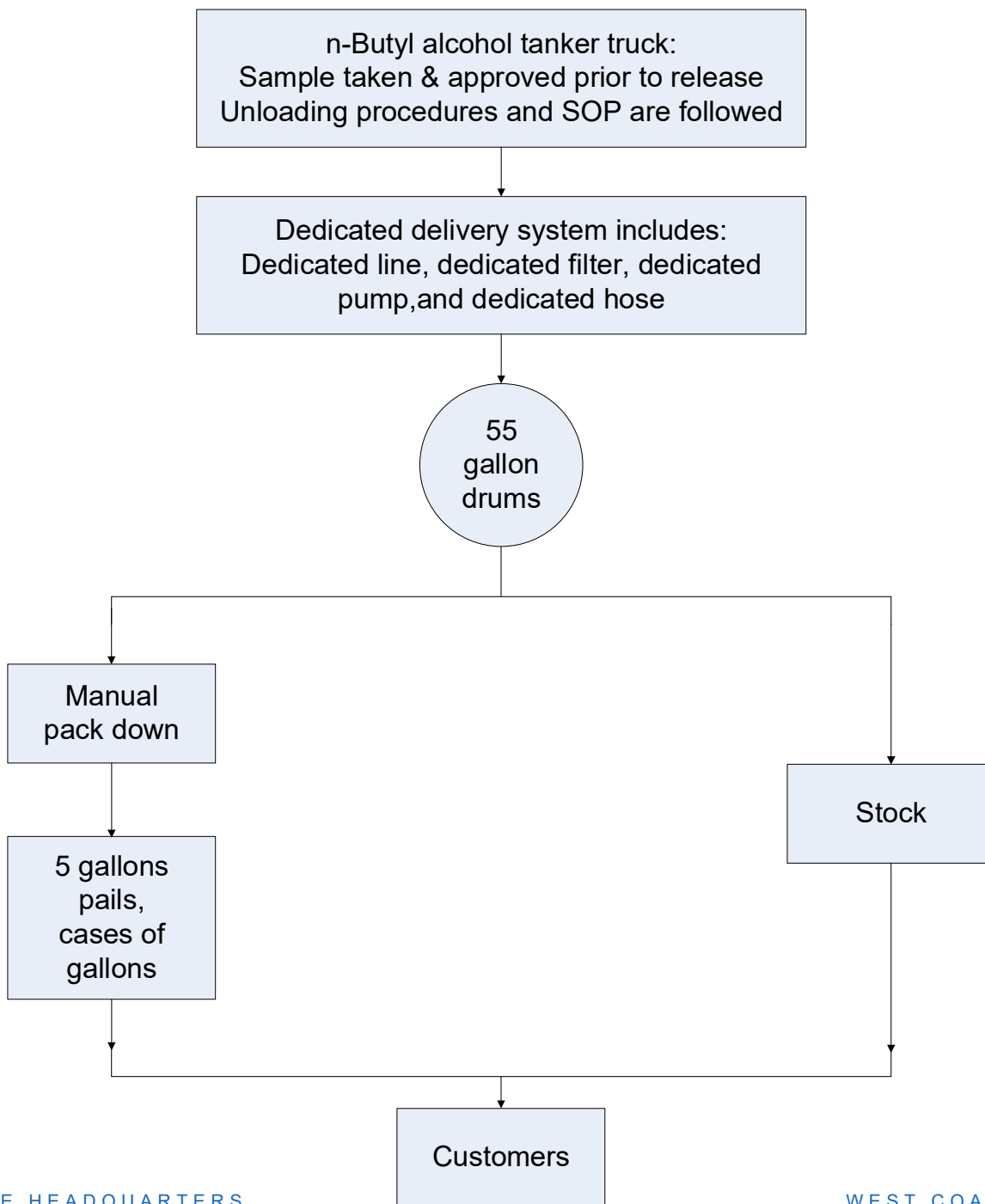
Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Butyl Alcohol, NF – B1197



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

B1197, Butyl Alcohol, 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
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- 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, 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:

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



RE: Elemental Impurities - Butyl Alcohol, NF (Cat# B1197)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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

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RE: Residual Solvents - Butyl Alcohol, NF (Cat# B1197)

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
Ethanol	3	< 5000 ppm
1-Propanol	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

Additionally, the Class 3 solvents 2-Butanol and 2-Methyl-1-propanol are present in the above mentioned material below the maximum limits set by the requirements of the NF monograph. 2-Butanol is present below the limit of 0.1% and 2-Methyl-1-propanol is present below the limit of 0.1% under the specification *Limit of Butyraldehyde, 2-Butanol, Isobutyl Alcohol (2-Methyl-1-propanol), and Butyl Ether*.

No Class 1, Class 2, 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

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WEST COAST FACILITY

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PHONE 310.516.8000

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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.

A Retest Date: 03-31-2025

C **DANGER**

- Flammable liquid and vapor • Harmful if swallowed or if inhaled • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • May cause drowsiness or dizziness • Causes damage to organs through prolonged or repeated exposure • May be harmful in contact with skin.
- 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 • Do not eat, drink or smoke when using this product • Wear protective gloves, 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:** 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 (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing 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. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

L **KEEP FROM CHILDREN**

spectrum®
CHEMICAL MFG CORP

B1197 **D** **F** **4 L**

E **Butyl Alcohol**
(1-Butanol; *n*-Butyl Alcohol)

H **NF**

G **CAS 71-36-3**

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

DOT: UN1120, Butanol, 3, PG III **I**

Chemical Emergency: (800)424-9300

J www.SpectrumChemical.com

K $C_4H_{10}O$ **F.W. 74.12**

AssayMin. 99.5%
AcidityTo pass test

MAXIMUM LIMITS

Water Determination0.1%
Nonvolatile Residue0.004%
Butyraldehyde, 2-Butanol,
Isobutyl Alcohol (2-Methyl-1-Propanol), and
Butyl EtherTo pass test
Elemental ImpuritiesAs reported
Residual SolventsTo pass test

M **Lot No. 062233**

O **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

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