



# MATERIAL SAFETY DATA SHEET

Revision date: 22-Sep-2009

Version: 1.4

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
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New York, New York 10017  
1-212-573-2222

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd  
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Sandwich, Kent  
CT13 9NJ  
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Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Viracept® (Nelfinavir Mesylate) Oral Powder, 50 mg/g**

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** White to off-white powder

**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 irritant . 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     | 5.85 |
| Microcrystalline cellulose | 9004-34-6   | 232-674-9             | Not Listed     | *    |

| Ingredient                  | CAS Number | EU EINECS/ELINCS List | Classification | % |
|-----------------------------|------------|-----------------------|----------------|---|
| Dibasic Potassium Phosphate | 7758-11-4  | 231-834-5             | Not Listed     | * |
| Sucrose Palmitate           | 26446-38-8 | 247-706-7             | Not Listed     | * |

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|                 |              |            |            |   |
|-----------------|--------------|------------|------------|---|
| Prosweet Powder | NOT ASSIGNED | Not listed | Not Listed | * |
| Maltodextrin    | 9050-36-6    | 232-940-4  | Not Listed | * |
| Aspartame       | 22839-47-0   | 245-261-3  | Not Listed | * |
| Crospovidone    | 9003-39-8    | Not listed | Not Listed | * |
| Hypromellose    | 9004-65-3    | Not listed | 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:** Emits fumes of carbon monoxide, nitrogen oxides, and sulphur dioxide.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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. Avoid breathing dust, vapor or mist. 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.

|                                   |                            |
|-----------------------------------|----------------------------|
| <b>Nelfinavir Mesylate</b>        |                            |
| Pfizer OEL TWA-8 Hr:              | 3000µg/m <sup>3</sup>      |
| <b>Microcrystalline cellulose</b> |                            |
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup> TWA   |
| Australia TWA                     | 10 mg/m <sup>3</sup>       |
| Belgium OEL - TWA                 | Listed                     |
| Estonia OEL - TWA                 | Listed                     |
| France OEL - TWA                  | Listed                     |
| Ireland OEL - TWAs                | Listed                     |
| Latvia OEL - TWA                  | Listed                     |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup> total |
|                                   | 5 mg/m <sup>3</sup>        |
| Portugal OEL - TWA                | Listed                     |
| Romania OEL - TWA                 | Listed                     |
| Spain OEL - TWA                   | Listed                     |

**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:** 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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder  
Molecular Formula: Mixture  
Color: White to off-white  
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: None known

### 11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Nelfinavir Mesylate

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

##### Hypromellose

Rat Oral LD50 > 10,000 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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### 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))

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### 11. TOXICOLOGICAL INFORMATION

#### **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

#### **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

### 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

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## 15. REGULATORY INFORMATION

### 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

#### Dibasic Potassium Phosphate

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

Listed  
Listed  
231-834-5

#### Sucrose Palmitate

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

Listed  
Listed  
247-706-7

#### Maltodextrin

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
REACH - Annex IV - Exemptions from the  
obligations of Register:  
EU EINECS/ELINCS List

Listed  
Listed  
Present  
232-940-4

#### Aspartame

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

Listed  
Listed  
245-261-3

#### Crospovidone

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

Listed  
Listed

#### Hypromellose

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
Standard for the Uniform Scheduling  
for Drugs and Poisons:

Listed  
Listed  
Schedule 4

#### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

Listed  
Listed

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 232-674-9

#### Purified water

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

Australia (AICS): Listed

REACH - Annex IV - Exemptions from the Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

### 16. OTHER INFORMATION

**Data Sources:** Pfizer proprietary drug development 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 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**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**