

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



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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

| | |
|---------------------------------------|------------------------------------|
| <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 | 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

Certificate of Analysis Results Approved By:

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

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



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

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 (CO ₂). 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 (NOx).

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. |
|----------------------|-----------|------------|-------------|---------------------|-------------|-------------|------------------|----------------------|
| Orphenadrine Citrate | 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: |
|----------------------|-----------|------------|------------------------|----------------------------|-------------------------------|
| Orphenadrine Citrate | 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 |
|----------------------|-----------|---|---|--|---------------------------------|------------------------------------|
| Orphenadrine Citrate | 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 |
|----------------------|-----------|---|--|
| Orphenadrine Citrate | 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-phrases(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,

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

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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • 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.

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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.



Exp. Date: 00-00-0000

* 4 9 4 5 2 0 1 0 4 7 *



01047 **SIZ SY**

**Orphenadrine
Citrate**

USP

CAS 4682-36-4

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

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---------------------------------------|---------------------------------------|-----------------------|-------------------------------|----------------------|-----------------------------|-----------------------|----------------------------|-----------------------------|-------------------------------------|----------------------------|----------------------|--------------------------------|-----------------------|----------------------------|----------------------|----------------------|-----------------------|-----------------------------|----------------------------|--|----------------------|--|-----------------------------|---|
| <p>Manufacturer/Supplier Code ?</p> <p>Manufacturer Lot Number ?</p> <p>Assay ($C_{18}H_{23}NO \cdot C_6H_8O_7$, Dried Basis) 98.0-101.5%</p> <p style="text-align: center;">MAXIMUM LIMITS</p> <p>Loss on Drying 0.5%</p> <p>Residue on Ignition 0.1%</p> <p>Organic Impurities, Procedure 1 (HPLC):</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Orphenadrine Related</td> <td style="width: 50%;">Organic Impurities, Procedure 2 (GC):</td> </tr> <tr> <td>Compound B 0.1%</td> <td>Methylbenzophenone 0.3%</td> </tr> <tr> <td>Orphenadrine Related</td> <td>Methylbenzhydrol 0.3%</td> </tr> <tr> <td>Compound C 0.3%</td> <td>Diphenhydramine 0.3%</td> </tr> <tr> <td>Methylbenzhydrol 0.1%</td> <td>Didesmethyl Orphenadrine 0.3%</td> </tr> <tr> <td>Diphenhydramine 0.3%</td> <td>Orphenadrine Related</td> </tr> <tr> <td>Methyl Orphenadrine 0.1%</td> <td>Compound E 0.3%</td> </tr> <tr> <td>Any Individual Unspecified</td> <td>Orphenadrine Related</td> </tr> <tr> <td>Impurity 0.10%</td> <td>Compound F 0.3%</td> </tr> <tr> <td>Total Impurities 0.5%</td> <td>Any individual Unspecified</td> </tr> <tr> <td></td> <td>Impurity 0.10%</td> </tr> <tr> <td></td> <td>Total Impurities 1.0%</td> </tr> </table> | Orphenadrine Related | Organic Impurities, Procedure 2 (GC): | Compound B 0.1% | Methylbenzophenone 0.3% | Orphenadrine Related | Methylbenzhydrol 0.3% | Compound C 0.3% | Diphenhydramine 0.3% | Methylbenzhydrol 0.1% | Didesmethyl Orphenadrine 0.3% | Diphenhydramine 0.3% | Orphenadrine Related | Methyl Orphenadrine 0.1% | Compound E 0.3% | Any Individual Unspecified | Orphenadrine Related | Impurity 0.10% | Compound F 0.3% | Total Impurities 0.5% | Any individual Unspecified | | Impurity 0.10% | | Total Impurities 1.0% | <p>Isomer Content To pass test</p> <p>Elemental Impurities As reported</p> <p>Residual Solvents To pass test</p> <p>LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.</p> |
| Orphenadrine Related | Organic Impurities, Procedure 2 (GC): | | | | | | | | | | | | | | | | | | | | | | | | |
| Compound B 0.1% | Methylbenzophenone 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Orphenadrine Related | Methylbenzhydrol 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Compound C 0.3% | Diphenhydramine 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Methylbenzhydrol 0.1% | Didesmethyl Orphenadrine 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Diphenhydramine 0.3% | Orphenadrine Related | | | | | | | | | | | | | | | | | | | | | | | | |
| Methyl Orphenadrine 0.1% | Compound E 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Any Individual Unspecified | Orphenadrine Related | | | | | | | | | | | | | | | | | | | | | | | | |
| Impurity 0.10% | Compound F 0.3% | | | | | | | | | | | | | | | | | | | | | | | | |
| Total Impurities 0.5% | Any individual Unspecified | | | | | | | | | | | | | | | | | | | | | | | | |
| | Impurity 0.10% | | | | | | | | | | | | | | | | | | | | | | | | |
| | Total Impurities 1.0% | | | | | | | | | | | | | | | | | | | | | | | | |

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