SECTION 1. IDENTIFICATION

Product name: INVIRASE(R) F. C. Tablets (500 mg)
Product code: 00010064943
Common name(s), synonym(s) of the substance: Tablets
Manufacturer or supplier's details
Company name of supplier: Genentech, Inc.
Address: 1 DNA Way
South San Francisco, CA 94080
USA
Telephone: 001-(650) 225-1000
E-mail address: info.sds@roche.com
Emergency telephone: US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use: Formulated pharmaceutical active substance
Restrictions on use: For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Eye irritation: Category 2A
Carcinogenicity: Category 1A

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H319 Causes serious eye irritation.
H350 May cause cancer.
Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Saquinavir mesylate</td>
<td>149845-06-7</td>
<td>69.7</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>11.6</td>
</tr>
<tr>
<td></td>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>4.9</td>
</tr>
<tr>
<td></td>
<td>Lactose-monohydrate</td>
<td>10039-26-6</td>
<td>4.7</td>
</tr>
<tr>
<td></td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>Cellulose, hydrogen 1,2-benzenedicarboxylate, 2-hydroxypropyl methyl ether</td>
<td>9050-31-1</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>1,2,3-Propanetriol, 1,2,3-triacetate</td>
<td>102-76-1</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>C.I. Pigment Yellow 42</td>
<td>51274-00-1</td>
<td>0.08</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
If inhaled: Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.

In case of skin contact: If on skin, rinse well with water.

In case of eye contact: Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.

If swallowed: Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation. May cause cancer.

Notes to physician: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: No information available.

Hazardous combustion products: In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx) Sulfur oxides

Further information: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and: Use personal protective equipment. Avoid dust formation.
SAFETY DATA SHEET

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Date of last issue: 01-10-2020
Date of first issue: 12-04-2015

emergency procedures
Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion
Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling
Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions
See label, package insert or internal guidelines

Storage temperature
Protected from heat and light
Protect from moisture.

Further information on storage stability
No decomposition if stored and applied as directed.

Packaging material
Suitable material: Plastic container of HDPE, Polyethylene bag in metal drum

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saquinavir mesylate</td>
<td>149845-06-7</td>
<td>IOEL</td>
<td>0.1 mg/m3</td>
<td>Roche Industrial Hygiene</td>
</tr>
</tbody>
</table>
## SAFETY DATA SHEET

**INVIRASE(R) F. C. Tablets (500 mg)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>10-13-2021</td>
<td>01-10-2020</td>
<td>12-04-2015</td>
</tr>
</tbody>
</table>

### Chemicals

<table>
<thead>
<tr>
<th>Material</th>
<th>CAS Number</th>
<th>TWA (Respirable)</th>
<th>Committee (RIHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>2 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 Million particles per cubic foot</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

### Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saquinavir mesylate</td>
<td>Surface waters</td>
<td>10.2 µg/l</td>
<td>Based on acute data</td>
</tr>
</tbody>
</table>

### Engineering measures:

- No data available

### Personal protective equipment

- Hand protection:
  - Material: Nitrile rubber
  - Break through time: > 30 min
  - Glove thickness: > 0.11 mm

---

5 / 20
In case of full contact:

<table>
<thead>
<tr>
<th>Material</th>
<th>butyl-rubber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break through time</td>
<td>&gt; 480 min</td>
</tr>
<tr>
<td>Glove thickness</td>
<td>&gt; 0.4 mm</td>
</tr>
</tbody>
</table>

Remarks:
- Wear appropriate protective gloves to prevent skin contact.
- Replace torn or punctured gloves promptly.
- Wear appropriate protective gloves to prevent skin contact.
- Replace torn or punctured gloves promptly.

Eye protection:
- Eye wash bottle with pure water
- Tightly fitting safety goggles
- Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection:
- Dust impervious protective suit
- Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures:
- When using do not eat or drink.
- When using do not smoke.
- Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>tablet</td>
</tr>
<tr>
<td>Color</td>
<td>yellow-orange</td>
</tr>
<tr>
<td>Odor</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>does not flash</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Self-ignition</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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flammability limit

Vapor pressure: No data available
Relative vapor density: Not applicable
Relative density: No data available

Solubility(ies)
- Water solubility: No data available
- Solubility in other solvents: No data available

Partition coefficient: n-octanol/water: No data available

Autoignition temperature: No data available
Decomposition temperature: No data available

Viscosity
- Viscosity, dynamic: Not applicable
- Viscosity, kinematic: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: No dangerous reaction known under conditions of normal use.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: No decomposition if stored and applied as directed.
Incompatible materials: No data available
Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
- Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method
- Acute inhalation toxicity: Acute toxicity estimate: 106.12 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
- Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

**Components:**

**Saquinavir mesylate:**
Acute oral toxicity: LD50 Oral (Mouse): > 5,000 mg/kg
LD50 Oral (Rat): > 5,000 mg/kg

**Cellulose:**
Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg

**Lactose-monohydrate:**
Acute oral toxicity: LD50 Oral (Rat): > 10,000 mg/kg

**Octadecanoic acid, magnesium salt (2:1):**
Acute oral toxicity: LD50 Oral (Rat): > 2,000 mg/kg

**Titanium oxide (TiO2):**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Product:**
Remarks: May cause skin irritation in susceptible persons.

**Components:**

**Saquinavir mesylate:**
Species: Human
Result: No skin irritation

**Titanium oxide (TiO2):**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Talc (Mg3H2(SiO3)4):**
Remarks: This information is not available.
Serious eye damage/eye irritation
Causes serious eye irritation.

Product:
Remarks : May cause irreversible eye damage.

Components:
Saquinavir mesylate:
Species : Human
Result : Irritating to eyes.

Titanium oxide (TiO2):
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Talc (Mg3H2(SiO3)4):
Remarks : This information is not available.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Saquinavir mesylate:
Species : Humans
Result : Not a skin sensitizer.

Titanium oxide (TiO2):
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

Germ cell mutagenicity
Not classified based on available information.

Components:
Saquinavir mesylate:
Genotoxicity in vitro : Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity
May cause cancer.

Components:
Saquinavir mesylate:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Cellulose:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Lactose-monohydrate:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP Known to be human carcinogen
Talc (Mg3H2(SiO3)4) 14807-96-6
(Silica, Crystalline (Respirable Size))

Reproductive toxicity
Not classified based on available information.

Components:
Saquinavir mesylate:
STOT-single exposure
Not classified based on available information.

Components:
Saquinavir mesylate:
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Octadecanoic acid, magnesium salt (2:1):
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Talc (Mg3H2(SiO3)4):
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.
Components:

Saquinavir mesylate:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Octadecanoic acid, magnesium salt (2:1):
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Talc (Mg3H2(SiO3)4):
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity
Not classified based on available information.

Components:

Saquinavir mesylate:
No data available

Octadecanoic acid, magnesium salt (2:1):
No data available

Talc (Mg3H2(SiO3)4):
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Saquinavir mesylate:
Toxicity to fish: NOEC (Oncorhynchus mykiss (rainbow trout)): 38.8 mg/l Exposure time: 96 h
LC50 (Oncorhynchus mykiss (rainbow trout)): > 50 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: NOEC (Daphnia magna (Water flea)): 36 mg/l Exposure time: 48 h
EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 400 mg/l Exposure time: 72 h
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Method: OECD Test Guideline 201
GLP: yes

NOEC (Desmodesmus subspicatus (green algae)): 25.3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

EyC50 (Desmodesmus subspicatus (green algae)): > 37 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

Lowest Observed Effect Concentration (Anabaena flos-aquae (cyanobacterium)): 312 mg/l
Exposure time: 72 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 156 mg/l
Exposure time: 72 h

ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 10.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration

Toxicity to microorganisms

NOEC (Bacteria): 156 mg/l
Exposure time: 48 h

EC50 (activated sludge): > 59 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yes

NOEC (activated sludge): 29.5 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yes

Toxicity to soil dwelling organisms

LC50 (Lumbricus terrestris (Earth worm)): > 882 mg/kg
Exposure time: 28 d

Lowest Observed Effect Concentration (Lumbricus terrestris (Earth worm)): 686 mg/kg
Exposure time: 28 d
Remarks: average measured concentration

Ecotoxicology Assessment

Acute aquatic toxicity: This product has no known ecotoxicological effects.

Chronic aquatic toxicity: This product has no known ecotoxicological effects.

Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available

### Cellulose:

**Ecotoxicology Assessment**

Acute aquatic toxicity: This product has no known ecotoxicological effects.

Chronic aquatic toxicity: This product has no known ecotoxicological effects.

