

ITOVEBI Tablets 3 mgVersion
1.0Revision Date:
06/16/2025Date of last issue: -
Date of first issue: 06/16/2025**SECTION 1. IDENTIFICATION**

Product name : ITOVEBI Tablets 3 mg

Product code : RO711-3755/F17-01

Common name(s),
synonym(s) of the substance : Inavolisib Drug Product FC Tablets 3 mg
GDC-0077

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

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Carcinogenicity : Category 2

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 1
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H351 Suspected of causing cancer.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: 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) |
|--|--------------|-----------------------|
| Inavolisib | 2060571-02-8 | 2.9 |
| Cellulose | 9004-34-6 | 66.4 |
| D-Glucose, 4-O-.beta.-D-galactopyranosyl- | 63-42-3 | 22.1 |
| Starch, carboxymethyl ether, sodium salt | 9063-38-1 | 3.8 |
| Ethenol, homopolymer | 9002-89-5 | 1.52 |
| Octadecanoic acid, magnesium salt (2:1) | 557-04-0 | 1 |
| Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy- | 25322-68-3 | 0.77 |
| Iron oxide (Fe2O3) | 1309-37-1 | 0.57 |
| Talc (Mg3H2(SiO3)4) | 14807-96-6 | 0.56 |
| Titanium oxide (TiO2) | 13463-67-7 | 0.38 |

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 : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

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| | |
|---|--|
| In case of skin contact | : Wash off with soap and water. |
| In case of eye contact | : Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist. |
| If swallowed | : Induce vomiting immediately and call a physician. 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. Take victim immediately to hospital. |
| Most important symptoms and effects, both acute and delayed | : Suspected of causing cancer. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection and use the recommended protective clothing |
| Notes to physician | : Treat symptomatically. |

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 | : Do not allow run-off from fire fighting to enter drains or water courses. |
| Hazardous combustion products | : Carbon oxides Sodium oxides Fluorinated hydrocarbons Carbon monoxide Nitrogen oxides (NO _x) |
| Further information | : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. |
| Special protective equipment for fire-fighters | : Wear self-contained breathing apparatus for firefighting if necessary. |

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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 exposure - obtain special instructions before use.
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.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Storage temperature : Protect from heat and light
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

SAFETY DATA SHEET

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| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|--------------|-------------------------------------|--|---|
| 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 |
| Inavolisib | 2060571-02-8 | OEL | 0,6 microgram per cubic meter | Roche Industrial Hygiene Committee (RIHC) |
| 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 (Respirable particulate matter) | 0.2 mg/m3 (Titanium dioxide) | ACGIH |
| | | TWA (Respirable particulate matter) | 2.5 mg/m3 (Titanium dioxide) | ACGIH |
| Substance name | | Environmental Compartment | | Value |
| Inavolisib | | | | 0.0306 mg/l |
| | | Remarks:Based on chronic data | | |

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and

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use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

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

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.

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

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 : red brown

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/ range : No data available

Boiling point/boiling range : No data available

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| | | |
|--|---|-------------------|
| Flash point | : | Not applicable |
| Evaporation rate | : | No data available |
| Self-ignition | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | No data available |
| Relative vapor density | : | Not applicable |
| Relative density | : | No data available |
| 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 |
| Explosive properties | : | No data available |
| Oxidizing properties | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | No data available |

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. |
| Conditions to avoid | : | No data available |

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No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition products : No data available

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: 3,401 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 3,765 mg/kg
Method: Calculation method

Components:**Cellulose:**

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

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

Inavolisib:

Acute oral toxicity : Maximum tolerated dose (Rat): 40 mg/kg
LD50 Oral (Rat): > 50 mg/kg
Remarks: Expert judgment

Ethenol, homopolymer:

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg
Symptoms: muscle weakness

Octadecanoic acid, magnesium salt (2:1):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

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Date of first issue: 06/16/2025**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 due to lack of data.

Components:**Inavolisib:**Method : in silico model
Result : negative
Remarks : Expert judgment**Titanium oxide (TiO₂):**Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified due to lack of data.

Components:**Titanium oxide (TiO₂):**Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

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

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Not classified due to lack of data.

Components:**Inavolisib:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Micronucleus test
Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:**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.

Titanium oxide (TiO₂):

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

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 No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:**Inavolisib:**

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Result: male reproductive effects, female reproductive effects

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: >0.6 mg/kg bw/day
Duration of Single Treatment: 10 d
Result: Teratogenic effects., Based on its mechanism of

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action, effects on embryofetal development can be assumed

Reproductive toxicity -
Assessment : Suspected of damaging fertility. Suspected of damaging the
unborn child.

Suspected human reproductive toxicant

STOT-single exposure

Not classified due to lack of data.

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

Causes damage to organs through prolonged or repeated exposure.

Components:**Inavolisib:**Assessment : Causes damage to organs through prolonged or repeated
exposure.**Octadecanoic acid, magnesium salt (2:1):**Assessment : The substance or mixture is not classified as specific target
organ toxicant, repeated exposure.**Repeated dose toxicity****Components:****Inavolisib:**Species : Rat
NOAEL : 1.5 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Dose : 1, 3, 10
Remarks : Subacute toxicitySpecies : Dog
LOAEL : 1,5 mg/kg bw/day
Application Route : Oral
Exposure time : 4 Weeks
Dose : 0,5, 1,5, 5/3
Remarks : Subacute toxicitySpecies : Rat
NOAEL : 1.5 mg/kg
LOAEL : 1,5 mg/kg bw/day

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Application Route : Oral
Exposure time : 13 Weeks
Dose : 1,5, 5
Remarks : Subacute toxicity

Species : Dog
NOAEL : 0.3 mg/kg
LOAEL : 1,5 mg/kg bw/day
Application Route : Oral
Exposure time : 13 Weeks
Dose : 0,3, 1,5/1,0
Remarks : Subacute toxicity

Aspiration toxicity

Not classified due to lack of data.

