



Scientific Documentation

B1197, 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

B1197, Butyl Alcohol, NF

Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Animal Testing Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label
- General Lot Numbering System Guidance

spectrum®

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
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	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

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	B1197	Lot Number	2KC0374
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	
ASSAY (GC-FID)	99.5 %		99.92 %
ACIDITY		2.5 ml	0.4 ML
WATER DETERMINATION		0.1 %	0.03 %
NONVOLATILE RESIDUE		0.004 %	0.000 %
BUTARALDEHYDE		0.1 %	< 0.01 %
2-BUTANOL		0.1 %	< 0.01 %
ISOBUTYL ALCOHOL (2-METHYL-1-PROPANOL)		0.1 %	0.05 %
BUTYL ETHER		0.2 %	0.02 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
RETEST DATE			23-DEC-2025
DATE OF MANUFACTURE			23-DEC-2020
APPEARANCE			CLEAR, COLORLESS LIQUID
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) 38

Spectrum Chemical Mfg Corp
 755 Jersey Avenue
 New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

Jigisha Patel

Jigisha Patel
 VP Regulatory Compliance & Technical Services,
 Regulatory

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

Preparation Date: 1/17/2014

Revision Date: 7/30/2018

Revision Number: G3

1. IDENTIFICATION

Product identifier

Product code: B1197
Product Name: BUTYL ALCOHOL, NF

Other means of identification

Synonyms: 1-Butanol
 1-Butyl alcohol
 1-Hydroxybutane
 Alcool butylique (French)
 Butan-1-ol
 Butanol
 Butyl hydroxide
 Butyric or normal primary butyl alcohol
 Hemostyp
 Methylolpropane
 n-Butan-1-ol
 n-Butanol
 n-Butyl alcohol
 Propylcarbinol
 Propylmethanol

CAS #: 71-36-3
RTECS # EO140000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Solvent. Chemical intermediate. Stabilizer.
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 according to 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
Acute toxicity - Inhalation (Gases)	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

Label elements

Danger

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



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

May be harmful in contact with skin
 Can burn with an invisible flame

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Use only outdoors or in a well-ventilated area
 Wear protective gloves/protective clothing/eye protection/face protection
 Keep away from heat/sparks/open flames/hot surfaces. — 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
 Keep cool

Precautionary Statements - Response

In case of fire: Use CO2, dry chemical, or foam to extinguish.
 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): Remove/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/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

Components	CAS-No.	Weight %
Butyl Alcohol	71-36-3	100

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 breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms	Irritating to eyes, respiratory system and skin Central nervous system effects Hearing impairment
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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: Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam. Water spray.

Unsuitable Extinguishing Media: Do not use a solid (straight) water stream as it may scatter and spread fire.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide.

Specific hazards: Flammable. May be ignited by heat, sparks or flames. Material can burn with invisible flame. Vapor may travel considerable distance to source of ignition and flash back.

Vapors may form explosive mixtures with air. Most vapors are heavier than air. They will spread along the ground and collect in low or confined areas (sewers, basements, tanks). Container explosion may occur under fire conditions or when heated. Fire may produce irritating, corrosive and/or toxic gases.

Special Protective Actions for Firefighters

Specific Methods:

Water mist may be used to cool closed containers. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out.

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. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use spark-proof tools and explosion-proof equipment. In case of large spill, water spray or vapor suppressing foam may be used to reduce vapors, but may not prevent ignition in closed spaces.

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. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods and material for containment and cleaning up

Methods for containment

Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).

Methods for cleaning up

Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Use clean non-sparking tools to collect absorbed material. 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. Remove all sources of ignition. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. 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. Keep away from heat and sources of ignition. Store in a segregated and approved area. Store away from incompatible materials.

