

SAFETY DATA SHEET

Oseltamivir Phosphate for Oral Suspension 6 mg/mL

EMERGENCY OVERVIEW

Oseltamivir Phosphate for Oral Suspension contains active drug substances Oseltamivir Phosphate and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

- Product name** : Oseltamivir Phosphate for Oral suspension 6 mg/mL
- Chemical Formula** : Oseltamivir Phosphate : C₁₆H₂₈N₂O₄
- Chemical Name** : **Oseltamivir Phosphate:** (3R, 4R, 5S)-4-acetylamino-5-amino-3(1-ethylpropoxy)-1-cyclohexene-1-carboxylic acid, ethyl ester, phosphate (1:1).
- Therapeutic Category** : Antiviral.
- Marketed by** : **Ajanta Pharma USA Inc.**
440 US Highway 22 East, Bridgewater, NJ 08807.
Made in India
- Contact Information** : 1-855-664-7744

Section 2. Hazard (s) Identification

- Potential Health Effects** :
- Inhalation:** Not expected to be hazardous in final pharmaceutical form.
 - Eye Contact:** Not expected to be hazardous in final pharmaceutical form.
 - Skin Contact:** Not expected to be hazardous in final pharmaceutical form.
 - Indigestion:** Health injuries are not known or expected under normal use. Exposures above clinical dosage could

result in adverse effects. Minor occupational exposures are not expected to be harmful.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Oseltamivir Phosphate, USP	Not Found	204255-11-8

Inactive ingredients: Trisodium citrate, saccharin sodium, sodium benzoate, sorbitol, titanium dioxide, tutti-frutti flavoring, and xanthan gum.

Section 4. First-aid measures

General : **Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Never give anything by mouth to an unconscious person.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: 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.

Overdose Treatment : Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice

Section 5. Fire-fighting measures

Flash Point : Not Reported

Extinguishing Media : Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

- Fire and Explosion Hazard** : This material is assumed to be combustible. Keep it away from the open fires.
- Fire Fighting Procedures** : As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.
- Hazardous Combustion by Products** : Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride

Section 6. Accidental release measures

- Personal Precautions** : Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Environmental Protections** : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Clean-up Methods** : Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
- 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.

Section 7. Handling and storage

- General Handling** : Minimize dust generation and accumulation. Avoid breathing dust and avoid contact to eyes, skin and clothing. When handling, use appropriate personal protective equipment.
- Storage** : Store dry powder at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
- Store constituted oral suspension under refrigeration for up to 17 days at 2°C to 8°C (36°F to 46°F). Do not freeze. Alternatively, store constituted oral suspension for up to 10 days at 25°C (77°F); excursions permitted to 15°C to

30°C (59°F to 86°F) [See USP Controlled Room Temperature].

Section 8. Exposure controls / personal protection

- Respiratory Protection** : Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
- Skin Protection** : Skin protection is not normally necessary, however it is good practice to avoid direct contact with chemical to use suitable gloves when handling.
- Eye protection** : Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
- Protective Clothing** : Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties
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- Appearance** : White to yellow powder blend in a glass bottle with a child-resistant closure.

After constitution, the powder blend produces a white to yellow tutti-frutti-flavored oral suspension. After constitution with 55 mL of water, each bottle delivers a usable volume of 60 mL of oral suspension equivalent to 360 mg oseltamivir base (6 mg/mL),

Presentations and NDC codes	Strength
Glass bottle with child-resistant closure enclosed in a guset puch and individually packed in a carton	6 mg/mL 27241-139-09

- Solubility in water** : No Data Available
- Odor** : Odorless
- Boiling point** : No Data Available
- Melting Point** : No Data Available
- Evaporation rate** : No Data Available
- Specific gravity** : No Data Available
- Vapor density** : No Data Available
- Reactivity in water** : No Data Available

Evaporation rate	: No Data Available
Percentage Volatileby volume	: No Data Available
Vapor pressure	: No Data Available
Other information	: No Data Available

Section 10. Stability and reactivity

Condition to avoid	: Avoid exposure to extreme heat, light and moisture.
Stable	: Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	: No data available
Hazardous Reaction	: No data available. In finished dosage form there is least possibility that product will undergo any hazardous reaction.
Incompatibilities	: No data available

Section 11. Toxicological information

General	: Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	: Eye contact, Skin contact and inhalation is not great risk as this product is orally administered in suspension formulation.
Acute Toxicity	: LD50 (oral rat) > 2000 mg/kg

Section 12. Ecological information

No data available on Ecotoxicity of API. In the finished product form there is no potential for air borne contamination since the product is in suspension.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

At home: Discard away from children's reach.

Section 14. Transport information

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

DOT: Not Regulated

IATA: Not Regulated

IMDG: Not Regulated

Section 15. Regulatory information

DEA: Oseltamivir Phosphate not a controlled substance.

FDA: Oseltamivir Phosphate is an approved prescription medication.

Section 16. Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: Apr 05, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION