

# **Scientific Documentation**

# Liquefied Phenol, 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 Liquefied Phenol, USP (PH125)**

Item Number	PH125
Item	Liquefied Phenol, USP
CAS Number	
Molecular Formula	C <sub>6</sub> H <sub>6</sub> O
Molecular Weight	
MDL Number	
Synonyms	Carbolic Acid

Test	Specification		
	Min	Max	
ASSAY (C <sub>6</sub> H <sub>6</sub> O; by Wt.)	89.0 %		
CLARITY OF SOLUTION AND REACTION	CLEAR AND NEUTRAL ON ACID TO LITMUS		
STABILIZER		NONE/YES ?	
DISTILLING RANGE		182.5°C	
NONVOLATILE RESIDUE		0.05 %	
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION (A)	WHITE PRECIPITATE FORMS		
IDENTIFICATION (B)	VIOLET COLOR PRODUCED		
CERTIFIED HALAL			
APPEARANCE			
EXPIRATION DATE			
DATE OF MANUFACTURE			
RESIDUAL SOLVENTS:	AS REPORTED		
CLASS 1 (solvent) / BENZENE			
CLASS 2 (solvent) / CYCLOHEXANE			
CLASS 2 (SOLVENT) / CUMENE	· ·		
CLASS 2 (solvent) / HEXANE			
CLASS 2 (SOLVENT) / METHANOL			
CLASS 2 (solvent) / METHYLISOBUTYLKETONE			

Test	Specification	
	Min	Max
CLASS 2 (solvent) / TOLUENE		
CLASS 3 (solvent) / ACETIC ACID		
CLASS 3 (solvent) / ACETONE		
CLASS 3 (solvent) / ANISOLE		
CLASS 3 (solvent) / ETHANOL		
CLASS 3 (solvent) / HEPTANE		
CLASS 3 (solvent) / METHYLETHYLKETONE		
CLASS 3 (solvent) / 2-PROPANOL		
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	PH125	Lot Number	1MK0045
Item	Liquefied Phenol, USP	Manufacturer Lot	20792520
Manufacturer Code	7209	Molecular Formula	C <sub>6</sub> H <sub>6</sub> O

TFCT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
ASSAY (C <sub>6</sub> H <sub>6</sub> O; by Wt.)	89.0 %		89.2 %	
CLARITY OF SOLUTION AND REACTION	CLEAR AND NEUTRAL ON ACID TO LITMUS		CLEAR AND NEUTRAL ON ACID TO LITMUS	
STABILIZER		NONE/YES ?	20 ppm (citric acid)	
DISTILLING RANGE		182.5°C	180.0°C	
NONVOLATILE RESIDUE		0.05 %	0.02 %	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT (M)	
IDENTIFICATION (A)	WHITE PRECIPITATE FORMS		WHITE PRECIPITATE FORMS	
IDENTIFICATION (B)	VIOLET COLOR PRODUCED		VIOLET COLOR PRODUCED	
CERTIFIED HALAL			CERTIFIED HALAL	
APPEARANCE			CLEAR COLORLESS LIQUID	
EXPIRATION DATE			01-OCT-2025	
DATE OF MANUFACTURE			01-OCT-2023	
RESIDUAL SOLVENTS:	AS REPORTED			
CLASS 1 (solvent) / BENZENE	•		<2 ppm (M)	
CLASS 2 (solvent) / CYCLOHEXANE			<3880 (M)	
CLASS 2 (SOLVENT) / CUMENE			<70 ppm (M)	
CLASS 2 (solvent) / HEXANE			<290 ppm (M)	
CLASS 2 (SOLVENT) / METHANOL			<3000 (M)	
CLASS 2 (solvent) / METHYLISOBUTYLKETONE	•		<4500 (M)	

TEST	SPECIFICATION		
IESI	MIN	MAX	RESULT
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm (M)
CLASS 3 (solvent) / ACETONE			<5000 ppm (M)
CLASS 3 (solvent) / ANISOLE			<5000 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)
CLASS 3 (solvent) / HEPTANE			<5000 ppm (M)
CLASS 3 (solvent) / METHYLETHYLKETONE			<5000 ppm (M)
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm (M)
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 04-DEC-23 13:48:32

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 A & C American Chemicals Ltd at 3010 rue de Baene, Saint Laurent, Quebec H4S 1L2, Canada. 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.

Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 05-DEC-23 13:28:40

# SAFETY DATA SHEET

Revision date 03-December-2021

1. Identification	
Product identifier	
Product Name	LIQUEFIED PHENOL, USP
Other means of identification	
Product Code(s)	PH125
UN/ID no	UN2821
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
Acute toxicity - Dermal	Category 3
Acute toxicity - Inhalation (Gases)	Category 3
Acute toxicity - Inhalation (Vapors)	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 3
Skin corrosion/irritation	Category 1 Sub-category A
Serious eye damage/eye irritation	Category 1
Germ cell mutagenicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2
Flammable liquids	Category 4

Hazards not otherwise classified (HNOC)

Not applicable



Revision Number 2

#### Label elements Danger

Hazard statements Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage Suspected of causing genetic defects May cause damage to organs through prolonged or repeated exposure Combustible liquid



#### Physical state Liquid

Odor Aromatic and sweet

#### **Precautionary Statements - Prevention**

Obtain special instructions before use Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Use only outdoors or in a well-ventilated area Do not breathe dust/fume/gas/mist/vapors/spray Wear respiratory protection Keep away from flames and hot surfaces. - No smoking Keep cool

#### **Precautionary Statements - Response**

Specific treatment (see .? on this label) Specific treatment is urgent (see .? on this label) Immediately call a POISON CENTER or doctor 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 Immediately call a POISON CENTER or doctor Call a POISON CENTER or doctor if you feel unwell IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower Wash contaminated clothing before reuse IF INHALED: Remove person to fresh air and keep comfortable for breathing Immediately call a POISON CENTER or doctor IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth Do NOT induce vomiting In case of fire: Use CO2, dry chemical, or foam to extinguish

#### **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

#### Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas) 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

#### Other information

No information available.

## 3. Composition/information on ingredients

#### Substance

Not applicable.

#### Mixture

Chemical name	CAS No	Weight-%	Trade secret
Phenol	108-95-2	88 - 91	*
Water	7732-18-5	9 - 12	*

\*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. Immediate medical attention is required.
Inhalation	If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. 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. Delayed pulmonary edema may occur. Get immediate medical advice/attention.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.
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	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe vapor or mist. 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. Avoid contact with skin, eyes or clothing.
Most important symptoms and effe	cts, both acute and delayed
Symptoms	Coughing and/ or wheezing. Difficulty in breathing. Burning sensation.
Indication of any immediate medica	I attention and special treatment needed
Note to physicians	Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure.

Suitable Extinguishing Media	Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam.
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	om the Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.		
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.		
Explosion data Sensitivity to mechanical impac	et none.		
Sensitivity to static discharge	yes.		
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	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Take precautionary measures against static discharges. Do not touch or walk through spilled material. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Do not breathe vapor or mist. Keep people away from and upwind of spill/leak. Attention! Corrosive material.		
Other information	Refer to protective measures listed in Sections 7 and 8.		
Methods and material for containm	ent and cleaning up		
Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. Dike far ahead of liquid spill for later disposal.		
Methods for cleaning up	Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.		

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling Use personal protection equipment. Do not breathe vapor or mist. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. 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. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

#### Conditions for safe storage, including any incompatibilities

Storage ConditionsKeep containers tightly closed in a dry, cool and well-ventilated place. Keep away from<br/>heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static<br/>electricity). Keep in properly labeled containers. Store in accordance with the particular<br/>national regulations. Store in accordance with local regulations. Keep out of the reach of<br/>children. Store locked up. Protect from moisture. Store away from other materials.

#### 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.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Phenol	No data available	5 ppm TWA	-
108-95-2		19 mg/m <sup>3</sup> TWA	

#### Appropriate engineering controls

Engineering controls	Showers
	Eyewash stations
	Ventilation systems.

