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.
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- GMO Statement
- Melamine Statement
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- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label
General Lot Numbering System Guidance
Specification for Racepinephrine Hydrochloride, USP (E1418)

<table>
<thead>
<tr>
<th>Item Number</th>
<th>E1418</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Racepinephrine Hydrochloride, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>329-63-5</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C₉H₁₃NO₃•HCl</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>219.67</td>
</tr>
<tr>
<td>MDL Number</td>
<td></td>
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<tr>
<td>Synonyms</td>
<td>(+/-)Epinephrine Hydrochloride ; (+/-) Adrenaline Hydrochloride ; Racemic Epinephrine Hydrochloride ; Racepinephrine Hydrochloride</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPEARANCE</td>
<td></td>
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<tr>
<td>IDENTIFICATION A (UV)</td>
<td>SPECTRUM MATCHES REFERENCE</td>
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<tr>
<td>IDENTIFICATION (B)</td>
<td>POSITIVE FOR CHLORIDE</td>
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<tr>
<td>ASSAY (ANHYDROUS BASIS)</td>
<td>97.0</td>
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<tr>
<td>SPECIFIC ROTATION</td>
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<tr>
<td>WATER DETERMINATION</td>
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<tr>
<td>RESIDUE ON IGNITION</td>
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<tr>
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<tr>
<td>PLATINUM (Pt)</td>
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<tr>
<td>EXPIRATION DATE</td>
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<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
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<tr>
<td>RESIDUAL SOLVENTS</td>
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</table>

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**

<table>
<thead>
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<td>Racepinephrine Hydrochloride, USP</td>
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<td>CLASS 3 (solvent) / ETHANOL</td>
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<td>MONOGRAPH EDITION</td>
<td>(USP) 2021</td>
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</table>
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 Wuhan Wuyao Pharmaceutical Co.,Ltd. at No.18,Wangfen Rd., Fuchi Town, Yangxin County, Huangshi, Hubei 435229, China. 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.
1. IDENTIFICATION

Product identifier

Product code: E1418
Product Name: RACEPINEPHRINE HYDROCHLORIDE, USP

Other means of identification

Synonyms:
- (+)-Adrenaline hydrochloride
- dl-Adrenaline hydrochloride
- 1,2-Benzenediol, 4-(1-hydroxy-2-(methylamino)ethyl)-, hydrochloride, (+)- (9CI)
- (+)-3,4-Dihydroxy-alpha-((methylamino)methyl)benzyl alcohol hydrochloride
- (+)-Epinephrine hydrochloride
dl-Epinephrine hydrochloride

CAS #: 329-63-5
RTECS # DO3330000
CI#: Not available

Recommended use of the chemical and restrictions on use

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

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

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

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Acute toxicity - Oral</th>
<th>Acute toxicity - Dermal</th>
<th>Skin corrosion/irritation</th>
<th>Serious eye damage/eye irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Category 3</td>
<td>Category 3</td>
<td>Category 2</td>
<td>Category 2B</td>
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</tbody>
</table>

Label elements

Danger

Hazard statements

Product code: E1418
Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
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
Wear protective gloves
Wear protective clothing

Precautionary Statements - Response
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage
Store locked up

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
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<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>100</td>
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</tbody>
</table>

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)

Product code: E1418  Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
involved and take precautions to protect themselves. First aider needs to protect himself.

**Skin Contact:**
Toxic in contact with skin. Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Immediate medical attention is required. Call a physician or Poison Control Centre immediately.

