

**1. Identification**

<b>Product identifier</b>	<b>Nevirapine</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Active pharmaceutical ingredient.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	Boehringer Ingelheim Vetmedica, Inc.
<b>Address</b>	2621 North Belt Hwy St. Joseph, MO 64506-2002
<b>Transportation emergency</b>	For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted)
<b>Medical Emergency (24HR):</b>	(866)638-2226
<b>Non-Emergency calls:</b>	(800) 821-7467

**2. Hazard(s) identification**

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2B
<b>Environmental hazards</b>	Hazardous to the aquatic environment, long-term hazard	Category 3
<b>OSHA defined hazards</b>	Combustible dust	
<b>Label elements</b>		



<b>Signal word</b>	Warning	
<b>Hazard statement</b>	May form combustible dust concentrations in air. Harmful if swallowed. Causes eye irritation. Harmful to aquatic life with long lasting effects.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Prevent dust accumulation to minimize explosion hazard. Observe good industrial hygiene practices.	
<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse mouth. If eye irritation persists: Get medical advice/attention.	
<b>Storage</b>	Store away from incompatible materials.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

**3. Composition/information on ingredients****Mixtures**

Chemical name	CAS number	%
6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one, 11-cyclopropyl-5,11-dihydro-4-methyl-	129618-40-2	100

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes. Exposed individuals may experience eye tearing, redness, and discomfort. Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Apply extinguishing media carefully to avoid creating airborne dust.
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk. Water runoff can cause environmental damage. Dike and collect water used to fight fire. Avoid discharge into drains, water courses or onto the ground.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	May form combustible dust concentrations in air.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.  Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.
<b>Environmental precautions</b>	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Recommended storage temperature: 25°C Keep away from food, drink and animal feeding stuffs.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m <sup>3</sup>	Respirable particles.
		10 mg/m <sup>3</sup>	Inhalable particles.

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Provide easy access to water supply and eye wash facilities.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields (or goggles). Unvented, tight fitting goggles should be worn in dusty areas.

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves.

#### Skin protection

##### Other

Wear suitable protective clothing. Use of protective coveralls and long sleeves is recommended.

#### Respiratory protection

If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Recommended use: High-efficiency particulate respirator.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

#### Physical state

Solid.

#### Form

Powder.

#### Color

Light yellow.

#### Odor

Very faint.

#### Odor threshold

Not available.

#### pH

Not available.

#### Melting point/freezing point

469.4 °F (243 °C)

#### Initial boiling point and boiling range

Not available.

#### Flash point

Not available.

#### Evaporation rate

Not available.

#### Flammability (solid, gas)

Combustible dust.

### Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.

Vapor pressure 1.16 hPa (77 °F (25 °C))

Vapor density Not available.

Relative density Not available.

### Solubility(ies)

Solubility (water) 0.09 g/l (68 °F (20 °C))

Partition coefficient (n-octanol/water) 1.81 as log Pow

Auto-ignition temperature 950 °F (510 °C)

Decomposition temperature Not available.

Viscosity Not available.

### Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

Surface tension 72 mN/m (77 °F (25 °C))

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Keep away from heat, sparks and open flame. Minimize dust generation and accumulation. Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Dust may irritate respiratory system. Prolonged inhalation may be harmful.

**Skin contact** Dust or powder may irritate the skin.

**Eye contact** Causes eye irritation.

**Ingestion** Harmful if swallowed.

**Symptoms related to the physical, chemical and toxicological characteristics** Irritation of eyes. Dusts may irritate the respiratory tract, skin and eyes. Exposed individuals may experience eye tearing, redness, and discomfort.

### Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

Components	Species	Test Results
6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg (male and female)
<b>Inhalation</b>		
LC50	Rat	> 1280 mg/l, 4 h
<b>Oral</b>		
LD50	Female Rat	502 mg/kg

Components	Species	Test Results
	Male Rat	800 mg/kg
	Mouse	> 2000 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Causes eye irritation.	
<b>Eye</b>	6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2) Result: Mild irritation Species: Rabbit	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Buehler test</b>	6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2) Result: Not sensitizing Species: Guinea pig	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Germ cell mutagenicity: Ames test</b>	6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2) Result: Negative	
<b>Germ cell mutagenicity: Micronucleus</b>	6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2) Result: Negative Species: Mouse	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	Not listed.	
<b>NTP Report on Carcinogens</b>	Not listed.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>	Not regulated.	
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not an aspiration hazard.	
<b>Chronic effects</b>	Prolonged inhalation may be harmful.	
<b>12. Ecological information</b>		
<b>Ecotoxicity</b>	Harmful to aquatic life with long lasting effects.	
<b>Components</b>	<b>Species</b>	<b>Test Results</b>
6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	LC50	Oncorhynchus mykiss > 65 mg/l, 96 h
<i>Chronic</i>		
Algae	EC50	Selenastrum capricornutum > 43 mg/l
Crustacea	EC50	Daphnia magna > 76.9 mg/l, 48 h
<b>Persistence and degradability</b>	The product is not readily biodegradable. BOD 132 mg/g / 5 days COD 1,455 mg/g	
<b>Bioaccumulative potential</b>	Not expected to bioaccumulate on the basis of the low octanol-water partition coefficient.	
<b>Partition coefficient n-octanol / water (log Kow)</b>		
Nevirapine	1.81, as log Pow	

**Partition coefficient n-octanol / water (log Kow)**

6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5, Ƴ.89  
1-dihydro-4-methyl- (CAS 129618-40-2)

**Mobility in soil** The product is insoluble or slightly soluble in water. Expected to have low mobility in soil.  
**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

**13. Disposal considerations**

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.  
**Local disposal regulations** Dispose in accordance with all applicable regulations.  
**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.  
**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).  
**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information**

**DOT**  
Not regulated as dangerous goods.  
**IATA**  
Not regulated as dangerous goods.  
**IMDG**  
Not regulated as dangerous goods.  
**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**15. Regulatory information**

**US federal regulations** One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.  
**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**  
Not regulated.  
**CERCLA Hazardous Substance List (40 CFR 302.4)**  
Not listed.  
**SARA 304 Emergency release notification**  
Not regulated.  
**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**  
Not regulated.  
**Superfund Amendments and Reauthorization Act of 1986 (SARA)**  
**SARA 302 Extremely hazardous substance**  
Not listed.  
**SARA 311/312 Hazardous chemical** Yes  
**Classified hazard categories** Combustible dust  
Acute toxicity (any route of exposure)  
Serious eye damage or eye irritation  
**SARA 313 (TRI reporting)**  
Not regulated.  
**Other federal regulations**  
**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**  
Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 06-May-2015**Revision date** 30-May-2018**Version #** 02

**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

**HMIS® ratings** Health: 2  
Flammability: 1  
Physical hazard: 0

**NFPA ratings**

## Disclaimer

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