

1. Identification

Product identifier	Nevirapine Hemihydrate	
Other means of identification	None.	
Recommended use	Antiviral.	
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)	
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
Environmental hazards	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning	
Hazard statement	Harmful if swallowed. Harmful to aquatic life with long lasting effects.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.	
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.	
Supplemental information	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-,hemihydrate	220988-26-1	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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	Rinse with water. 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	Rash, difficulty in breathing, gastrointestinal discomfort, drowsiness, nausea, vomiting, or diarrhea, paraesthesia (prickling, tingling skin sensation), myalgia, or changes in liver function. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Harmful if swallowed.
Indication of immediate medical attention and special treatment needed	Not for human use. For use in animals only. Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.
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).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides, nitrogen oxides.
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. Take precautionary measures against static discharge. 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	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Collect dust using a vacuum cleaner equipped with HEPA filter. Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Prevent product from entering drains. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling	Minimize dust generation and accumulation. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. 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). Store away from foodstuffs.

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 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

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. 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.

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 Crystalline powder.

Color Off-white.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 476.6 - 480.2 °F (247 - 249 °C)

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Will burn if involved in a fire.

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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	< 100 mg/l
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	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	Direct contact with eyes may cause temporary irritation.
Ingestion	Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Rash, difficulty in breathing, gastrointestinal discomfort, drowsiness, nausea, vomiting, or diarrhea, paraesthesia (prickling, tingling skin sensation), myalgia, or changes in liver function. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Harmful if swallowed.

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-,hemihydrate (CAS 220988-26-1)		

Acute

Oral

LD50	Rat	400 mg/kg
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Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

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

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

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

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.
Further information	U.S. Food and Drug Administration's Pregnancy Category C.

12. Ecological information

Ecotoxicity	Harmful to aquatic life with long lasting effects.
Persistence and degradability	The product is not readily biodegradable. BOD 132 mg O ₂ /g / 5 days COD 1,455 mg O ₂ /g
Bioaccumulative potential	No data available.
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	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** Acute toxicity (any route of exposure)**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.

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	10-July-2015
Revision date	30-April-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



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