

Scientific Documentation

Epinephrine, USP

Not appropriate for regulatory submission.

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

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



Table of Contents

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

Specification for Epinephrine, USP (EP130)

| | |
|-------------------|--|
| Item Number | EP130 |
| Item | Epinephrine, USP |
| CAS Number | 51-43-4 |
| Molecular Formula | C ₉ H ₁₃ NO ₃ |
| Molecular Weight | 183.20 |
| MDL Number | |
| Synonyms | (R)-1-(3,4-Dihydroxyphenyl)-2-methylaminoethanol ; Adrenaline ; L-Adrenaline |

| Test | Specification | |
|----------------------------|--|-------------|
| | Min | Max |
| ASSAY (DRIED BASIS) | 98.0 | 102.0 % |
| LOSS ON DRYING | | 1.0 % |
| RESIDUE ON IGNITION | | 0.1 % |
| ENANTIOMERIC PURITY | | 3.0 % |
| ORGANIC IMPURITIES: | | |
| EPINEPHRINE SULFAONATE | | 0.2 % |
| NOREPINEPHRINE | | 0.2 % |
| OXEDRINE | | 0.10 % |
| ADRENALONE | | 0.2 % |
| EPININE | | 0.10 % |
| EPINEPHRINE METHOXY ANALOG | | 0.10 % |
| N-BENZYL EPINEPHRINE | | 0.1 % |
| N-BENZYL ADRENALONE | | 0.1 % |
| ANY INDIVIDUAL IMPURITY | | 0.10 % |
| Total impurities | | 0.5 % |
| ELEMENTAL IMPURITIES: | | |
| PLATINUM (Pt) | | AS REPORTED |
| IDENTIFICATION (A) FTIR | SPECTRUM MATCHES REFERENCE | |
| IDENTIFICATION (B) | RETENTION TIME CORRESPONDS TO STANDARD | |

| Test | Specification | |
|------------------------------|---------------|-------------|
| | Min | Max |
| APPEARANCE | | |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |
| RESIDUAL SOLVENTS | | AS REPORTED |
| CLASS 2 (SOLVENT) / METHANOL | . | |
| CLASS 3 (solvent) / ETHANOL | . | |
| MONOGRAPH EDITION | | |

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 | EP130 | Lot Number | 4NB0021 |
| Item | Epinephrine, USP | Manufacturer Lot | C09-231011 |
| CAS Number | 51-43-4 | Manufacturer Code | 7630 |
| Molecular Formula | C ₉ H ₁₃ NO ₃ | Molecular Weight | 183.20 |

| TEST | SPECIFICATION | | RESULT |
|----------------------------|---|-------------|---|
| | MIN | MAX | |
| ASSAY (DRIED BASIS) | 98.0 | 102.0 % | 101.0% |
| LOSS ON DRYING | | 1.0 % | 0.7 % |
| RESIDUE ON IGNITION | | 0.1 % | <0.1 % |
| ENANTIOMERIC PURITY | | 3.0 % | 1.4 % |
| ORGANIC IMPURITIES: | | | . |
| EPINEPHRINE SULFAONATE | | 0.2 % | <0.2 % |
| NOREPINEPHRINE | | 0.2 % | <0.2 % |
| OXEDRINE | | 0.10 % | <0.10 % |
| ADRENALONE | | 0.2 % | <0.2 % |
| EPININE | | 0.10 % | <0.10 % |
| EPINEPHRINE METHOXY ANALOG | | 0.10 % | <0.10 % |
| N-BENZYL EPINEPHRINE | | 0.1 % | <0.1 % |
| N-BENZYL ADRENALONE | | 0.1 % | <0.1 % |
| ANY INDIVIDUAL IMPURITY | | 0.10 % | <0.10 % |
| Total impurities | | 0.5 % | <0.5 % |
| ELEMENTAL IMPURITIES: | | | NO ELEMENTAL IMPURITIES PRESENT |
| PLATINUM (Pt) | | AS REPORTED | NOT DETECTED |
| IDENTIFICATION (A) FTIR | SPECTRUM MATCHES REFERENCE | | SPECTRUM MATCHES REFERENCE |
| IDENTIFICATION (B) | RETENTION TIME CORRESPONDS TO STANDARD | | RETENTION TIME CORRESPONDS TO STANDARD |

