



# Scientific Documentation

CO138, Hydrocortisone Acetate, Micronized,  
USP

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://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

Ver4.04 23.July.2019



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang  
Director, Quality Systems & GMP Compliance  
[mdang@spectrumchemical.com](mailto:mdang@spectrumchemical.com)

23.July.2019

**CO138**, Hydrocortisone Acetate, Micronized, USP

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CHEMICAL MFG CORP



## Specification for Hydrocortisone Acetate, Micronized, USP (CO138)

Item Number	CO138
Item	Hydrocortisone Acetate, Micronized, USP
CAS Number	50-03-3
Molecular Formula	$C_{23}H_{32}O_6$
Molecular Weight	404.50
MDL Number	
Synonyms	Cortisol 21-Acetate ; Cortisol Acetate ; Hydrocortisone 21-Acetate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0	102.0 %
SPECIFIC ROTATION @ 20 C	+158° to +167°	
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.5 %
ORGANIC IMPURITIES	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

### *Spectrum Chemical Mfg Corp*

**Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000

## SAFETY DATA SHEET

Preparation Date: 6/3/2017

Revision Date: 6/3/2017

Revision Number: G1

### 1. IDENTIFICATION

**Product identifier**

**Product code:** CO138  
**Product Name:** HYDROCORTISONE ACETATE, MICRONIZED, USP

**Other means of identification**

**Synonyms:** 4-Pregnene-11-beta,17-alpha,21-triol 3,20-dione acetate  
 21-Acetoxy-11-beta,17-alpha-dihydroxypregn-4-ene-3,20-dione  
 Corticosterone, 17-hydroxy-, 21-acetate  
 Cortisol acetate  
 Hycortole acetate  
 17-alpha-Hydroxycorticosterone acetate  
 17-alpha-Hydrocorticosterone 21-acetate  
 Hydrocortisone 21-acetate  
 Hydrocortone acetate  
 Hydroxy corticosterone acetate  
 17-Hydroxycorticosterone acetate  
 17-Hydroxycorticosterone-21-acetate  
 Pregn-4-ene-3,20-dione, 21-(acetoxy)-11,17-dihydroxy-, (11-beta)-  
 Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11-beta)- (9CI)  
 Pregn-4-ene-3,20-dione, 11-beta,17,21-trihydroxy-, 21-acetate  
 11-beta,17-alpha-Dihydroxy-21-acetoxypregesterone

**CAS #:** 50-03-3  
**RTECS #** GM8960000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** 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:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

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

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

Reproductive toxicity	Category 2
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## Label elements

### Warning

#### Hazard statements

Suspected of damaging fertility or the unborn child



#### Hazards not otherwise classified (HNOC)

Not Applicable

#### Other hazards

May be harmful if swallowed

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

Obtain special instructions before use

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

Use personal protective equipment as required

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

*IF exposed or concerned: Get medical advice/attention*

#### **Precautionary Statements - Storage**

Store locked up

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Hydrocortisone Acetate	50-03-3	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 irritation develops. Consult a physician if necessary.

#### **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. Consult a physician if necessary.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Glucocorticoids (Corticosteroids) may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia).

**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:** Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Dioxide, Carbon Monoxide.

**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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering 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. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapors/dust. 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. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Hydrocortisone Acetate	50-03-3	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Hydrocortisone Acetate	50-03-3	None	None	None	None

##### **Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Hydrocortisone Acetate	50-03-3	None	None

### Appropriate engineering controls

#### **Engineering measures to reduce exposure:**

Ensure adequate ventilation. 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**



<b>Eye protection:</b>	Safety glasses with side-shields or Goggles
<b>Skin and body protection:</b>	Chemical resistant apron Gloves Long sleeved clothing
<b>Respiratory protection:</b>	Effective dust mask. 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.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula:</b> C23H32O6
<b>Molecular/Formula weight:</b> 404.50	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> No information available	<b>Decomposition temperature(°C/°F):</b> 223°C/433.4°F
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> 1.289	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Insoluble in cold water Partially soluble in acetone Partially soluble in diethyl ether Very slightly soluble in Methanol	

## 10. STABILITY AND REACTIVITY

**Reactivity**  
Reactive with oxidizing agents

**Chemical stability**

**Stability:** Stable under recommended storage conditions.

**Product code:** CO138

**Product name:** HYDROCORTISONE  
ACETATE, MICRONIZED, USP

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Excess Heat. Incompatible materials.

