

Scientific Documentation

Orphenadrine Citrate, USP

Not appropriate for regulatory submission.

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

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



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Orphenadrine Citrate, USP (O1047)

Item Number	O1047
Item	Orphenadrine Citrate, USP
CAS Number	4682-36-4
Molecular Formula	$C_{18}H_{23}NO \cdot C_6H_8O_7$
Molecular Weight	461.50
MDL Number	
Synonyms	(RS)-Dimethyl[2-(2-methylbenzhydryloxy)ethyl]amine Dihydrogen Citrate ; Mephenamine Citrate

Test	Specification	
	Min	Max
ASSAY ($C_{18}H_{23}NO \cdot C_6H_8O_7$ @; DRIED BASIS)	98.0	101.5 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES, PROCEDURE 1 (HPLC):		
ORPHENADRINE RELATED COMPOUND B		0.1 %
ORPHENADRINE RELATED COMPOUND C		0.3 %
METHYLBENZHYDROL		0.1 %
DIPHENHYDRAMINE		0.3 %
METHYL ORPHENADRINE		0.1 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
ORGANIC IMPURITIES, PROCEDURE 2 (GC):		
METHYLBENZOPHENONE		0.3 %
METHYLBENZHYDROL.		0.3 %
DIPHENHYDRAMINE.		0.3 %
DIDESMETHYL ORPHANADRINE		0.3 %
ORPHENADRINE RELATED COMPOUND E		0.3 %
ORPHENADRINE RELATED COMPOUND F		0.3 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY.		0.10 %

Test	Specification	
	Min	Max
TOTAL IMPURITIES.		1.0 %
ISOMER CONTENT		0.3 %
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
MOLYBDENUM (Mo)	AS REPORTED	
COPPER (Cu)	AS REPORTED	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CITRATE	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters: **West Coast Facility:**
769 Jersey Ave. 14422 S. San Pedro St.
New Brunswick, NJ 08901 Gardena, CA 90248
732.214.1300 310.516.8000

Certificate Of Analysis

Item Number	O1047	Lot Number	11G0967
Item	Orphenadrine Citrate, USP	Manufacturer Lot	ORPC/1301
CAS Number	4682-36-4	Manufacturer Code	13524
Molecular Formula	C ₁₈ H ₂₃ NO•C ₆ H ₈ O ₇	Molecular Weight	461.50

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (C ₁₈ H ₂₃ NO•C ₆ H ₈ O ₇ @; DRIED BASIS)	98.0	101.5 %	99.78 %
LOSS ON DRYING		0.5 %	0.22 %
RESIDUE ON IGNITION		0.1 %	0.07 %
ORGANIC IMPURITIES		TO PASS TEST	PASSES TEST
ISOMER CONTENT		TO PASS TEST	PASSES TEST
ELEMENTAL IMPURITIES:			.
NICKEL (Ni)	AS REPORTED		<0.25 µg/g
CHROMIUM (Cr)	AS REPORTED		<0.25 µg/g
MOLYBDENUM (Mo)	AS REPORTED		<0.25 µg/g
COPPER (Cu)	AS REPORTED		3.98 µg/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			30-JUN-2023
DATE OF MANUFACTURE			01-JUL-2018
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
CLASS 2 (solvent) / TOLUENE			<890 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
02-AUG-19 12:26:45

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



Certificate of Analysis Results Approved By:

HBERMUDEZ
Hernan Bermudez
02-AUG-19 12:26:57

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 R.L.Fine Chem Private Limited at Plot No. 15, KHB Industrial Area, Yelahanka, Bengaluru, Karnataka 560064, India. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 3/20/2019

Revision date 3/20/2019

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: O1047
Product Name: ORPHENADRINE CITRATE, USP

Other means of identification

Synonyms: No information available
CAS #: 4682-36-4
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

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

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

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by 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
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Toxic if swallowed
 May cause drowsiness or dizziness



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
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
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

Component	CAS No	Weight-%
Orphenadrine Citrate	4682-36-4	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.

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. Get medical attention.

Ingestion: Toxic if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms

- May cause digestive (gastrointestinal) tract irritation
- May cause nausea and vomiting
- May cause constipation
- Dryness of mouth
- May cause headache
- May cause drowsiness or dizziness
- Lightheadedness
- Agitation
- Hallucinations
- Tremors
- Weakness
- May cause mydriasis (dilated pupils)
- Blurred vision
- Urinary retention
- May cause difficult and painful urination
- Heart palpitations
- Weak, rapid pulse or rapid heart rate (Tachycardia)
- May cause hypotension
- May cause seizures
- Fainting

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 (NO_x).

Specific hazards May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters:

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

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

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Orphenadrine Citrate	4682-36-4	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Orphenadrine Citrate	4682-36-4	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Orphenadrine Citrate	4682-36-4	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. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White.
Odor: No information available.	Taste No information available.	Formula C18H23NO.C6H8O7
Molecular/Formula weight (g/mole): 461.50	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 134-138 °C/273.2-280.4 °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:
Sparingly soluble in water

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. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: carbon oxides. Nitrogen oxides (NO_x).

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

Orphenadrine Citrate

CAS No 4682-36-4

LD50/oral/rat = 255 mg/kg (EDQM)

LD50/oral/mouse = No information available

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 = Minimum oral lethal dose for adults (LDL) = 2 to 3 grams

Product Information

LD50/oral/rat =

Value - Acute Tox = 255 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

Value - Acute Tox = No information available

LD50/dermal/rat

VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Toxic if swallowed. May cause dry mouth. May cause constipation. May cause gastrointestinal (digestive) tract irritation with nausea, vomiting. May affect behavior (hallucinations). May cause headache. May affect behavior/central nervous system (dizziness, drowsiness). It may cause twitching or tremors/trembling. May affect behavior/central nervous system (convulsions/seizures). May cause weakness. May cause blurred or foggy vision. May cause mydriasis (dilated pupils). May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (hypotension). May cause urinary retention. May cause fainting.

Aspiration hazard No information available.

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

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Orphenadrine Citrate	4682-36-4	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure central nervous 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: No information available.
Mobility in soil No information available
Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Orphenadrine Citrate	4682-36-4	None	None	None	None

14. TRANSPORT INFORMATION

DOT

Product code: O1047

Product name: ORPHENADRINE
CITRATE, USP

Page

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (orphenadrine citrate)
Hazard Class 6.1
Subsidiary Class No information available
Packing group: III
Emergency Response Guide Number 154
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions IB8, IP3, T1, TP33
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. (Orphenadrine Citrate), 6.1, 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 No Information available
Description: UN2811, Toxic solid, organic, n.o.s. (Orphenadrine Citrate), 6.1, III

ADR

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group III
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Orphenadrine Citrate), 6.1, III

IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (orphenadrine citrate)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No information available
EMS: F-A
Special Provisions 223, 274
Description UN2811, Toxic solid, organic, n.o.s. (Orphenadrine Citrate), 6.1, III

RID

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Orphenadrine Citrate), 6.1, III

ICAO (air)

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. (Orphenadrine Citrate), 6.1, III
Special Provisions A3, A5

IATA

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Precautionary Statements - Response 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s. (Orphenadrine Citrate), 6.1, III

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Orphenadrine Citrate</i>	4682-36-4	Not Listed	Not present	Present	Not present	Not listed	Present	Present 225-137-5

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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Orphenadrine Citrate</i>	4682-36-4	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Orphenadrine Citrate</i>	4682-36-4	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Orphenadrine Citrate</i>	4682-36-4	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

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Orphenadrine Citrate	4682-36-4	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Orphenadrine Citrate	4682-36-4	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Orphenadrine Citrate	4682-36-4	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Orphenadrine Citrate	4682-36-4	Harmful if swallowed (H302); Suspected of causing cancer (H351)

EU - CLP (1272/2008)

R-phrase(s)

Not determined

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Orphenadrine Citrate	4682-36-4		No information	

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

Indication of danger:

Xn - Harmful

16. OTHER INFORMATION

Preparation Date: 3/20/2019
Revision date 3/20/2019
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may

pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

Catalog Number	Product Name
O1047	Orphenadrine Citrate, USP

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

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

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

O1047, Orphenadrine Citrate, 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Orphenadrine Citrate, USP (Cat# O1047)

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
Nickel	Ni	2A	< 0.25 ppm
Molybdenum	Mo	3	< 0.25 ppm
Chromium	Cr	3	< 0.25 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



RE: Residual Solvents - Orphenadrine Citrate, USP (Cat# O1047)

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
Toluene	2	< 890 ppm
Acetone	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,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Label Information

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

DANGER

- Toxic if swallowed • May cause drowsiness or dizziness.
- Do not eat, drink or smoke when using this product • 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 INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN



01047 SIZ SY

Orphenadrine Citrate

USP
CAS 4682-36-4

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. (orphenadrine citrate), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{18}H_{23}NO \cdot C_6H_8O_7$ F.W. 461.50

Manufacturer/Supplier Code.....?	Manufacturer Lot Number.....?
Assay ($C_{18}H_{23}NO \cdot C_6H_8O_7$; Dried Basis).....	98.0-101.5%
MAXIMUM LIMITS	
Loss on Drying.....	0.5%
Residue on Ignition.....	0.1%
Organic Impurities, Procedure 1 (HPLC):	Organic Impurities, Procedure 2 (GC):
Orphenadrine Related.....	Methylbenzophenone.....0.3%
Compound B.....0.1%	Methylbenzhydrol.....0.3%
Orphenadrine Related.....	Diphenhydramine.....0.3%
Compound C.....0.3%	Didesmethyl Orphenadrine.....0.3%
Methylbenzhydrol.....0.1%	Orphenadrine Related.....
Diphenhydramine.....0.3%	Compound E.....0.3%
Methyl Orphenadrine.....0.1%	Orphenadrine Related.....
Any Individual Unspecified.....	Compound F.....0.3%
Impurity.....0.10%	Any individual Unspecified.....
Total Impurities.....0.5%	Impurity.....0.10%
	Total Impurities.....1.0%
Isomer Content.....To pass test	Elemental Impurities.....As reported
Residual Solvents.....To pass test	

Isomer Content.....To pass test
Elemental Impurities.....As reported
Residual Solvents.....To pass test

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

Repackaged by Spectrum as:
B 8/J2GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000