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	SAFETY DATA SHEET (SDS)	
Product Name	Oseltamivir Phosphate for Oral Suspension, Eq. 6 mg base/ mL	

1. Product Information

Product Name: **Oseltamivir Phosphate for Oral Suspension, Eq. 6 mg base/ mL**

2. Composition

Oseltamivir Phosphate: About 4%

3. Hazards Identification

Form Granular powder

Color white

Hazard Overview - May cause allergic reactions.
- Possible dust explosion hazard based on information on related materials

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: eye, skin, gastrointestinal system, Immune System

- Acute Effects: May cause eye irritation., May cause skin irritation., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

- Chronic Effects: May cause allergic reactions.

- Carcinogenicity: formulation not listed by NTP, IARC or OSHA
- Carcinogenicity: IARC Gr3 not classifiable

*1 referring to: Titanium dioxide

*1

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4. First Aid Measures

General advice	:	Move out of dangerous area. Show this material safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. Rinse mouth with water.
Most important symptoms: and effects, both acute and delayed		May cause genetic defects. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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5. Fire Fighting Measures

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from firefighting to enter drains or water courses.
Hazardous products	combustion :	Carbon oxides In case of fire hazardous decomposition products may be produced such as: Carbon monoxide Ammonia Nitrogen oxides (NOx) Gaseous hydrogen chloride (HCl).
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

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.

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7. Handling and Storage

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. Exposure Controls/Personal Protection

Control Parameters

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

Oseltamivir Phosphate:
IOEL : 0.2 mg/m³ (for Oseltamivir Phosphate)
NIOSH-REL: 0.2 mg/m³ (for Titanium Dioxide)

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).

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.

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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: Powder
Odor: No data available

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: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
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

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

Oseltamivir Phosphate

MNLD 100 mg/kg (iv mouse)

MNLD >2000 mg/kg (oral rat)

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.

Mutagenicity: Not Mutagenic

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12. Ecological Information

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

Toxicity:

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

moderately toxic for algae (*Selenastrum capricornutum*)

Mobility in Soil: moderate to strong adsorption (water-activated sludge, 28 d, ~22 °C)

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

International Regulations

Not applicable

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15. Regulatory Information

- Reporting Requirements**
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
 - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
 - State and local regulations vary and may impose additional reporting requirements

16. Other Information

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554

MSN Pharmaceutical 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.

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End Of Safety Data Sheet