



MATERIAL SAFETY DATA SHEET

Revision date: 15-Sep-2009

Version: 1.4

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Viracept® (Nelfinavir Mesylate) Tablets, 250 and 625 mg

Trade Name: Viracept
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as HIV protease inhibitor

2. HAZARDS IDENTIFICATION

Appearance: Clear film coated, light blue, capsule shaped, tablets - 250 mg Clear film coated, white to off white oval shaped tablets - 625 mg

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Dust may cause irritation . Active ingredient is not a skin sensitizer . Not acutely toxic (based on animal data) .

Known Clinical Effects: Diarrhea is the most common side effect seen during clinical use.
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Nelfinavir Mesylate	159989-65-8	Not listed	Not Listed	47% / 61% (250/625 mg)
Calcium Silicate	1344-95-2	215-710-8	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Opadry clear	NOT ASSIGNED	Not listed	Not Listed	*
Crospovidone	9003-39-8	Not listed	Not Listed	*
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	*
Purified water	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Nelfinavir Mesylate

Pfizer OEL TWA-8 Hr: 3000µg/m³

Calcium Silicate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Estonia OEL - TWA Listed
Greece OEL - TWA Listed
Ireland OEL - TWAs Listed
OSHA - Final PELs - TWAs: 15 mg/m³ total
5 mg/m³
Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Colloidal silicon dioxide

Australia TWA 2 mg/m³
Austria OEL - MAKs Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³ MAK
Ireland OEL - TWAs Listed
Latvia OEL - TWA Listed
OSHA - Final PELs - Table Z-3 Mineral D: - (80)/(% SiO₂) mg/m³ TWA
TWA-20 mppcf
Slovenia OEL - TWA Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Ireland OEL - TWAs Listed
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs Listed

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method:	Analytical method available for Nelfinavir Mesylate. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	Light blue, White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Polymerization:	Will not occur		

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
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Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Nelfinavir Mesylate

Rat Oral LD50 > 1000 mg/kg
Mouse Oral LD50 > 1000 mg/kg
Rat Dermal LD50 > 2000 mg/kg

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FD&C Blue No. 2

Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Nelfinavir Mesylate

Skin Sensitization - Beuhler Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Nelfinavir Mesylate

26 Week(s) Rat Oral 1000 mg/kg/day LOAEL Liver
26 Week(s) Monkey Oral 250 mg/kg/day LOAEL Gastrointestinal system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nelfinavir Mesylate

Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 1000 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Nelfinavir Mesylate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

FD&C Blue No. 2

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nelfinavir Mesylate

2 Year(s) Rat Oral 300 mg/kg/day LOAEL Thyroid, neoplasms
2 Year(s) Mouse Oral 1000 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Crospovidone

IARC: Group 3

Colloidal silicon dioxide

IARC: Group 3

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Nelfinavir Mesylate

**Standard for the Uniform Scheduling
for Drugs and Poisons:** Schedule 4

Calcium Silicate

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 215-710-8

Crospovidone

Inventory - United States TSCA - Sect. 8(b) Listed

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15. REGULATORY INFORMATION

Australia (AICS):	Listed
Colloidal silicon dioxide	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4
FD&C Blue No. 2	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	212-728-8
Purified water	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet