

Viramune® oral suspension

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031199 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Viramune® oral suspension
Synonyms : Active ingredient: Nevirapin <= 5 %
Product code : 000000031199

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated
Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368
Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours
Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Solution for production of finished medicinal products.
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Nevirapine	129618-40-2	<= 5

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SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Keep patient calm, remove to fresh air, seek medical attention.
- In case of skin contact : Wash off thoroughly with ample water.
Seek medical attention.
- In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- If swallowed : Rinse mouth immediately and then drink plenty of water, seek medical attention.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus and chemical-protective clothing.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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- Personal precautions, protective equipment and emergency procedures : Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No hazards which require special first aid measures.
- Advice on safe handling : Ensure thorough ventilation of stores and work areas. Do not open until use.
- Conditions for safe storage : Protect from heat and direct sunlight. Keep container tightly closed. Jointless smooth floor
- Materials to avoid : Keep away from food, drink and animal feedingstuffs. Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Category	Values	Remark
5,6-Dihydro-11-cyclopropyl-4-methyl-6H-dipyrido[3,2-b:2',3'-e][1,4]diazepin-6-one 129618-40-2	ECL		3A	50 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Engineering measures : Local exhaust

Personal protective equipment

- Respiratory protection : Not required; except in case of aerosol formation.
- Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms
- Eye protection : Safety glasses with side-shields

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Skin and body protection	: Laboratory: laboratory coat; factory: disposable Overall.
Protective measures	: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing.
Hygiene measures	: General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: does not ignite
Upper explosion limit	: Not applicable
Lower explosion limit	: Not applicable
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n- octanol/water	: No data available
Auto-ignition temperature	: Not applicable

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Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No data available

Conditions to avoid : No data available

Incompatible materials : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Nevirapine:**

Acute oral toxicity : LD50 (Rat, female): = 502 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1,282 mg/l
Exposure time: 4 h

Acute dermal toxicity : LD50 (Rabbit, male and female): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Nevirapine:**

Species: Rabbit
Exposure time: 24 h

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Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Nevirapine:**

Species: Rabbit

Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Nevirapine:**

Test Type: Buehler test

Species: Guinea pig

Result: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**Nevirapine:**

Genotoxicity in vitro

: Test Type: Ames-test

Species: Salmonella typhimurium

Concentration: 1,7- 500 µg/plate

Result: negative

: Test Type: HGPRT assay

Species: CHO (chinese hamster ovary)

Concentration: 51-816 µg/mL

Result: negative

: Test Type: Cytogenetic assay

Species: CHO (chinese hamster ovary)

Concentration: 100 - 800 µg/plate

Result: negative

Genotoxicity in vivo

: Test Type: Micronucleus test

Species: Mouse

Dose: 2000 mg/kg

Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Nevirapine:**

Remarks: Show carcinogenic effects in animal experiments.

IARC

No component of this product present at levels greater than or

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equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Nevirapine:**

Toxicity to fish : LC50 (Onchorhynchus mykiss): > 65 mg/l
Exposure time: 96 h
Test Type: static test
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 76.9 mg/l
Exposure time: 48 h
Test Type: static test
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (microalgae)): > 43 mg/l
End point: Growth rate

EC50 (Selenastrum capricornutum (green algae)): = 5.2 mg/l
End point: Biomass

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

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Toxicity to bacteria : Remarks: No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Nevirapine:**

Partition coefficient: n-octanol/water : log Pow: 1.81

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 311/312 Hazards : No SARA Hazards

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SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Nevirapine	129618-40-2	5 - 10 %

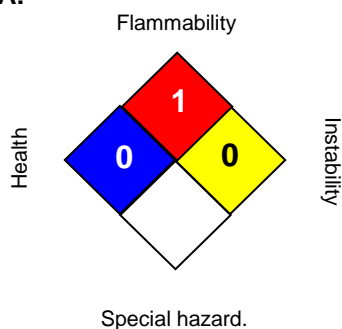
New Jersey Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Nevirapine	129618-40-2	5 - 10 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version.
Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.
Revision Date : 06/03/2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.