

# **Scientific Documentation**

# Phenol, Fused Crystal, USP

Not appropriate for regulatory submission.

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

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





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# Specification for Phenol, Fused Crystal, USP (PH120)

Item Number	PH120
Item	Phenol, Fused Crystal, USP
CAS Number	108-95-2
Molecular Formula	C <sub>6</sub> H <sub>6</sub> O
Molecular Weight	94.11
MDL Number	
Synonyms	Carbolic Acid; Phenyl, Hydrate; Phenylic Acid

Test	Test Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	99.0	100.5 %
CLARITY OF SOLUTION AND REACTION	CLEAR AND NEUTRAL TO LITMUS	
CONGEALING TEMPERATURE	39°C	
WATER DETERMINATION		0.5 %
NONVOLATILE RESIDUE		0.05 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
IDENTIFICATION (A)	WHITE PRECIPITATE IS FORMED	
IDENTIFICATION (B)	VIOLET COLOR IS PRODUCED	
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 1 (solvent) / BENZENE		
CLASS 2 (SOLVENT) / CUMENE		

Test	Specification		
	Min	Max	
CLASS 2 (SOLVENT) / METHANOL	•		
CLASS 2 (solvent) / METHYLISOBUTYLKETONE			
CLASS 3 (solvent) / ACETONE			
CLASS 3 (solvent) / ANISOLE			
MONOGRAPH EDITION			

#### Spectrum Chemical Mfg Corp

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

732.214.1300 310.516.8000



# **Certificate Of Analysis**

Item Number	PH120	Lot Number	1NA0221
Item	Phenol, Fused Crystal, USP	CAS Number	108-95-2
Molecular Formula	C <sub>6</sub> H <sub>6</sub> O	Molecular Weight	94.11

TECT	SPECIFICATION		DECLUIT.	
TEST	MIN	MAX	RESULT	
APPEARANCE			WHITE CRYSTALS	
ASSAY (ANHYDROUS BASIS)	99.0	100.5 %	99.8 %	
CLARITY OF SOLUTION AND REACTION	CLEAR AND NEUTRAL TO LITMUS		CLEAR AND NEUTRAL TO LITMUS	
CONGEALING TEMPERATURE	39°C		39.5°C	
WATER DETERMINATION		0.5 %	0.2 %	
NONVOLATILE RESIDUE		0.05 %	0.01 %	
ELEMENTAL IMPURITIES:				
CADMIUM (Cd)	AS REPORTED		<0.2 μg/g	
LEAD (Pb)	AS REPORTED		<0.5 μg/g	
ARSENIC (As)	AS REPORTED		<1.5 μg/g	
IDENTIFICATION (A)	WHITE PRECIPITATE IS FORMED		WHITE PRECIPITATE IS FORMED	
IDENTIFICATION (B)	VIOLET COLOR IS PRODUCED		VIOLET COLOR IS PRODUCED	
CERTIFIED HALAL			CERTIFIED HALAL	
EXPIRATION DATE			30-NOV-2025	
DATE OF MANUFACTURE			23-NOV-2022	
RESIDUAL SOLVENTS	AS REPORTED			
CLASS 1 (solvent) / BENZENE			<2 ppm	
CLASS 2 (SOLVENT) / CUMENE			<70 ppm	
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm	
CLASS 2 (solvent) / METHYLISOBUTYLKETONE			<4500 ppm	

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
CLASS 3 (solvent) / ACETONE			<5000 ppm	
CLASS 3 (solvent) / ANISOLE			<5000 ppm	
MONOGRAPH EDITION			(USP-NF) 2023	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 31-JAN-24 17:49:01

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



Certificate of Analysis Results Approved By:

AMENDEZ Ana Mendez 05-FEB-24 10:19:52

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.

