



MATERIAL SAFETY DATA SHEET

Revision date: 21-Aug-2006

Version: 1.2

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

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Material Name: Capravirine Film-Coated Tablets 400 mg and 700 mg

Trade Name: Not determined
Chemical Family: Not determined
Intended Use: inhibitor for HIV

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Capravirine	178979-85-6	Not listed	72.4
Croscarmellose sodium	74811-65-7	Not listed	*
Corn Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Mannitol	69-65-8	200-711-8	*
Povidone	9003-39-8	Not listed	*
Opadry II white	NOT ASSIGNED	Not listed	*
Opadry clear	NOT ASSIGNED	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: White to off-white oval biconvex film-coated tablet
Signal Word: CAUTION

Statement of Hazard: Dangerous for the environment
Eye Contact: Not expected to cause eye irritation.
Skin Contact: Not expected to cause skin irritation. Dust may be absorbed through the skin and cause systemic effects.
Inhalation: Not expected to cause respiratory irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. See 'Known clinical effects' and 'Other potential health effects', below.
Known Clinical Effects: Effects reported during clinical use included vomiting and diarrhea.

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Potential Health Effects: Repeat-dose studies in animals have shown a potential to cause adverse effects on the vascular and gastrointestinal systems.

EU Indication of danger: Dangerous for the Environment

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Nitrogen oxides, carbon monoxide, sulphur dioxide, and hydrogen chloride

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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

Additional Information: High concentrations of airborne dust may form combustible mixtures.

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: Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.

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: Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust. Transfer all waste to a labeled container and move it to a secure holding area. Prevent discharge to drains.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

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7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store in a cool, dry, well-ventilated area. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Capravirine

Pfizer OEL TWA-8 Hr: 0.4 mg/m³, Skin

Corn Starch

OSHA - Final PELs - TWAs: 15 mg/m³ total dust
5 mg/m³ respirable fraction

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

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. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Rubber gloves

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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: Film-coated tablets

Molecular Formula: Mixture

Color: White to off-white

Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: None known

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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General Information:	There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient.
Carcinogenicity:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
<u>Acute Toxicity: (Species, Route, End Point, Dose)</u>	
Mannitol	
Rat Oral LD50	13500 mg/kg
Mouse Oral LD50	22 g/kg
Magnesium stearate	
Rat Oral LD50	> 2000 mg/kg
Rat Inhalation LC50	> 2000 mg/m ³
Povidone	
Rat Oral LD50	100 g/kg
Capravirine	
Rat Oral LD50	> 2000 mg/kg
Dog Oral LD50	> 500 mg/kg
Rabbit Dermal LD50	> 2000 mg/kg
Inhalation Acute Toxicity	Not expected to cause respiratory tract irritation
Ingestion Acute Toxicity	See Acute toxicity table
Eye Irritation / Sensitization	Not expected to cause eye irritation
Skin Irritation / Sensitization	Not a sensitizer in experimental animals Not expected to cause skin irritation.
Subchronic Effects	Studies of varying length (2-26 weeks) in dogs resulted in emesis and liver enzyme induction. No serious toxicity was observed in rats.
Chronic Toxicity	Twelve-month studies in dogs resulted in a dose related elevation of liver enzymes and emesis at all dose levels. Emesis was severe enough at 150 and 300 mg/kg/day that several animals were sacrificed. Vasculitis (an inflammation of the blood vessels) and amyloidosis were seen at dose levels of 120, 150, and 300 mg/kg/day.
Reproductive Effects	A dose of 1000 mg/kg/day produced a slight estrous cycle disturbance in female rats. No other effects were observed in either rats or rabbits.
Teratogenicity	Capravirine did not cause any adverse reproductive effects in rats or rabbits except at doses greater than those which caused maternal toxicity.
Mutagenicity	Not mutagenic in bacterial cells Not clastogenic in mammalian cells.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Povidone	
IARC:	Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:	Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.
Mobility, Persistence and Degradability:	The active ingredient in this formulation is water soluble and is expected to remain primarily in water
Bioaccumulation and Toxicity:	High acute toxicity to aquatic organisms is expected. See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

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Capravirine

Daphnia magna EC50/1.25 h 3.54

Mysid Shrimp LC50/48h (NPDES) 2.24

Red Algae IC50 (7 days) 0.18

Skeletonema Algae IC50/96h (NPDES) 0.4

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

** This material is regulated for transportation as a hazardous material/dangerous good when shipped in bulk (all modes) or non-bulk (water only)

Proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (tetra-substituted imidazole) Marine Pollutant

UN / ID No: UN 3077

Hazard class: 9

Packing group: III

IATA Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (tetra-substituted imidazole) Marine Pollutant **

IATA UN / ID No: UN 3077

IATA Hazard Class: 9

IATA Packing Group: III

IMDG Technical Shipping Name: Environmentally hazardous substance, solid, n.o.s. (tetra-substituted imidazole) Marine Pollutant **

IMDG UN / ID No: UN3077

IMDG Hazard Class: 9

IMDG Packing Group: III

ADR/RID Technical Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetra-substituted imidazole) Marine Pollutant **

ADR / RID Hazard Class: 9

ADR / RID Packing Group: III

ADR / RID Item Number: UN 3077

DOT Technical Shipping Name: Environmentally Hazardous Substance, Solid, n.o.s (tetra-substituted imidazole) Marine Pollutant **

DOT UN / ID No: UN 3077

DOT Hazard Class: 9

DOT Packing Group: III

15. REGULATORY INFORMATION

EU Symbol: N

EU Indication of danger: Dangerous for the Environment

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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EU Safety Phrases:

S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:

CAUTION

Dangerous for the environment

Canada - WHMIS: Classifications

WHMIS hazard class:

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.

Mannitol

EU EINECS List	200-711-8
Inventory - United States TSCA - Sect. 8(b)	Listed

Povidone

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

EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet