

# Scientific Documentation

## Buspirone Hydrochloride, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
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# Specification for Buspirone Hydrochloride, USP (B2850)

Item Number	B2850
Item	Buspirone Hydrochloride, USP
CAS Number	33386-08-2
Molecular Formula	C <sub>21</sub> H <sub>31</sub> N <sub>5</sub> O <sub>2</sub> •HCl
Molecular Weight	421.96
MDL Number	
Synonyms	8-(4-[4-(2-Pyrimidinyl)-1-piperazinyl]butyl)-8-azaspiro[4,5]decane-7,9-dione Hydrochloride

Test	Specification	
	Min	Max
ASSAY	97.5	102.5%
WATER DETERMINATION		0.5%
RESIDUE ON IGNITION		0.5%
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES DETECTED AT (UV 240 nm):		
Buspirone related compound A		0.10 %
Spiroammonium salt		0.10 %
Bispyrimidinylpiperazinyl butane		0.10 %
Bispyrimidinylpiperazinyl butyl ether		0.10 %
Buspirone open ring		0.3 %
Buspirone open ring dimer		0.10 %
Buspirone related compound G		0.10 %
Buspirone diester dimer		0.10 %
Chlorobuspirone		0.10 %
Buspirone open ring spirodimer		0.2 %
Any other individual impurity.		0.10 %
Total impurities.		0.4 %
ORGANIC IMPURITIES DETECTED AT (UV 210 nm):		
Buspirone related compound K		0.1 %

Test	Specification	
	Min	Max
Buspirone related compound L		0.1 %
Buspirone bromobutyl analog		0.10 %
Buspirone related compound N		0.10 %
Any other individual impurity		0.10 %
Total impurities		0.2 %
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME MATCHES STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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	B2850	Lot Number	2JF0235
Item	Buspirone Hydrochloride, USP	Manufacturer Lot	PBSPP90003
CAS Number	33386-08-2	Manufacturer Code	15045
Molecular Formula	C <sub>21</sub> H <sub>31</sub> N <sub>5</sub> O <sub>2</sub> •HCl	Molecular Weight	421.96

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	97.5	102.5%	99.1 %
WATER DETERMINATION		0.5%	0.08 %
RESIDUE ON IGNITION		0.5%	0.1 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES DETECTED AT (UV 240 nm):			.
Buspirone related compound A		0.10 %	0.00 %
Spiroammonium salt		0.10 %	0.00 %
Bispyrimidinylpiperazinyl butane		0.10 %	0.00 %
Bispyrimidinylpiperazinyl butyl ether		0.10 %	0.00 %
Buspirone open ring		0.3 %	0.00 %
Buspirone open ring dimer		0.10 %	0.00 %
Buspirone related compound G		0.10 %	0.00 %
Buspirone diester dimer		0.10 %	0.00 %
Chlorobuspirone		0.10 %	0.00 %
Buspirone open ring spirodimer		0.2 %	0.00 %
Any other individual impurity.		0.10 %	0.00 %
Total impurities.		0.4 %	0.00 %
ORGANIC IMPURITIES DETECTED AT (UV 210 nm):			.
Buspirone related compound K		0.1 %	0.00 %
Buspirone related compound L		0.1 %	0.00 %
Buspirone bromobutyl analog		0.10 %	0.00 %
Buspirone related compound N		0.10 %	0.00 %
Any other individual impurity		0.10 %	0.00 %

TEST	SPECIFICATION		RESULT
	MIN	MAX	
Total impurities		0.2 %	0.00 %
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME MATCHES STANDARD		RETENTION TIME MATCHES STANDARD
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			30-SEP-2024
DATE OF MANUFACTURE			01-OCT-2019
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
CLASS 3 (solvent) / BUTYL ACETATE			<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Certificate of Analysis Results Entered By:

MPEREZ  
Melchor Perez  
24-JUN-20 09:15:17

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MPEREZ  
Melchor Perez  
24-JUN-20 09:15:39

**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 Unichem Laboratories Limited at Plot No. 197, Sector-1, Pithampur, Dhar, Madhya Pradesh 454775, 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

# spectrum®



Revision date 18-October-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** BUSPIRONE HYDROCHLORIDE, USP

### Other means of identification

**Product Code(s)** B2850

**UN/ID no** UN2811

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Acute toxicity - Oral	Category 3
Serious eye damage/eye irritation	Category 2B

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Toxic if swallowed  
Causes eye irritation



**Appearance** Crystalline powder

**Physical state** Solid

**Odor** No information available

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product

**Precautionary Statements - Response**

Specific treatment (see .? on this label)

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: Immediately call a POISON CENTER or doctor

Rinse mouth

**Precautionary Statements - Storage**

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%
Buspirone Hydrochloride	33386-08-2	100

### 4. First-aid measures

**Description of first aid measures**

**General advice**

Show this safety data sheet to the doctor in attendance.

**Inhalation**

Remove to fresh air.

**Eye contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists.  
Remove contact lenses, if present and easy to do. Continue rinsing.

**Skin contact**

Wash skin with soap and water.

