

Release : 2.5
 Reviewed on : 12.06.2012
 Replaces the version of : 15.03.2012
 Date of Print : 18.11.2013
 Product : Viramune®, solid (Bulk), <= 25 %

1. Identification of the substance/mixture and of the company/undertaking

Designation : **Viramune®, solid (Bulk), <= 25 %**

Synonyms : Active ingredient: Nevirapine
 Viramune® XR 50 mg tablets, Viramune® XR 100 mg tablets,
 Viramune® XR 400 mg tablets, Viramune® 200 mg tablets

Identified uses : Mixture for production of finished medicinal products.

Company : Boehringer Ing. Pharma GmbH & Co.KG
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Information providing division : Quality & Environmental Health & Safety

Emergency information : (+49) (0)61 32 / 77 23 22 (24 h)

2. Hazards Identification

Classification according to Regulation (EC) No. 1272/2008:

Acute toxicity, Category 4, Oral
 Chronic aquatic toxicity, Category 3,

Classification (67/548/EWG,1999/45/EG):

R20 Harmful by inhalation.
 R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Labelling according Regulation (EC) No 1272/2008 [CLP]:

Pictogram(s)




Warning

Hazard Statement(s):	H302 H412	Harmful if swallowed. Harmful to aquatic life with long lasting effects.
Safety precaution(s):	P280 P260 P273 P301 + P312	Wear protective gloves/ protective clothing/ eye protection/ face protection. Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. Avoid release to the environment. IF SWALLOWED: Call a POISON CENTER or

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P501 doctor/ physician if you feel unwell.
 Dispose of contents/ container to an approved waste disposal plant.

Labelling according to EEC Directive (67/548/EWG,1999/45/EG):

Symbol(s) : **Xn**

 Harmful

R phrase(s) : R20 Harmful by inhalation.
 R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrase(s) : S22 Do not breathe dust.
 S46 If swallowed, seek medical advice immediately and show this container or label.

3. Composition/Information on Ingredients
Hazardous ingredients

Chemical name	Classification	GHS classification	Concentration
5,6-Dihydro-11-cyclopropyl-4-methyl- 6H-dipyrido[3,2-b:2',3'-e][1,4]diazepin-6-one	Xn; R22, R52/53	Category 4, H302 Category 3, H412	<= 25%
Molecular formula:	C15-H14-N4-O	CAS-No.	129618-40-2
Molecular weight:	266,30		

Chemical name	Classification	GHS classification	Concentration
Non-hazardous galenic excipients			>= 75%

4. First-aid Measures

General advice : Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety.

Eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

Skin contact : Wash off thoroughly with ample water. Seek medical attention.

Inhalation : Keep patient calm, remove to fresh air, seek medical attention.

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Ingestion : Rinse mouth immediately and then drink plenty of water, seek medical attention.

Notes to physician

Treatment : Observe the summary of product characteristics of proprietary medicinal products

5. Fire-fighting Measures

Suitable extinguishing media : Use extinguishing measures to suit surroundings., Water, Dry chemical, Foam, carbon dioxide
 Hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes. Can be released in case of fire:, nitrogen oxides, Carbon oxides
 Further information : Collect separately contaminated extinguishing water, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions : Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.
 Environmental precautions : Do not discharge into drains/surface waters/groundwater.
 Methods for cleaning-up or taking-up : For large amounts: Dampen, pick up mechanically and dispose of. Avoid raising dust. For residues: Use approved industrial vacuum cleaner for removal. Pack in tightly closed containers for disposal.
 Additional information : Never return spills in original containers for re-use.

7. Handling and Storage

Handling

Advice on safe handling : Do not open until use. Provide good ventilation of working area (local exhaust ventilation if necessary). Keep away from sources of ignition - No smoking. Protect from moisture.
 Hygienic measures : General safety and hygiene measures. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

Storage

Requirements for storage rooms and vessels : Store in original container. Protect from heat and direct sunlight. Jointless smooth floor Keep container tightly closed.
 Advice on storage compatibility : Keep away from food, drink and animal feedingstuffs. Advice on Segregation
 Storage class according to VCI : 11 Combustible Solids

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8. Exposure controls/personal protections

Exposure controls

Personal protective equipment

Respiratory protection : Use breathing apparatus if exposed to vapours/dust/aerosol. half mask (EN 140) particle filter P2 (EN 143)
 Hand protection : Chemical resistant protective gloves (EN 374)
 Eye protection : Safety glasses with side-shields (frame goggles) (EN 166)
 Body protection : Laboratory: laboratory coat; factory: disposable Overall.
 Additional information : Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
 General protective measures : Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