**Eye Contact:**
Flush eyes with water for 15 minutes. Get medical attention.

**Inhalation:**
Toxic by inhalation. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **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**
- Irritating to eyes, respiratory system and skin
- Ingestion may cause nausea, vomiting, and diarrhea
- Central nervous system effects
  - Dizziness
  - Headache
  - Convulsions
  - Tremors
  - Somnolence
  - Hallucinations
- May affect respiration
- Dyspnea (Shortness of breath and difficulty breathing)
- May affect the cardiovascular system
  - Weak, rapid pulse or rapid heart rate (Tachycardia)
  - Cardiac arrhythmias
  - Cardiac arrest

**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:**

**Specific hazards:**
May be combustible at high temperatures.

**Product code:** E1418  **Product name:** RACEEPINEPHRINE HYDROCHLORIDE, USP
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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. 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. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. 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


Incompatible Materials:
- Oxidizing agents
- Acid chlorides
- Acid anhydrides
- Acids

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

Product code: E1418
Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
United States

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
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<tbody>
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<td>329-63-5</td>
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Canada

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<th>Canada - Ontario</th>
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Australia and Mexico

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<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering measures to reduce exposure:
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: Goggles
Skin and body protection: Long sleeved clothing, Chemical resistant apron, Gloves
Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures: Avoid contact with skin, eyes and clothing. 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: Fine powder.
Color: White.
Odor: Odorless.
Taste: No information available.
Formula: C9-H13-N-O3.HCl
Molecular/Formula weight (g/mole): 219.67
Flammability: No information available
Flashpoint (°C/°F): No information available
Autoignition Temperature (°C/°F):
Product code: E1418
Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents
Sensitive to light. It gradually darkens on exposure to light

Chemical stability
Stability:
Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions:
Hazardous polymerization does not occur

Conditions to avoid:

Incompatible Materials:
Oxidizing agents
Acid chlorides
Acid anhydrides
Acids

Hazardous decomposition products:

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. Skin.

Acute Toxicity

Product code: E1418
Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
Component Information

<table>
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<tr>
<th>Component Information</th>
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<td>Racepinephrine Hydrochloride</td>
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<td>CAS-No.</td>
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<tr>
<td>LD50/oral/mouse =</td>
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<tr>
<td>LD50/dermal/rabbit =</td>
</tr>
<tr>
<td>LD50/dermal/rat =</td>
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<tr>
<td>LC50/inhalation/rat =</td>
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<td>LC50/inhalation/mouse =</td>
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<td>Other LD50 or LC50 information =</td>
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</table>

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = 90 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:
Causes skin irritation. Toxic in contact with skin.

Eye Contact:
Causes eye irritation. Mild eye irritation.

Inhalation
May cause irritation of respiratory tract.

Ingestion
Toxic if swallowed. May cause digestive (gastrointestinal) tract irritation. Ingestion may cause nausea, vomiting, diarrhea. May cause pallor. May cause excessive sweating. May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). It may affect the heart (cardiomyopathy including myocardial infarction, arrhythmias). It may cause central nervous system depression. May affect behavior/central nervous system (somnolence, tremor, hallucinations). May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (tremor, convulsions). May also cause anxiety and stress. May affect respiration (acute pulmonary edema). May affect respiration (dyspnea - difficulty breathing and shortness of breath).

Aspiration hazard
No information available.

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

Product code: E1418  Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
Chronic Toxicity: No information available.

Sensitization: No information available.

Mutagenic Effects: DNA damage - human leukocyte

Carcinogenic effects: Not considered carcinogenic.

<table>
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<th>Components</th>
<th>CAS-No.</th>
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<th>NTP</th>
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<th>Australia - Prohibited Carcinogenic Substances</th>
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</table>

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: 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: Potential for bioconcentration in aquatic organisms is low.

Mobility: It is expected to have high mobility in soil.

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.