### Octadecanoic acid, magnesium salt (2:1):

**Ecotoxicology Assessment**

Acute aquatic toxicity: This product has no known ecotoxicological effects.

Chronic aquatic toxicity: This product has no known ecotoxicological effects.

Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available

### Titanium oxide (TiO2):

**Toxicity to fish**

LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**

LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

**Ecotoxicology Assessment**
Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available

**Talc (Mg3H2(SiO3)4):**
- Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100,000 mg/l
  Exposure time: 24 h

**Ecotoxicology Assessment**
- Acute aquatic toxicity: This product has no known ecotoxicological effects.
- Chronic aquatic toxicity: This product has no known ecotoxicological effects.

**Persistence and degradability**

**Components:**

**Saquinavir mesylate:**
- Biodegradability: Result: Not readily biodegradable.
  Biodegradation: 4 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301B
  GLP: yes

**Titanium oxide (TiO2):**
- Biodegradability: Remarks: Not applicable

**Bioaccumulative potential**

**Components:**

**Saquinavir mesylate:**
- Bioaccumulation: Remarks: Bioaccumulation is unlikely.
- Partition coefficient: n-octanol/water: log Pow: 2.12

**Cellulose:**
- Partition coefficient: n-octanol/water: Remarks: No data available

**Lactose-monohydrate:**
- Bioaccumulation: Remarks: No bioaccumulation is to be expected (log Pow <= 4).
### INVIRASE(R) F. C. Tablets (500 mg)

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>10-13-2021</td>
<td>01-10-2020</td>
<td>12-04-2015</td>
</tr>
</tbody>
</table>

**Partition coefficient:** n-octanol/water  
**log Pow:** -5.03

**Magnesium stearate:**  
Partition coefficient: n-octanol/water  
**log Pow:** 0.8

**Titanium dioxide:**  
Partition coefficient: n-octanol/water  
Remarks: No data available

**Talc:**  
Partition coefficient: n-octanol/water  
Remarks: No data available

### Mobility in soil

**Components:**

**Saquinavir mesylate:**  
Distribution among environmental compartments:  
Koc method  
Medium: Soil  
Koc: 10692 - 22919  
Remarks: Slightly mobile in soils

### Other adverse effects

**Product:**

**Ozone-Depletion Potential:**  
Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

**Components:**

**Saquinavir mesylate:**  
Additional ecological information:  
No data available

**Talc (Mg3H2(SiO3)4):**  
Adsorbed organic bound halogens (AOX):  
Remarks: Not applicable  
Additional ecological information:  
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging: Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Carcinogenicity
Serious eye damage or eye irritation

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App. A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC’s (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.
This product does not contain any priority pollutants related to the U.S. Clean Water Act.

US State Regulations

Massachusetts Right To Know
Cellulose 9004-34-6

Pennsylvania Right To Know
Saquinavir mesylate 149845-06-7
Cellulose 9004-34-6
Crocarmellose sodium 74811-65-7
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8
Lactose-monohydrate 10039-26-6

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Octadecanoic acid, magnesium salt (2:1) 557-04-0

California Regulated Carcinogens
Talc (Mg3H2(SiO3)4) 14807-96-6

The ingredients of this product are reported in the following inventories:

AIIC: Not in compliance with the inventory
This product contains the following components that are not on the Canadian DSL nor NDSL:

- Saquinavir mesylate
- Croscarmellose sodium
- Cellulose, hydrogen 1,2-benzenedicarboxylate, 2-hydroxypropyl methyl ether

- Not in compliance with the inventory
- Not in compliance with the inventory
- Not in compliance with the inventory
- Not in compliance with the inventory
- Not in compliance with the inventory
- On the inventory, or in compliance with the inventory
- Product contains substance(s) not listed on TSCA inventory.
- Not in compliance with the inventory

**TSCA list**
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.
SAFETY DATA SHEET

INVIRASE(R) F. C. Tablets (500 mg)

NFPA 704:

Flammability Instability

Health

Special hazard

HMIS® IV:

HEALTH 2

FLAMMABILITY 0

PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3
AICG / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; NIOSH - National Institute for Occupational Safety and Health; OSHA - Occupational Safety and Health Administration; TWA - Time-weighted average; WHO - World Health Organization.
SAFETY DATA SHEET

INVIRASE(R) F. C. Tablets (500 mg)

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Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co- operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date: 10-13-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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