| TEST | SPECIFICATION | | RESULT |
|------------------------------|---------------|-------------|--|
| | MIN | MAX | |
| APPEARANCE | | | PRACTICALLY WHITE MICROCRYSTALLINE POWDER |
| EXPIRATION DATE | | | 01-SEP-2025 |
| DATE OF MANUFACTURE | | | 29-OCT-2023 |
| RESIDUAL SOLVENTS | | AS REPORTED | . |
| CLASS 2 (SOLVENT) / METHANOL | . | | <3000 ppm |
| CLASS 3 (solvent) / ETHANOL | . | | <5000 ppm |
| MONOGRAPH EDITION | | | USP 2023 |

Certificate of Analysis Results Entered By:

CACEVEDO
Charmian Acevedo
19-APR-24 13:09:29

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

RVANZILE
Robert Van Zile
19-APR-24 14:23:32

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 11-January-2023

Revision Number 3

1. Identification

Product identifier

Product Name EPINEPHRINE, USP

Other means of identification

Product Code(s) EP130

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 2 |
| Acute toxicity - Inhalation (Dusts/Mists) | Category 3 |
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2A |
| Specific target organ toxicity (single exposure) | Category 3 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Toxic if swallowed

Fatal in contact with skin
Toxic if inhaled
Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Appearance powder or Crystalline powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not get in eyes, on skin, or on clothing
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear protective gloves/protective clothing/eye protection/face protection

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
Immediately call a POISON CENTER or doctor
Take off immediately all contaminated clothing and wash it before reuse
If skin irritation occurs: Get medical advice/attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor
IF SWALLOWED: Immediately call a POISON CENTER or doctor
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

Other information

No information available.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% |
|---------------|---------|----------|
| Epinephrine | 51-43-4 | 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. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. |
| 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. Do not rub affected area. |
| 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. Avoid contact with skin, eyes or clothing. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information. |

Most important symptoms and effects, both acute and delayed

| | |
|-----------------|---|
| Symptoms | May cause redness and tearing of the eyes. Burning sensation. Coughing and/ or wheezing. Difficulty in breathing. |
|-----------------|---|

Indication of any immediate medical attention and special treatment needed

| | |
|---------------------------|------------------------|
| Note to physicians | Treat symptomatically. |
|---------------------------|------------------------|

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. |
| 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. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak. |
| 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 skin, eyes or clothing. Take off contaminated clothing and wash before reuse. Do not eat, drink or smoke when using this product. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. |
|--------------------------------|---|

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. Protect from light. Flushed with nitrogen. |
|---------------------------|---|

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). |
| Hand protection | Wear suitable gloves. Impervious gloves. |
| Skin and body protection | Impervious clothing. 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. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|-----------------------|------------------------------|
| Physical state | Solid |
| Appearance | powder or Crystalline powder |
| Color | White to Off-White |
| Odor | No information available |
| Odor threshold | No information available |

| Property | Values | Remarks • Method |
|---|---|-------------------------|
| pH | no data available | None known |
| Melting point / freezing point | 211 °C / 411.8 °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 | 1.3 | None known |
| Water solubility | Very slightly soluble in water | None known |
| Solubility(ies) | Soluble in acids Soluble in strong bases | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | 215 - °C 419 °F | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |

Other information

| | |
|-----------------------------|--------------------------|
| 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 | 400 kg/cu.m. |

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 | Excessive heat. Contact with air/oxygen. |
| 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. Toxic by inhalation. (based on components). |
| Eye contact | Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation. |
| Skin contact | Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components). Causes skin irritation. |
| 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. Coughing and/ or wheezing. Difficulty in breathing. |
|-----------------|---|

Acute toxicity

Numerical measures of toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|------------------------|-----------|--------------------|-----------------|
| Epinephrine 51-43-4 | - | = 62 mg/kg (Rat) | - |

