

# SAFETY DATA SHEETS

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078946121

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# HETERO LABS LIMITED

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## SAFETY DATA SHEET

### Section 1: Product and Company Identification

<b>Material Name</b>	<b>Oseltamivir Phosphate Capsules 30mg, 45mg, 75 mg</b>
<b>Use</b>	Used to treat influenza
<b>Manufacturer</b>	<b>Hetero Labs Limited Unit III</b> 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc., Piscataway, NJ 08854</b>

### Section 2: Hazard Identification

<b>Emergency Overview</b>	
<b>Form</b>	Capsules
<b>Color</b>	light yellow grey
<b>Hazard Overview</b>	May cause allergic reactions.
<b>Potential Health Effects</b>	<ul style="list-style-type: none"><li>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</li><li>- Target Organs: eye, skin, gastrointestinal system</li><li>- 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.</li><li>- Chronic Effects: May cause allergic reactions.</li><li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li><li>- Carcinogenicity: IARC Gr3 not classifiable</li></ul>
<b>*1 referring to:</b>	Talc

### Section 3: Composition/Information on Ingredients

<b>Characterization</b>	final product
<b>Ingredients</b>	Concentration
<b>Oseltamivir phosphate</b> CAS: 204255-11-8	~ 60 %
<b>Modified Food Starch</b> CAS: 9005-84-9	~ 28 %
<b>Talc</b> CAS: 14807-96-6	~ 5 %
<b>Povidone</b> CAS: 9003-39-8	~ 4 %

### Section 4: First-Aid Measures

<b>Eye Contact</b>	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
<b>Skin Contact</b>	- remove immediately contaminated clothes, wash affected skin with plenty of water
<b>Inhalation</b>	- in case of inhalation remove to fresh air and seek medical aid
<b>Ingestion</b>	- consult physician



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## Section 5: Fire-Fighting Measures

<b>Suitable extinguishing media</b>	- water spray jet, dry powder, foam, carbon dioxide
<b>Flash point (liquid)</b>	- not applicable
<b>Specific hazards</b>	- Toxic emissions may be given off in a fire
<b>Protection of fire-fighters</b>	- use self-contained breathing apparatus
<b>Special method of fire-fighting</b>	- cool endangered containers with water spray

## Section 6: Accidental Release Measures

<b>Personal precautions</b>	- ensure adequate ventilation
<b>Environmental Protection</b>	- avoid release to the environment
<b>Methods for cleaning up</b>	- Scoop or shovel spilled material into a suitable labeled open head drum - Secure the drum cover and move the container to a safe holding area - Clean spill area thoroughly - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. - Check area for residual material and repeat clean up if detected

## Section 7: Handling and Storage

<b>Handling</b>	
<b>Technical measures</b>	- local exhaust ventilation necessary
<b>Storage</b>	
<b>Storage conditions</b>	- keep containers tightly closed - room temperature - store in a dry place - protected from light

## Section 8: Exposure Controls/Personal Protection

<b>Engineering Measures</b>	- See 7.	
<b>Threshold value (USA) air</b>	- ACGIH-TLV: 10 mg/m <sup>3</sup>	*2
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total particulate)	*2
	- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable fraction)	*2
	- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)	*2
	- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable fraction)	*2
	- ACGIH-TLV: 2 mg/m <sup>3</sup> (respirable fraction) (use asbestos TLV-TWA, should not exceed 2mg/m <sup>3</sup> respirable particulates)	*1
	- OSHA-PEL: 2 mg/m <sup>3</sup> (respirable fraction)	*1
	- NIOSH-REL: 2 mg/m <sup>3</sup> (respirable fraction)	*1
<b>Threshold value (Roche) air</b>	- IOEL (Internal Occupational Exposure Limit): 0.2 mg/m <sup>3</sup>	*3
<b>Personal protective equipment</b>		
<b>Respiratory protection</b>	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - respiratory protection not necessary	



