

Scientific Documentation

Chloroxylenol, 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
Kosher Certification



Specification for Chloroxylenol, USP (CH136)

| Item Number | CH136 |
|-------------------|--|
| Item | Chloroxylenol, USP |
| CAS Number | 88-04-0 |
| Molecular Formula | C ₈ H ₉ ClO |
| Molecular Weight | 156.61 |
| MDL Number | |
| Synonyms | 4-Chloro-3,5-dimethylphenol; p-Chloro-m-xylenol; Parachlorometaxylenol; PCMX |

| Test | Specification | | |
|----------------------------------|--|-------------|--|
| | Min | Max | |
| ASSAY | 98.5 % | | |
| WATER DETERMINATION | | 0.5 % | |
| TETRACHLOROETHYLENE | | 0.4 % | |
| RESIDUE ON IGNITION | | 0.1 % | |
| IRON | | 0.01 % | |
| ORGANIC IMPURITIES | | | |
| 3,5-DIMETHYLPHENOL | | 0.2 % | |
| CHLOROXYLENOL RELATED COMPOUND A | | 0.2 % | |
| ANY INDIVIDUAL IMPURITY | | 0.5 % | |
| TOTAL IMPURITIES | | 1.5 % | |
| ELEMENTAL IMPURITIES: | | | |
| COPPER (Cu) | AS REPORTED | | |
| IDENTIFICATION A (FTIR) | SPECTRUM MATCHES REFERENCE | | |
| IDENTIFICATION (B) | RETENTION TIME CORRESPONDS TO STANDARD | | |
| CERTIFIED KOSHER | | | |
| EXPIRATION DATE | | | |
| DATE OF MANUFACTURE | | | |
| APPEARANCE | | | |
| RESIDUAL SOLVENTS | | AS REPORTED | |

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 | CH136 | Lot Number | 4MH0032 |
|-------------------|-----------------------------------|-------------------|----------|
| Item | Chloroxylenol, USP | Manufacturer Lot | 23021812 |
| CAS Number | 88-04-0 | Manufacturer Code | 12066 |
| Molecular Formula | C ₈ H ₉ ClO | Molecular Weight | 156.61 |

| TECT | SPECIFICATION | | DECLU T | |
|----------------------------------|---|-------------|---|--|
| TEST | MIN | MAX | RESULT | |
| ASSAY | 98.5 % | | 99.5 % | |
| WATER DETERMINATION | | 0.5 % | 0.1 % | |
| TETRACHLOROETHYLENE | | 0.4 % | 0.1 % | |
| RESIDUE ON IGNITION | | 0.1 % | 0.08 % | |
| IRON | | 0.01 % | 0.0009 % | |
| ORGANIC IMPURITIES | | | | |
| 3,5-DIMETHYLPHENOL | | 0.2 % | 0.1 % | |
| CHLOROXYLENOL RELATED COMPOUND A | | 0.2 % | 0.2 % | |
| ANY INDIVIDUAL IMPURITY | | 0.5 % | <0.5 % | |
| TOTAL IMPURITIES | | 1.5 % | 0.4 % | |
| ELEMENTAL IMPURITIES: | | | | |
| COPPER (Cu) | AS REPORTED | | <50 ppm | |
| IDENTIFICATION A (FTIR) | SPECTRUM MATCHES REFERENCE | | SPECTRUM MATCHES REFERENCE | |
| IDENTIFICATION (B) | RETENTION TIME CORRESPONDS TO STANDARD | | RETENTION TIME CORRESPONDS TO STANDARD | |
| CERTIFIED KOSHER | | | CERTIFIED KOSHER | |
| EXPIRATION DATE | | | 17-FEB-2026 | |
| DATE OF MANUFACTURE | | | 18-FEB-2023 | |
| APPEARANCE | | | COLORLESS CRYSTALS | |
| RESIDUAL SOLVENTS | | AS REPORTED | NO RESIDUAL SOLVENTS PRESENT | |

| TECT | SPECIFICATION | | DECLUIT. |
|-------------------|---------------|-----|----------|
| TEST | MIN | MAX | RESULT |
| MONOGRAPH EDITION | | | USP 2023 |

