



Scientific Documentation

PH901, Phenylephrine 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

PH901, Phenylephrine Hydrochloride, USP

Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- EU Fragrance Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Animal Testing Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label

spectrum®

- General Lot Numbering System Guidance

spectrum®

Item Number	PH901
Item	Phenylephrine Hydrochloride, USP
CAS Number	61-76-7
Molecular Formula	C ₉ H ₁₃ NO ₂ .HCl
Molecular Weight	203.67
MDL Number	
Synonyms	(1R)-1-(3-Hydroxyphenyl)-2-methylaminoethanol Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (CHLORIDE)	TO PASS TEST	
IDENTIFICATION (HPLC)	TO PASS TEST	
SPECIFIC ROTATION @25 C	-43° to -47°	
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.2 %
SULFATE		0.20 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:	ACCEPTANCE CRITERIA	
NORPHENYLEPHRINE		0.10 %
PHENYLEPHRINE RELATED COMPOUND C		0.1 %
PHENYLEPHRINE RELATED COMPOUND D		0.10 %
PHENYLEPHRINE RELATED COMPOUND E		0.1 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.2 %
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 ³ CFU/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 ² CFU/g
ENDOTOXIN BY LAL		25 EU/mg
IDENTIFICATION	TO PASS TEST	
APPEARANCE		
RETEST DATE		
MANUFACTURE DATE		
RESIDUAL SOLVENTS	TO PASS TEST	

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

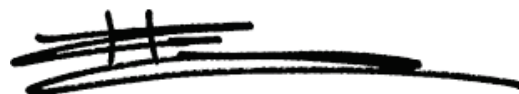
Item Number	PH901	Lot Number	4JG0003
Item	Phenylephrine Hydrochloride, USP	Manufacturer Lot	P70-18015
CAS Number	61-76-7	Manufacturer Code	15062
Molecular Formula	C ₉ H ₁₃ NO ₂ .HCl	Molecular Weight	203.67

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0	102.0 %	99.4 %
IDENTIFICATION (IR)	TO PASS TEST		PASSES TEST
IDENTIFICATION (CHLORIDE)	TO PASS TEST		PASSES TEST
IDENTIFICATION (HPLC)	TO PASS TEST		PASSES TEST
SPECIFIC ROTATION @25 C	-43° to -47°		-45.7°
LOSS ON DRYING		1.0 %	0.0 %
RESIDUE ON IGNITION		0.2 %	0.1 %
SULFATE		0.20 %	< 0.20 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES:	ACCEPTANCE CRITERIA		.
NORPHENYLEPHRINE		0.10 %	0.0 %
PHENYLEPHRINE RELATED COMPOUND C		0.1 %	0.0 %
PHENYLEPHRINE RELATED COMPOUND D		0.10 %	0.0 %
PHENYLEPHRINE RELATED COMPOUND E		0.1 %	0.0 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %	0.0 %
TOTAL IMPURITIES		0.2 %	0.0 %
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 ³ CFU/g	< 10 ³ CFU/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 ² CFU/g	< 10 ² CFU/g
ENDOTOXIN BY LAL		25 EU/mg	< 25 EU/mg
IDENTIFICATION	TO PASS TEST		PASSES TEST
APPEARANCE			WHITE POWDER
RETEST DATE			27-SEP-2023
MANUFACTURE DATE			28-SEP-2018
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			< 3000 ppm
CLASS 3 (solvent) / 2-PROPANOL			< 5000 ppm

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



Certificate of Analysis Results Certified by:



Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

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.

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 Syn-Tech Chem. & Pharm. Co., Ltd. at No. 168 Kai Yuan Rd., Hsin-Ying, Tainan City 73055, Taiwan. 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 21-October-2020

Revision Number 1

1. Identification

Product identifier

Product Name PHENYLEPHRINE HYDROCHLORIDE, USP

Other means of identification

Product Code(s) PH901

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 4
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

Warning

Hazard statements

Harmful if swallowed
Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Appearance Crystalline or 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
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear protective gloves/eye protection/face protection

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 and soap
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor if you feel unwell
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
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-%	Trade secret
Phenylephrine Hydrochloride	61-76-7	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.