# SAFETY DATA SHEET SPECTRUM®



Revision date 09-October-2023

**Revision Number** 4

#### 1. Identification

**Product identifier** 

Product Name PHENOL, FUSED CRYSTAL, USP

Other means of identification

Product Code(s) PH120

UN/ID no UN1671

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
Serious eye damage/eye irritation	Category 1
Germ cell mutagenicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Danger

#### Hazard statements

Fatal if inhaled

Causes severe skin burns and eye damage

Toxic in contact with skin

Harmful if swallowed

Suspected of causing genetic defects

May cause damage to organs through prolonged or repeated exposure



**Appearance** Crystals

Physical state Solid

Odor No information available

#### **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

#### **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

#### **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

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### **Substance**

Chemical name	CAS No	Weight-%
Phenol	108-95-2	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 If breathing has stopped, give artificial respiration. Get medical attention immediately.

Remove to fresh air. 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. Delayed pulmonary edema may occur. Get

immediate medical advice/attention.

Get immediate medical advice/attention. Rinse immediately with plenty of water, also under Eye contact

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. Wash off immediately with soap and plenty of Skin contact

water while removing all contaminated clothes and shoes.

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Ingestion

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. 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. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Coughing and/ or wheezing. Difficulty in breathing. Burning sensation. **Symptoms** 

Indication of any immediate medical attention and special treatment needed

Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Note to physicians

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.

#### 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

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 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. Attention!

Corrosive material.

**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 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. Do not eat, drink or smoke when using this product. Remove contaminated

clothing and shoes.

#### 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. Store away from other materials. Sensitive to light. Store in

light-resistant containers. Air sensitive. Protect from moisture.

#### 8. Exposure controls/personal protection

#### Control parameters

#### **Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Phenol	No data available	5 ppm TWA	-
108-95-2		19 mg/m³ 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** 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 Crystals

Color

Odor

Odor

Odor

Odor

Odor threshold

Odor threshold

Odor threshold

Odor threshold

Odor threshold

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

no data available None known pН Melting point / freezing point 41 °C / 105.8 °F None known 182 °C / 359.6 °F **Boiling point / boiling range** None known 79 °C / 174.2 °F None known Flash point None known **Evaporation rate** no data available Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityno data availableNone knownRelative density1.07None knownWater solubilitySoluble in waterNone knownSolubility(ies)Very soluble in AcetoneNone known

Very soluble in chloroform Very soluble in alcohol

Very soluble in Dimethyl Sulfoxide Soluble in Carbon Disulfide Soluble in alkaline solutions

Partition coefficientNo data availableNone knownAutoignition temperatureno data availableNone known

Decomposition temperatureNone knownKinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties
Oxidizing properties
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** Excessive heat. Exposure to air or moisture over prolonged periods.

**Incompatible materials** Acids. Bases. Oxidizing agent.

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. 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 blindness.

**Acute toxicity** 

Numerical measures of toxicity

#### Unknown acute toxicity

**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			

#### 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. Causes burns.

Serious eye damage/eye irritation Classification based on data available for ingredients. Risk of serious damage to eyes.

Causes burns.

**Respiratory or skin sensitization** No information available.

Germ cell mutagenicity Contains a known or suspected mutagen. Classification based on data available for

ingredients. Suspected of causing genetic defects.

#### Carcinogenicity

#### No information available.

The table below indicates whether each agency has 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

#### IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive toxicity No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** May cause damage to organs through prolonged or repeated exposure.

Target organ effects 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
			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)
		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/L	
(96h, Pimephales	
promelas)	

Persistence and degradability No information available.

Bioaccumulation 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

d Dispose of in accordance with local regulations. Dispose of waste in accordance with

products

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

#### 14. Transport information

#### DOT

UN/ID no UN1671 Proper shipping name Phenol, solid

Hazard class 6.1 Special Provisions II

Special Provisions IB8, IP2, IP4, N78, T3, TP33

Marine Pollutant Severe Marine Pollutant

Description UN1671, Phenol, solid, 6.1, II

#### TDG

UN/ID no. UN1671
Proper shipping name Phenol, solid

Hazard class 6.1
Packing Group II
Special Provisions 43

**Description** UN1671, Phenol, solid, 6.1, II

#### **MEX**

UN-No UN1671
Proper Shipping Name Phenol, solid

Hazard class 6.1 Special Provisions 279 Packing Group II

**Description** UN1671, Phenol, solid, 6.1, II

#### ICAO (air)

UN/ID no. UN1671
Hazard class 6.1
Packing Group II
Special Provisions A113

#### <u>IATA</u>

UN number UN1671

Hazard Class 6.1
Packing group II
Emergency Response Guide 6L

Number

Special Provisions A113

<u>IMDG</u>

UN number UN1671
Hazard Class 6.1
Packing group II
EmS-No F-A, S-A
Special Provisions 279
Marine Pollutant NP1