Individual protection measures, such as personal protective equipment			
Eye/face protection	Tight sealing safety goggles. Face protection shield.		
Hand protection	Wear suitable gloves. Impervious gloves.		
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.		
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.		
General hygiene considerations	Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Do not breathe vapor or mist.		

#### 9. Physical and chemical properties

Information on basic physical and o Physical state Appearance Color Odor Odor Odor threshold	<u>chemical properties</u> Liquid Clear Colorless; light yellow; light pink Aromatic and sweet No information available	
Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability or explosive limits Lower flammability or explosive	Values no data available no data available no data available > 91 °C / 195.8 °F no data available no data available No data available	Remarks • Method None known None known None known None known None known None known
limits Vapor pressure Vapor density Relative density Water solubility	No data available no data available 1.05 No data available	None known None known None known None known

Solubility(ies) Partition coefficient Autoignition temperature	Soluble in water No data available no data available	None known None known None known
Decomposition temperature Kinematic viscosity	no data available	None known 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	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	Heat, flames and sparks. Excessive heat. Exposure to air or moisture over prolonged periods.
Incompatible materials	Acids. Bases. Oxidizing agent.
	Next here does not be set of the second set of t

Hazardous decomposition products None known based on information supplied.

.

blindness.

## 11. Toxicological information

#### Information on likely routes of exposure

#### **Product Information**

Inhalation	Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components). Corrosive by inhalation. Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.
Skin contact	Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns. Toxic in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	Coughing and/ or wheezing. Difficulty in breathing. Redness. Burning. May cause

#### Acute toxicity

#### Numerical measures of toxicity

#### The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (inhalation-gas) 795.50 ppm

ATEmix (inhalation-dust/mist) 0.57 mg/l

#### Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

#### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Phenol	= 340 mg/kg (Rat)	= 630 mg/kg (Rabbit)	= 316 mg/m <sup>3</sup> (Rat) 4 h
108-95-2			-
Water	90 mL/kg (Rat)	-	-
7732-18-5			

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

Skin corrosion/irritation	Classification	n based on data available fo	or ingredients. Causes bur	ms.
Serious eye damage/eye irri	tation Classification	h based on data available fo	or ingredients. Risk of seri	ous damage to eyes.
	Causes burn	S.		
Respiratory or skin sensitiz	ation No information	on available.		
Germ cell mutagenicity	Contains a ki	nown or suspected mutage	en. Classification based on	data available for
	ingredients. S	Suspected of causing gene	tic defects.	
Carcinogenicity	No information	on available.		
The table below indicates wh	ether each agency has	s listed any ingredient as a	carcinogen.	

Chemical name	ACGIH	IARC	NTP	OSHA
Phenol	-	Group 3 - Not classifiable	-	-
108-95-2		- Monograph 71 [1999]		
		Monograph 47 [1989]		

#### Legend

Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Target organ effects	No information available. May cause damage to organs through prolonged or repeated exposure. liver, kidney, respiratory system, Eyes, Skin.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

## 12. Ecological information

#### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
Chemical hame	Aigae/aqualic plants	F1511	· · · ·	Clusiacea
			microorganisms	
Phenol	EC50: 0.0188 -	LC50: 11.9 - 25.3mg/L	-	EC50: 10.2 - 15.5mg/L
108-95-2	0.1044mg/L (96h,	(96h, Lepomis		(48h, Daphnia magna)
	Pseudokirchneriella	macrochirus) LC50: 11.9		EC50: 4.24 - 10.7mg/L
	subcapitata) EC50: 187 -	- 50.5mg/L (96h,		(48h, Daphnia magna)
	279mg/L (72h,	Pimephales promelas)		_
	Desmodesmus	LC50: 20.5 - 25.6mg/L		
	subspicatus) EC50:	(96h, Pimephales		
	=46.42mg/L (96h,	promelas) LC50: 23.4 -		
	Pseudokirchneriella	36.6mg/L (96h, Oryzias		
	subcapitata)	latipes) LC50: 33.9 -		
		43.3mg/L (96h, Oryzias		

latipes) LC50: 34.09 -	
47.64mg/L (96h, Poecilia	
reticulata) LC50: 4.23 -	
7.49mg/L (96h,	
Oncorhynchus mykiss)	
LC50: 5.0 - 12.0mg/L	
(96h, Oncorhynchus	
mykiss) LC50: 5.449 -	
6.789mg/L (96h,	
Oncorhynchus mykiss)	
LC50: 7.5 - 14mg/L (96h,	
Oncorhynchus mykiss)	
LC50: =0.00175mg/L	
(96h, Cyprinus carpio)	
LC50: =11.5mg/L (96h,	
Lepomis macrochirus)	
LC50: =13.5mg/L (96h,	
Lepomis macrochirus)	
LC50: =27.8mg/L (96h,	
Brachydanio rerio) LC50:	
=31mg/L (96h, Poecilia	
reticulata) LC50:	
=32mg/Ĺ (96h,	
Pimephales promelas)	

# Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

#### **Component Information**

Chemical name	Partition coefficient
Phenol	1.5
108-95-2	

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	UN2821
Proper Shipping Name:	Phenol solutions
Hazard class	6.1
Packing group:	II
Special Provisions	IB2, T7, TP2
Marine Pollutant	Severe Marine Pollutant
Description:	UN2821, Phenol solutions, 6.1, II
Emergency Response Guide	153
Number	
TDG	

UN-No: Proper Shipping Name: Hazard class UN2821 Phenol solution 6.1 Packing Group: **Description:** 

#### MEX

UN-No **Proper Shipping Name** Hazard class Packing Group Description

#### ICAO (air)

UN-No: **Proper Shipping Name: Hazard class** Packing Group: **Special Provisions Description:** 

#### ΙΑΤΑ

**UN number Proper Shipping Name:** Transport hazard class(es) Packing group **Description:** 

#### IMDG

**UN number** Proper shipping name Transport hazard class(es) Packing group EmS-No Marine pollutant Description

#### RID

**UN number Proper Shipping Name:** Transport hazard class(es) Packing group **Classification code Description:** Labels

#### ADR

**UN number Proper Shipping Name:** Transport hazard class(es) **Packing group** Ш **Classification code** T1 **Tunnel restriction code** Description: Labels

#### ADN

UN/ID No UN2821 Proper shipping name Phenol solution Transport hazard class(es) 6.1 Packing Group Ш **Classification code** T1 **Special Provisions** 802 Description Hazard label(s) 6.1 Limited quantity (LQ) 100 ml **VE02** ventilation **Equipment Requirements** PP, EP, TOX, A

6.1 UN2821, Phenol solution, 6.1, II UN2821 Phenol solution 6.1 Ш A3 UN2821, Phenol solution, 6.1, II UN2821 Phenol solution 6.1 UN2821, Phenol solution, 6.1, II

UN2821, Phenol solution, 6.1, II

Ш

Ш

Ш

UN2821

Phenol solution

#### UN2821 Phenol solution 6.1 Ш F-A, S-A NP1 UN2821, Phenol solution, 6.1, II

UN2821 Phenol solution 6.1 Ш T1 UN2821, Phenol solution, 6.1, II 6.1

2821 Phenol solution 6.1 (D/E) 2821, Phenol solution, 6.1, II, (D/E) 6.1

# UN2821, Phenol solution, 6.1, II

#### 15. Regulatory information

#### International Inventories

**TSCA** 

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies 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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Phenol - 108-95-2	1.0

#### 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
Phenol	1000 lb final RQ	-
108-95-2	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

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

#### U.S. EPA Label Information

#### 16. Other information

NFPA Health hazards 4 Flammability 2 Instability 0 Physical and chemical properties -HMIS Health hazards \* 4 Flammability 2 Physical hazards 0 Personal protection X Chronic Hazard Star Legend \* = Chronic Health Hazard 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** 03-December-2021 **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
PH125	Liquefied Phenol, 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: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

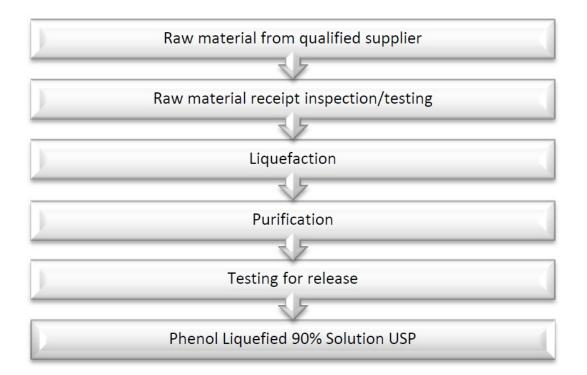
Oulu Umy

Oralia Chavez Quality Assurance Specialist



# **Manufacturing Process Flowchart**

[Liquefied Phenol, USP] (PH125)



#### 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

AN ISO 9001:2015 REGISTERED COMPANY

# PH125, Liquefied Phenol, 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates

#### **RE: Elemental Impurities - Liquefied Phenol, USP (Cat# PH125)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 <u>TechServices@spectrumchemical.com.</u>

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

AN ISO 9001:2015 REGISTERED COMPANY

## RE: Residual Solvents - Liquefied Phenol, USP (Cat# PH125)

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
Benzene	1	< 2 PPM
Cyclohexane	2	< 3880 PPM
Cumene	2	< 70 PPM
Hexane	2	< 290 PPM
Methanol	2	< 3000 PPM
Methylisobutylketone	2	< 4500 PPM
Toluene	2	< 890 PPM
Acetic Acid	3	< 5000 PPM
Acetone	3	< 5000 PPM
Anisole	3	< 5000 PPM
Ethanol	3	< 5000 PPM
Heptane	3	< 5000 PPM
Methylethylketone	3	< 5000 PPM
2-Propanol	3	< 5000 PPM

No 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 <u>TechServices@spectrumchemical.com.</u>

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

AN ISO 9001:2015 REGISTERED COMPANY

# **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.



 Fatal if inhaled 

 Toxic in contact with skin •
 Harmful if swallowed • Causes severe skin burns and eye damage • Suspected of causing genetic defects
 May cause damage to organs through prolonged or repeated exposure • Combustible liquid.
 Obtain special instructions before use • Do not

 Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection, protective gloves, protective clothing a • Do not breathe mist or vapors • Use only outdoors or in a well-ventilated area • Wash tace, hands and any exposed skin thoroughly after handling. strike T AID: Immediately call a POISON CENTER or o physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air with water. IF INHALED: Remove person to fresh air with water. IF INHALED: Remove person to fresh air with water. IF INHALED: Remove person to fresh air with water. IF INHALED: Remove person to fresh air with water. IF INHALED: Remove person to fresh air with water.

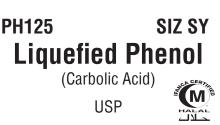
and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

**KEEP FROM CHILDREN** 

0000-00-00

Date:

Exp.



**CAUTION:** For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2821, Phenol solution, 6.1, PG II

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

Components:	
Phenol	.CAS 108-95-2
Water	CAS 7732-18-5
Manufacturer/Supplier Code	
Manufacturer Lot Number	?
Assay (C <sub>6</sub> H <sub>6</sub> O; by Wt.)	Min. 89.0%
Clarity of Solution and Reaction	
Stabilizer (?)	?
MAXIMUM LIMITS	
Distilling Range	
Nonvolatile Residue	
Elemental Impurities	As reported
Residual Solvents	To pass test
LIGHT AND AIR SENSITIVE: Keep to	ightly closed in
light-resistant containers.	
FLUSHED WITH NITROGEN	
Repackaged by Sp	pectrum as:

Componente

B 18/K10GHS-A ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave. New Brunswick, NJ 08901 *West Coast Facility:* 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

732.214.1300