



# MATERIAL SAFETY DATA SHEET

Revision date: 21-Aug-2006

Version: 1.4

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

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ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Capravirine Tablets 200 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	%
Purified water	7732-18-5	231-791-2	*
Mannitol	69-65-8	200-711-8	*
Povidone	9003-39-8	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 scored tablets  
**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/m<sup>3</sup>, Skin

#### Corn Starch

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup> total dust  
5 mg/m<sup>3</sup> respirable fraction

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> TWA

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> 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:

<b>Physical State:</b>	Tablet	<b>Color:</b>	White to off-white
<b>Odor:</b>	Odorless	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	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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<b>General Information:</b>	There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient.
<b>Carcinogenicity:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
<b><u>Acute Toxicity: (Species, Route, End Point, Dose)</u></b>	
<b>Mannitol</b>	
Rat Oral LD 50	13500 mg/kg
Mouse Oral LD 50	22 g/kg
<b>Povidone</b>	
Rat Oral LD50	100 g/kg
<b>Magnesium stearate</b>	
Rat Oral LD50	> 2000 mg/kg
Rat Inhalation LC50	> 2000 mg/m <sup>3</sup>
<b>Capravirine</b>	
Rat Oral LD50	> 2000 mg/kg
Dog Oral LD50	> 500 mg/kg
Rabbit Dermal LD50	> 2000 mg/kg
<b>Inhalation Acute Toxicity</b>	Not expected to cause respiratory tract irritation
<b>Ingestion Acute Toxicity</b>	See Acute toxicity table
<b>Eye Irritation / Sensitization</b>	Not expected to cause eye irritation
<b>Skin Irritation / Sensitization</b>	Not a sensitizer in experimental animals Not expected to cause skin irritation.
<b>Subchronic Effects</b>	Studies of varying length (2-26 weeks) in dogs resulted in emesis and liver enzyme induction. No serious toxicity was observed in rats.
<b>Chronic Toxicity</b>	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.
<b>Reproductive Effects</b>	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.
<b>Teratogenicity</b>	Capravirine did not cause any adverse reproductive effects in rats or rabbits except at doses greater than those which caused maternal toxicity.
<b>Mutagenicity</b>	Not mutagenic in bacterial cells Not clastogenic in mammalian cells.
<b>Carcinogen Status:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
<b>Povidone</b>	
<b>IARC:</b>	Group 3

## 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.
<b>Mobility, Persistence and Degradability:</b>	The active ingredient in this formulation is water soluble and is expected to remain primarily in water
<b>Bioaccumulation and Toxicity:</b>	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.

**EU Safety Phrases:**

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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.

### Purified water

EU EINECS List	231-791-2
Inventory - United States TSCA - Sect. 8(b)	Listed

### 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**