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

Product Identifier

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

Trade Name: Viracept
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as HIV protease inhibitor

Details of the Supplier of the Safety Data Sheet

ViiV Healthcare
Five Moore Drive
Research Triangle Park
North Carolina 27709-3398
+1 877 ViiVUSA (+1 877 844 8872)

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspartame</td>
<td>22839-47-0</td>
<td>245-261-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Dibasic Potassium Phosphate</td>
<td>7758-11-4</td>
<td>231-834-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Maltodextrin</td>
<td>9050-36-6</td>
<td>232-940-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose Palmitate</td>
<td>26446-38-8</td>
<td>247-706-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavors</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Emits fumes of carbon monoxide, nitrogen oxides, and sulphur dioxide.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

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.

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.

7. HANDLING AND STORAGE

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Incompatible Materials: None known
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Ireland OEL - TWAs 4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
Vietnam OEL - TWAs 5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Nelfinavir Mesylate
Pfizer OEL TWA-8 Hr: 3000µg/m³

Exposure Controls
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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Powder</th>
<th>Color:</th>
<th>White to off-white</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sucrose Palmitate
No data available

Dibasic Potassium Phosphate
No data available

Aspartame
No data available

Crospovidone
No data available

Maltodextrin
No data available

Microcrystalline cellulose
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Nelfinavir Mesylate
Predicted  N/A  Log D  4.07
Hydroxypropyl methylcellulose
No data available
Flavors
No data available
Decomposition Temperature (°C):  No data available.
Evaporation Rate (Gram/s):  No data available
Vapor Pressure (kPa):  No data available
Vapor Density (g/ml):  No data available
Relative Density:  No data available
Viscosity:  No data available
Flammability:
Autoignition Temperature (Solid) (°C):  No data available
Flammability (Solids):  No data available
Flash Point (Liquid) (°C):  No data available
Upper Explosive Limits (Liquid) (% by Vol.):  No data available
Lower Explosive Limits (Liquid) (% by Vol.):  No data available
Polymerization:  Will not occur

10. STABILITY AND REACTIVITY

Reactivity:  No data available
Chemical Stability:  Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties:  No data available
Conditions to Avoid:  Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:  None known
Hazardous Decomposition Products:  No data available

11. TOXICOLOGICAL INFORMATION

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

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

Dibasic Potassium Phosphate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 0.83mg/L
Rabbit  Dermal  LD50  > 5000mg/kg

Microcrystalline cellulose
Rat  Oral  LD50  > 5000 mg/kg
11. TOXICOLOGICAL INFORMATION

Rabbit Dermal LD50 > 2000 mg/kg

Nelfinavir Mesylate

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 1000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>&gt; 1000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Dermal</td>
<td>&gt; 2000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Hydroxypropyl methylcellulose

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 10,000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

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

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
</tr>
</tbody>
</table>

Nelfinavir Mesylate

Skin Sensitization - Beuhler Guinea Pig Negative

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

Nelfinavir Mesylate

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>LOAEL</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>1000 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>26 Week(s)</td>
<td>Monkey</td>
<td>Oral</td>
<td>250 mg/kg/day</td>
<td>LOAEL</td>
<td>Gastrointestinal system</td>
</tr>
</tbody>
</table>

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

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

Nelfinavir Mesylate

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>LOAEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>300 mg/kg/day</td>
<td>LOAEL</td>
<td>Thyroid, neoplasms</td>
</tr>
<tr>
<td>2 Year(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>1000 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>

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

Crosopovidone

<table>
<thead>
<tr>
<th>IARC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 3 (Not Classifiable)</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Partition Coefficient: (Method, pH, Endpoint, Value)

Nelfinavir Mesylate
Predicted N/A Log D 4.07

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Aspartame
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>245-261-3</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Dibasic Potassium Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-834-5</td>
</tr>
<tr>
<td>Maltodextrin</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-674-9</td>
</tr>
<tr>
<td>Nelfinavir Mesylate</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

Sucrose Palmitate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 247-706-7

Flavors
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Revision date: 03-Nov-2016

Prepared by: Product Stewardship Hazard Communication

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