

Scientific Documentation

Clonidine Hydrochloride, 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 Clonidine Hydrochloride, USP (CL118)

Item Number	CL118
Item	Clonidine Hydrochloride, USP
CAS Number	4205-91-8
Molecular Formula	$C_9H_9Cl_2N_3 \cdot HCl$
Molecular Weight	266.55
MDL Number	
Synonyms	Catapres ; 2-(2,6-Dichloroanilino)-2-imidazoline Hydrochloride

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME OF SAMPLE CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
ASSAY (DRIED BASIS)	98.5	101.0 %
pH OF A 5% SOLUTION	3.5	5.5
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES		
CLONIDINE RELATED COMPOUND RELATED COMPOUND A		0.1 %
2,6-DICHLOROANILINE		0.1 %
ANY OTHER UNSPECIFIED IMPURITY		0.1 %
TOTAL IMPURITIES		0.2 %
ELEMENTAL IMPURITIES	AS REPORTED	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

Test	Specification	
	Min	Max
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	CL118	Lot Number	4NA0022
Item	Clonidine Hydrochloride, USP	Manufacturer Lot	CLD0020005
CAS Number	4205-91-8	Manufacturer Code	14738
Molecular Formula	C ₉ H ₉ Cl ₂ N ₃ •HCl	Molecular Weight	266.55

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE CRYSTALLINE POWDER
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME OF SAMPLE CORRESPONDS TO STANDARD		RETENTION TIME OF SAMPLE CORRESPONDS TO STANDARD
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
ASSAY (DRIED BASIS)	98.5	101.0 %	100.6 %
pH OF A 5% SOLUTION	3.5	5.5	5.0
LOSS ON DRYING		0.5 %	0.2 %
RESIDUE ON IGNITION		0.1 %	0.1 %
ORGANIC IMPURITIES			.
CLONIDINE RELATED COMPOUND RELATED COMPOUND A		0.1 %	0.0 %
2,6-DICHLOROANILINE		0.1 %	0.0 %
ANY OTHER UNSPECIFIED IMPURITY		0.1 %	0.0 %
TOTAL IMPURITIES		0.2 %	0.0 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
EXPIRATION DATE			20-OCT-2025
DATE OF MANUFACTURE			21-OCT-2020
MONOGRAPH EDITION			USP 2023

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS:	AS REPORTED		NO RESIDUAL SOLVENT PRESENT

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
24-JAN-24 09:28:39

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
24-JAN-24 10:56:54

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

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 YUNG ZIP CHEMICAL INDUSTRIAL .CO., LTD. at No. 59, You Shih Road, Youth Industrial District, Dajia, Taichung City, 43767, Taiwan (TWN). 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: 10/26/2017

Revision Date: 10/30/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CL118
Product Name: CLONIDINE HYDROCHLORIDE, USP

Other means of identification

Synonyms: 2,6-Dichloro-N-2-imidazolidinylidenebenzeneamine hydrochloride
 1H-Imidazol-2-amine, N-(2,6-dichlorophenyl)-4,5-dihydro-, monohydrochloride (9CI)
 2-((2,6-Dichlorophenyl)amino)-2-imidazoline hydrochloride
 2-((2,6-Dichlorophenyl)imino)imidazolidine monohydrochloride
 2-(2,6-Dichloroanilino)-2-imidazoline hydrochloride
 2-(2,6-Dichlorophenylamino)-2-imidazoline hydrochloride
 Benzenamine, 2,6-dichloro-N-2-imidazolidinylidene-, hydrochloride
 Capresin
 Catapres
 Catapresan
 Chlophazolin
 Clofelin
 Clonidine monohydrochloride
 Clophelinum
 Clophilin

CAS #: 4205-91-8
RTECS # NJ2490000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

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

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: 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
Acute toxicity - Inhalation (Vapors)	Category 1

Label elements

Danger

Hazard statements

Toxic if swallowed

Fatal if inhaled



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

Do not breathe dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Wear respiratory protection

Precautionary Statements - Response

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

Precautionary Statements - Storage

Store locked up

Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Clonidine Hydrochloride	4205-91-8	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.

