

INVIRASE(R) F. C. Tablets (500 mg)Version
2.1Revision Date:
10-13-2021Date of last issue: 01-10-2020
Date of first issue: 12-04-2015**SECTION 1. IDENTIFICATION**

Product name : INVIRASE(R) F. C. Tablets (500 mg)

Product code : 00010064943

Common name(s),
synonym(s) of the substance : Tablets
INVIRASE Film Coated 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

Emergency telephone : US Chemtrec phone (800)-424-9300
number**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.

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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

Components

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

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.

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- 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 fire fighting : 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.

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- 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 : Keep in suitable, closed containers for disposal.
containment and cleaning up

SECTION 7. HANDLING AND STORAGE

- Advice on protection against : Avoid dust formation.
fire and explosion 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 : See label, package insert or internal guidelines
storage conditions
- Storage temperature : Protected from heat and light
Protect from moisture.
- Further information on : No decomposition if stored and applied as directed.
storage stability
- Packaging material : Suitable material: Plastic container of HDPE, Polyethylene bag in metal drum

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Saquinavir mesylate	149845-06-7	IOEL	0.1 mg/m3	Roche Industrial Hygiene

SAFETY DATA SHEET

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				Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Titanium dioxide)	10 mg/m3	ACGIH
Talc (Mg3H2(SiO3)4)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m3	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Saquinavir mesylate	Surface waters	10.2 µg/l
	Remarks: Based on acute data	

Engineering measures : No data available

Personal protective equipment

Hand protection

In case of contact through splashing:
 Material : Nitrile rubber
 Break through time : > 30 min
 Glove thickness : > 0.11 mm

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	In case of full contact:
Material	: butyl-rubber
Break through time	: > 480 min
Glove thickness	: > 0.4 mm
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

Appearance	: tablet
Color	: yellow-orange
Odor	: Not applicable
Odor Threshold	: Not applicable
pH	: Not applicable
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower	: No data available

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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 methodAcute 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

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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 425Acute 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.

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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:

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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.

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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 hLC50 (Oncorhynchus mykiss (rainbow trout)): > 50 mg/l
Exposure time: 96 hToxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 36 mg/l
aquatic invertebrates Exposure time: 48 hEC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 hToxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 400 mg/l
plants Exposure time: 72 h

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GLP: yesNOEC (Desmodesmus subspicatus (green algae)): 25.3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yesEyC50 (Desmodesmus subspicatus (green algae)): > 37 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yesLowest Observed Effect Concentration (Anabaena flos-aquae (cyanobacterium)): 312 mg/l
Exposure time: 72 hNOEC (Anabaena flos-aquae (cyanobacterium)): 156 mg/l
Exposure time: 72 hErC50 (Raphidocelis subcapitata (freshwater green alga)): > 10.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentrationToxicity to microorganisms : NOEC (Bacteria): 156 mg/l
Exposure time: 48 hEC50 (activated sludge): > 59 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yesNOEC (activated sludge): 29.5 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yesToxicity to soil dwelling organisms : LC50 (Lumbricus terrestris (Earth worm)): > 882 mg/kg
Exposure time: 28 dLowest 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.

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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

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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.

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

Other organisms relevant to
the environment : No data available**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).

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octanol/water : log Pow: -5.03**Magnesium stearate:**Partition coefficient: n-
octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107**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 applicableAdditional ecological
information : No data available

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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.

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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 SOCOMI 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
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Pennsylvania Right To Know

Saquinavir mesylate	149845-06-7
Cellulose	9004-34-6
Croscarmellose 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
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California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Octadecanoic acid, magnesium salt (2:1)	557-04-0

California Regulated Carcinogens

Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6
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The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

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- DSL : 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
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : On the inventory, or in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : 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.

SECTION 16. OTHER INFORMATION

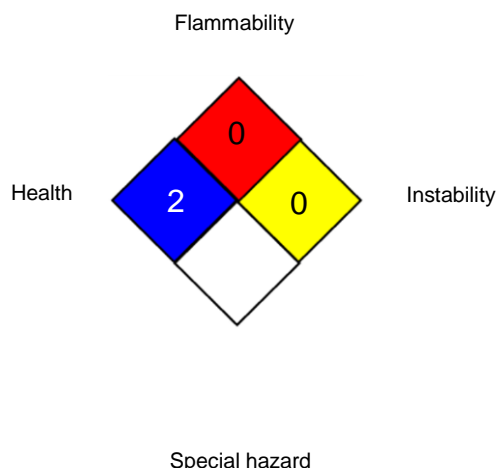
INVIRASE(R) F. C. Tablets (500 mg)

Version
2.1

Revision Date:
10-13-2021

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

NFPA 704:



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 Limits for Air Contaminants
- OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / 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

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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; TECl - 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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