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 01-SEP-23 08:02:07

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 11-SEP-23 07:19:18

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 Jiangsu Huanxin High-Tech Materials Co., Ltd. at North Wei'er Road, Bio-tech Zone, Dafeng Harbor, Dafeng, Yancheng, 224100, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SPECTION®



Revision date 20-June-2022 Revision Number 2

1. Identification

Product identifier

Product Name CHLOROXYLENOL, USP

Other means of identification

Product Code(s) CH136

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 - Dermal | Category 4 |
|-----------------------------------|-------------|
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2A |
| Skin sensitization | Category 1A |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful in contact with skin Causes skin irritation Causes serious eye irritation May cause an allergic skin reaction



powder

Appearance Crystals or Crystalline

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Avoid breathing dust/fume/gas/mist/vapors/spray

Contaminated work clothing must not be allowed out of the workplace

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

Specific treatment (see .? on this label)

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap Call a POISON CENTER or doctor if you feel unwell Take off contaminated clothing and wash it before reuse If skin irritation or rash occurs: Get medical advice/attention

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Unknown acute toxicity

Other information

May be harmful if swallowed. Toxic to aquatic life with long lasting effects. Toxic to aquatic life.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% | Trade secret |
|---------------|---------|----------|--------------|
| Chloroxylenol | 88-04-0 | 100 | * |

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

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep

eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

Skin contact May cause an allergic skin reaction. Wash off immediately with soap and plenty of water for

at least 15 minutes. If symptoms persist, call a physician.

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

Never give anything by mouth to an unconscious person. Call a physician.

Self-protection of the first aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

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

Product is or contains a sensitizer. May cause sensitization by skin contact.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. hydrogen chloride gas.

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. Keep people away

from and upwind of spill/leak.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take

off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThe following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. Impervious gloves.

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

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

AppearanceCrystals or Crystalline powderColorColorless to White to Off-WhiteOdorNo information availableOdor thresholdNo information available

| <u>Property</u> | Values_ | Remarks • Method |
|-----------------|---------|------------------|
| | | |

pН no data available None known 115 °C / 239 °F Melting point / freezing point None known 245 °C / 473 °F **Boiling point / boiling range** None known 132 °C / 269.6 °F None known Flash point None known no data available **Evaporation rate** 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 density0.9None knownWater solubilityVery slightly soluble in waterNone known

Solubility(ies) Soluble in Acetone None known

Soluble in Alcohol

Partition coefficient No data available Autoignition temperature no data available

Decomposition temperature

Kinematic viscosity no data available

Dynamic viscosity No data available

None known None known None known None known

None known

Other information

Explosive properties

Oxidizing properties

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 None known based on information supplied.

Incompatible materials Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information .

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Irritating to eyes. (based on

components). Causes serious eye irritation.

Skin contact May cause sensitization by skin contact. Specific test data for the substance or mixture is

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons. (based on components). Causes skin irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Unknown acute toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------|-------------|-------------|-----------------|
| i Chemical name | l Olai LD30 | | |

| Chloroxylenol | = 3830 mg/kg (Rat) | > 2 g/kg (Rat) | - |
|---------------|--------------------|----------------|---|
| 88-04-0 | | | |

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

Skin corrosion/irritation

Classification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation

Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization

May cause sensitization by skin contact.

Germ cell mutagenicity

No information available.

Reproductive toxicity

No information available.

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

Aspiration hazard

No information available.

Other adverse effects

No information available.

Interactive effects

No information available.

12. Ecological information

Ecotoxicity Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to | Crustacea |
|---------------|----------------------|-----------------------|----------------|-------------------------|
| | | | microorganisms | |
| Chloroxylenol | - | LC50: 0.13 - 1.0mg/L | - | EC50: 6.7 - 9mg/L (48h, |
| 88-04-0 | | (96h, Oncorhynchus | | Daphnia magna) |
| | | mykiss) LC50: 1.3 - | | |
| | | 2.1mg/L (96h, Lepomis | | |
| | | macrochirus) | | ļ |

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

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

environmental legislation.

Contaminated packaging

Do not reuse empty containers.

