



Material Safety Data Sheet

INVIRASE(R) Capsule Mix (200 mg)

1. Product and Company Identification

Product name	INVIRASE(R) Capsule Mix (200 mg)	
Product code	03 4301 3	
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	
Roche Nutley Inventory Code	27070155	

2. Composition/Information on ingredients

Ingredients (CAS no.)	Concentration
Saquinavir mesylate (149845-06-7)	50-60 %
Microcrystalline cellulose (9004-34-6)	10-15 %
Talc (14807-96-6)	5-10 %
Sodium starch glycolate (9063-38-1)	< 5 %

3. Hazards identification

Emergency Overview

Form	powder or powder with lumps
Color	white to off-white
Hazard Overview	- Possible dust explosion hazard based on information on related materials

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- Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
 - Target Organs: eye, mucous membranes, gastrointestinal system, Central nervous system
 - Acute Effects: May cause eye irritation., May cause mucous membrane irritation (inflammation)., 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.
 - Chronic Effects: No adverse effects known
 - Carcinogenicity: formulation not listed by NTP, IARC or OSHA
 - Carcinogenicity: IARC Gr3 not classifiable ^{*1}

*1 referring to: Talc

4. First-aid measures

- Eye contact
- Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
- Skin contact
- Remove contaminated clothing and shoes. Flush skin with plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
- Inhalation
- Remove to fresh air. If discomfort occurs or persists, get medical attention.
- Ingestion
- If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

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

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6. Accidental release measures

- | | |
|--------------------------|--|
| Personal precautions | - ensure adequate ventilation |
| Environmental protection | - do not allow to enter drains or waterways |
| Methods for cleaning up | - 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
- Wash spill area thoroughly with soapy water
- 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 |

7. Handling and storage

Handling

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

Storage

- | | |
|--------------------|--|
| Storage conditions | - 15 - 25 °C
- keep containers tightly closed
- store in a dry place |
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8. Exposure controls/Personal protection

- | | |
|--------------------------------------|--|
| Engineering Measures | - see 7. |
| Threshold value (USA) air | - ACGIH-TLV: 2 mg/m ³ (not classifiable as a human carcinogen, respirable fraction) *1
- ACGIH-TLV: 10 mg/m ³ *2
- ACGIH-TLV: 10 mg/m ³ *3 |
| Threshold value (Roche) air | - IOEL: 2 mg/m ³ *4 |
| 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.
- Respiratory protection is recommended for dusty operations.
- Use of a negative pressure air purifying, half face respirator with a toxic/dust/mist/fume high efficiency filter in the laboratory or a supplied-air full facepiece respirator or supplied-air hood for production operations is recommended. |
| Hand protection | - protective gloves |
| Eye protection | - safety glasses |

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Body protection - protective clothing

*1 referring to: Talc
*2 referring to: Sodium starch glycolate
*3 referring to: Microcrystalline cellulose
*4 referring to: Saquinavir mesylate

9. Physical and chemical properties

Color white to off-white

Form powder or powder with lumps

10. Stability and reactivity

Stability - stable under normal conditions

11. Toxicological information

Acute toxicity - LD₅₀ > 5'000 mg/kg (oral, mouse) *4
- LD₅₀ > 2'000 mg/kg (oral, marmoset) *4
- LD₅₀ > 5'000 mg/kg (oral, rat) *4

Local effects - skin: non-irritant (man) *4
- eye: irritant (man) *4

Sensitization - not sensitizing (man) *4

Chronic toxicity - low toxicity (oral, several species) *4

Mutagenicity - not mutagenic (various in vivo and in vitro test systems) *4

Reproduction toxicity - not teratogenic, not embryotoxic (several species) *4

*4 referring to: Saquinavir mesylate

12. Ecological information

Ready biodegradability - not readily biodegradable
4 %, 28 days
(CO₂ Evolution Test (Modified Sturm Test), OECD No. 301 B) *4

Ecotoxicity - moderately toxic for fish (rainbow trout)
NOEC 38 mg/l
LC₅₀ > 38 mg/l *4
- barely toxic for planktonic crustaceans (Daphnia magna)
NOEC 36 mg/l
EC₅₀ > 100 mg/l *4
- moderately toxic for algae (Selenastrum capricornutum)
NOEbC 20 mg/l *4
- moderately toxic for microorganisms (activated sludge)
EC₅₀ > 59 mg/l
(Activated Sludge Respir. Inhib. Test, OECD No. 209) *4

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	<ul style="list-style-type: none">- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEbC 312 mg/l (FDA Technical Assistance Document No. 4.02) *4- barely toxic for earthworms (earthworms) LD₅₀ > 1000 mg/l (method not known) *4
Mobility	<ul style="list-style-type: none">- low mobility (Soil-Water, 23 °C) K_{OC} = 10692 (silty loam) K_{OC} = 22919 (clay loam) K_{OC} = 13711 (loam) (FDA Technical Assistance Document No. 3.08) *4
*4 referring to:	Saquinavir mesylate
13. Disposal considerations	
Waste from residues	<ul style="list-style-type: none">- observe local/national regulations regarding waste disposal- incinerate in qualified installation with flue gas scrubbing
Contaminated packaging	<ul style="list-style-type: none">- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	<ul style="list-style-type: none">- not regulated under RCRA
14. Transport information	
Note	<ul style="list-style-type: none">- not classified by transport regulations, proper shipping name non-regulated
15. Regulatory information	
TSCA Status	<ul style="list-style-type: none">- FDA Exemption - not on inventory
Reporting Requirements	<ul style="list-style-type: none">- 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	
Use	<ul style="list-style-type: none">- HIV-protease inhibitor
Edition documentation	<ul style="list-style-type: none">- first edition
<p>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.</p>	