



MATERIAL SAFETY DATA SHEET

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1. Product Information

Product Name: OSELTAMIVIR PHOSPHATE CAPSULES USP 30 mg, 45 mg AND 75 mg

2. Composition/Information on Ingredients

C.A.S. No:

: 204225-11-8

Molecular Formula

 $: C_{16}H_{28}N_2O_4 \bullet H_3 PO_4$

Formula Weight

: 410.4

Chemical Name

: 4R-(acetylamino)-5S-amino-3R-(1-ethylpropoxy)-ethyl ester-1-cyclohexene-

1-carboxylicacid, phosphate.

3. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients

Moderate to severe irritant to the skin and eyes.

4. First Aid Measures

After Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

After skin contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

After eye contact: check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

After swallowing: if swallowed, wash out mouth with copious amounts of water; call a physician.

5. Emergency Overview

Major Health Hazards: No major health hazards are known.

6. Fire Fighting Measures

Suitable extinguishing agents: water spray, carbon dioxide, dry chemical powder or foam

Protective equipment: wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Unusual fire hazard: emits toxic fumes such as carbon monoxide, etc.



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7. Accidental Release Measures

Person-related safety precautions: cordon off area of spill; wear self-contained breathing apparatus, protective clothing and heavy rubber gloves

Measures for cleaning/collecting:absorb solutions with finely- powdered liquid-binding material (diatomite, universal binders); decontaminate surfaces and equipment by scrubbing with alcohol; dispose of contaminated material according to Section 13.

8. 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. Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

9. Exposure Controls/Personal Protection

Personal protective equipment as follows:

- Breathing equipment: NIOSH/MSHA-approved respirator
- Protection of hands: chemical-resistant rubber gloves
- Eye protection: chemical safety goggles

10. Physical and Chemical Properties

Appearance:

30 mg: Size"4" hard gelatin capsules with light yellow opaque colour body with black colour band, imprinted with "M" and light yellow opaque colour cap imprinted with "30 mg".

45 mg: Size"4" hard gelatin capsules with grey opaque colour body with black colour band, imprinted with "M" and grey opaque colour cap imprinted with "45 mg".

75 mg: Size"2" hard gelatin capsules with grey opaque colour body with black colour band, imprinted with "M" and light yellow opaque colour cap imprinted with "75 mg".

11. Stability and Reactivity

Stability: Stable under normal conditions of use.





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Conditions to Avoid: NO data available.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

12. Toxicological Information

Acute toxicity: none known

Primary irritant effect:not known

On the skin:none known

On the eye:not known; may be an irritant

13. Disposal Considerations

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 waste water.

14. Transport Information

IATA: This substance is considered to be non-hazardous for transport. DOT: This substance is considered to be non-hazardous for transport.

15. Regulatory Information

Indication of danger: No data

Risk Statement: No data

Safety Statement: In case of contact with eyes, rinse immediately with plenty of water and seek medical

advice. Wear suitable gloves and eye/face protection.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

