

Scientific Documentation

Albuterol Sulfate, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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 Albuterol Sulfate, USP (AL156)

Item Number	AL156
Item	Albuterol Sulfate, USP
CAS Number	51022-70-9
Molecular Formula	$(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$
Molecular Weight	576.70
MDL Number	
Synonyms	Salbutamol Sulfate

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.5	101.0 %
CHROMATOGRAPHIC PURITY	.	
SINGLE SPOT		0.5 %
TOTAL		2.0 %
WATER DETERMINATION		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (C)	POSITIVE FOR SULFATE	
IDENTIFICATION (D)	RETENTION TIME MATCHES REFERENCE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS:	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300

310.516.8000

Certificate Of Analysis

Item Number	AL156	Lot Number	4MK0019
Item	Albuterol Sulfate, USP	Manufacturer Lot	SS/23017
CAS Number	51022-70-9	Manufacturer Code	14118
Molecular Formula	(C ₁₃ H ₂₁ NO ₃) ₂ •H ₂ SO ₄	Molecular Weight	576.70

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.5	101.0 %	101.0 %
CHROMATOGRAPHIC PURITY	.		PASSES TEST
SINGLE SPOT		0.5 %	< 0.5 %
TOTAL		2.0 %	< 2.0 %
WATER DETERMINATION		0.5 %	0.04 %
RESIDUE ON IGNITION		0.1 %	0.0 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (C)	POSITIVE FOR SULFATE		POSITIVE FOR SULFATE
IDENTIFICATION (D)	RETENTION TIME MATCHES REFERENCE		RETENTION TIME MATCHES STANDARD
EXPIRATION DATE			01-JUN-2028
DATE OF MANUFACTURE			01-JUL-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS:	AS REPORTED		.
CLASS 1 (solvent) / BENZENE			< 2 ppm
CLASS 2 (SOLVENT) / METHANOL			< 3000 ppm

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 2 (solvent) / METHYLENE CHLORIDE			< 600 ppm
CLASS 2 (solvent) / TOLUENE			< 890 ppm
CLASS 3 (solvent) / ACETONE			< 5000 ppm
CLASS 3 (solvent) / ETHYL ACETATE			< 5000 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

CMARIN
Catherine Marin
05-MAR-24 13:24:20

Certificate of Analysis Results Approved By:

GHERRERA
Genaro Herrera
05-MAR-24 13:26:38

Spectrum Chemical Mfg Corp
777 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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Melody Healthcare Pvt. Ltd. at Plot No. J-73, M.I.D.C. Tarapur Boisar, Palghar, 401506, India. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.



SAFETY DATA SHEET

Preparation Date: 4/1/2019

Revision date 4/1/2019

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: AL156
Product Name: ALBUTEROL SULFATE, USP

Other means of identification

Synonyms: Salbutamol sulfate
CAS #: 51022-70-9
RTECS # CZ6430100
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
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: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Albuterol Sulfate	51022-70-9	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 irritation develops.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs.
Inhalation:	Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.
Ingestion:	Induce vomiting if person is conscious. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause central nervous system effects Nervousness Restlessness Insomnia Dizziness Headache Tremors Sleepiness Drowsiness Confusion May cause muscle pain Upset stomach Ingestion may cause nausea, vomiting, and diarrhea May affect the cardiovascular system Hypertension Weak, rapid pulse or rapid heart rate (Tachycardia) Heart palpitations May cause hypotension Seizures Hypokalemia May cause hyperglycemia May cause difficult and painful urination Dryness of mouth
-----------------	---

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. Water spray mist or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous combustion products

Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Sulfur oxides.

Specific hazards

May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods:

No information available

Special Protective Equipment for Firefighters:

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions:

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Wear personal protective equipment.

Environmental precautions

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

Methods and material for containment and cleaning up

Methods for containment

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

Methods for cleaning up

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

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

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

Safe Handling Advice

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

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

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

moisture. Air sensitive.

Incompatible Materials:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Albuterol Sulfate	51022-70-9	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Albuterol Sulfate	51022-70-9	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Albuterol Sulfate	51022-70-9	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Safety glasses with side-shields. or Goggles
Skin and body protection:	Chemical resistant apron Long sleeved clothing Gloves
Respiratory protection:	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. 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: Solid	Appearance: Crystalline powder. Powder.	Color: White. Practically white.
Odor: Odorless.	Taste No information available.	Formula (C13H21NO3)2.H2SO4
Molecular/Formula weight (g/mole): 576.70	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water Slightly soluble in Ethanol	

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Sensitive to light. Hygroscopic. Sensitive to air. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: No information available.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Product code: AL156

Product name: ALBUTEROL
SULFATE, USP

Page 5 / 11

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Albuterol Sulfate	
CAS No	51022-70-9

LD50/oral/rat = > 2500 mg/kg Oral LD50 Rat

LD50/oral/mouse = 1950 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = > 2500 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 1950 mg/kg

LD50/dermal/rabbit

Value - Acute Tox = No information available

LD50/dermal/rat

VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause upset stomach. Ingestion may cause nausea, vomiting, diarrhea. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (tremor, insomnia, drowsiness). It may cause twitching or tremors/trembling. May cause muscle weakness and/or muscle pain. It may affect

cardiovascular system (hypertension). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (hypotension). May affect behavior/central nervous system (convulsions/seizures). May cause hypokalemia. May cause painful or difficult urination. May cause dry mouth.

Aspiration hazard No information available.

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

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Albuterol Sulfate	51022-70-9	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: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soil No information available

Other adverse effects No information available.

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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Albuterol Sulfate	51022-70-9	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

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

ADR

UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

IMDG

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

RID

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)

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

IATA

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Albuterol Sulfate</i>	51022-70-9	Not Listed	Present KE-11364	Not present	Not present	Not listed	Present	Present 256-916-8

U.S. Regulations

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

Chemicals Known to the State of California to Cause Cancer:

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

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

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

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Albuterol Sulfate</i>	51022-70-9	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	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>Albuterol Sulfate</i>	51022-70-9	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Albuterol Sulfate	51022-70-9	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

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

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Albuterol Sulfate	51022-70-9	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Albuterol Sulfate	51022-70-9	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Albuterol Sulfate	51022-70-9	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Albuterol Sulfate	51022-70-9	

EU - CLP (1272/2008)

R-phrases

Not determined

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Albuterol Sulfate	51022-70-9		No information	

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

Indication of danger:

not determined

16. OTHER INFORMATION

Preparation Date: 4/1/2019
Revision date: 4/1/2019

Product code: AL156

Product name: ALBUTEROL
SULFATE, USP

Page 10 / 11

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
AL156	Albuterol Sulfate, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

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

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 Flow Albuterol Sulfate, USP (Cat# AL156)

Manufacturing process description of Albuterol Sulfate:

AD is first dissolved in methanol, adjust the pH of reaction mass 8.0-8.5 with acetic acid, catalyst palladium on carbon added to solution and the solution is hydrogenated at a pressure of 1-5 Kg and at a temperature 12-18°C. A sample of the reaction mass is withdrawn and analyzed for completion of reaction by checking for AD content by TLC (Limit: Below 0.5%). If the content of AD is more than 0.5%, hydrogenation is continued further and a sample is again checked for AD content. If the reaction is complete, then the reaction mass is filtered through a Sparkler filter, the filter washed with methanol, the filtrate and washing are combined dilute with methanol and treated with activated charcoal, filtered. The pH of the solution is then adjusted to 3.5-4.0 with Sulphuric acid and maintained at this pH for about 30 min and the product formed is centrifuged, washed with methanol. And spin dried.

The wet product is then dried in a vacuum tray dryer at 70 – 75°C for 8 hours. The dried Salbutamol Sulphate is tested for water content (Limit: NMT 0.3%) and Mill the material through 1 mm # mesh completely than shift the material through 20 mm# mesh after shifting the material blend the material. The Blended material is then unloaded and packed in double antistatic polyethylene (Transparent and Black) in a HDPE drum and analyzed as per the finished product specification.

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

AL156, Albuterol Sulfate, USP

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

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

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 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:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Albuterol Sulfate, USP (Cat# AL156)

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 – Albuterol Sulfate, USP (Cat# AL156)

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
Benzene	1	< 2 PPM
Methanol	2	< 3000 PPM
Methylisobutylketone	2	< 600 PPM
Toluene	2	< 890 PPM
Acetone	3	< 5000 PPM
Ethyl Acetate	3	< 5000 PPM

No 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

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

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.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

AL156 **SIZ SY**
Albuterol Sulfate
 (Salbutamol Sulfate)

USP

CAS 51022-70-9

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$
 F.W. 576.70

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Anhydrous Basis) 98.5-101.0%
 Chromatographic Purity To pass test
MAXIMUM LIMITS

Water Determination 0.5%
 Residue on Ignition 0.1%
 Elemental Impurities As reported
 Residual Solvents To pass test

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

Repackaged by Spectrum as:

G 12/16GHS-A ? Lot No. XQ####

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