Eye contact

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. Get medical attention if irritation develops and persists. Do not rub affected area.

Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms May cause redness and tearing of the eyes. Burning sensation.

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 Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).
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	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
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. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

Conditions for safe storage, including any incompatibilities

Storage Conditions Sensitive to light. Store in light-resistant containers. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

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 If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

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 Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline or 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	140 - 145 °C / 284 - 293 °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	Easily soluble in hot water Easily soluble in cold 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

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	203.67
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 recommended storage 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 serious eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. May cause redness and tearing of the eyes.
-----------------	---

Acute toxicity

Numerical measures of toxicity

350 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Phenylephrine Hydrochloride 61-76-7	= 350 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	May cause respiratory irritation.
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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Complies
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/NDSL - 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 21-October-2020

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
PH901	Phenylephrine 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

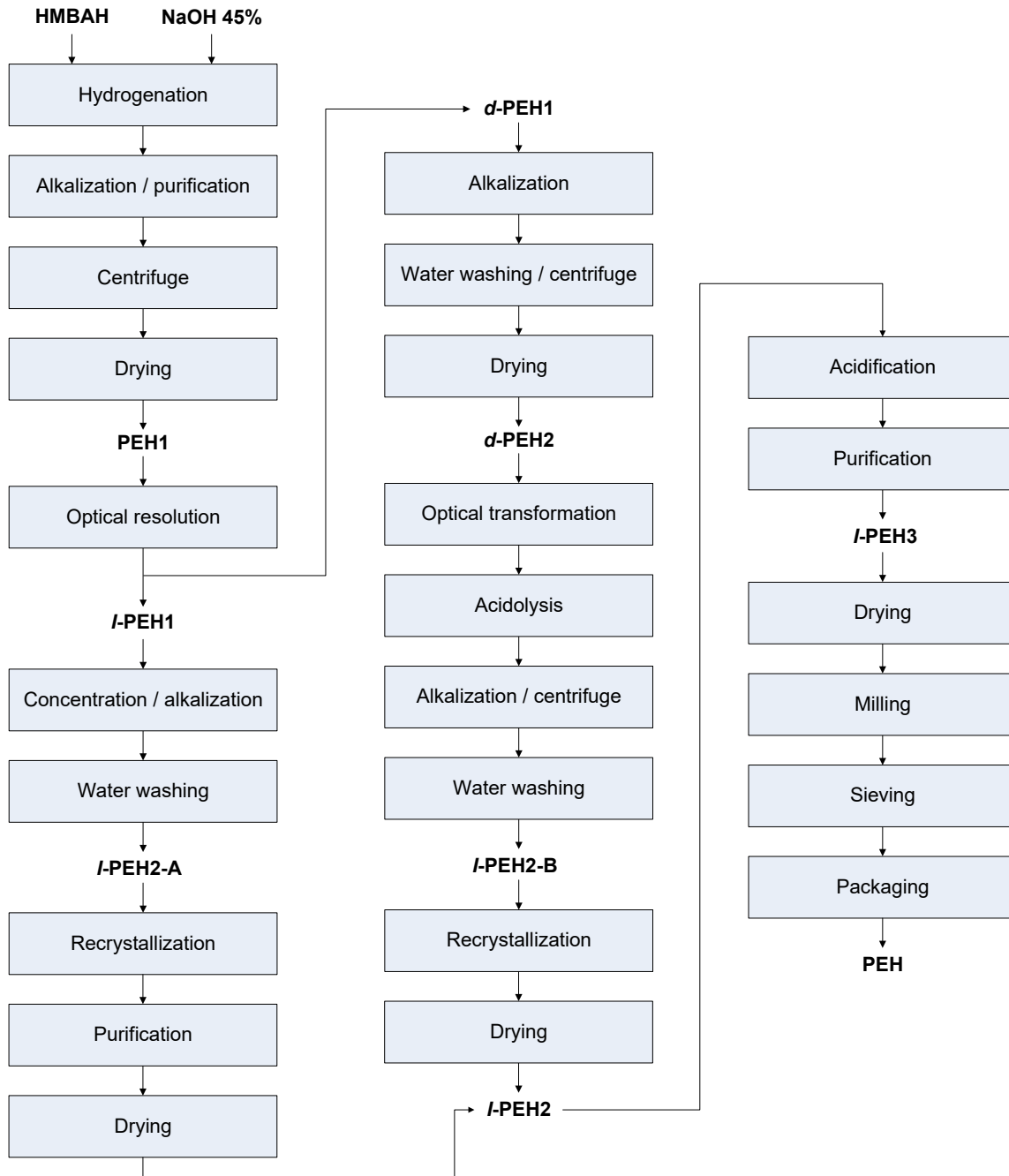
Spectrum-New Brunswick, NJ: 2246824

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,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Phenylephrine Hydrochloride, USP – PH901



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

PH901, Phenylephrine 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 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives



**RE: Elemental Impurities - Phenylephrine Hydrochloride, USP
(Cat# PH901)**

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
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	<1.5 ppm
Mercury	Hg	1	< 3 ppm
Vanadium	V	2A	<0.02 ppm
Nickel	Ni	2A	<0.02 ppm
