

Scientific Documentation

Clioquinol, 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 Clioquinol, USP (CL108)

Item Number	CL108
Item	Clioquinol, USP
CAS Number	130-26-7
Molecular Formula	C ₉ H ₅ ClinO
Molecular Weight	305.50
MDL Number	
Synonyms	5-Chloro-7-iodo-8-quinolinol; Iodochlorhydroxyquin

Test	Specifica	tion
	Min	Max
ASSAY (DRIED BASIS)	93.0	100.5 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.5 %
FREE IODINE AND IODIDE:		0.05 %
ELEMENTAL IMPURITIES		AS REPORTED
RESIDUAL SOLVENTS		AS REPORTED
IDENTIFICATION (A)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (B)		3.0 %
IDENTIFICATION (C)	VIOLET VAPORS EVOLVED	
DATE OF MANUFACTURE		
EXPIRATION DATE		
APPEARANCE		

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	CL108	Lot Number	4MJ0043
Item	Clioquinol, USP	Manufacturer Lot	08194L22
CAS Number	130-26-7	Manufacturer Code	13524
Molecular Formula	C ₉ H ₅ Clino	Molecular Weight	305.50

TECT	SPECIFI	CATION	DECLUT	
TEST	MIN	MAX	RESULT	
ASSAY (DRIED BASIS)	93.0	100.5 %	100.2 %	
LOSS ON DRYING		0.5 %	0.4 %	
RESIDUE ON IGNITION		0.5 %	0.3 %	
FREE IODINE AND IODIDE:		0.05 %	< 0.05 %	
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS PRESENT	
IDENTIFICATION (A)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (B)		3.0 %	0.1 %	
IDENTIFICATION (C)	VIOLET VAPORS EVOLVED		VIOLET VAPORS EVOLVED	
DATE OF MANUFACTURE			01-DEC-2022	
EXPIRATION DATE			30-NOV-2027	
APPEARANCE			BEIGE POWDER	
MONOGRAPH EDITION			USP 2023	

Certificate of Analysis Results Entered By:

MCAMACHO Matheu Camacho 30-OCT-23 11:48:03

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 30-OCT-23 11:50:12

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 ESKAY IODINE PVT. LTD. at PLOT NO. 907/2, JHAGADIA GIDC ESTATE,, BHARUCH, GUJURAT 393110, India (IND). 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

Preparation Date: 10/5/2016 Revision date 3/7/2019 Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CL108

Product Name: CLIOQUINOL, USP

Other means of identification

Synonyms: No information available

CAS #: 130-26-7
RTECS # VC5075000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: For manufacturing, processing, or repacking. Antifungal.

Uses advised against No information available

<u>Supplier:</u> Spectrum Chemical Mfg. Corp

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

Order Online At: https://www.spectrumchemical.com

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person:Tom Tyner (USA - West Coast)Contact Person:Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin sensitization	Category 1
Reproductive toxicity	Category 2

Label elements

Warning

Hazard statements

Harmful if swallowed

May cause an allergic skin reaction

Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

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

Contaminated work clothing must not be allowed out of the workplace

Wear protective gloves

Wear protective clothing

Wear eye/face protection

Precautionary Statements - Response

Call a POISON CENTER or doctor/physician if you feel unwell

IF ON SKIN: Wash with plenty of water

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

IF SWALLOWED: Rinse mouth.

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Clioquinol	130-26-7	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call

1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms May cause an allergic skin reaction

May cause iodism
It may affect the thyroid

May cause abdominal pain, nausea, vomiting, diarrhea

May cause muscle weakness

May affect eyes/vision

May affect the optic nerve (optic atrophy)

May result in permanent impairment of vision. even blindness

May affect the liver It may affect the kidneys

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray, mist, or

foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).

hydrogen chloride gas. Hydrogen iodide.

Specific hazards May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid

contact with skin, eyes and clothing. Wear personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Avoid breathing dust. Avoid dust formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent

spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated

surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Ensure adequate ventilation. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Protect from light. Sensitive to light. Store in light-resistant containers. Store at room temperature in the original container.

Incompatible Materials:

Strong oxidizing agents Acids Acid chlorides Acid anhydrides

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Clioquinol	130-26-7	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Clioquinol	130-26-7	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Clioquinol	130-26-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas.

Use process enclosures, local exhaust ventilation, or other

engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure

limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields.

