



Material Safety Data Sheet

# FORTOVASE(R) Capsules (Soft) (200 mg)

## 1. Product and Company Identification

Product name	FORTOVASE(R) Capsules (Soft) (200 mg)	
Product code	03 4101 0	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Characterization	final product	

## 2. Composition/Information on ingredients

Ingredients	Concentration
Saquinavir CAS: 127779-20-8	~ 20 %
Glycerides of fatty acids CAS: 67701-32-0	~ 77 %
Povidone CAS: 9003-39-8	~ 3 %

## FORTOVASE(R) Capsules (Soft) (200 mg)

### 3. Hazards identification

#### Emergency Overview

Form	capsules
Color	beige
Potential Health Effects	<ul style="list-style-type: none"><li>- Exposure: Ingestion</li><li>- Target Organs: skin, eyes, mucous membranes, gastrointestinal system, Central nervous system</li><li>- Acute Effects: May cause eye irritation., May cause skin irritation., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.</li><li>- Chronic Effects: No adverse effects known</li><li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li></ul>

### 4. First-aid measures

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

### 5. Fire-fighting measures

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

## FORTOVASE(R) Capsules (Soft) (200 mg)

### 6. Accidental release measures

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

### 7. Handling and storage

#### Handling

- |                    |   |
|--------------------|---|
| Technical measures | - local exhaust ventilation necessary<br>- avoid dust formation; consider dust explosion hazard |
|--------------------|---|

#### Storage

- |                    |  |
|--------------------|--|
| Storage conditions | - keep containers tightly closed<br>- room temperature<br>- store in a dry place |
|--------------------|--|

### 8. Exposure controls/Personal protection

- |                      |          |
|----------------------|----------|
| Engineering Measures | - see 7. |
|----------------------|----------|

#### Monitoring

- |                             |  |
|-----------------------------|--|
| Threshold value (USA) air   | - ACGIH-TLV: 10 mg/m <sup>3</sup> (ACGIH) *1<br>- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust) *1<br>- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable fraction) *1 |
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 2 mg/m <sup>3</sup> *2  |

#### Personal protective equipment

- |                        |   |
|------------------------|---|
| Respiratory protection | - 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.<br>- respiratory protection not necessary |
| Hand protection        | - protective gloves   |
| Eye protection         | - safety glasses  |

## FORTOVASE(R) Capsules (Soft) (200 mg)

Body protection - protective clothing

\*1 referring to: Glycerides of fatty acids

\*2 referring to: Saquinavir mesylate

### 9. Physical and chemical properties

Color beige

Form capsules

### 10. Stability and reactivity

Stability - stable under normal conditions

Conditions to avoid - None known

Materials to avoid - None known

### 11. Toxicological information

Acute toxicity - LD<sub>50</sub> > 5'000 mg/kg (oral, mouse) \*2  
- LD<sub>50</sub> > 5'000 mg/kg (oral, rat) \*2

Local effects - skin: non-irritant (man) \*2  
- eye: irritant (man) \*2  
- mucous membranes: irritant (man) \*2

Sensitization - not sensitizing (man) \*2

Chronic toxicity - low toxicity (oral, several species) \*2

Mutagenicity - not mutagenic (various in vivo and in vitro test systems) \*2

Reproduction toxicity - not teratogenic, not embryotoxic (several species) \*2

\*2 referring to: Saquinavir mesylate

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### 12. Ecological information

Ready biodegradability	<ul style="list-style-type: none"> <li>- not readily biodegradable 4 %, 28 days (CO<sub>2</sub> Evolution Test, Modified Sturm Test, OECD No. 301B)</li> </ul>	*2
Inherent biodegradability	<ul style="list-style-type: none"> <li>- not inherently biodegradable &lt; 10 %, 1 d &lt; 10 %, 16 d &lt; 10 %, 28 d (flask shaking test Roche Basel)</li> <li>- well inherently biodegradable ~ 72 %, 24 h (batch-wise test similar to SCAS with adaptation phase)</li> </ul>	*3  *1
Ecotoxicity	<ul style="list-style-type: none"> <li>- moderately toxic for microorganisms (activated sludge) EC<sub>50</sub> &gt; 59 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)</li> <li>- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEBC 312 mg/l (FDA Technical Assistance Document No. 4.02)</li> <li>- barely toxic for earthworms (earthworms) LD<sub>50</sub> &gt; 1000 mg/l (method not known)</li> <li>- moderately toxic for fish (rainbow trout) NOEC (96 h) 38 mg/l LC<sub>50</sub> (96 h) &gt; 38 mg/l</li> <li>- barely toxic for planktonic crustaceans (Daphnia magna) NOEC (48 h) 36 mg/l EC<sub>50</sub> (48 h) &gt; 100 mg/l</li> </ul>	*2      *2     *2
Mobility	<ul style="list-style-type: none"> <li>- low mobility (Soil-Water, 23 °C) K<sub>oc</sub> = 10692 (silty loam) K<sub>oc</sub> = 22919 (clay loam) K<sub>oc</sub> = 13711 (loam) (FDA Technical Assistance Document No. 3.08)</li> </ul>	*2
*1 referring to:	Glycerides of fatty acids	
*2 referring to:	Saquinavir mesylate	
*3 referring to:	POVIDONE K 30	

### 13. Disposal considerations

Waste from residues	<ul style="list-style-type: none"> <li>- incinerate in qualified installation with flue gas scrubbing</li> <li>- observe local/national regulations regarding waste disposal</li> </ul>
Contaminated packaging	<ul style="list-style-type: none"> <li>- Empty containers must be triple rinsed prior to disposal, recycling or reuse.</li> </ul>
RCRA waste	<ul style="list-style-type: none"> <li>- not regulated under RCRA</li> </ul>

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### 14. Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

### 15. Regulatory information

TSCA Status - FDA Exemption - not on inventory

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 enter a waterway or into soil, or 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

Use - HIV-protease inhibitor

Edition documentation - first edition

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.