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Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
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 not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. 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. Immediate medical attention is required.

Most important symptoms and effects, both acute and delayed

Symptoms	<p>Ingestion of large amounts may cause nausea, vomiting, abdominal pain</p> <p>May cause constipation</p> <p>May cause anorexia</p> <p>Dryness of mouth</p> <p>May cause pupillary constriction</p> <p>Respiratory depression</p> <p>May cause central nervous system effects</p> <p>May affect the cardiovascular system</p> <p>May cause muscle weakness</p> <p>May cause muscle and joint pain</p> <p>May affect the liver</p>
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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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 (CO ₂). Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Hydrogen chloride.
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Specific hazards:	No information available.
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Special Protective Actions for Firefighters

Specific Methods:	No information available.
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Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent)
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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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Avoid breathing dust.

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

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. All equipment used when handling the product must be grounded.

Safe Handling Advice

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

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers. Store in a segregated and approved area.

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
Clonidine Hydrochloride	4205-91-8	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec

Clonidine Hydrochloride	4205-91-8	None	None	None	None
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Australia and Mexico

Components	CAS-No.	Australia	Mexico
Clonidine Hydrochloride	4205-91-8	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles or Safety glasses with side-shields.
Skin and body protection:	Gloves Chemical resistant apron Long sleeved clothing
Respiratory protection:	Wear respirator with dust filter. or. Effective dust mask.
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: C ₉ H ₉ Cl ₂ N ₃ .HCl
Molecular/Formula weight (g/mole): 266.56 g/mole	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): 130°C (266°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): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in cold water	

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Soluble in Methanol
Insoluble in diethyl ether

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Excess Heat. Incompatible materials. Exposure to light. Avoid dust formation.

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:

Inhalation. Ingestion.

Acute Toxicity

Component Information

Clonidine Hydrochloride

CAS-No. 4205-91-8

LD50/oral/rat = 126 mg/kg Oral LD50 Rat

LD50/oral/mouse = 135 mg/kg Oral LD50 Mouse

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = 0.0197 g/m³ Inhalation LC50 Rat 4 h

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = 30 mg/kg Oral LD50 Dog

150 mg/kg Oral LD50 Monkey

80 mg/kg Oral LD50 Rabbit

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 126 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 135 mg/kg

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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** = 19.7 mg/m³ (4-hr.)**LC50/Inhalation/mouse****VALUE-Vapor** = No information available**VALUE - Gas** = No information available**VALUE - Dust/Mist** = No information available**Symptoms****Skin Contact:** May cause skin irritation.**Eye Contact:** May cause eye irritation.**Inhalation** May be fatal if inhaled. May cause irritation of respiratory tract.

Ingestion Toxic if swallowed. May cause nausea, vomiting, constipation, anorexia, and abdominal pain. May cause dry mouth. May affect respiration (respiratory depression). May affect behavior/central nervous system (dizziness, headache). It may affect behavior/central nervous system (irritability). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (somnolence, tremor, hallucinations). It may affect behavior/central nervous system (drowsiness). May cause muscle weakness. May cause pallor. May affect the cardiovascular system (tachycardia, bradycardia, hypotension, cardiac failure). It may affect cardiovascular system (hypertension). May affect the cardiovascular system (cardiac arrhythmias). May affect liver. May affect respiration (dyspnea, respiratory depression). May cause joint and muscle pain. May cause pupillary constriction (miosis).

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
Clonidine Hydrochloride	4205-91-8	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)***Product code:** CL118**Product name:** CLONIDINE
HYDROCHLORIDE, USP**7 / 11**

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
Clonidine Hydrochloride	4205-91-8	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811

Proper Shipping Name: Toxic solids, organic, n.o.s. (clonidine hydrochloride)

Hazard Class: 6.1

Subsidiary Class No information available

Packing group: III

Emergency Response Guide No information available

Number

Marine Pollutant No data available

DOT RQ (lbs): No information available

Special Provisions No Information available

Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical

names of the hazardous material must be entered in parentheses, in association with the basic description.

