



Scientific Documentation

HA103, Haloperidol, 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

Ver4.03 7.December.2017



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is positioned above the printed name and title.

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com

HA103, Haloperidol, USP

Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Certificate of Analysis Sample(s)
- General Label Information – Sample Label
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance

spectrum[®]
CHEMICAL MFG CORP



Specification for Haloperidol, USP (HA103)

Item Number	HA103
Item	Haloperidol, USP
CAS Number	52-86-8
Molecular Formula	C ₂₁ H ₂₃ ClFNO ₂
Molecular Weight	375.86
MDL Number	
Synonyms	4-[4-(p-Chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0 - 102.0 %	
IDENTIFICATION	TO PASS TEST	
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES	TO PASS TEST	
EXPIRATION DATE		
RESIDUAL SOLVENTS	TO PASS TEST	

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

SAFETY DATA SHEET

Preparation Date: 12/7/2017

Revision Date: 12/7/2017

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: HA103
Product Name: HALOPERIDOL, USP

Other means of identification

Synonyms: Aloperidolo (Italian)
 1-Butanone, 4-(4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl)-1-(4-fluorophenyl)-
 Butyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxypiperidino)-
 gamma-(4-(p-Chlorophenyl)-4-hydroxypiperidino)-p-fluorobutyrophenone
 4-(4-(4-Chlorophenyl)-4-hydroxy-1-piperidinyl)-1-(4-fluorophenyl)-1-butanone
 1-(3-p-Fluorobenzoylpropyl)-4-p-chlorophenyl-4-hydroxypiperidine
 4'-Fluoro-4-(4-(p-chlorophenyl)-4-hydroxypiperidinyl)butyrophenone
 4'-Fluoro-4-(4-hydroxy-4-(4'-chlorophenyl)piperidino)butyrophenone
 4-[4-(p-Chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone
 4-(4-Hydroxy-4'-chloro-4-phenylpiperidino)-4'-fluorobutyrophenone

CAS #: 52-86-8
RTECS # EU1575000
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 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3

Label elements

Product code: HA103

Product name: HALOPERIDOL, USP

1 / 13

Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation
Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

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 ON SKIN: Wash with plenty of water
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Haloperidol	52-86-8	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. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.
- 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. If symptoms persist, call a physician.
- Inhalation:** Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.
- Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Toxic if swallowed. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- Symptoms**
- Causes serious eye irritation
 - Moderately irritating to the eyes
 - Causes skin irritation
 - Moderately irritating to the skin
 - Irritating to respiratory system
 - May affect the cardiovascular system
 - Central nervous system effects
 - Central nervous system depression
 - May affect the urinary system
 - May affect the liver
 - It may affect the blood
 - Difficult/painful and/or frequent urination
 - Dyspnea (Difficulty breathing and shortness of breath)
 - Ingestion may cause nausea, vomiting, and diarrhea
 - May cause heartburn
 - May cause constipation
 - Dryness of mouth
 - Sweating
 - It may affect the urinary system
 - May affect eyes/vision
 - Pinpoint pupils
 - May cause involuntary eye movements

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 fluoride. Hydrogen chloride.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: Dike fire-control water for later disposal; do not scatter the material. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions 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. 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. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe dust. 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. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Haloperidol	52-86-8	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Haloperidol	52-86-8	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Haloperidol	52-86-8	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. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Microcrystalline solid powder.	Color: White. Faintly yellowish.
Odor: Odorless.	Taste No information available.	Formula: C21H23ClFNO2
Molecular/Formula weight: 375.86	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): 148-152 °C/298.4-306 °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: 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): log Kow = 4.30	Viscosity: No information available
Miscibility: No information available	Solubility: Practically insoluble in water Freely soluble in Methanol Freely soluble in Chloroform Freely soluble in Acetone Freely soluble in Benzene	

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. Avoid dust formation. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide. Nitrogen oxides (NOx). Hydrogen chloride gas. Hydrogen fluoride.

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

Haloperidol	
CAS-No.	52-86-8

LD50/oral/rat = 128 mg/kg Oral LD50 Rat
LD50/oral/mouse = 71 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 Oral = 128 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 71 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: Causes skin irritation. Moderately irritating to the skin.

Eye Contact: Causes serious eye irritation. Moderately irritating to the eyes.

Inhalation Irritating to respiratory system.

Ingestion Toxic if swallowed. Ingestion may cause nausea, vomiting. May cause heartburn. May cause diarrhea. May cause constipation. May cause loss of appetite. May cause dry mouth. May cause salivation. May cause excessive sweating. May cause difficulty breathing. May cause muscle rigidity. May cause vision disturbances. May cause blurred or foggy vision. May cause nystagmus (involuntary eye movements). May affect eyes (pupillary constriction). May affect the cardiovascular system (hypotension or hypertension, tachycardia,

dysrhythmias). May affect the cardiovascular system (cardiac arrhythmias). May cause dystonia, which is defined as prolonged or abnormal contractions of muscle groups. Symptoms may include: spasm of the neck muscles, sometimes progressing tightness of the throat, difficulty swallowing, difficulty breathing, and/or protusion of the tongue. May cause muscle weakness. May affect behavior/central nervous system (lethargy, fatigue). May affect behavior/central nervous system (depression or excitement). May affect behavior/central nervous system (muscle contraction or spasticity). May affect behavior/central nervous system (tetany). May affect behavior/central nervous system (headache, weakness, dizziness, nervousness, lightheadedness, trembling). May affect behavior/central nervous system (Hallucinations, anxiety, agitation). May affect behavior/central nervous system (somnolence). May affect behavior/central nervous system (tremor, insomnia, drowsiness). May affect behavior/central nervous system (convulsions/seizures). May affect behavior/central nervous system (confusion). May cause painful or difficult urination. May affect the blood. May cause skin rash, redness or itching.

Aspiration hazard No information available.

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

Chronic Toxicity May cause Tardive Dyskinesia. It most commonly occurs in patients with psychiatric conditions who are treated with antipsychotic drugs for many months or years. This is a disorder that involves involuntary movements, especially of the lower face. Symptoms include facial grimacing, finger movement, jaw swinging, repetitive chewing and tongue thrusting. Prolonged or repeated ingestion may cause menstrual irregularities or loss of menstrual periods women, abnormal production of breast milk in non-breast feeding women, breast enlargement in men, ejaculatory disorders/impotence in men. Prolonged or repeated ingestion may cause spontaneous flow of milk from the breast, breast enlargement, absence of menstrual period. Prolonged or repeated ingestion may affect the urinary system. Prolonged or repeated ingestion may affect behavior/central nervous system. Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired).

Sensitization: No information available.

Mutagenic Effects: Mutations in microorganisms
Experiments with bacteria and/or yeast have shown mutagenic effects

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Haloperidol	52-86-8	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 Suspected of damaging fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects based on animal data
Experiments have shown reproductive toxicity effects on laboratory animals
Excreted in maternal milk in human

Developmental Effects: May cause adverse developmental effects based on animal data
There are no adequate and well-controlled studies in humans

Teratogenic Effects: There are no well controlled studies with haloperidol in pregnant women. There are reports, however, of cases of limb malformations observed following maternal use of haloperidol along with other drugs which have suspected teratogenic potential during the first trimester of pregnancy. Causal relationships were not established in these cases

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
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: Potential for bioconcentration in aquatic organisms is moderate.

Mobility: Expected to be immobile in soil based on estimated Koc.

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
Haloperidol	52-86-8	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 Description: No Information available
 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>Haloperidol</i>	52-86-8	Not Listed	Present KE-05840	Not present	Present (9)-1138	Not present	Present	Present 200-155-6

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:

⚠️ WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause birth defects or other reproductive harm. For more information go to www.p65warnings.ca.gov.