Product code: E1418

Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
<table>
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<th></th>
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<td>329-63-5</td>
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<td>None</td>
<td>None</td>
<td>None</td>
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</tbody>
</table>

### 14. TRANSPORT INFORMATION

**DOT**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** Toxic solids, organic, n.o.s. (epinephrine hydrochloride)
- **Hazard Class:** 6.1
- **Subsidiary Class:** No information available
- **Packing group:** No information available
- **Emergency Response Guide Number:** No information available
- **Marine Pollutant:** No data available
- **DOT RQ (lbs):** No information available
- **Special Provisions:** No Information available
- **Symbol(s):** [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 II

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

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

**IMO / IMDG**
- **UN-No:** UN2811
- **Proper Shipping Name:** Toxic solid, organic, n.o.s.
- **Hazard Class:** 6.1
- **Packing Group:** II
- **Subsidiary Risk:** No information available
- **Description:** F-A

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

**ICAO**
- **Product code:** E1418
- **Product name:** RACEPINEPHRINE HYDROCHLORIDE, USP
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, PG II

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

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>U.S. TSCA</th>
<th>KOREA KECL (PICCS)</th>
<th>Philippines</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Present</td>
<td>Not present</td>
<td>Not present</td>
<td>Not present</td>
<td>Not present</td>
<td>Present</td>
<td>206-346-0</td>
</tr>
</tbody>
</table>

U.S. Regulations


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)

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPGs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Canada
WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification

Information:
The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation

This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR.

WHMIS 1988 Hazard Class

D1B  Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Not Listed</td>
<td>Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CEPA Schedule I - Toxic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

EU Classification

EU GHS - SV - CLP 1272/2008

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EU GHS - SV - CLP (1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>No information</td>
</tr>
</tbody>
</table>

EU - CLP (1272/2008)

R-phrase(s)

R25 - Toxic if swallowed.

S-phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racepinephrine Hydrochloride</td>
<td>329-63-5</td>
<td>No information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Indication of danger:

T - Toxic

Product code: E1418  Product name: RACEPINEPHRINE HYDROCHLORIDE, USP
16. OTHER INFORMATION

Preparation Date: 4/14/2016
Revision Date: 8/14/2018
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
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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1418</td>
<td>Racepinephrine Hydrochloride, USP</td>
</tr>
</tbody>
</table>

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
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 24 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 - Racepinephrine Hydrochloride, USP (Cat# E1418)

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:

<table>
<thead>
<tr>
<th>Elemental Impurity</th>
<th>Class</th>
<th>Expected Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platinum</td>
<td>Pt</td>
<td>2B &lt; 1 ppm</td>
</tr>
</tbody>
</table>

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.
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:

<table>
<thead>
<tr>
<th>Residual Solvent</th>
<th>Class</th>
<th>Expected Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>3</td>
<td>&lt; 5000 ppm</td>
</tr>
<tr>
<td>Ethanol</td>
<td>3</td>
<td>&lt; 5000 ppm</td>
</tr>
<tr>
<td>2-Propanol</td>
<td>3</td>
<td>&lt; 5000 ppm</td>
</tr>
</tbody>
</table>

No Class 1, Class 2 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.
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.

Racepinephrine Hydrochloride
[(±)Epinephrine Hydrochloride] USP
CAS 329-63-5

CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.

FIRST AID:
• Toxic if swallowed or in contact with skin • Causes eye irritation • Causes skin irritation.
• Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing • Wash face, hands and any exposed skin thoroughly after handling.

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

KEEP FROM CHILDREN

C₆H₁₃NO₃•HCl  F.W. 219.67

Manufacturer/Supplier Code .........................................?
Manufacturer Lot Number .............................................?
Assay (Anhydrous Basis) ............................................ 97.0-102.0%
Specific Rotation ................................................... -1° to +1°

MAXIMUM LIMITS
Water Determination .................................................. 0.5%
Residue on Ignition .................................................... 0.5%
Adrenaline ............................................................... To pass test
Norepinephrine ........................................................ 4.0%
Elemental Impurities ................................................ As reported
Residual Solvents ........................................................ To pass test

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

Repackaged by Spectrum as:
E1418 06-25-2019 FV ghs
DOT: UN2811, Toxic solid, organic, n.o.s. (epinephrine hydrochloride), 6.1, PG II

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

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
RE: Lot Numbering System

Dear Valued Customer:

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

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

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

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

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

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

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

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

Sincerely,

Oralia Chavez,
Quality Assurance Specialist