

1. Identification

Product identifier	Nevirapine
Other means of identification	None.
Recommended use	Active pharmaceutical ingredient.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Boehringer Ingelheim Vetmedica, Inc.
Address	2621 North Belt Hwy St. Joseph, MO 64506-2002
Transportation emergency	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) (866)638-2226
Medical Emergency (24HR):	(866)638-2226
Non-Emergency calls:	(800) 821-7467

2. Hazard(s) identification

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



Signal word	Warning
Hazard statement	Harmful if swallowed. Causes eye irritation. Harmful to aquatic life with long lasting effects. May form combustible dust concentrations in air.
Precautionary statement	
Prevention	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.
Response	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. In case of fire: Use appropriate media to extinguish.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

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

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	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.
Ingestion	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.
Most important symptoms/effects, acute and delayed	Irritation of eyes. Exposed individuals may experience eye tearing, redness, and discomfort. Dusts may irritate the respiratory tract, skin and eyes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
General information	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

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	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.
Environmental precautions	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

Precautions for safe handling	Minimize dust generation and accumulation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	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-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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

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

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m ³	Respirable particles.
		10 mg/m ³	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 (typically 10 air changes per hour) 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 eyewash station.

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.

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

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)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg, (male and female)
<i>Inhalation</i>		
LC50	Rat	> 1280 mg/l, 4 h
<i>Oral</i>		
LD50	Female Rat	502 mg/kg
	Male Rat	800 mg/kg
	Mouse	> 2000 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Causes eye irritation.

Eye

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

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Buehler test

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

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Germ cell mutagenicity: Ames test

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

Germ cell mutagenicity: Micronucleus

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

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

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)		
Aquatic		
<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

Persistence and degradability The product is not readily biodegradable.
BOD 132 mg/g / 5 days
COD 1,455 mg/g

Bioaccumulative potential Not expected to bioaccumulate on the basis of the low octanol-water partition coefficient.

Partition coefficient n-octanol / water (log Kow)

Nevirapine 1.81, as log Pow
6H-Dipyrido[2,3-B:3',2'-E][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl- (CAS 129618-40-2) 3.89

Mobility in soil No data available.

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.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
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

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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
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 -

Version # 01

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



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