14. Transport information

not regulated DOT

Proper Shipping Name: No information available

TDG not regulated UN-No: Not regulated

Proper Shipping Name: No information available

not regulated MEX

ICAO (air) not regulated Not regulated UN-No:

Proper Shipping Name: No information available

<u>IATA</u> not regulated

UN number Not regulated

IMDG not regulated

RID not regulated
UN number Not regulated

ADR not regulated
UN number Not regulated

ADN not regulated

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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

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

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2 Flammability 1 Instability 0

Physical and chemical properties -

HMIS

Health hazards 2 Flammability 1 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 20-June-2022

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 |
|----------------|--------------------|
| CH136 | Chloroxylenol, 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

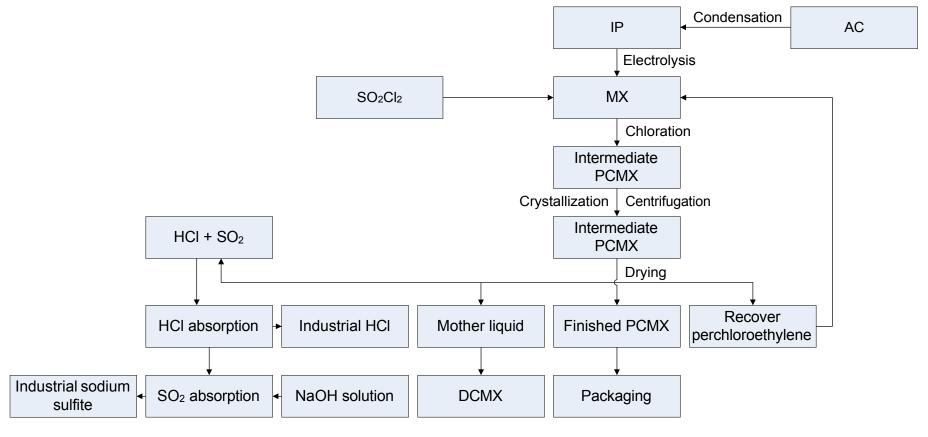
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Chloroxylenol, USP - CH136



Spectrum Chemical Mfg Corp

Corporate Headquarters:

West Coast Facility:

769 Jersey Ave.

14422 S. San Pedro St. Gardena, CA 90248

New Brunswick, NJ 08901



CH136, Chloroxylenol, 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 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:

- Antibiotics
- Parabens
- Phthalates
- Preservatives



RE: Elemental Impurities - Chloroxylenol, USP (Cat# CH136)

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 |
|--------------------|----|-------|------------------------|
| Copper | Cu | 3 | < 50 ppm |

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

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



RE: Residual Solvents - Chloroxylenol, USP (Cat# CH136)

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

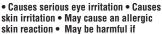
14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



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



swallowed.

• • Wear protective gloves, eye protection, face of protection • Avoid breathing dust • Wash face, phands and any exposed skin thoroughly after handling • Contaminated work clothing must ont be allowed out of the workplace.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical attention.

KEEP FROM CHILDREN

CH136 SIZ SY Chloroxylenol

(4-Chloro-3,5-dimethylphenol; p-Chloro-m-xylenol)

USP

KSA KOSHER

CAS 88-04-0

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

C₈H₉CIO F.W. 156.61

| Manufacturer/Supplier Code | | | | |
|----------------------------------|------------|--|--|--|
| Manufacturer Lot Number | ? | | | |
| | | | | |
| Assay | Min. 98.5% | | | |
| MAXIMUM LIMITS | | | | |
| Water Determination | 0.5% | | | |
| Tetrachloroethylene | 0.4% | | | |
| Residue on Ignition | 0.1% | | | |
| Iron | 0.01% | | | |
| Organic Impurities: | | | | |
| 3,5-Dimethylphenol | 0.2% | | | |
| Chloroxylenol Related Compound A | 0.2% | | | |
| Any individual Impurity | 0.5% | | | |
| Total Impurities | | | | |
| Elemental Impurities | | | | |
| Residual Solvents | | | | |
| | | | | |

Repackaged by Spectrum as:

G 12/K8GHS-A

Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300





The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA

Product Name CH136, Chloroxylenol, USP

Brand Spectrum

UKD-ID KSAV3-G4U1O46

D/P/M P

Symbol Required KSA

Special Conditions

This certificate expires on **Feb 01, 2025**

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.