**Incompatible Materials:** Oxidizing agents

**Hazardous decomposition products:** Carbon oxides.

**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:**

Ingestion. Inhalation. Skin.

### Acute Toxicity

#### Component Information

Hydrocortisone Acetate	
CAS-No.	50-03-3

**LD50/oral/rat** = 5000 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = 3267 mg/kg Oral LD50 Mouse

**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 LC50 information** = 2300 mg/kg Intraperitoneal LD50 Mouse;  
45050 µg/kg Subcutaneous LD50 Mouse

#### Product Information

**LD50/oral/rat** =

**VALUE- Acute Tox Oral** = 5000 mg/kg

**LD50/oral/mouse** =

**Value - Acute Tox Oral** = 3267 mg/kg

**LD50/dermal/rabbit**

**VALUE-Acute Tox Dermal** = 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**

**Product code:** CO138

**Product name:** HYDROCORTISONE  
ACETATE, MICRONIZED, USP

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

**Symptoms**

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause respiratory tract irritation.

**Ingestion** May be harmful if swallowed. Corticosteroids(glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression. May affect behavior/central nervous system (somnolence). May affect liver. May affect urinary system (kidneys). It may affect the spleen. May affect the adrenal gland.

**Aspiration hazard** No information available.

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

**Chronic Toxicity** Prolonged or repeated ingestion may affect behavior/central nervous system (somnolence). Prolonged or repeated exposure may affect the heart. Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections), thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women). Prolonged or repeated ingestion may cause hyperglycemia.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic	Australia - Prohibited Carcinogenic

						<b>Substances</b>	<b>Substances</b>
Hydrocortisone Acetate	50-03-3	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 based on animal data

**Developmental Effects:**

Possible risk of harm to the unborn child

**Teratogenic Effects:**

May cause birth defects (teratogenic effects)

**Specific Target Organ Toxicity**

**STOT - single exposure**

No information available.

**STOT - repeated exposure**

No information available.

**Target Organs:**

No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:**

No data available.

**Persistence and degradability:**

No information available

**Bioaccumulative potential:**

No information available.

**Mobility:**

No 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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Hydrocortisone Acetate	50-03-3	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**

**UN-No:**

Not Regulated

**Proper Shipping Name:**

No information available

**Hazard Class:**

No information available

**Subsidiary Class**

No information available

**Packing group:**

No information available

**Product code:** CO138

**Product name:** HYDROCORTISONE ACETATE, MICRONIZED, USP

**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

**TDG (Canada)**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

**ADR**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

**IMO / IMDG**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

**RID**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

## 15. REGULATORY INFORMATION

### International Inventories

**Product code:** CO138

**Product name:** HYDROCORTISONE  
ACETATE, MICRONIZED, USP

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Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Hydrocortisone Acetate	50-03-3	Not Listed	Present KE-00135	Not present	Not present	Not present	Present	Present 200-004-4

## 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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Hydrocortisone Acetate	50-03-3	Not Listed	Not Listed	Not Listed	Not Listed

## CERCLA/SARA

Components	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
Hydrocortisone Acetate	50-03-3	None	None	None	None	None

## U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Hydrocortisone Acetate	50-03-3	Not Applicable	Not Applicable

## Canada

### WHMIS 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

### WHMIS 1988 Hazard Class

The classification of this product has not been validated yet

### Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

## Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Hydrocortisone Acetate	50-03-3	Present	Not Listed

Product code: CO138

Product name: HYDROCORTISONE  
ACETATE, MICRONIZED, USP

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<b>Components</b>	CAS-No.	CEPA Schedule I - Toxic Substances
Hydrocortisone Acetate	50-03-3	Not listed
<b>Components</b>	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Hydrocortisone Acetate	50-03-3	Not listed

### EU Classification

#### EU GHS - SV - CLP 172/2008

Components	CAS-No.	EU GHS - SV - CLP (172/2008)
Hydrocortisone Acetate	50-03-3	No information

#### EU - CLP (1272/2008)

### R-phrase(s)

Not determined

### S-phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Hydrocortisone Acetate	50-03-3		No information	

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

### Indication of danger:

None.