Skin and body protection: Gloves

Long sleeved clothing Chemical resistant apron

Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator

under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to

use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands and face before breaks

and immediately after handling the product When using, do not eat, drink or

smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:Appearance:Color:SolidPowder.Light brown.

Odor: Taste Formula

Slight. No information available. No information available

Molecular/Formula weight (g/mole): Flammability (solid, gas)

Flashpoint (°C/°F):

178.5°C (353.3°F) no data available 165.7°C (330.26°F)

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%): Not available

No information available

No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

350.4°C (662.72°F) No information available 2.0

Specific gravity: pH Vapor pressure @ 20°C (kPa):

No information available
No information available
No information available

Evaporation rate:No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

3.47

Miscibility: Solubility:

No information available Insoluble in cold water Insoluble in hot water

Practically insoluble in Chloroform Practically insoluble in alcohol

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Stable under recommended storage conditions.

<u>Possibility of Hazardous Reactions:</u> Hazardous polymerization does not occur

Conditions to avoid: Exposure to light. Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Acids

Acid chlorides Acid anhydrides

Hazardous decomposition

products:

Carbon oxides. Hydrogen chloride gas. Nitrogen oxides (NOx). Hydrogen iodide.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure: Skin. Eyes. Ingestion. Inhalation.

Acute Toxicity

Component Information

Clioquinol
CAS No | 130-26-7

LD50/oral/rat = > 5 g/kg Oral LD50 Rat

LD50/oral/mouse = 69 mg/kg

LD50/dermal/rabbit = No information available **LD50/dermal/rat** = No information available

LC50/inhalation/rat = No information available LC50/inhalation/mouse = No information available Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = No information available

LD50/oral/mouse =

Value - Acute Tox Oral = 69 mg/kg

LD50/dermal/rabbit

Value - Acute Tox = No information available

LD50/dermal/rat

VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation. May cause allergic skin reaction.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Harmful if swallowed. May cause digestive (gastointestinal) tract irritation. May

cause abdominal pain, nausea, vomiting, diarrhea. May affect liver. May affect urinary system (kidneys). May affect respiration. May cause weakness. May affect the spinal cord (degenerative changes). May affect behavior/central nervous

system (convulsions/seizures).

Aspiration hazard No information available.

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

Chronic Toxicity Prolonged exposure to iodides may result in "lodism" which is characterized by

skin rash, runny nose, headache, increased salivation, metallic taste, nausea, vomiting, epigastric pain, diarrhea, bronchitis, laryngitis, stomatitis, fever, conjunctivitis, and irritation of the mucous membranes and anemia. In severe cases, the skin may show pimples, boils, redness, black and blue spots, hives and blisters. It may also affect the thyroid gland (goiter, hypothyroidism). Chronic ingestion of iodides (in animals) during pregnancy has resulted in severe goiter and cretinoid appearance of the newborn. Prolonged or repeated ingestion may affect respiration (pulmonary edema). Prolonged or repeated ingestion may affect respiration (dyspnea - shortness of breath and difficulty breathing). Prolonged or repeated ingestion may affect the spinal cord (demyelination, degenerative changes). Prolonged or repeated exposure may affect the eyes and vision. May

cause visual disturbances ranging from visual field changes, visual impairment, optic atrophy to blindess. Prolonged or repeated ingestion may cause peripheral neuritis/neuropathy. Chronic exposure may affect the liver and kidneys. Prolonged

or repeated ingestion may affect the blood (normocytic anemia).

Sensitization: May cause sensitization by skin contact.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Clioquinol	130-26-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects

May impair fertility

Developmental Effects: Possible risk of harm to the unborn child

May cause adverse developmental effects

Teratogenic Effects: May cause birth defects (teratogenic effects)

Specific Target Organ Toxicity

STOT - single exposureSTOT - repeated exposure
No information available.
No information available.

Target Organs: Central nervous system. Eyes. Liver. Urinary Tract. Blood. Respiratory system.

Musculoskeletal system (joints, tendons).