Description: UN2811, Toxic solids, organic, n.o.s., 6.1, PG III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant Description: No Information available
UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, PG III

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Description: UN2811 Toxic solid, organic, n.o.s., 6.1, III

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant EMS: No information available
F-A

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811 Toxic solid, organic, n.o.s., 6.1, III

ICAO

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, PG III

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 6L
Special Provisions Description: No information available
UN2811, Toxic solid, organic, n.o.s., 6.1, PG III

15. REGULATORY INFORMATION

International Inventories

Product code: CL118

Product name: CLONIDINE
HYDROCHLORIDE, USP

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Clonidine Hydrochloride	4205-91-8	Not Listed	Not present	Not present	Present (9)-2186	Not present	Present	Present 224-121-5

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:
Clonidine Hydrochloride	4205-91-8	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
Clonidine Hydrochloride	4205-91-8	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
Clonidine Hydrochloride	4205-91-8	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

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Clonidine Hydrochloride	4205-91-8	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Clonidine Hydrochloride	4205-91-8	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting

Product code: CL118

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Clonidine Hydrochloride	4205-91-8	Not listed
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EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Clonidine Hydrochloride	4205-91-8	

EU - CLP (1272/2008)

R-phrases(s)

R26 - Very toxic by inhalation.

R25 - Toxic if swallowed.

S -phrase(s)

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

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Clonidine Hydrochloride	4205-91-8		No information	

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

Indication of danger:

T+ - Very toxic.

T - Toxic



16. OTHER INFORMATION

Preparation Date: 10/26/2017
Revision Date: 10/30/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet

Product code: CL118

Product name: CLONIDINE
HYDROCHLORIDE, USP

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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
CL118	Clonidine 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

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

CL118, Clonidine 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 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 - Clonidine Hydrochloride, USP (Cat# CL118)

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	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 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 substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

September 30, 2020

RE: Residual Solvents Statement – Clonidine Hydrochloride, USP (Cat# CL118)

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:

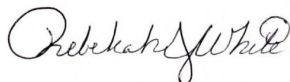
Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Acetone	3	< 5000 ppm
1-Butanol	3	< 5000 ppm

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,



Rebekah J. White
Technical Service Representative
Spectrum Chemical Mfg. Corp.

CORPORATE HEADQUARTERS

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New Brunswick, NJ 08901
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Gardena, California 90248
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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.

DANGER

- Fatal if inhaled • Toxic if swallowed.
- Do not eat, drink or smoke when using this product • Wear respiratory protection • Do not breathe 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 INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN



CL118

SIZ SY

Clonidine Hydrochloride

2-(2,6-Dichloroanilino)-
2-imidazoline Hydrochloride
USP
CAS 4205-91-8

CAUTION: For manufacturing, processing or repacking. Rx only. Further processing and testing required for use in parenteral applications.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_9H_9Cl_2N_3 \cdot HCl$ F.W. 266.55

Manufacturer/Supplier Code?

Manufacturer Lot Number?

Assay (Dried Basis) 98.0-102.0%

pH of a 5% Solution 3.5-5.5

MAXIMUM LIMITS

Loss on Drying 0.5%

Residue on Ignition 0.1%

Organic Impurities:

 Clonidine Related Compound A 0.1%

 2,6-Dichloroaniline 0.1%

 Any Unspecified Impurity 0.1%

 Total Impurities 0.2%

Elemental Impurities As reported

Residual Solvents To pass test

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

Repackaged by Spectrum as:

Lot No. XQ####

Exp. Date: 00-00-0000



Spectrum Chemical Mfg Corp

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West Coast Facility:

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