

Scientific Documentation

Racepinephrine Hydrochloride, USP

Not appropriate for regulatory submission.

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

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



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Specification for Racepinephrine Hydrochloride, USP (E1418)

Item Number	E1418
Item	Racepinephrine Hydrochloride, USP
CAS Number	329-63-5
Molecular Formula	C ₉ H ₁₃ NO ₃ •HCl
Molecular Weight	219.67
MDL Number	
Synonyms	Racepinephrine Hydrochloride ; Racemic Epinephrine Hydrochloride ; (+/-)Epinephrine Hydrochloride ; (+/-) Adrenaline Hydrochloride

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION A (UV)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE	
ASSAY (ANHYDROUS BASIS)	97.0	102.0 %
SPECIFIC ROTATION	-1° to +1°	
WATER DETERMINATION		0.5 %
RESIDUE ON IGNITION		0.5 %
ADRENALONE		0.2
NOREPINEPHRINE		4.0 %
ELEMENTAL IMPURITIES:		
PLATINUM (Pt)		AS REPORTED
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	E1418	Lot Number	1NA0110
Item	Racpinephrine Hydrochloride, USP	Manufacturer Lot	C33-230301
CAS Number	329-63-5	Manufacturer Code	7630
Molecular Formula	C ₉ H ₁₃ NO ₃ •HCl	Molecular Weight	219.67

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			OFF-WHITE POWDER
IDENTIFICATION A (UV)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
ASSAY (ANHYDROUS BASIS)	97.0	102.0 %	99.9 %
SPECIFIC ROTATION	-1° to +1°		0°
WATER DETERMINATION		0.5 %	0.3 %
RESIDUE ON IGNITION		0.5 %	0.0 %
ADRENALONE		0.2	0.0
NOREPINEPHRINE		4.0 %	<4.0 %
ELEMENTAL IMPURITIES:			.
PLATINUM (Pt)		AS REPORTED	<0.01 µg/g (M)
EXPIRATION DATE			01-FEB-2025
DATE OF MANUFACTURE			12-MAR-2023
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 3 (solvent) / ACETONE			<5000 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm (M)
MONOGRAPH EDITION			(USP-NF) 2023
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
24-JAN-24 11:28:31

Certificate of Analysis Results Approved By:

AMENDEZ
Ana Mendez
24-JAN-24 11:45:16

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 Wuhan Wuyao Pharmaceutical Co.,Ltd. at No.18,Wangfen Rd., Fuchi Town, Yangxin County, Huangshi, Hubei 435229, China (CHN). 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

spectrum®



Revision date 27-September-2022

Revision Number 2

1. Identification

Product identifier

Product Name RACEPINEPHRINE HYDROCHLORIDE, USP

Other means of identification

Product Code(s) E1418

UN/ID no UN2811

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 3
Acute toxicity - Dermal	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Toxic if swallowed
Toxic in contact with skin
Causes skin irritation

Causes eye irritation



Appearance Fine powder

Physical state Solid

Odor Odorless

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/protective clothing

Precautionary Statements - Response

Specific treatment (see .? on this label)

Specific treatment (see .? on this label)

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 and soap

Call a POISON CENTER or doctor if you feel unwell

Take off immediately all contaminated clothing and wash it before reuse

If skin irritation occurs: Get medical advice/attention

IF SWALLOWED: Immediately call a POISON CENTER or doctor

Rinse mouth

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Racinephrine Hydrochloride	329-63-5	100

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact

Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing.

Skin contact

Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO ₂). Hydrocarbons. Produce flammable and toxic gases on contact with water.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with
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skin, eyes or clothing. Ensure adequate ventilation. Take off contaminated clothing and wash before reuse. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up. Flushed with nitrogen. Air sensitive. Sensitive to light. Store in light-resistant containers.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles). None required for consumer use.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Fine powder
Color	White
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	157 °C / 314.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known

Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information	.
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). Toxic in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. May cause redness and tearing of the eyes.
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Acute toxicity

Numerical measures of toxicity

No information available

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

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal considerations**Waste treatment methods**

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information**DOT**

UN/ID no	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.(epinephrine hydrochloride)
Hazard class	6.1
Packing group:	II
Description:	UN2811, Toxic solids, organic, n.o.s. ,6.1,PG II

TDG

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	II
Description:	UN2811, TOXIC SOLID, ORGANIC, N.O.S.,6.1,PG II