RID

UN number UN1671

Proper shipping name PHENOL, SOLID

Hazard Class 6.1
Packing group II
Classification code T2
Special Provisions 279

**Description** UN1671, PHENOL, SOLID, 6.1, II

Labels 6.1

<u>ADR</u>

UN number UN1671
Proper shipping name Phenol, solid

Hazard Class 6.1
Packing group II
Classification code T2
Tunnel restriction code (D/E)
Special Provisions 279

**Description** UN1671, Phenol, solid, 6.1, II, (D/E)

Labels 6.1

<u>ADN</u>

UN/ID No UN1671
Proper shipping name Phenol, solid

Hazard Class 6.1
Packing Group II
Classification code T2
Special Provisions 279, 802

**Description** UN1671, Phenol, solid, 6.1, II

Hazard label(s) 6.1 Equipment Requirements PP, EP

#### 15. Regulatory information

#### **International Inventories**

TSCA Complies

**DSL/NDSL** Complies **EINECS/ELINCS** Complies

**ENCS** This product complies with ENCS: 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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Phenol	1487	Present	Environmental hazard
108-95-2			

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 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

#### 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 09-October-2023
Revision Note 09-October-2023
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
PH120	Phenol, Fused Crystal, 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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

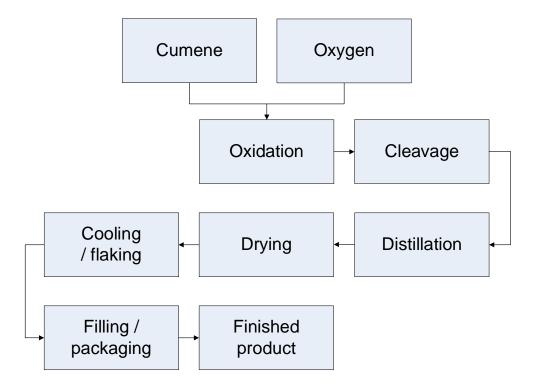
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

# Phenol, Fused Crystal, USP - PH120



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



# PH120, Phenol, Fused Crystal, 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

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- Latex
- Sulfites > 10 ppm

#### **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 or ethylene oxide (EtO).

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 36 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
- CMR Substances
- Parabens

- Pesticides
- Phthalates
- Preservatives



#### RE: Elemental Impurities – Phenol, Fused Crystal, USP (Cat# PH120)

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
Cadmium	Cd	1	< 0.2 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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#### RE: Residual Solvents – Phenol, Fused Crystal, USP (Cat# PH120)

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
Cumene	2	< 70 ppm
Methanol	2	< 3000 ppm
Methyl Isobutyl Ketone	2	< 4500 ppm
Acetone	3	< 5000 ppm
Anisole	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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
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#### **Label Information**

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

#### **DANGER**

0000-00-00



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

\* 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 \* Do not breathe 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 INHALED: Remove person to fresh air and keep comfortable for breathing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

**KEEP FROM CHILDREN** 

PH120

SIZ SY

#### SIZ SI

(Carbolic Acid)

Phenol

Fused Crystal, USP

CAS 108-95-2



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

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

DOT: UN1671, Phenol, solid, 6.1, PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $C_6H_6O$ 

F.W. 94.11

Contains 20 ppm citric acid as stabilizer.

Assay (Anhydrous Basis)	99.0-100.5%
Clarity of Solution and Reaction	To pass test
Congealing Temperature	Min. 39°C
MAXIMUM LIMITS	
Water Determination	0.5%
Nonvolatile Residue	
	0.05%

LIGHT SENSITIVE, AIR SENSITIVE, MOISTURE SENSITIVE: Keep tightly closed in light-resistant containers. Store under nitrogen.

B 20/I8GHS ?

Lot No. XQ####

#### Spectrum Chemical Mfg Corp

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