

## SAFETY DATA SHEET

Preparation Date: 07/14/2015

Revision date 4/26/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** D1103  
**Product Name:** DANAZOL, USP

#### Other means of identification

**Synonyms:** Danazol  
 Danocrine  
 Danol  
 Pregna-2,4-dien-20-yno(2,3-d)isoxazol-17-ol, (17-alpha)- (9CI)  
 17-alpha-2,4-Pregnadien-20-yno(2,3-d)isoxazol-17-ol  
 17-alpha-Pregn-4-en-20-yno(2,3-d)isoxazol-17-ol  
**CAS #:** 17230-88-5  
**RTECS #** TU4157070  
**Cl#:** Not available

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

**Recommended use:** Drug. Therapeutic agent.  
**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:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

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

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

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**

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

**Precautionary Statements - Response***IF exposed or concerned: Get medical attention***Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Danazol	17230-88-5	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. Obtain 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**May cause eye irritation  
May cause skin irritation  
May cause digestive tract irritation  
May cause nausea and vomiting  
May cause constipation

May cause elevation on blood pressure, thromboembolism, thrombotic and thrombophlebitic events, visual disturbances, muscle cramps or spasms, or pains, joint pain, joint lockup, and joint swelling, pain in back, neck, or extremities and rarely carpal tunnel syndrome, androgen-like effects in women (weight gain, acne, seborrhea, mild hirsutism, hair loss, voice change), menstrual disturbances (spotting, alteration of the timing of the menstrual cycle, amenorrhea), vaginal dryness, reduction in breast size, hypertrophy of the clitoris(rare)), flushing, sweating, skin rashes, and rarely sun sensitivity  
May affect the liver  
May cause cardiovascular effects  
May cause central nervous system effects

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

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

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray. Foam.

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

**Specific hazards arising from the chemical**

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO<sub>x</sub>).

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

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not let product enter 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 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. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

## Conditions for safe storage, including any incompatibilities

### **Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Store away from incompatible materials.

### **Incompatible Materials:**

Oxidizing agents

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Control parameters

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

##### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Danazol	17230-88-5	None	None	None	None

##### **Canada**

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Danazol	17230-88-5	None	None	None	None

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

Component	CAS No	Australia	Mexico
Danazol	17230-88-5	None	None

### Appropriate engineering controls

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

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:** Safety glasses with side-shields. or Goggles

**Skin and body protection:** Long sleeved clothing

Chemical resistant apron  
Gloves

**Respiratory protection:** Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White to yellowish.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula</b> C22H27NO2
<b>Molecular/Formula weight (g/mole):</b> 337.46	<b>Flammability (solid, gas)</b> no data 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> 225°C/ 437°F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> 478.19°C/ 892.7°F	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> 1.21
<b>Specific gravity:</b> No information available	<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> 4.21	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Soluble in Acetone Insoluble in cold water	

## 10. STABILITY AND REACTIVITY

**Reactivity**  
Reactive with oxidizing agents

### Chemical stability

**Stability:** Sensitive to light. Exposure to light accelerates decomposition. 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. Nitrogen oxides (NOx).

**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:**  
Inhalation. Ingestion.

### Acute Toxicity

#### Component Information

Danazol
CAS No 17230-88-5

**LD50/oral/rat** = > 17 g/kg Oral LD50 Rat  
**LD50/oral/mouse** = 4830 mg/kg LD50 Oral 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** = No information available

#### Product Information

**LD50/oral/rat** =  
**Value - Acute Tox** = 17000 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = 4830 mg/kg

**LD50/dermal/rabbit**  
**Value - Acute Tox** = No information available

**LD50/dermal/rat**  
**VALUE - Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

### Symptoms

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

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

**Inhalation** May cause respiratory tract irritation.

**Ingestion** May cause gastrointestinal tract irritation with nausea, vomiting, constipation, chills, changes in appetite, and rarely pancreatitis. May cause elevation on blood pressure, thromboembolism, thrombotic and thrombophlebitic events, visual disturbances, muscle cramps or spasms, or pains, joint pain, joint lockup, and joint swelling, pain in back, neck, or extremities and rarely carpal tunnel syndrome, androgen-like effects in women (weight gain, acne, seborrhea, mild hirsutism, hair loss, voice change), menstrual disturbances (spotting, alteration of the timing of the menstrual cycle, amenorrhea), vaginal dryness, reduction in breast size, hypertrophy of the clitoris(rare)), flushing, sweating, skin rashes, and rarely, sun sensitivity, Stevens-Johnson syndrome. May affect the liver (hepatic dysfunction, jaundice, hepatitis, hepatic adenoma), behavior/central nervous system (headache, nervousness, emotional lability, dizziness, fainting, depression, fatigue, sleep disorders, tremor, weakness, anxiety), Peripheral Nervous system (paresthesias, Spastic paralysis), urinary system (hematuria), blood (reversible erythrocytosis, leukocytosis or polycythemia, as well as eosinophilia, leukopenia, thrombocytopenia, and an increase in red blood cell and platelet count). Other symptoms may include elevation in blood pressure, and rarely, cataracts, benign intracranial hypertension, bleeding gums, fever, pelvic pain, nipple discharge.

**Aspiration hazard** No information available.

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

**Chronic Toxicity** Chronic exposure may affect the liver and kidneys.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** May cause cancer.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Danazol	17230-88-5	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

**Developmental Effects:** No information available

**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: Kidneys. Reproductive System. Liver.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.  
**Persistence and degradability:** No information available  
**Bioaccumulative potential:** No information available.  
**Mobility in soil** No information available  
**Other adverse effects** 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Danazol	17230-88-5	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 Number** Not regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

**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 Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

**ICAO (air)**

**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 Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** No information available  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Danazol</i>	17230-88-5	Not Listed	Not present	Present	Not present	Not listed	X	Present 241-270-1

**U.S. Regulations***Danazol*

Massachusetts RTK: Present

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

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

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

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

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Danazol	17230-88-5	Not Listed	developmental toxicity	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Danazol	17230-88-5	None	None	None	None	None

**U.S. TSCA**

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Danazol	17230-88-5	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

**DSL/NDSL**

Component	CAS No	Canada (DSL)	Canada (NDSL)
Danazol	17230-88-5	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Danazol	17230-88-5	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Danazol	17230-88-5	Not listed

**EU Classification****EU GHS - SV - CLP 1272/2008**

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Danazol	17230-88-5	

**EU - CLP (1272/2008)****R-phrases(s)**

R62 - Possible risk of impaired fertility

R63 - Possible risk of harm to the unborn child

**S -phrase(s)**

S 2 - Keep out of the reach of children.

S36/37 - Wear suitable protective clothing and gloves

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Danazol	17230-88-5		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC****Indication of danger:**

Xn - Harmful

Xn

**16. OTHER INFORMATION**

**Preparation Date:** 07/14/2015  
**Revision date** 4/26/2019  
**Prepared by:** Sonia Owen

**Disclaimer:**

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

**End of Safety Data Sheet**