## 16. OTHER INFORMATION

Preparation Date: 6/3/2017  
Revision Date: 6/3/2017  
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**

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street,  
Gardena, California, 90248, United States

Additional Site: 13915 South Main Street,  
Los Angeles, California, 90061, United States

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

## ISO 9001:2015

The management system is applicable to:

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

**Certificate Number:**

94-316m

**Initial Certification Date:**

27 December 1994

**Date of Certification Decision:**

22 January 2019

**Issuing Date:**

22 January 2019

**Valid Until:**

28 January 2022



**Intertek**

A handwritten signature in black ink, appearing to read "Calin Moldovean".

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.,  
900 Chelmsford Street,  
Lowell, MA 01851.  
USA.





# APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations covered by the management system of:

## **Spectrum Chemicals and Laboratory Products, Inc.**

This appendix is linked to the Main Certificate # 94-316m and cannot be shown nor reproduced without it.

### **Spectrum Chemicals and Laboratory Products, Inc.**

769 Jersey Avenue,  
New Brunswick, New Jersey, 08901, United States

755 Jersey Avenue,  
New Brunswick, New Jersey, 08901, United States

777 Jersey Avenue,  
New Brunswick, New Jersey, 08901, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

### **Spectrum Chemicals and Laboratory Products, Inc.**

7400 N. Oracle, Suite 201,  
Tucson, Arizona, 85704, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.



# 管理体系认证 注册证书

兹证明，以下组织：

## 斯百全化学(上海) 有限公司

注册地址：上海市松江区申港路3802号41幢

经营地址：上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

### ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售。

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2018年10月15日

签发日期：

2018年10月15日

有效期至：

2021年11月10日



014

**Calin Moldovean**

President, Business Assurance

Intertek Certification Limited, 10A Victory  
Park, Victory Road, Derby DE24 8ZF, United  
Kingdom

Intertek Certification Limited  
是 UKAS 认可的认证机构，  
注册号为 014



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Spectrum China Ltd.

Registered Address: Building 41, No.3802, Shengang Road,  
Songjiang District, Shanghai, China

Business Address: Building A20, No.3802, Shengang Road,  
Songjiang District, Shanghai, China

has been registered by Intertek as conforming to the requirements of:

## ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals.

**Unified Social Credit Identifier:**

91310000777627048K

**Certificate Number:**

111310001

**Initial Certification Date:**

17 November 2015

**Date of Certification Decision:**

15 October 2018

**Issuing Date:**

15 October 2018

**Valid Until:**

10 November 2021



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

**Calin Moldovean**

President, Business Assurance

Intertek Certification Limited, 10A Victory  
Park, Victory Road, Derby DE24 8ZF, United  
Kingdom

Intertek Certification Limited is a  
UKAS accredited body under  
schedule of accreditation no. 014.



January 08, 2019

**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP, and food grade products are 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 and parts 110 and 111 of the Code of Federal Regulations, respectively.

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum Gardena, California: 2020632  
Spectrum New Brunswick, New Jersey: 2246824

Thank you for your interest in Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at [mdang@spectrumchemical.com](mailto:mdang@spectrumchemical.com) if I may be of further assistance.

Sincerely,



Michael Dang  
Director, Quality Systems & GMP Compliance

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

July 23, 2019

**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
CO138	Hydrocortisone Acetate, Micronized, 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  
Spectrum-Shanghai, China: 03006174778

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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,



Oralia Chavez  
Quality Assurance Specialist



May 24, 2016

Re: Hydrocortisone Acetate, Micronized, USP- CO138

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Hydrocortisone Acetate, Micronized, USP- CO138

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

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



May 24, 2016

Re: Hydrocortisone Acetate, Micronized, USP- CO138

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Tree nuts; Wheat; Peanuts; Sesame Seed).