Palladium	Pd	2B	< 10 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 Statement - Phenylephrine Hydrochloride, USP (Cat# PH901)

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
2-Propanol	3	< 5000 ppm

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

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

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

Label Information

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


Retest Date: 03-31-2025

WARNING

- Harmful if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.
- Do not eat, drink or smoke when using this product
- Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. 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 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



spectrum
CHEMICAL MFG CORP

PH901 **1 KG**

Phenylephrine Hydrochloride

USP

CAS 61-76-7

bio
CERTIFIED

CAUTION: For manufacturing, processing or repacking. Rx only. Further processing and testing required for use in parenteral applications. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

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

C₉H₁₃NO₂•HCl **F.W. 203.67**

Not sterile.

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%
Identification (IR) To pass test
Identification (Chloride) To pass test
Identification (HPLC) To pass test
Specific Rotation @ 25°C -43° to -47°

MAXIMUM LIMITS

Loss on Drying 1.0%
Residue on Ignition 0.2%
Sulfate 0.20%
Organic Impurities Acceptance criteria

Acceptance criteria

Norphenylephrine 0.10%
Phenylephrine Related Compound C 0.1%
Phenylephrine Related Compound D 0.10%
Phenylephrine Related Compound E 0.1%
Any Individual Unspecified Impurity 0.10%
Total Impurities 0.2%

Elemental Impurities As reported
Residual Solvents To pass test
Endotoxin by LAL 25 EU/mg

MICROBIAL LIMITS

Total Aerobic Microbial Count 10⁶ cfu/g
Total Molds and Yeasts Count 10⁶ cfu/g

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers. Store at 25°C.

Repackaged by Spectrum as:

B 2/J8GHS-A **A** **0** **Lot No. 062233**

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- F** Size/Quantity
- G** Chemical Abstracts Service (CAS) Registry Number
- H** Caution Information
- I** DOT Shipping Information
- J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- K** Empirical Formula, Formula Weight and Technical Specifications Panel
- L** Expiration Information
- M** Lot Number
- N** Kosher Certified by Kosher Supervision of America (KSA).
- O** Storage Color Band
- P** Halal Certified by IFANCA
- Q** bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- **YELLOW:** Oxidizer
- **RED:** Flammable
- **GREEN:** General Storage
- **BLUE:** Health Hazard
- WHITE:** Corrosive

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



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

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