**Ingestion**

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.  
Never give anything by mouth to an unconscious person. Get medical attention.

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

**Symptoms**

No information available.

**Indication of any immediate medical attention and special treatment needed**



Note to physicians

Treat symptomatically.

## 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	Carbon dioxide (CO <sub>2</sub> ). Hydrocarbons. none.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

### Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## 7. Handling and storage

### Precautions for safe handling

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice.
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### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Keep refrigerated. Protect from light.
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## 8. Exposure controls/personal protection

### Control parameters

<b>Exposure Limits</b>	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
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<b>Engineering controls</b>	Showers
	Eyewash stations
	Ventilation systems.

<b>Eye/face protection</b>	If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.
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<b>Skin and body protection</b>	No special protective equipment required.
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<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
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**General hygiene considerations**      Avoid contact with skin, eyes or clothing.

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Crystalline powder
<b>Color</b>	White
<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	> 200 °C / 392 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.2	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Soluble in Methanol	None known
	Soluble in Dimethyl Sulfoxide	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	May cause redness and tearing of the eyes.
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### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Buspirone Hydrochloride 33386-08-2	= 196 mg/kg ( Rat )	-	-

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

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

### DOT

<b>UN/ID no</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solids, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing group:</b>	III
<b>Special Provisions</b>	IB8, IP3, T1, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description:</b>	UN2811, Toxic solids, organic, n.o.s., 6.1, III

### TDG

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III
<b>Special Provisions</b>	16
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### MEX

<b>UN-No</b>	UN2811
<b>Proper Shipping Name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	223, 274
<b>Packing Group</b>	III
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### ICAO (air)

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III
<b>Special Provisions</b>	A3, A5
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### IATA

<b>UN number</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	III
<b>ERG Code</b>	6L
<b>Special Provisions</b>	A3, A5

**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, III

**IMDG**

**UN number** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**EmS-No** F-A, S-A  
**Special Provisions** 223, 274  
**Marine pollutant** NP1  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, III

**RID**

**UN number** UN2811  
**Proper Shipping Name:** TOXIC SOLID, ORGANIC, N.O.S.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**Classification code** T2  
**Special Provisions** 274, 614  
**Description:** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III  
**Labels** 6.1

**ADR**

**UN number** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**Classification code** T2  
**Tunnel restriction code** (E)  
**Special Provisions** 274, 614  
**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E)  
**Labels** 6.1

**ADN**

**UN/ID No** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing Group** III  
**Classification code** T2  
**Special Provisions** 274, 614, 802  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, III  
**Hazard label(s)** 6.1  
**Equipment Requirements** PP, EP

## 15. Regulatory information

**International Inventories**

**TSCA** Not listed

**Note** \*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

**DSL/NDL** Does not Comply  
**EINECS/ELINCS** Complies  
**ENCS** This product complies with ENCS:  
**IECSC** This product does not comply with china:  
**KECL** Complies  
**PICCS** Does not Comply  
**AICS** This product does not comply with AICS

**Legend:**

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

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

#### **NFPA**

**Health hazards** 1

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 1

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

#### **Key or legend to abbreviations and acronyms used in the safety data sheet**

##### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 18-October-2022  
**Revision Note** No information available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
B2850	Buspirone Hydrochloride, 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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

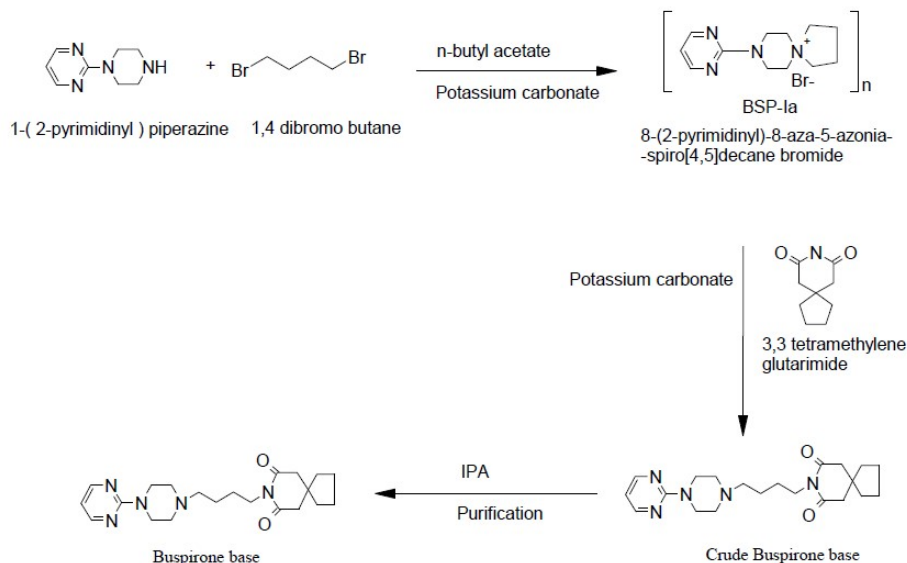
A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

