

Scientific Documentation

Ipratropium Bromide, 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



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Specification for Ipratropium Bromide, USP (I1178)

Item Number	I1178
Item	Ipratropium Bromide, USP
CAS Number	66985-17-9
Molecular Formula	$C_{20}H_{30}BrNO_3 \cdot H_2O$
Molecular Weight	430.40
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
pH of 10 % SOLUTION	5.0	7.0
WATER DETERMINATION	3.9	4.4 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
LIMIT OF IPRATROPIUM BROMIDE RELATED COMPOUND A		0.10 %
ORGANIC IMPURITIES:		
IPRATROPIUM RELATED COMPOUND C		0.10 %
IPRATROPIUM RELATED COMPOUND B		0.10 %
N-ISOPROPYLNORATROPINIUM BROMIDE		0.10 %
APO-IPRATROPIUM BROMIDE		0.10 %
ANY UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.25 %
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR BROMIDE	
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

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	I1178	Lot Number	1MF0320
Item	Ipratropium Bromide, USP	Manufacturer Lot	IPT-0150523(M)
CAS Number	66985-17-9	Manufacturer Code	14855
Molecular Formula	C ₂₀ H ₃₀ BrNO ₃ •H ₂ O	Molecular Weight	430.40

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	99.1 %
pH of 10 % SOLUTION	5.0	7.0	5.2
WATER DETERMINATION	3.9	4.4 %	4.2 %
RESIDUE ON IGNITION		0.1 %	0.1 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
LIMIT OF IPRATROPIUM BROMIDE RELATED COMPOUND A		0.10 %	0.002 %
ORGANIC IMPURITIES:			.
IPRATROPIUM RELATED COMPOUND C		0.10 %	<0.10 %
IPRATROPIUM RELATED COMPOUND B		0.10 %	<0.10 %
N-ISOPROPYLNORATROPINIUM BROMIDE		0.10 %	<0.10 %
APO-IPRATROPIUM BROMIDE		0.10 %	<0.10 %
ANY UNSPECIFIED IMPURITY		0.10 %	<0.10 %
TOTAL IMPURITIES		0.25 %	<0.25 %
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	POSITIVE FOR BROMIDE		POSITIVE FOR BROMIDE
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			01-APR-2028

TEST	SPECIFICATION		RESULT
	MIN	MAX	
DATE OF MANUFACTURE			01-MAY-2023
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / CHLOROFORM			<60 ppm (M)
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm (M)
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ACETONE			<5000 ppm (M)
CLASS 3 (solvent) / ETHYL ACETATE			<5000 ppm (M)
CLASS 3 (solvent) / ETHYL FORMATE			<5000 ppm (M)
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm (M)

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
25-SEP-23 09:08:48

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



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
26-SEP-23 13:31:19

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.

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 Vamsi Labs Limited at A 14 & 15, MIDC Area, Pune Road Chincholi, Solapur, MAHARASHTRA 413255, India (IND). 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: 2/13/2018

Revision Date: Not applicable

Revision Number: Not applicable

1. IDENTIFICATION

Product identifier

Product code: I1178
Product Name: IPRATROPIUM BROMIDE, USP

Other means of identification

Synonyms: 3-alpha-Hydroxy-8-isopropyl-1-alpha-H,5-alpha-H-tropanium bromide (+-)-tropate, monohydrate
 (8r)-3-alpha-Hydroxy-8-isopropyl-1-alpha-H,5-alpha-H-tropiumbromide-(+)-tropate, monohydrate
 8-Isopropylnoratropine methobromide, monohydrate
 N-Isopropylnoratropinium bromomethylate, monohydrate
CAS #: 66985-17-9; 22254-24-6 (anhydrous)
RTECS # YM3700000 (for CAS no. 22254-24-6)
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
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
Serious eye damage/eye irritation	Category 2A

Label elements

Warning

Hazard statements

Harmful if swallowed
 Causes serious eye irritation

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Wear eye/face protection

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 SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Ipratropium Bromide	66985-17-9	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.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed**Symptoms**

Causes serious eye irritation
Moderately irritating to the eyes
Upset stomach
Dyspnea (Difficulty breathing and shortness of breath)
Heart palpitations
Weak, rapid pulse or rapid heart rate (Tachycardia)

May cause nausea
Dryness of mouth
Sore throat
May affect eyes/vision
Blurred vision
May cause headache
Dizziness
May cause constipation
Coughing

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: Dry chemical. Carbon dioxide (CO₂). 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. Hydrogen Bromide Gas.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Remove all sources of ignition.
<u>Environmental precautions</u>	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

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. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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. Keep in a well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Ipratropium Bromide	66985-17-9	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Ipratropium Bromide	66985-17-9	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Ipratropium Bromide	66985-17-9	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: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Effective dust mask. 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.

Color:

White. Off-white.

Odor:

No information available.

Taste

No information available.

Formula:

C₂₀H₃₀BrNO₃.H₂O

Molecular/Formula weight:

430.40

Flammability:

No information 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):

223-232 °C/433.4-449.6 °F

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:

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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:
Freely soluble in Methanol
Insoluble in Ether
Insoluble in Chloroform

10. STABILITY AND REACTIVITY

Reactivity

No information available

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

**Hazardous decomposition
products:** No information available.

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. Inhalation.