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. Causes serious eye irritation. |
| 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. |
| Hazard class | 6.1 |
| Special Provisions | II |
| Special Provisions | IB8, IP2, IP4, T3, TP33 |
| Marine Pollutant | Severe Marine Pollutant |
| Description | UN2811, Toxic solids, organic, n.o.s. (Epinephrine), 6.1, II |
| Emergency Response Guide Number | 154 |

TDG

| | |
|-----------------------------|---|
| UN/ID 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. (Epinephrine), 6.1, II |

MEX

| | |
|-----------------------------|---|
| UN-No | UN2811 |
| Proper Shipping Name | Toxic solid, organic, n.o.s. |
| Hazard class | 6.1 |
| Special Provisions | 274 |
| Packing Group | II |
| Description | UN2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II |

ICAO (air)

| | |
|-----------------------------|---|
| UN/ID no. | UN2811 |
| Proper shipping name | Toxic solid, organic, n.o.s. |
| Hazard class | 6.1 |
| Packing Group | II |
| Special Provisions | A3, A5 |
| Description | UN2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II |

IATA

| | |
|-----------------------------|---|
| UN number | 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. (Epinephrine), 6.1, II |

IMDG

| | |
|-----------------------------|---|
| UN number | UN2811 |
| Proper shipping name | Toxic solid, organic, n.o.s. |
| Hazard Class | 6.1 |
| Packing group | II |
| EmS-No | F-A, S-A |
| Special Provisions | 274 |
| Marine Pollutant | NP1 |
| Description | UN2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II |

RID

| | |
|----------------------|---|
| UN number | UN2811 |
| Proper shipping name | Toxic solid, organic, n.o.s. |
| Hazard Class | 6.1 |
| Packing group | II |
| Classification code | T2 |
| Special Provisions | 274, 614 |
| Description | UN2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II |
| Labels | 6.1 |

ADR

| | |
|-------------------------|--|
| UN number | 2811 |
| Proper shipping name | Toxic solid, organic, n.o.s. |
| Hazard Class | 6.1 |
| Packing group | II |
| Classification code | T2 |
| Tunnel restriction code | (D/E) |
| Special Provisions | 274, 614 |
| Description | 2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II, (D/E) |
| Labels | 6.1 |

ADN

| | |
|------------------------|---|
| UN/ID No | UN2811 |
| Proper shipping name | Toxic solid, organic, n.o.s. |
| Hazard Class | 6.1 |
| Packing Group | II |
| Classification code | T2 |
| Special Provisions | 274, 614, 802 |
| Description | UN2811, Toxic solid, organic, n.o.s. (Epinephrine), 6.1, II |
| Hazard label(s) | 6.1 |
| Limited quantity (LQ) | 500 g |
| Equipment Requirements | PP, EP |

15. Regulatory information**International Inventories**

| | |
|----------------------|---|
| TSCA | Complies |
| DSL/NDL | Complies |
| EINECS/ELINCS | Complies |
| ENCS | This product complies with ENCS: |
| IECSC | This product complies with China: |
| KECL | Does not Comply |
| PICCS | Complies |
| AICS | All the constituents of this material are listed on the Australian Inventory of Chemical Substances (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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

| Chemical name | Hazardous Substances RQs | Extremely Hazardous Substances RQs |
|------------------------|-------------------------------------|------------------------------------|
| Epinephrine 51-43-4 | 1000 lb final RQ 454 kg final RQ | - |

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

| Chemical name | New Jersey | Massachusetts | Pennsylvania |
|------------------------|------------|---------------|----------------------|
| Epinephrine 51-43-4 | - | Present | Environmental hazard |

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information**NFPA**

Health hazards 3

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 3

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) (AELG(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 11-January-2023
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 |
|----------------|------------------|
| EP130 | Epinephrine, USP |