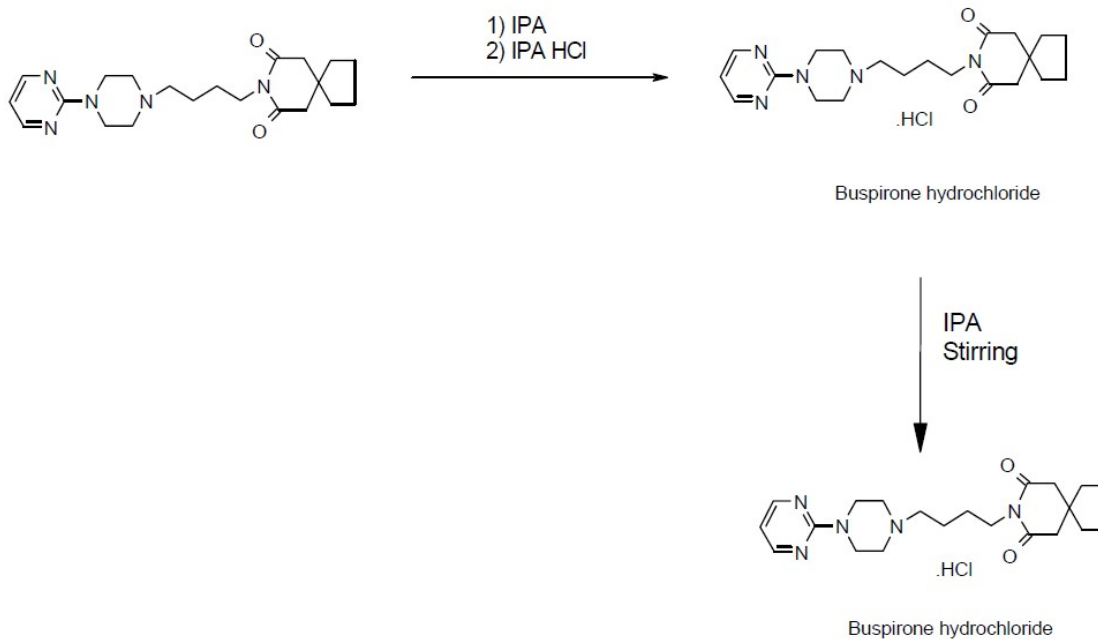


## Manufacturing Process Flowchart Buspirone Hydrochloride, USP (Cat# B2850)

### Stage I : Buspirone Base- stage-I (BSP - I)



### Stage II : Buspirone Hydrochloride- II (BSP - II)



#### CORPORATE HEADQUARTERS

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FAX 732.246.7132

#### WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## **B2850, Buspirone Hydrochloride, 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 this material 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 by Spectrum Chemical.

## 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 – Buspirone Hydrochloride, USP (Cat# B2850)**

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](mailto: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 – Buspirone Hydrochloride, USP (Cat# B2850)**

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
Methylene chloride	2	< 600 ppm
Butyl acetate	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](mailto: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.

**Exp. Date: 00-00-0000**

**DANGER**

- Toxic if swallowed • Causes eye irritation.
- Do not eat, drink or smoke when using this product • 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 eye irritation persists: Get medical attention. **IF SWALLOWED:** Immediately call a POISON CENTER or physician. Rinse mouth.

**KEEP FROM CHILDREN**

**WARNING:** Cancer and Reproductive Harm - [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)



**B2850**

**SIZ SY**

**Buspirone Hydrochloride**

{8-[4-[4-(2-Pyrimidinyl)-1-piperazinyl]butyl]-8-azaspiro[4,5]decane-7,9-dione Hydrochloride}

USP

CAS 33386-08-2

**CAUTION:** For manufacturing, processing, repackaging, or for prescription compounding. Rx only.

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

DOT: UN2811, Toxic solid, organic, n.o.s. (buspirone hydrochloride), 6.1, PG III

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

**REFRIGERATE**

$C_{21}H_{31}N_5O_2 \cdot HCl$  F.W. 421.96

Manufacturer/Supplier Code ?

Manufacturer Lot Number ?

Assay 97.5-102.5%

Water Determination MAXIMUM LIMITS 0.5%

Organic Impurities at 240 nm:	Organic Impurities at 210 nm:
Buspirone Related Compound A 0.10%	Buspirone Related Compound K 0.1%
Spinnaminum Salt 0.10%	Buspirone Related Compound L 0.10%
Bispyrimidinylpiperazinyl Butane 0.10%	Buspirone Bromobutyl Analog 0.10%
Bispyrimidinylpiperazinyl Butyl Ether 0.10%	Buspirone Related Compound N 0.10%
Buspirone Open Ring 0.5%	Any Other Individual Impurity 0.10%
Buspirone Open Ring Dimer 0.10%	Total Impurities 0.2%
Buspirone Related Compound G 0.10%	
Buspirone Diester Dimer 0.10%	
Chlorobuspirone 0.10%	
Buspirone Open Ring Spiro-Dimer 0.2%	
Any Other Individual Impurity 0.10%	
Total Impurities 0.4%	

Residue on Ignition 0.5%

Elemental Impurities As reported

Residual Solvents To pass test

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

Repackaged by Spectrum as:

B 10/J2GHS-A ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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