MEX

not regulated

ICAO (air)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard class 6.1
Packing Group: II
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, PG II

IATA

UN number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, PG II

IMDG

not regulated

RID

UN number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Description: UN2811 Toxic solid, organic, n.o.s., 6.1, II

ADR

UN number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Description: UN2811 Toxic solid, organic, n.o.s., 6.1, II

ADN

not regulated

15. Regulatory information**International Inventories**

TSCA	Complies
DSL/NDL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Does not Comply
PICCS	Does not Comply
AICS	This product does not comply with AICS

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 27-September-2022
Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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
E1418	Racpinephrine Hydrochloride, USP

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

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

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

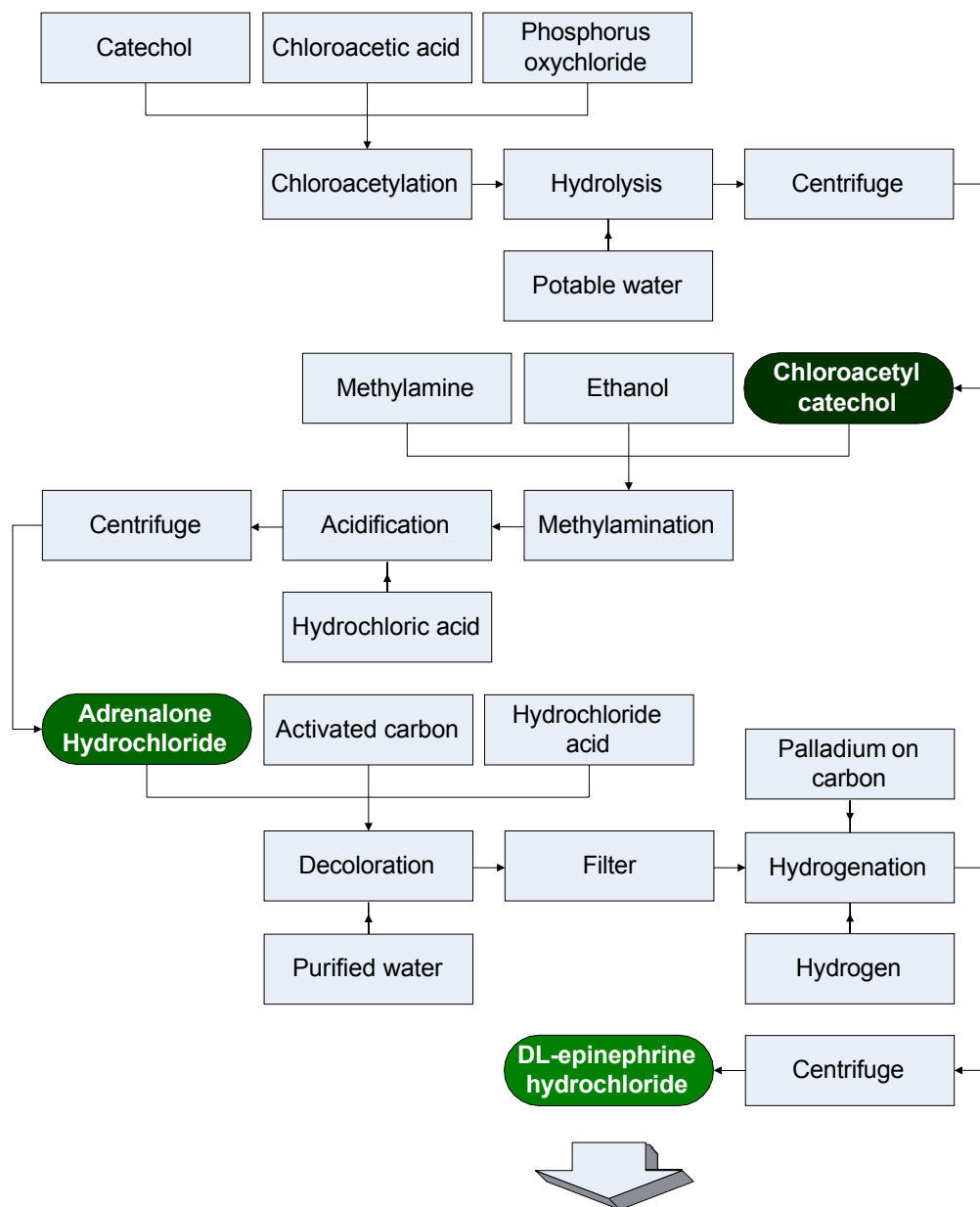
Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Racepinephrine Hydrochloride, USP - E1418



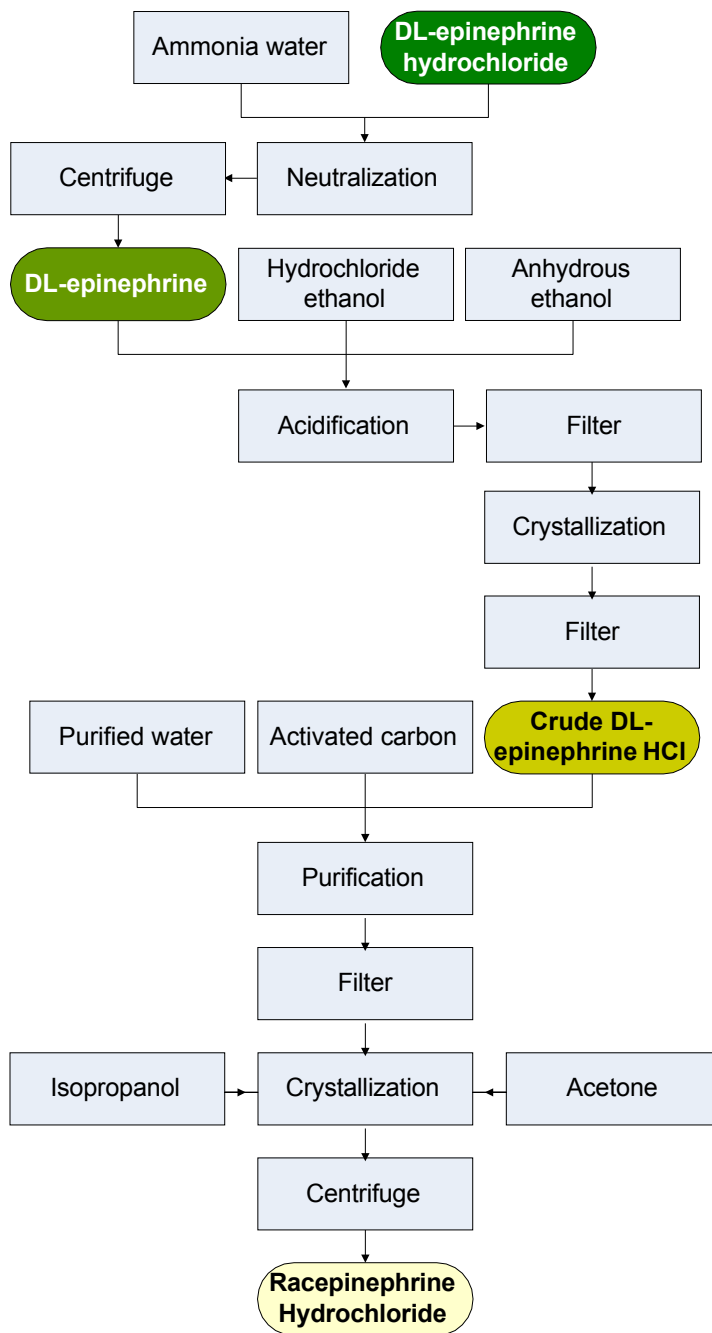
Spectrum Chemical Mfg Corp

Corporate Headquarters:

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14422 S. San Pedro St.
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E1418, Racepinephrine Hydrochloride, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • 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:

Elemental Impurity		Class	Expected Concentration
Platinum	Pt	2B	< 1 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 - Racepinephrine Hydrochloride, USP (Cat# E1418)

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
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

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.

CORPORATE HEADQUARTERS

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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 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



E1418

SIZ SY

Racpinephrine Hydrochloride

[(±)Epinephrine Hydrochloride]

USP

CAS 329-63-5

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

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

C₉H₁₃NO₃•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%
 Adrenalone To pass test
 Norepinephrine 4.0%
 Elemental Impurities As reported
 Residual Solvents To pass test

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

FLUSHED WITH NITROGEN

Repackaged by Spectrum as:

B 10/16GHS-A ? **Lot No. XQ####**

Exp. Date: 00-00-0000



Spectrum Chemical Mfg Corp

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