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soilNo information availableOther adverse effectsNo information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component			RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Clioquinol	130-26-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Class
Packing group:
No information available

Number

Marine Pollutant No data available

DOT RQ (lbs):

Special Provisions

Symbol(s):

No information available
No information available
No information available
No information available

TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:
Marine Pollutant
Description:
No information available
No information available
No Information available
No information available

ADR

UN Number Not regulated

Proper Shipping Name:
Transport hazard class(es)
Packing group
Subsidiary Risk:

No information available
No information available
No information available

IMDG

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant

No information available
No information available
No information available
No information available

RID

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
No information available
No information available
No information available
No information available

ICAO (air)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:

No information available
No information available
No information available

IATA

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
Packing group
Precautionary Statements No information available
No information available
No information available
IF exposed or concerned

Response

Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Clioquinol	130-26-7	Present	Not present	Not present	Not present	Not listed	Present	Present 204-984-4

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male	Female
				Reproductive	Reproductive
				Toxicity	Toxicity:
Clioquinol	130-26-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Clioquinol	130-26-7	None	None	None	None	None

U.S. TSCA

Component		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Clioquinol	130-26-7	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Clioquinol	130-26-7	Not Listed	Present

Component	CAS No	CEPA Schedule I - Toxic Substances
Clioquinol	130-26-7	Not listed
Component		CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
Clioquinol	130-26-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Clioquinol	130-26-7	

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed

R43 - May cause sensitization by skin contact

R36/38 - Irritating to eyes and skin

S -phrase(s)

S24 - Avoid contact with skin

S37 - Wear suitable gloves

S46 - If swallowed, seek medical advice immediately and show this container or label

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Clioquinol	130-26-7		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful Xi - Irritant

16. OTHER INFORMATION

Preparation Date: 10/5/2016 **Revision date** 3/7/2019 Prepared by: Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This

Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

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
CL108	Clioquinol, 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

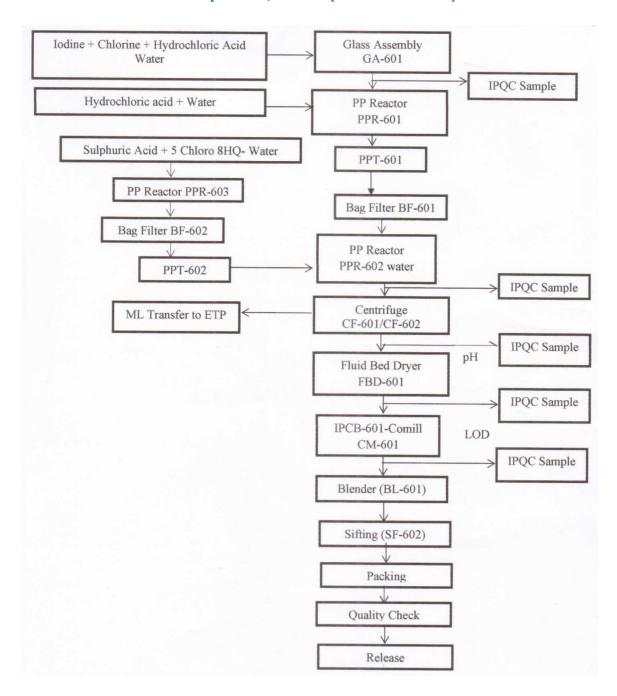
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Clioquinol, USP (Cat# CL108)



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



CL108, Clioquinol, 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 - Clioquinol, USP (Cat# CL108)

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 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 - Clioquinol, USP (Cat# CL108)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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. Below you will find a typical label example for this catalog item.

WARNING



 Harmful if swallowed • May cause an allergic skin reaction • Suspected of damaging fertility or the unborn child.

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
protective gloves, protective clothing, eye
protection, face protection • Avoid breathing
dust • Wash face, hands and any exposed
skin thoroughly after handling • Contaminated
work clothing must not be allowed out of the
workplace.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

CL108

SIZ SY

Clioquinol

(5-Chloro-7-iodo-8-quinolinol; lodochlorhydroxyquin)

USP

CAS 130-26-7

CAUTION: For manufacturing, processing or repacking.

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 C_9H_5CIINO F

resistant containers.

F.W. 305.50

Manufacturer/Supplier Code? Manufacturer Lot Number?
Assay (Dried Basis)93.0-100.5% MAXIMUM LIMITS
Loss on Drying0.5%
Residue on Ignition0.5%
Free Iodine and IodideTo pass test
Elemental ImpuritiesAs reported
Residual SolventsTo pass test
LIGHT SENSITIVE: Keep tightly closed in light-

Repackaged by Spectrum as:

G 11//6GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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