

# Scientific Documentation

## Fluocinolone Acetonide, Anhydrous, 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



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# Specification for Fluocinolone Acetonide, Anhydrous, Micronized, USP (F1118)

Item Number	F1118
Item	Fluocinolone Acetonide, Anhydrous, Micronized, USP
CAS Number	67-73-2
Molecular Formula	C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub>
Molecular Weight	452.49
MDL Number	
Synonyms	6alpha,9alpha-Difluoro-16alpha-hydroxyprednisolone Acetonide

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0	102.0 %
SPECIFIC ROTATION [α] <sub>D</sub>	+98° to +108°	
LOSS ON DRYING		1.0 %
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*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
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# Certificate Of Analysis

Item Number	F1118	Lot Number	4LK0045
Item	Fluocinolone Acetonide, Anhydrous, Micronized, USP	Manufacturer Lot	2151NM1 B0042223
CAS Number	67-73-2	Manufacturer Code	13524
Molecular Formula	C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub>	Molecular Weight	452.49

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	97.0	102.0 %	100.6 %
SPECIFIC ROTATION [α] <sub>D</sub>	+98° to +108°		+104°
LOSS ON DRYING		1.0 %	0.4 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			07-JUL-2027
DATE OF MANUFACTURE			07-JUL-2022
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
05-JAN-23 04:07:55

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

TANDERSON  
Trevor Anderson  
05-JAN-23 04:08:19

**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 Farmabios S.p.A. at Via Pavia 1, Gropello Cairoli, Pavia 27027, Italy (ITA). 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: 6/28/2018

Revision Date: 6/29/2018

Revision Number: G1

## 1. IDENTIFICATION

### Product identifier

**Product code:** F1118  
**Product Name:** FLUOCINOLONE ACETONIDE, ANHYDROUS, MICRONIZED, USP

### Other means of identification

**Synonyms:** 6-alpha,9-alpha-Difluoro-16-alpha-hydroxyprednisolone 16,17-acetonide  
**CAS #:** 67-73-2  
**RTECS #** TU3830000  
**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)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3

### Label elements

#### **Warning**

#### **Hazard statements**

Harmful if swallowed  
Causes skin irritation  
Causes serious eye irritation

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Suspected of damaging fertility or the unborn child  
May cause respiratory irritation



**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  
Wear protective gloves/protective clothing/eye protection/face protection  
Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area  
Wear protective gloves

**Precautionary Statements - Response**

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

*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

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

Rinse mouth

**Precautionary Statements - Storage**

Store locked up

Store in a well-ventilated place. Keep container tightly closed

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Fluocinolone Acetonide, Anhydrous	67-73-2	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.

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<b>Skin Contact:</b>	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.
<b>Eye Contact:</b>	Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a physician.
<b>Inhalation:</b>	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion:</b>	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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

<b>Symptoms</b>	Glucocorticoids (Corticosteroids): Ingestion 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) Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy) May cause burning or stinging sensation, redness of the skin, inflammation of the skin.
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**Indication of any immediate medical attention and special treatment needed**

<b>Notes to Physician:</b>	Treat symptomatically.
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**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**

<b>Suitable Extinguishing Media:</b>	Dry chemical. Carbon dioxide (CO <sub>2</sub> ). Water spray, mist, or foam.
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<b>Unsuitable Extinguishing Media:</b>	No information available.
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**Specific hazards arising from the chemical**

<b>Hazardous Combustion Products:</b>	Carbon Monoxide, Carbon Dioxide. Hydrogen fluoride.
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<b>Specific hazards:</b>	May be combustible at high temperatures. Highly toxic hydrogen fluoride gas is produced during combustion.
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**Special Protective Actions for Firefighters**

<b>Specific Methods:</b>	No information available.
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<b>Special Protective Equipment for Firefighters:</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
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## 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Prevent product from entering drains.

### 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. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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**

Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Use only in well-ventilated areas. Do not ingest. Do not breathe dust. Keep away from sources of ignition - no smoking. 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 WEEL
Fluocinolone Acetonide, Anhydrous	67-73-2	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
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Fluocinolone Acetonide, Anhydrous	67-73-2	None	None	None	None
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### Australia and Mexico

Components	CAS-No.	Australia	Mexico
Fluocinolone Acetonide, Anhydrous	67-73-2	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

**Skin and body protection:** Chemical resistant apron  
Gloves  
Long sleeved clothing

**Respiratory protection:** Effective dust mask. Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent. 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. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:**  
Solid

**Appearance:**  
Crystalline powder.

**Color:**  
White.

**Odor:**  
Odorless. Nearly odorless.

**Taste**  
No information available.

**Formula:**  
C<sub>24</sub>H<sub>30</sub>F<sub>2</sub>O<sub>6</sub>

**Molecular/Formula weight:**  
452.49 g/mol

**Flammability:**  
No information available

**Flashpoint (°C/°F):**  
No information available.

**Flash Point Tested according to:**  
Not available

**Autoignition Temperature (°C/°F):**  
No information available

**Lower Explosion Limit (%):**  
No information available

**Upper Explosion Limit (%):**  
No information available

**Melting point/range(°C/°F):**  
266-269°C/511-516°F

**Decomposition temperature(°C/°F):**  
No information available

**Boiling point/range(°C/°F):**  
No information available

**Bulk density:**  
No information available

**Density (g/cm<sup>3</sup>):**  
No information available

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**Specific gravity:**  
No information available

