

1. Identification

Product identifier	Nevirapine Oral Suspension
Other means of identification	None.
Recommended use	For use in combination with other antiretroviral agents for the treatment of HIV-1 infection.
Recommended restrictions	None known.

Manufacturer/Importer/Supplier/Distributor information

Company name	Boehringer Ingelheim Roxane Inc.
Address	1809 Wilson Road Columbus, Ohio 43228
Telephone	(614) 276-4000
Emergency phone number	(614) 276-4000

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F).
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
Nevirapine		129618-40-2	50mg/5mL

Composition comments	Refer to Physician's Desk Reference for common components present at <1%
-----------------------------	--

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Rash.

Indication of immediate medical attention and special treatment needed	No specific antidote known. Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

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.
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.
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. Wear appropriate personal protective equipment. Ensure adequate ventilation.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store at 20 – 25 °C (68 - 77°F). Keep away from heat. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ventilation should be matched to conditions.
Individual protection measures, such as personal protective equipment	
Eye/face protection	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
Skin protection	
Hand protection	For consumer use, no unusual precautions are necessary.
Other	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
Respiratory protection	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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	Liquid.
Form	Suspension.
Color	White to off-white.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

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)	Moderately soluble
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	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides, Nitrogen oxides

11. Toxicological information**Information on likely routes of exposure**

Inhalation	Not expected to be hazardous in final pharmaceutical form.
Skin contact	Not expected to be hazardous in final pharmaceutical form.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.
Ingestion	Not expected to be hazardous in final pharmaceutical form. Ingestion may cause irritation and malaise.

Symptoms related to the physical, chemical and toxicological characteristics Rash.

Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities.

Components	Species	Test Results
Nevirapine (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 This product is not expected to be a skin hazard.

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

Eye

Nevirapine (CAS 129618-40-2) Result: Mild irritation
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization This product is not expected to cause respiratory sensitization.

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

Buehler test

Nevirapine (CAS 129618-40-2) Result: Not sensitizing
Species: Guinea pig

Germ cell mutagenicity No data available, but none expected.

Germ cell mutagenicity: Ames test

Nevirapine (CAS 129618-40-2) Result: Negative

Germ cell mutagenicity: Micronucleus

Nevirapine (CAS 129618-40-2) Result: Negative
Species: Mouse

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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Pregnancy Category B

There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

This product passes into breast milk. Breast-feeding is not advised in mothers being treated.

Specific target organ toxicity - single exposure No data available.

Specific target organ toxicity - repeated exposure No data available.

Aspiration hazard Not classified.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous.

Components	Species	Test Results
Nevirapine (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 No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Nevirapine (CAS 129618-40-2) 3.89

Mobility in soil Expected to be slightly to moderately mobile in soil.

Other adverse effects None.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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 This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

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 - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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.

Not listed.

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 25-April-2015
Revision date -
Version # 01

References

- 1) Nevirapine Oral Suspension, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio.
- 2) PDR – Physicians Desk Reference.
- 3) Ariel Websight. Regulatory and ChemExpert Database.

Disclaimer

Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.