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Haloperidol	52-86-8	Not Listed	developmental toxicity	Not Listed	female reproductive toxicity

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
Haloperidol	52-86-8	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
Haloperidol	52-86-8	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

D1B Toxic materials

D2A Very toxic materials

D2B Toxic materials

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)
Haloperidol	52-86-8	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Haloperidol	52-86-8	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Haloperidol	52-86-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Haloperidol	52-86-8	No information

EU - CLP (1272/2008)

R-phrase(s)

R25 - Toxic if swallowed.

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

R36/37/38 - Irritating to eyes, respiratory system and skin.

S-phrase(s)

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Haloperidol	52-86-8		No information	

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

Indication of danger:

T - Toxic

Xi - Irritant.

Xn - Harmful.

T



Xi



Xn



16. OTHER INFORMATION

Preparation Date: 12/7/2017
Revision Date: 12/7/2017
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



Manufacturer

Product Covered: HA103, Haloperidol, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248,
USA,

Additional sites: 13915 South Main Street, Los Angeles, California,
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the
requirements of:

ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine
chemicals, solutions, equipment, supplies and products for the
laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance,
biotechnology, environmental and process industries.

Certificate Number:

94-316m-03

Initial Certification Date:

27 December 1994

Certificate Issue Date:

31 July 2017

Certificate Expiry Date:

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

Authorized Signature

Calin Moldovean

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
900 Chelmsford Street, Lowell, MA, USA



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

*Authorised Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.*

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.

July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum-Shanghai, China:	<u>3006174778</u>

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

December 7, 2017

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
HA103	Haloperidol, 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
Spectrum-Shanghai, China: 03006174778

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



Oct. 6, 2017

Re: Haloperidol, USP- HA103

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Haloperidol, USP- HA103

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfg. Corp.

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

Item Number	HA103	Lot Number	2EF0021
Item	Haloperidol, USP		
CAS Number	52-86-8		
Molecular Formula	C ₂₁ H ₂₃ ClFNO ₂	Molecular Weight	375.86

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0 - 102.0 %		100.23 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
LOSS ON DRYING		0.5 %	0.31 %
RESIDUE ON IGNITION		0.1 %	0.07 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
EXPIRATION DATE			28-FEB-2020
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / TETRAHYDROFURAN			<720 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
APPEARANCE			OFF WHITE CRYSTALS
DATE OF MANUFACTURE			01-MAR-2015

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by



Ibad Tirmizi
Director of Quality
Spectrum Chemical Mfg. Corp.

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.

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.

SPECTRUM[®]

HA103 **1 KG**

Haloperidol
{4-[4-(p-Chlorophenyl)-4-hydroxy-piperidino]-4'-fluorobutylphenone}
U.S.P.
CAS 52-86-8

C₂₁H₂₃ClFNO₂ F.W. 375.86

DANGER

• Toxic if swallowed • Causes serious eye irritation
• Causes skin irritation • May cause respiratory irritation • Suspected of damaging fertility or the unborn child.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood
• Do not eat, drink or smoke when using this product
• Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

CAUTION: For manufacturing, processing, repacking, 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. (haloperidol), 6.1, PG III

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

Assay (Dried Basis)..... 98.0-102.0%
IdentificationTo pass test

MAXIMUM LIMITS

Loss on Drying..... 0.5%
Residue on Ignition..... 0.1%
Organic ImpuritiesTo pass test
Residual SolventsTo pass test

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

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

Exp. Date: 03-31-2025

B 12/E5GHS A O Lot No. 062233

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|---|--|---|
| A Bar Code | F Size/Quantity | K Empirical Formula, Formula Weight and Technical Specifications Panel |
| B GHS Hazard Pictograms | G Chemical Abstracts Service (CAS) Registry Number | L Expiration Information |
| C Warning, Safety Data and Precautionary Information | H Caution Information | M Lot Number |
| D Product Catalog Number | I DOT Shipping Information | N Kosher Certified by Kosher Supervision of America (KSA). |
| E Item Name, Form, Grade | J Toll-Free 24-Hour Chemical Emergency Telephone Number | |
| O Storage Color Band | | |

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

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

January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,



Michael Dang
Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: HA103, Haloperidol, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, HA103, Haloperidol, USP, is assigned a 60 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605