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

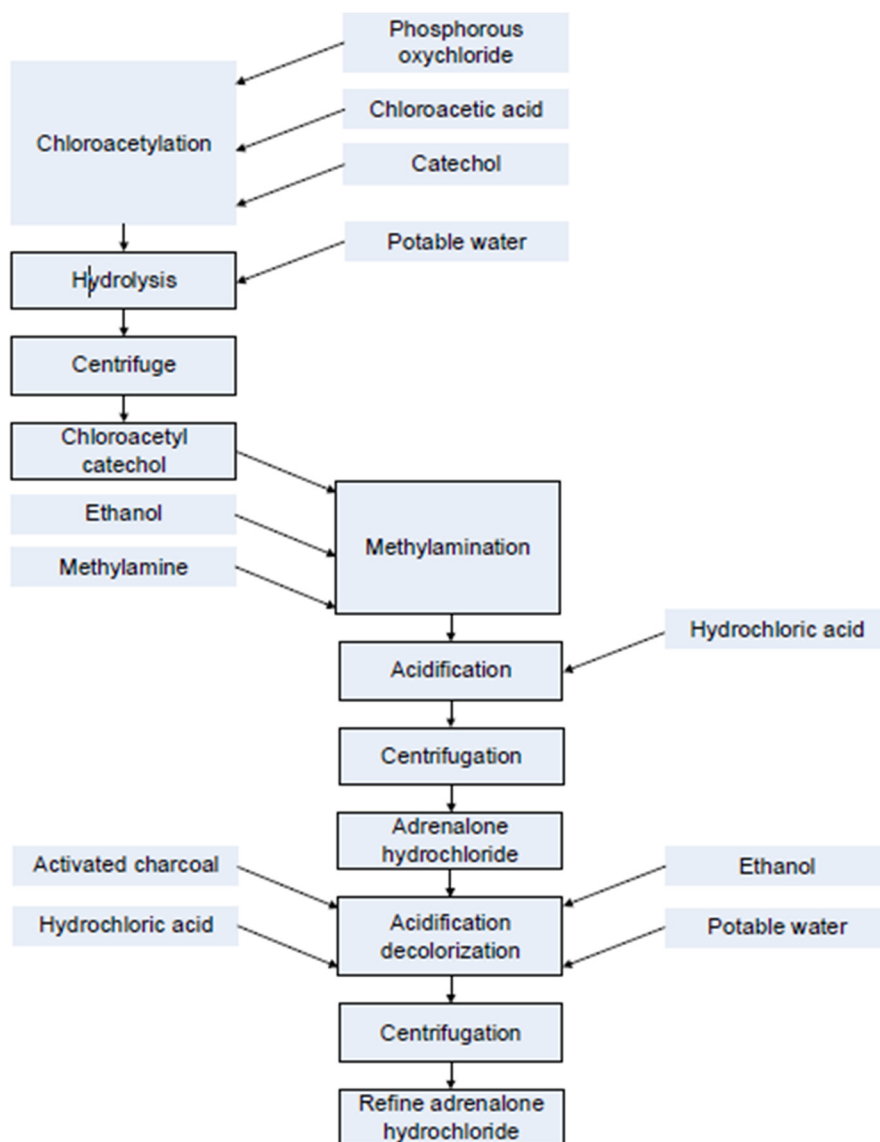
| | |
|-----------------------------|---------|
| Spectrum-Gardena, CA: | 2020632 |
| Spectrum-New Brunswick, NJ: | 2246824 |

