



MATERIAL SAFETY DATA SHEET

Revision date: 11-Sep-2009

Version: 1.2

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
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
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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
Toxic to Reproduction: Category 3

EU Hazard Symbols:

Xn



EU Risk Phrases:

R36 - Irritating to eyes.
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Delavirdine mesylate	147221-93-0	Not listed	Repr. Cat.3;R63 Xi;R36	29.3

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

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.

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

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
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.

Analytical Method:	Analytical method available for delarvirdine 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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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

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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:

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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



Hypromellose

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
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Colloidal silicon dioxide

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

Croscarmellose sodium

Australia (AICS):	Listed
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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

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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