9. Physical and Chemical Properties

Form : solid
 Colour : white
 Odour : No data available.
 Odour threshold : No data available.
 pH value : No data available.
 Melting point/ -range : No data available.
 Boiling point/boiling range : not applicable
 Flash point : not applicable
 Ignition temperature : No data available.
 Evaporation rate : No data available.
 Flammability : No data available.
 Lower explosion limit : No data available.
 Upper explosion limit : No data available.
 Vapour pressure : not applicable
 Relative vapour density : No data available.
 Relative density : No data available.
 Solubility in water : No data available.
 Partitioning coefficient n-octanol/water (log Pow) : No data available.

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Self-ignition temperature : No data available.
 Thermal decomposition : No data available.
 Viscosity, dynamic : No data available.
 Explosiveness : No data available.
 Fire promoting properties : No data available.
 Peroxides : No data available.

Further information

Minimum ignition energy : No data available.

10. Stability and Reactivity

Conditions to avoid : No data available.
 Substances to avoid : No data available.
 Hazardous decomposition products : No data available.

11. Toxicological Information

Acute oral toxicity : LD50 = 502 mg/kg rat (female)
 The values mentioned are those of the active ingredient.
 LD50 = 800 mg/kg rat (male)
 The values mentioned are those of the active ingredient.

Acute inhalation toxicity : LC50 > 1.282 mg/l Exposition time: 4 h, rat
 The values mentioned are those of the active ingredient.

Acute dermal toxicity : LD50 > 2.000 mg/kg rabbit (male/female)
 The values mentioned are those of the active ingredient.

Skin irritation : Non-irritant (rabbit)
 The values mentioned are those of the active ingredient.

Eye irritation : Mild eye irritation (rabbit)
 The values mentioned are those of the active ingredient.

Sensitization : Buehler test Did not cause sensitization on laboratory animals.
 (guinea pig)
 The values mentioned are those of the active ingredient.

Genetic toxicity in vitro : Ames-test
 Salmonella typhimurium
 Concentration: 1,7- 500 µg/plate
 Result: negative
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HGPRT assay
 CHO (chinese hamster ovary)
 Concentration: 51-816 µg/mL
 Result: negative
 The values mentioned are those of the active ingredient.

Cytogenetic assay
 CHO (chinese hamster ovary)
 Concentration: 100 - 800 µg/plate
 Result: negative
 The values mentioned are those of the active ingredient.

Genetic toxicity in vivo : Micronucleus assay
 mouse
 Dose: 2000 mg/kg
 Result: negative
 The values mentioned are those of the active ingredient.

Carcinogenicity : No data available.

Reproductive toxicity : No data available.

Teratogenicity : No data available.

Aspiration hazard : No data available.

12. Ecological information

Ecotoxicity

Toxicity to fish : LC50 > 65 mg/l (Onchorhynchus mykiss) Exposition time: 96 h
 Method: Directive 67/548/EEC, Annex V, C.1.
 The values mentioned are those of the active ingredient.

Toxicity to daphnia : EC50 > 76,9 mg/l (Daphnia magna) Exposition time: 48 h
 Method: Directive 67/548/EEC, Annex V, C.2.
 The values mentioned are those of the active ingredient.

Toxicity to algae : EC50 (Growth rate) > 43 mg/l (Pseudokirchneriella subcapitata)
 The values mentioned are those of the active ingredient.
 EC50 (Biomass) = 5,2 mg/l (green algae)
 The values mentioned are those of the active ingredient.

Toxicity to bacteria : No data available.

Chronic toxicity to fish : No data available.

Chronic toxicity to aquatic invertebrates : No data available.

Persistence and degradability

Biological degradation : Not easily biodegradable (by OECD criteria).
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Transport between environmental compartments : No data available.
Bioaccumulation : No data available.
PBT and vPvB assessment : No data available.

13. Disposal Considerations

Product : 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.

14. Transport Information

Further information : Not classified as dangerous in the meaning of transport regulations. For the internal transport: Use only released containers. Use only tightly closed containers. The container must be correctly labelled. Protect container against fall down.

15. Regulatory information

National legislation/regulations

Water hazard class : VVWWS
WGK 2 water endangering
Annex 4 VwVwS (Germany) dated Mai, 17 th 1999

16. Other particulars

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.
