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

**Material Name:** Delavirdine Mesylate Tablets

- **Trade Name:** Rescriptor
- **Chemical Family:** Mixture
- **Intended Use:** Pharmaceutical product used as antiviral

2. HAZARDS IDENTIFICATION

**Appearance:** White tablets

**Signal Word:** WARNING

**Statement of Hazard:** May cause eye and skin irritation. Possible risk of harm to the unborn child.

**Additional Hazard Information:**

**Short Term:** May cause eye and skin irritation (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on heart, gastrointestinal system, endocrine system, bone marrow and lymphatic system.

**Known Clinical Effects:** The most common side effect seen in people taking delavirdine mesylate is skin rash, which may be severe. Other commonly reported adverse effects include headache, nausea, and weakness/fatigue.

**EU Indication of danger:** Irritant

**EU Hazard Symbols:**

- Xn

**EU Risk Phrases:**

- R36 - Irritating to eyes.
- R63 - Possible risk of harm to the unborn child.

**Australian Hazard Classification (NOHSC):**

2. HAZARDS IDENTIFICATION

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>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Delavirdine mesylate</td>
<td>147221-93-0</td>
<td>Not listed</td>
<td>Repr. Cat.3;R63 Xi;R36</td>
<td>29.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry white</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</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.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

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

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Belgium OEL - TWA</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>Listed</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³ total</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>Listed</td>
</tr>
</tbody>
</table>

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

Delavirdine mesylate
- Pfizer OEL TWA-8 Hr: 2000µg/m³

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


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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>White</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

DELAVIDRINE TABLETS
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.

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

Delavirdine mesylate
Rat Oral LD50 > 5000 mg/kg

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

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

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)

Delavirdine mesylate
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Irritant

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Delavirdine mesylate
1 Month(s) Dog Oral 50 mg/kg/day LOAEL Gastrointestinal System, Blood, Blood forming organs, Heart
3 Month(s) Rat Oral 50 mg/kg/day LOAEL Blood Thyroid Liver
3 Month(s) Dog Oral 12 mg/kg/day LOAEL Heart Blood Bone Marrow Gastrointestinal system Lungs
6 Month(s) Rat Oral 5 mg/kg/day NOAEL Blood Blood forming organs Liver Heart Endocrine system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Delavirdine mesylate
Reproductive & Fertility Rat Oral 20 mg/kg/day NOEL Maternal toxicity, Paternal toxicity
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOEL Maternal Toxicity, Fetotoxicity, Teratogenic
Embryo / Fetal Development Rabbit Oral 100 mg/kg/day NOEL Embryotoxicity, Maternal Toxicity
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOEL Maternal Toxicity, Developmental toxicity
11. TOXICOLOGICAL INFORMATION

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

Delavirdine mesylate
Bacterial Mutagenicity (Ames) Salmonella Negative
In Vitro Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vitro Unscheduled DNA Synthesis Rat Hepatocyte Negative
In Vivo Micronucleus Mouse Negative

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

Delavirdine mesylate
24 Month(s) Mouse Oral 62.5 mg/kg/day LOAEL Tumors, Liver
104 Week(s) Rat Oral 100 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. See below

Colloidal silicon dioxide
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 Symbol: Xn
EU Indication of danger: Irritant
Toxic to Reproduction: Category 3

EU Risk Phrases:
15. REGULATORY INFORMATION

**R36** - Irritating to eyes.
**R63** - Possible risk of harm to the unborn child.

**EU Safety Phrases:**
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37 - Wear suitable protective clothing and gloves.

**OSHA Label:**
WARNING
May cause eye and skin irritation.
Possible risk of harm to the unborn child.

**Canada - WHMIS: Classifications**
**WHMIS hazard class:**
Class D, Division 2, Subdivision A

**Hypermelllose**
- Inventory - United States TSCA - Sect. 8(b)
  - Listed
- Australia (AICS):
  - Listed
- Standard for the Uniform Scheduling for Drugs and Poisons:
  - Schedule 4

**Carnauba wax**
- Inventory - United States TSCA - Sect. 8(b)
  - Listed
- Australia (AICS):
  - Listed
- EU EINECS/ELINCS List
  - 232-399-4

**Lactose NF, monohydrate**
- Australia (AICS):
  - Listed

**Colloidal silicon dioxide**
- Inventory - United States TSCA - Sect. 8(b)
  - Listed
- Australia (AICS):
  - Listed
- EU EINECS/ELINCS List
  - 231-545-4

**Crocarmellose sodium**
- Australia (AICS):
  - Listed

**Microcrystalline cellulose**
- Inventory - United States TSCA - Sect. 8(b)
  - Listed
- Australia (AICS):
  - Listed
- EU EINECS/ELINCS List
  - 232-674-9

**Magnesium stearate**
- Inventory - United States TSCA - Sect. 8(b)
  - Listed
- Australia (AICS):
  - Listed
15. REGULATORY INFORMATION

EU EINECS/ELINCS List

209-150-3

Delavirdine mesylate
Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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. 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