Acute Toxicity

Component Information

Ipratropium Bromide

CAS-No. 66985-17-9

LD50/oral/rat = 1667-4000 mg/kg

LD50/oral/mouse = 1001-2010 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 = 400-1300 mg/kg oral LD50 Dog

Product Information

Product code: I1178

Product name: IPRATROPIUM
BROMIDE, USP

LD50/oral/rat =
VALUE- Acute Tox Oral = 1667 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 1001 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = 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: Causes serious eye irritation. Moderately irritating to the eyes.

Inhalation May cause irritation of respiratory tract. Symptoms may include chest tightness, coughing. May cause dizziness and headache. It may affect behavior/central nervous system (tremors). May cause upset stomach. May cause heartburn. May cause nausea. May cause dry mouth. May cause dry and sore throat. May cause constipation. May cause dyspnea (difficulty breathing or shortness of breath). It may affect the cardiovascular system (rapid heart beat (tachycardia), palpitations). May cause bronchitis. May cause nervousness, insomnia.

Ingestion Harmful if swallowed. May affect respiration (dyspnea, respiratory depression). May affect behavior/central nervous system (convulsions/seizures). May affect behavior/central nervous system (tetany). May affect behavior/central nervous system (ataxia).

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.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances

Ipratropium Bromide	66985-17-9	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
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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: 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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Ipratropium Bromide	66985-17-9	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 No information available

Product code: I1178

Product name: IPRATROPIUM
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Number	No data available
Marine Pollutant	No information 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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available

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

ICAO	
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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
ERG Code:	No information available
Special Provisions	No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Ipratropium Bromide</i>	66985-17-9	Not Listed	Not present	Not present	Not present	Not present	Not present	Not present

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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Ipratropium Bromide</i>	66985-17-9	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>Ipratropium Bromide</i>	66985-17-9	None	None	None	None	None

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>Ipratropium Bromide</i>	66985-17-9	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

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

The classification of this product has not been validated yet

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.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
<i>Ipratropium Bromide</i>	66985-17-9	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
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Product code: I1178

Product name: IPRATROPIUM
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Ipratropium Bromide	66985-17-9	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Ipratropium Bromide	66985-17-9	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Ipratropium Bromide	66985-17-9	No information

EU - CLP (1272/2008)

R-phrases(s)

Not determined

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Ipratropium Bromide	66985-17-9		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: 2/13/2018
Revision Date: Not applicable
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
I1178	Ipratropium Bromide, 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,

Oralia Chavez
Quality Assurance Specialist

I1178, Ipratropium Bromide, 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 - Ipratropium Bromide, USP (Cat# I1178)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.3 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 0.2 ppm
Mercury	Hg	1	< 0.1 ppm
Cobalt	Co	2A	< 0.3 ppm
Vanadium	V	2A	< 0.1 ppm
Nickel	Ni	2A	< 0.5 ppm
Thallium	Tl	2B	< 0.8 ppm
Gold	Au	2B	< 0.1 ppm
Palladium	Pd	2B	< 0.1 ppm
Iridium	Ir	2B	< 0.1 ppm
Osmium	Os	2B	< 0.2 ppm
Rhodium	Rh	2B	< 0.1 ppm
Ruthenium	Ru	2B	< 0.1 ppm
Selenium	Se	2B	< 13 ppm
Silver	Ag	2B	< 0.7 ppm
Platinum	Pt	2B	< 0.1 ppm
Lithium	Li	3	< 2.5 ppm
Antimony	Sb	3	< 2 ppm
Barium	Ba	3	< 30 ppm
Molybdenum	Mo	3	< 1 ppm
Copper	Cu	3	< 3 ppm
Tin	Sn	3	< 6 ppm
Chromium	Cr	3	< 0.3 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

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WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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RE: Residual Solvents - Ipratropium Bromide, USP (Cat# I1178)

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
Chloroform	2	< 60 ppm
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm
Ethyl Acetate	3	< 5000 ppm
Ethyl Formate	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No Class 1 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,

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Label Information

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

WARNING

- Harmful if swallowed
- Causes serious eye irritation.
- Do not eat, drink or smoke when using this product • Wear eye protection, face protection
- Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

KEEP FROM CHILDREN

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



I1178

SIZ SY

Ipratropium Bromide

USP

CAS 66985-17-9

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

$C_{20}H_{30}BrNO_3 \cdot H_2O$ F.W. 430.40

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Anhydrous Basis) 98.0-102.0%
 pH of 10% Solution 5.0-7.0
 Water Determination 3.9-4.4%

MAXIMUM LIMITS

Residue on Ignition 0.1%
 Elemental Impurities As reported
 Ipratropium Related Compound A To pass test

Organic Impurities:

Ipratropium Related Compound C 0.10%
 Ipratropium Related Compound B 0.10%
 Desmethyl Ipratropium 0.10%
 Ipratropium Atropic Analog 0.10%
 Any Unspecified Impurity 0.10%
 Total Impurities 0.25%
 Residual Solvents To pass test

Repackaged by Spectrum as:

G 5/K5GHS-A ? Lot No. XQ####

Exp. Date: 00-00-0000



1 1 7 8 0

4 5 2 1 1 7 8 0

Spectrum Chemical Mfg Corp

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