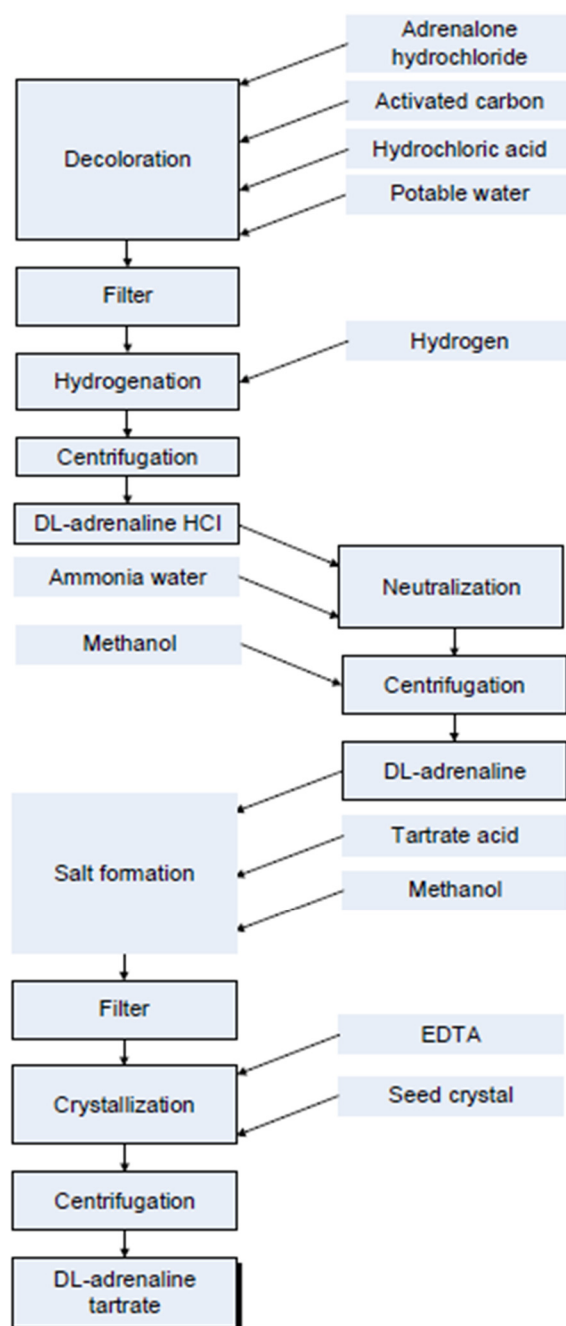
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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

Manufacturing Process Flowchart - Epinephrine, USP (Catalog No. EP130)





EP130, Epinephrine, 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 | ▪ Cereals containing Gluten |
| ▪ Egg | ▪ Celery |
| ▪ Fish | ▪ Mustard |
| ▪ Shellfish | ▪ Sesame Seed |
| ▪ Tree Nuts | ▪ Corn |
| ▪ Wheat | ▪ Latex |
| ▪ Peanuts | ▪ Sulfites > 10 ppm |
| ▪ Soy | |

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 the above-mentioned 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 |

Elemental Impurities - Epinephrine, USP (Catalog No. EP130)

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 the 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.

Residual Solvents - Epinephrine, USP (Catalog No. EP130)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above-mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

| Residual Solvent | Class | Expected Concentration |
|------------------|-------|------------------------|
| Methanol | 2 | < 3000 ppm |
| Ethanol | 3 | < 5000 ppm |

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

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

Sincerely,
Technical Services
Spectrum Chemical Mfg. Corp.

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



DANGER

• Fatal in contact with skin • Toxic if swallowed or if inhaled • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.

• Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Do not get in eyes, on skin, or on clothing • 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 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 INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

EP130

SIZ SY

Epinephrine

(L-Adrenaline)

USP

CAS 51-43-4

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only. Human use only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_9H_{13}NO_3$

F.W. 183.20

Manufacturer/Supplier Code ?

Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%

MAXIMUM LIMITS

Loss on Drying 1.0%

Residue on Ignition 0.1%

Enantiomeric Purity 3.0%

Organic Impurities:

Epinephrine Sulfonate 0.2%

Norepinephrine 0.2%

Oxedrine 0.10%

Adrenalone 0.2%

Epinephrine 0.10%

Epinephrine Methoxy Analog 0.10%

N-Benzyl Epinephrine 0.1%

N-Benzyl Adrenalone 0.1%

Any Individual Unspecified Impurity 0.10%

Total Impurities 0.5%

Elemental Impurities As reported

Residual Solvents To pass test

FLUSHED WITH NITROGEN, VACUUM SEALED

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

Relabeled by Spectrum as:

Lot No. XQ####

B 19/L11GHS-A

?

Exp. Date: 00-00-0000