Hydrocortisone Acetate, Micronized, USP- CO138

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

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

Item Number	CO138	Lot Number	2HD0132
Item	Hydrocortisone Acetate, Micronized, USP	Manufacturer Lot	HC0075
CAS Number	50-03-3	Manufacturer Code	3381
Molecular Formula	C <sub>23</sub> H <sub>32</sub> O <sub>6</sub>	Molecular Weight	404.50

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	97.0	102.0 %	98.0 %
SPECIFIC ROTATION @ 20 C	+158° to +167°		+163.2°
LOSS ON DRYING		1.0 %	0.02 %
RESIDUE ON IGNITION		0.5 %	0.00 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			01-OCT-2020
DATE OF MANUFACTURE			02-OCT-2017
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (solvent) / CHLOROFORM			<60 ppm
CLASS 2 (solvent) / N,N-DIMETHYLFORMAMIDE			<880 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by



Ibad Tirmizi  
Director of Quality  
Spectrum Chemical Mfg. Corp.

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, repackaging 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. Test results for 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.

## 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.

**A**   
Exp. Date: 03-31-2025  
**L**

**C** **WARNING**  
• Suspected of damaging fertility or the unborn child • May be harmful if swallowed.  
• 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.  
**FIRST AID:** If exposed or concerned: Get medical attention.  
**KEEP FROM CHILDREN**

**B** 

**SPECTRUM**<sup>®</sup>  
**C0138** **D** **F** **1 KG**

**E** **Hydrocortisone Acetate**  
(Hydrocortisone 21-Acetate; Cortisol 21-Acetate; Cortisol Acetate)  
Micronized, U.S.P.  
**H** **G** CAS 50-03-3

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**J** **Chemical Emergency: (800)424-9300**  
[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

**K**  $C_{23}H_{32}O_6$  **F.W. 404.50**

Assay (Dried Basis) ..... 97.0-102.0%  
Specific Rotation @ 20°C..... +158° to +167°  
**MAXIMUM LIMITS**  
Loss on Drying ..... 1.0%  
Residue on Ignition ..... 0.5%  
Organic Impurities ..... To pass test  
Residual Solvents ..... To pass test

Keep tightly closed.

**M** Lot No. 062233  
**O**

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

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li><b>A</b> Bar Code</li> <li><b>B</b> GHS Hazard Pictograms</li> <li><b>C</b> Warning, Safety Data and Precautionary Information</li> <li><b>D</b> Product Catalog Number</li> <li><b>E</b> Item Name, Form, Grade</li> <li><b>O</b> Storage Color Band</li> </ul> | <ul style="list-style-type: none"> <li><b>F</b> Size/Quantity</li> <li><b>G</b> Chemical Abstracts Service (CAS) Registry Number</li> <li><b>H</b> Caution Information</li> <li><b>I</b> DOT Shipping Information</li> <li><b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number</li> </ul> | <ul style="list-style-type: none"> <li><b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel</li> <li><b>L</b> Expiration Information</li> <li><b>M</b> Lot Number</li> <li><b>N</b> Kosher Certified by Kosher Supervision of America (KSA).</li> </ul> |
|---|--|--|

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

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

### Spectrum Chemical Mfg Corp

**Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901

732.214.1300

**West Coast Facility:**

14422 S. San Pedro St.  
Gardena, CA 90248

310.516.8000

February 1, 2019

**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Howard Lau,  
Quality Assurance Specialist

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

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



## Stability – Shelf Life Guidance

Product Covered: CO138, Hydrocortisone Acetate, Micronized, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, CO138, Hydrocortisone Acetate, Micronized, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez  
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters  
769 Jersey Avenue  
New Brunswick, NJ 08901-3605

23.July.2019