**pH:**  
No information available

**Vapor pressure @ 20°C (kPa):**  
No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Insoluble in water

## 10. STABILITY AND REACTIVITY

**Reactivity**  
Reactive with oxidizing agents

### Chemical stability

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

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

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Oxidizing agents

**Hazardous decomposition products:** Carbon oxides. Hydrogen fluoride.

### 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.

### Acute Toxicity

### Component Information

Fluocinolone Acetonide, Anhydrous

CAS-No. 67-73-2

**LD50/oral/rat** = > 4 g/kg Oral LD50 Rat

**LD50/oral/mouse** = No information available

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

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

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

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**Other LD50 or LC50 information =** No information available

#### **Product Information**

**LD50/oral/rat =**

**VALUE- Acute Tox Oral =** No information available

**LD50/oral/mouse =**

**Value - Acute Tox Oral =** No information available

**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**

**VALUE-Vapor =** No information available

**VALUE - Gas =** No information available

**VALUE - Dust/Mist =** No information available

#### **Symptoms**

##### **Skin Contact:**

Causes skin irritation. May cause stinging and burning sensation. May cause burning sensation, itching, redness. May cause dryness of the skin in cases of severe exposure.

##### **Eye Contact:**

Causes serious eye irritation.

##### **Inhalation**

Irritating to respiratory system.

##### **Ingestion**

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.

##### **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 skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Prolonged or repeated eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). 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 as 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).

**Sensitization:** No information available.

**Mutagenic Effects:** Cytogenic Analysis: human lymphocyte  
Sister Chromatid Exchange (human lymphocyte)

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Fluocinolone Acetonide, Anhydrous	67-73-2	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:** No information available  
**Developmental Effects:** May cause adverse developmental effects based on animal data  
Possible risk of harm to the unborn child  
**Teratogenic Effects:** No information available

#### **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.

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**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
Fluocinolone Acetonide, Anhydrous	67-73-2	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  
**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

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**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**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Fluocinolone Acetonide, Anhydrous	67-73-2	Not Listed	Not present	Present	Present (9)-750	Not present	Present	Present 200-668-5

**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:
Fluocinolone Acetonide, Anhydrous	67-73-2	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
Fluocinolone Acetonide, Anhydrous	67-73-2	None	None	None	None	None

**Product code:** F1118

**Product name:** FLUOCINOLONE  
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## 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
Fluocinolone Acetonide, Anhydrous	67-73-2	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)
Fluocinolone Acetonide, Anhydrous	67-73-2	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Fluocinolone Acetonide, Anhydrous	67-73-2	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Fluocinolone Acetonide, Anhydrous	67-73-2	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Fluocinolone Acetonide, Anhydrous	67-73-2	No information

### EU - CLP (1272/2008)

### R-phrases(s)

Not determined

### S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Fluocinolone Acetonide, Anhydrous	67-73-2		No information	

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

Product code: F1118

Product name: FLUOCINOLONE  
ACETONIDE, ANHYDROUS,  
MICRONIZED, USP

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**Indication of danger:**  
not determined

## 16. OTHER INFORMATION

**Preparation Date:** 6/28/2018  
**Revision Date:** 6/29/2018  
**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
F1118	Fluocinolone Acetonide, Anhydrous, 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

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,  
Quality Assurance  
Spectrum Chemical Mfg. Corp.

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

## 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.

**Exp. Date:** 00-00-0000



**WARNING**

- Causes serious eye irritation • Causes skin irritation
- May cause respiratory irritation • 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
- Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**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 occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

**KEEP FROM CHILDREN**

**F1118**

**Fluocinolone Acetonide**

(6 $\alpha$ ,9 $\alpha$ -Difluoro-  
16 $\alpha$ -hydroxyprednisolone Acetonide)

Anhydrous, Micronized, USP

CAS 67-73-2

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.

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

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

**SIZ SY**

$C_{24}H_{30}F_2O_6$  F.W. 452.49

Manufacturer/Supplier Code.....?

Manufacturer Lot Number.....?

Assay (Dried Basis)..... 97.0-102.0%

Specific Rotation,  $[\alpha]_D^{25}$ ..... +98° to +108°

**MAXIMUM LIMITS**

Loss on Drying..... 1.0%

Organic Impurities:

Any Individual Impurity ..... 1%

Total Impurities ..... 2.5%

Elemental Impurities ..... As reported

Residual Solvents ..... To pass test

Repackaged by Spectrum as:

G 10/J2GHS-A ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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Gardena, CA 90248  
310.516.8000