Components:**Ethenol, homopolymer:**

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

Further information**Product:**

Remarks : No data available

Components:**Inavolisib:**

Remarks : Not phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:****Ecotoxicology Assessment**

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

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

Inavolisib:Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 46.9 mg/l
End point: Immobilization

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 Exposure time: 48 h
 Test Type: static test
 Method: OECD Test Guideline 202
 GLP: yes

 NOEC (Daphnia magna (Water flea)): 46.9 mg/l
 End point: Immobilization
 Exposure time: 48 h
 Test Type: static test
 Method: OECD Test Guideline 202
 GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 42.8 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Method: OECD Test Guideline 201
 GLP: yes

 NOEC (Raphidocelis subcapitata (freshwater green alga)): 42.8 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to fish (Chronic toxicity) : EC10 (Danio rerio (zebra fish)): 0.306 mg/l
 Exposure time: 36 d
 Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
 Analytical monitoring: yes
 Method: OECD Test Guideline 210
 GLP: yes
 Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 1.26 mg/l
 End point: Immobilization
 Exposure time: 21 d
 Test Type: semi-static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 211
 GLP: yes
 Remarks: nominal concentration

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209
 GLP: yes

 NOEC (activated sludge): 1,000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition

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 Method: OECD Test Guideline 209
 GLP: yes

 NOEC (activated sludge): 48 mg/l
 Exposure time: 14 d
 Method: OECD Test Guideline 301F
 GLP: yes
 Remarks: no adverse influence on substrate biodegradation

Ethenol, homopolymer:
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

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

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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

Persistence and degradability**Components:****Inavolisib:**

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Physico-chemical removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable

Titanium oxide (TiO₂):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Cellulose:**

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

Inavolisib:

Partition coefficient: n-octanol/water : log Pow: 0.95 (72.5 °F / 22.5 °C)
pH: 5.0
Method: OECD Test Guideline 107
GLP: yes

log Pow: 0.93 (73 °F / 23 °C)
pH: 7.0
Method: OECD Test Guideline 107
GLP: yes

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pH: 9.0
Method: OECD Test Guideline 107
GLP: yes**Ethenol, homopolymer:**Partition coefficient: n-
octanol/water : Remarks: No data available**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n-
octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107**Titanium oxide (TiO₂):**Partition coefficient: n-
octanol/water : Remarks: No data available**Mobility in soil****Components:****Inavolisib:**Distribution among
environmental compartments : Adsorption/Soil
Medium: Soil
Koc: 73.37 ml/g
Method: OECD Test Guideline 106
Remarks: Highly mobile in soilsAdsorption/Soil
Medium: Sludge
Koc: 35.84 - 61.12 ml/g
Method: OECD Test Guideline 106
Remarks: Highly 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).Additional ecological
information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**Components:****Ethenol, homopolymer:**

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halogens (AOX)Additional ecological : No data available
information

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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

Special precautions for userRemarks : Not dangerous goods in the meaning of ADR/RID, ADN,
IMDG-Code, ICAO/IATA-DGR

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

| Components | CAS-No. | Component TPQ (lbs) |
|------------|---------|---------------------|
|------------|---------|---------------------|

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SARA 311/312 Hazards : Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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 SOCM 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

Cellulose 9004-34-6

D-Glucose, 4-O-.beta.-D-galactopyranosyl- 63-42-3

Starch, carboxymethyl ether, sodium salt 9063-38-1

Maine Chemicals of High Concern**Vermont Chemicals of High Concern****Washington Chemicals of High Concern****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 Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6

Octadecanoic acid, magnesium salt (2:1) 557-04-0

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Inavolisib

NZIoC : Not in compliance with the inventory

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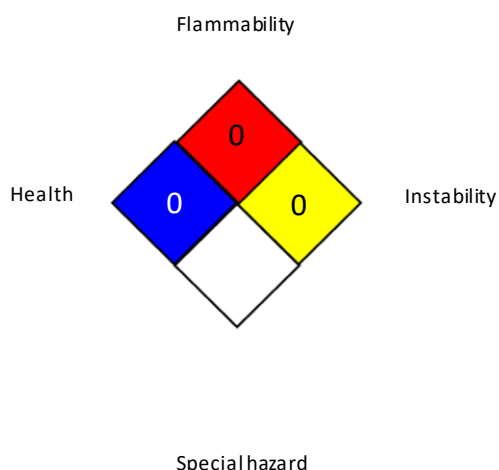
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| | |
|-------|---|
| ENCS | : Not in compliance with the inventory |
| ISHL | : Not in compliance with the inventory |
| KECI | : Not in compliance with the inventory |
| PICCS | : Not in compliance with the inventory |
| IECSC | : Not in compliance with the inventory |
| TCSI | : Not 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
Further information
NFPA 704:

HMIS® IV:

| | | |
|------------------------|---|----------|
| HEALTH | * | 3 |
| 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. Table Z-1-A Limits for Air Contaminants (1989 vacated values) |

ITOVEBITablets 3 mg

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| | | |
|-----------------|---|--|
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| 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 |

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; 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

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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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