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<b>Hand protection</b>	- protective gloves
<b>Eye protection</b>	- Safety glasses
<b>Body protection</b>	- protective clothing
<b>*1 referring to:</b>	Talc
<b>*2 referring to:</b>	Modified Food Starch
<b>*3 referring to:</b>	Oseltamivir phosphate (NS)
<b>Section 9: Physical and Chemical Properties</b>	
<b>Color</b>	light yellow grey
<b>Form</b>	capsules
<b>Solubility</b>	soluble, water
<b>Section 10: Stability and Reactivity</b>	
<b>Stability</b>	- stable under the conditions mentioned in chapter 7
<b>Conditions to avoid</b>	- high temperatures
<b>Materials to avoid</b>	- strong acids, oxidizing agents
<b>Note</b>	- Hazardous Polymerization: Will not occur.
<b>Section 11: Toxicological Information</b>	
<b>Acute toxicity</b>	- LD <sub>50</sub> > 2'000 mg/kg (oral, rat) *4 - MNLD 100 mg/kg (i.v., mouse) *3 - MNLD > 2'000 mg/kg (oral, mouse) *3 - MNLD > 2'000 mg/kg (oral, rat) *3
<b>Local effects</b>	- eye: irritant (rabbit; OECD No. 405) *3 - not phototoxic (in vitro) *3
<b>Sensitization</b>	- sensitizing (guinea pig) (OECD No. 406) *3 - not sensitizing (guinea pig) *3
<b>Subchronic toxicity</b>	- NOAEL 250 mg/kg/d (oral, rat; 4 weeks) *3 - NOAEL 500 mg/kg/d (oral, marmoset; 7 days) *3
<b>Mutagenicity</b>	- not mutagenic (Ames test) *3 - not mutagenic (various in vitro test systems) *3
<b>Reproduction toxicity</b>	- does not lower parental fertility (several species) *3 - not teratogenic (several species) *3
<b>Note</b>	- side effects: nausea, vomiting *3 - therapeutic dose: 2 x 75 mg/d p.o. for 5 days *3
<b>*3 referring to:</b>	Oseltamivir phosphate (NS)
<b>*4 referring to:</b>	POVIDONE K 30
<b>Section 12: Ecological Information</b>	
<b>Ready biodegradability</b>	- not readily biodegradable *3 3 %, 28 days 2.8 %, 14 days (CO <sub>2</sub> Evolution Test, Modified Sturm Test, OECD No. 301B)



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<b>Inherent biodegradability</b>	- not inherently biodegradable < 10 %, 1 d < 10 %, 16 d < 10 %, 28 d (flask shaking test Roche Basel, inherent biodegradation) *4
	- not inherently biodegradable 12 %, 28 days 12 %, 15 days 0 %, 8 days (flask shaking test Roche Basel, inherent biodegradation) *3
<b>Abiotic degradation</b>	- Slow degradation, photodegradation, no significant hydrolysis (204 mg/l (measured initial concentration), water; HPLC) ~ 13 %, 120 h, ~ 22 °C, under illumination ~ 2 %, 120 h, ~ 22 °C, dark *3
<b>Ecotoxicity</b>	- moderately toxic for algae ( <i>Selenastrum capricornutum</i> ) EbC <sub>50</sub> (96 h) 59 mg/l ErC <sub>50</sub> (96 h) 463 mg/l NOEbC (96 h) 10 mg/l NOErC (96 h) 46 mg/l (OECD No. 201) *3
	- moderately toxic for planktonic crustaceans ( <i>Daphnia magna</i> ) EC <sub>50</sub> (48 h) 33 mg/l (OECD No. 202) *3
	- barely toxic for fish (carp) LC <sub>50</sub> (96 h) > 100 mg/l (OECD No. 203) *3
	- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 30 mg/l (nominal concentration) (MITI Test II, OECD No. 302C) *3
<b>Mobility</b>	- moderate to strong adsorption (water-activated sludge, 28 d, ~22 °C) K <sub>d</sub> = 99 l/kg (activated sludge, 24 h) K <sub>d</sub> = 3247 l/kg (activated sludge, 28 d) (Adsorption to activated sludge in biodegradability test) *3
<b>Air pollution</b>	- observe local/national regulations
*3 referring to:	Oseltamivir phosphate (NS)
*4 referring to:	POVIDONE K 30

## Section 13: Disposal Considerations

<b>Waste from residues</b>	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.
<b>Contaminated packaging</b>	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.



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<b>RCRA waste</b>	- not regulated under RCRA
<b>Section 14: Transport Information</b>	
<b>Note</b>	- not classified by transport regulations, proper shipping name non-regulated
<b>Section 15: Regulatory Information</b>	
<b>TSCA Status Reporting Requirements</b>	<ul style="list-style-type: none"><li>- FDA Exemption - not on inventory</li><li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li><li>- 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.</li><li>- State and local regulations vary and may impose additional reporting requirements.</li></ul>
<b>Section 16: Other Information</b>	
<p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.</p> <p>Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS</p>	