Incompatible Materials:

- Oxidizing agents
- Acids
- Alkali Metals
- Halogens
- Aluminum
- Caustics
- isocyanates

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Butyl Alcohol	71-36-3	100 ppm TWA 300 mg/m ³ TWA	50 ppm Ceiling 150 mg/m ³ Ceiling	20 ppm TWA	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Butyl Alcohol	71-36-3	20 ppm TWA 60 mg/m ³ TWA	15 ppm TWA 30 ppm Ceiling	None	50 ppm Ceiling 152 mg/m ³ Ceiling

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Butyl Alcohol	71-36-3	None	50 ppm Ceiling 150 mg/m ³ Ceiling

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

- Eye protection:** Goggles Safety glasses with side-shields
- Skin and body protection:** Chemical resistant apron
Long sleeved clothing
Gloves
- Respiratory protection:** Vapor respirator. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid	Appearance: No information available.	Color: Clear. Colorless.
Odor: Rancid. Sweet. Strong. Characteristic. Mildly alcoholic. Similar to Amyl alcohol.	Taste Dry, burning taste.	Formula: CH ₃ (CH ₃) ₃ OH
Molecular/Formula weight (g/mole): 74.12	Flammability: No information available	Flash point (°C): 37
Flashpoint (°C/°F): 37 °C/98 °F	Flash Point Tested according to: Closed cup	Autoignition Temperature (°C/°F): 343 °C/650 °F
Lower Explosion Limit (%): 1.4%	Upper Explosion Limit (%): 11.2%	Melting point/range(°C/°F): -89.8 °C/-129.64 °F
Decomposition temperature(°C/°F): No information available	Boiling point/range(°C/°F): 117 °C/343 °F	Bulk density: No information available
Density (g/cm³): No information available	Specific gravity: 0.8-0.81	pH: No information available
Vapor pressure @ 20°C (kPa): No information available	Evaporation rate: 0.46 (butyl acetate = 1)	Vapor density: 2.6
VOC content (g/L): 800	Odor threshold (ppm): 0.83	Partition coefficient (n-octanol/water): 0.88
Viscosity: No information available	Miscibility: Miscible with Ethanol Miscible with Ether Miscible with many organic solvents	Solubility: Soluble in Water Solubility in water: 63.2 g/L @ 25 °C

10. STABILITY AND REACTIVITY

Reactivity

It may react with aluminum at temperatures above 49 degrees C (120 degrees F)

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials.

Incompatible Materials: Oxidizing agents
Acids
Alkali Metals
Halogens
Aluminum
Caustics
isocyanates

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. When heated to decomposition it emits acrid smoke and irritating fumes.

Other Information**Corrosivity:** No information available**Special Remarks on Corrosivity:** No information available**11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure****Principal Routes of Exposure:**

Ingestion. Skin. Eyes. Inhalation.

Acute Toxicity**Component Information**

Butyl Alcohol	
CAS-No.	71-36-3

LD50/oral/rat = 700 mg/kg Oral LD50 Rat(LOLI); 790 mg/kg Oral LD50 Rat (RTECS); 4360 mg/kg (RTECS)**LD50/oral/mouse** = 100 mg/kg (RTECS)**LD50/dermal/rabbit** = 3400 mg/kg**LD50/dermal/rat** = No information available**LC50/inhalation/rat** = >8000 ppm Inhalation LC50 Rat 4 h; 17.7 mg/l 4 hr.**LC50/inhalation/mouse** = No information available**Other LD50 or LC50 information** = 3484 mg/kg Oral LD50 Rabbit (RTECS)

1200 mg/kg Oral LD50 Hamster (RTECS)

1782 mg/kg Oral LD50 Dog (RTECS)

Product Information**LD50/oral/rat** =**VALUE- Acute Tox Oral** = 790 mg/kg**LD50/oral/mouse** =**Value - Acute Tox Oral** = 100 mg/kg**LD50/dermal/rabbit****VALUE-Acute Tox Dermal** = 3400 mg/kg**LD50/dermal/rat****VALUE -Acute Tox Dermal** = No information available**LC50/inhalation/rat****VALUE-Vapor** = > 17.7 mg/l (4-hr)**VALUE-Gas** = 8000 ppm (4-hr)**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:**

Contact causes skin irritation. Moderately irritating to the skin. It may be absorbed through the skin. If absorbed through skin it may cause systemic effects with symptoms similar to those of ingestion.

Eye Contact: Causes eye irritation. Severe eye irritation. Possible eye damage. No irreversible damage.

Inhalation Harmful by inhalation. Irritating to respiratory system. Symptoms may include coughing and wheezing. Can cause dyspnea (shortness of breath and difficulty breathing). May affect respiration (respiratory depression). May cause conjunctival irritation. May cause nausea, vomiting. May cause diarrhea. May cause headache. Inhalation of high concentrations of vapors may cause dizziness or suffocation. May affect behavior/central nervous system (dizziness, somnolence, muscle weakness, ataxia). May cause confusion, delirium, vertigo, giddiness. It may affect the liver. It may affect the blood (changes in serum composition). It may affect the blood (changes in white blood cell count, changes in other cell count). May affect vision (blurred vision). May affect hearing. Possible auditory nerve damage.

Ingestion Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause abdominal pain. May cause gastritis. May affect the cardiovascular system (change in heart rate). May affect the cardiovascular system (hypotension). It may affect the liver (fatty liver degeneration). May affect urinary system (kidneys). May affect the blood. May affect respiration (shortness of breath). May cause headache.

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. Prolonged or repeated inhalation of high concentrations may cause hearing impairment, with auditory nerve damage and vestibular system injury, and severe vertigo (diagnosed as Meniere's disease). Prolonged or repeated inhalation may affect the brain. Prolonged or repeated inhalation may affect the liver. Prolonged or repeated inhalation may affect the kidneys. Prolonged or repeated ingestion may affect behavior/central nervous system (somnolence, ataxia, muscle weakness). Prolonged or repeated ingestion may affect the blood (changes in red blood cell count). Prolonged or repeated inhalation may affect the adrenal gland. Prolonged or repeated ingestion may affect the adrenal gland.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Butyl Alcohol	71-36-3	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: May cause adverse developmental effects based on animal data

Teratogenic Effects: Possible risk of harm to the unborn child
 No information on developmental toxicity effects on humans was found
 There is limited and equivocal evidence that Butyl alcohol is a teratogen in animals
 It has not been shown to cause teratogenic effects in humans

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure. Skin. Eyes. Ears. central nervous system. kidney. liver.
Target Organs: Skin. Eyes. Central nervous system. Kidneys. Liver. Ears. Auditory nerve. Respiratory system.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.
Butyl Alcohol - 71-36-3
Freshwater Algae Data: 500 mg/L EC50 Desmodesmus subspicatus 96 h 500 mg/L EC50 Desmodesmus subspicatus 72 h
Freshwater Fish Species Data: 1730 - 1910 mg/L LC50 Pimephales promelas 96 h static 1 1740 mg/L LC50 Pimephales promelas 96 h flow-through 1 100000 - 500000 µg/L LC50 Lepomis macrochirus 96 h static 1 1910000 µg/L LC50 Pimephales promelas 96 h static 1
Water Flea Data: 1983 mg/L EC50 Daphnia magna 48 h 1897 - 2072 mg/L EC50 Daphnia magna 48 h
Persistence and degradability: Readily biodegradable
Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is low.
Mobility: It is expected to have high mobility in soil.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

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	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Butyl Alcohol	71-36-3	None	None	None	U031 ignitable waste

14. TRANSPORT INFORMATION

DOT
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Class No information available
Packing group: III
Emergency Response Guide No information available

Number
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): [DOT]: (R5) - Identifies a material that is a hazardous substance that has a reportable quantity (RQ) of 5000 pounds (2270 Kilograms).
Description: UN1120,Butanols ,3,,PG III

TDG (Canada)
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No Information available
Description: BUTANOLS,3,UN1120,PG III

ADR
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Packing Group: III
Subsidiary Risk: No information available
Description: UN1120 Butanols,3,III

IMO / IMDG
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No information available
EMS: F-E

RID
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Risk: 3
Packing Group: III
Description: UN1120 Butanols,3,III,RID

ICAO
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Risk: No information available
Packing Group: III
Description: Butanols,3,UN1120,PG III

IATA
UN-No: UN1120
Proper Shipping Name: Butanols
Hazard Class: 3
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 3L
Special Provisions No information available
Description: UN1120,Butanols,3,PG III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Butyl Alcohol</i>	71-36-3	Present(ACTIVE)	Present KE-03867	Present	Present (2)-3049	Present	Present	Present 200-751-6

