

1. Identification

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| 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



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| 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. |

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

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| 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. |
| 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 a 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

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| 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

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| 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

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|---|---|
| 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-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

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

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.

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.

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 |
|------|-----|-----------|

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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| 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

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|--------------------------------------|---|
| 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

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| 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 established.

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 - No
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 10-July-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**Disclaimer**

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