U.S. Regulations

Butyl Alcohol

Massachusetts RTK: Present

New Jersey RTK Hazardous Substance List: 1330

New Jersey (EHS) List: 1330 500 lb TPQ

New Jersey - Discharge Prevention - List of Hazardous Substances: Present

Pennsylvania RTK: Environmental hazard

Pennsylvania RTK - Environmental Hazard List Present

Minnesota - Hazardous Substance List: Present

New York Release Reporting - List of Hazardous Substances:

5000 lb RQ

1 lb RQ

Louisiana Reportable Quantity List for Pollutants: Listed

California Directors List of Hazardous Substances: Present

FDA - Direct Food Additives 21 CFR 172.515

FDA - 21 CFR - Total Food Additives 172.515, 172.560, 175.105, 175.320, 176.180, 176.200, 176.210, 177.1200, 177.1440, 177.1650, 177.2800, 73.1

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	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Butyl Alcohol</i>	71-36-3	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	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 de minimis
<i>Butyl Alcohol</i>	71-36-3	5000 lb final RQ 2270 kg final RQ	None	None	None	1.0 % de minimis concentration

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Butyl Alcohol</i>	71-36-3	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Product code: B1197

Product name: BUTYL ALCOHOL, NF

11 / 13

Component
Butyl Alcohol
71-36-3 (100)

WHMIS 2015 Hazard Classification
Flammable liquids - Category 3: H226 Flammable liquid and vapour.; Skin corrosion/irritation - Category 2: H315 Causes skin irritation.; Serious Eye Damage/Eye Irritation - Category 2: H319 Causes serious eye irritation.; Specific target organ toxicity - Single exposure - Category 3: H335 May cause respiratory irritation.; Specific target organ toxicity - Single exposure - Category 3: H336 May cause drowsiness or dizziness.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

B2 Flammable liquid
D2B Toxic materials

Components
Butyl Alcohol

WHMIS 1988
B2,D2B

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.

Components	WHMIS Ingredient Disclosure List -
Butyl Alcohol	1 %

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Butyl Alcohol	71-36-3	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Butyl Alcohol	71-36-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Butyl Alcohol	71-36-3	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Butyl Alcohol	71-36-3	Flammable liquids - Flam. Liq. 3: H226 Flammable liquid and vapour.; Acute toxicity - Oral - Acute Tox. 4: H302 Harmful if swallowed. (Minimum classification); Skin corrosion/irritation - Skin Irrit. 2: H315 Causes skin irritation.; Serious Eye Damage/Eye Irritation - Eye Dam. 1: H318 Causes serious eye damage.; Specific target organ toxicity - Single exposure - STOT SE 3: H335 May cause respiratory irritation.; Specific target organ toxicity - Single exposure - STOT SE 3: H336 May cause drowsiness or dizziness.603-004-00-6

EU - CLP (1272/2008)

R-phrases(s)

R10 - Flammable.
R22 - Harmful if swallowed.
R41 - Risk of serious damage to eyes.

R67 - Vapors may cause drowsiness and dizziness.
R37/38 - Irritating to respiratory system and skin.

S -phrase(s)

S 2 - Keep out of the reach of children.
S13 - Keep away from food, drink and animal feedingstuffs.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S46 - If swallowed, seek medical advice immediately and show this container or label.
S 7/9 - Keep container tightly closed and in a well-ventilated place.
S37/39 - Wear suitable gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Butyl Alcohol	71-36-3	R10 Xn; R22 Xi; R37/38-41 R67	No information	S: (2)-7/9-13-26-37/39-46

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

Indication of danger:

Xn - Harmful.
Xi - Irritant.

Xn



Xi



16. OTHER INFORMATION

Preparation Date: 1/17/2014
Revision Date: 7/30/2018
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



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:

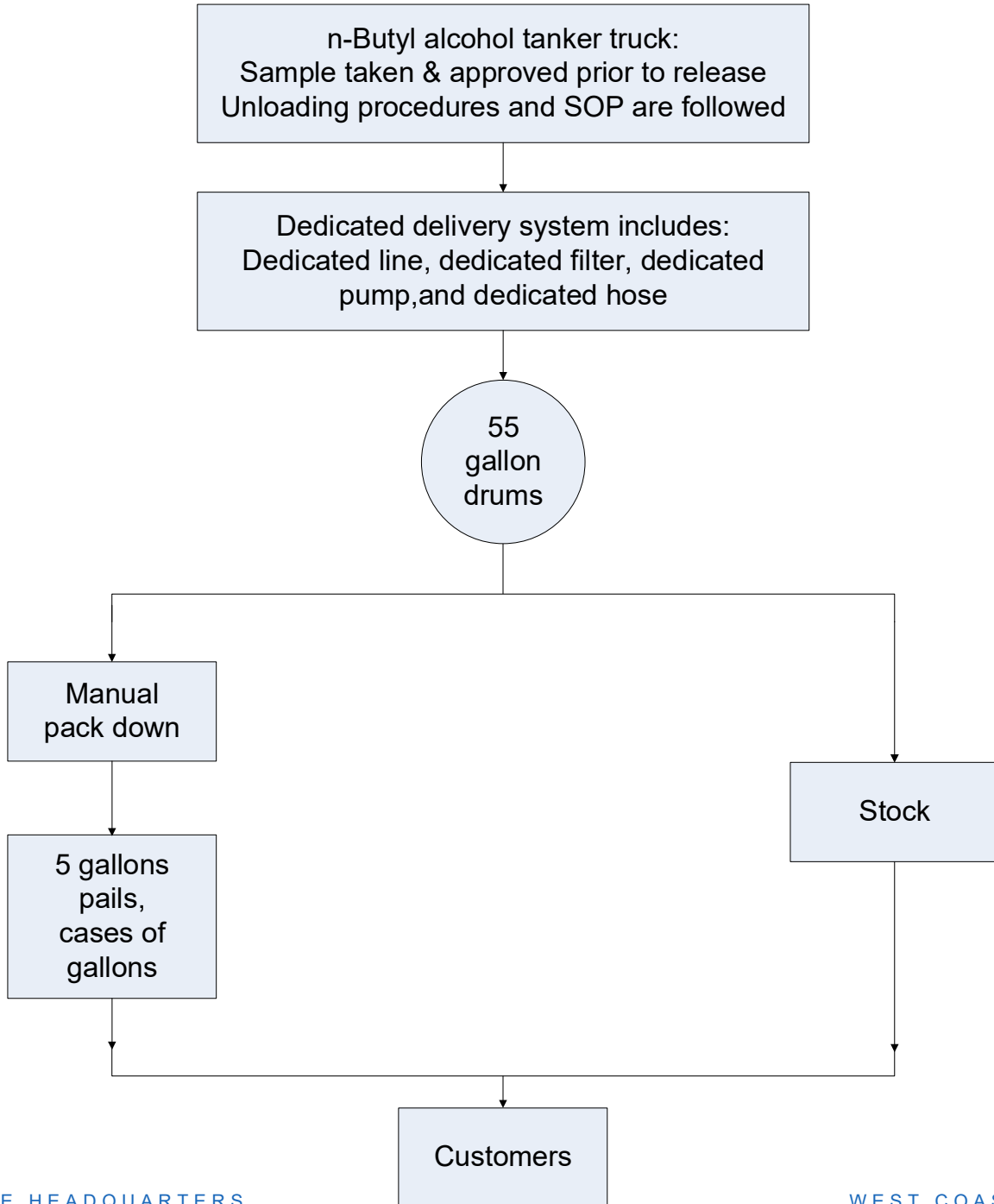
Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

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,

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

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 - 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.

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

Label Information

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

A **DANGER**

C • Flammable liquid and vapor • Harmful if swallowed or if inhaled • Causes serious eye irritation • Causes skin irritation

B • 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 Retest Date: 03-31-2025

J **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

I DOT: UN1120, Butanol, 3, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

K **C₄H₁₀O** — **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

R 10/H1GHS **A** **O**

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



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
- 4 = Pharmacy, NJ 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 quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

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