

ITOVEBI™ Tablets 3 mgVersion
1.1Revision Date:
09-11-2024Date of last issue: 06-10-2024
Date of first issue: 06-10-2024**SECTION 1. IDENTIFICATION**

Product name : ITOVEBI™ Tablets 3 mg
Product code : RO711-3755/F17
Common name(s), syno- : GDC-0077
nym(s) of the substance : GDC-0077 PI3K (free base)

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 num- : US Chemtrec phone (800)-424-9300
ber


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)**

Carcinogenicity : Category 1A
Reproductive toxicity : Category 2
Specific target organ toxicity : Category 1
- repeated exposure

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H350 May cause cancer.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

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Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
 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.

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		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. Take victim immediately to hospital. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed or in contact with skin. Suspected of causing cancer. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. May cause cancer. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.
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	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Carbon oxides In case of fire hazardous decomposition products may be produced such as: Sodium oxides Fluorinated hydrocarbons Carbon monoxide Nitrogen oxides (NOx)

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- 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Avoid dust formation. Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.
- 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.
- 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.

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Packaging material : Suitable material: Stainless steel, glass

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	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/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m ³	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH
		PEL (respirable)	0.05 mg/m ³	OSHA CARC
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m ³ (Titanium dioxide)	ACGIH

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		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH
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Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Inavolisib		0.0306 mg/l
	Remarks: Based on chronic data	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Dust safety masks are recommended when the dust concentration is more than 10 mg/m3.
Effective dust mask

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

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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	:	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
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

SECTION 10. STABILITY AND REACTIVITY

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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
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

May be harmful if swallowed or in contact with skin.
Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 3,402 mg/kg
		Method: Calculation method
		Acute toxicity estimate: 3,401 mg/kg
		Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 3,766 mg/kg
		Method: Calculation method
		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:

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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

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 due to lack of data.

Not classified due to lack of data.

Components:**Inavolisib:**

Method : in silico model
Result : negative
Remarks : Expert judgment

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

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.

Not classified due to lack of data.

Components:**Talc (Mg₃H₂(SiO₃)₄):**

Remarks : This information is not available.

Titanium oxide (TiO₂):

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Skin sensitization

Not classified due to lack of data.

Respiratory 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

Germ cell mutagenicity

Not classified due to lack of data.

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.

May cause 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 OSHA specifically regulated carcinogen
Talc (Mg3H2(SiO3)4) 14807-96-6

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(crystalline silica)

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

Reproductive toxicity

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

Talc (Mg₃H₂(SiO₃)₄):

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.
Causes damage to organs through prolonged or repeated exposure.

Components:**Inavolisib:**

Assessment : Causes damage to organs through prolonged or repeated exposure.

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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.

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 : mg/kg bw/day, 1,5
Application Route : Oral
Exposure time : 4 Weeks
Dose : 0,5, 1,5, 5/3
Remarks : Subacute toxicitySpecies : Rat
NOAEL : 1.5 mg/kg
LOAEL : mg/kg bw/day, 1,5
Application Route : Oral
Exposure time : 13 Weeks
Dose : 1,5, 5
Remarks : Subacute toxicitySpecies : Dog
NOAEL : 0.3 mg/kg
LOAEL : mg/kg bw/day, 1,5
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.

Not classified due to lack of data.

Components:**Ethenol, homopolymer:**

No data available

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No data available

Talc (Mg₃H₂(SiO₃)₄):

No data available

Further information**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
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yesNOEC (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: yesToxicity 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)):

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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
 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

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- 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

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

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

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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: yesPhysico-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: yeslog Pow: 0.93 (73 °F / 23 °C)
pH: 7.0
Method: OECD Test Guideline 107
GLP: yeslog Pow: 0.95 (73 °F / 23 °C)
pH: 9.0
Method: OECD Test Guideline 107

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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

Talc (Mg₃H₂(SiO₃)₄):

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

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 soils

Adsorption/Soil
 Medium: Sludge
 Koc: 35.84 - 61.12 ml/g
 Method: OECD Test Guideline 106
 Remarks: Highly mobile in soils

Stability in soil : Soil temperature: 54 °F / 12 °C
 Radio label: yes
 Dissipation time: 4.8 d
 Percentage dissipation: 50 % (DT50)
 Method: OECD Test Guideline 308
 GLP: yes
 Remarks: Product is not persistent.
 Fresh water sediment

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 manufac-

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Additional ecological information : tured 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).
: 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:**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

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 : 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.
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

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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 user

Remarks : 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

This material does not contain any components with a section 302 EHS TPQ.

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

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 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**

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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

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 dioxide, 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

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

Inavolisib
- 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 : 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.

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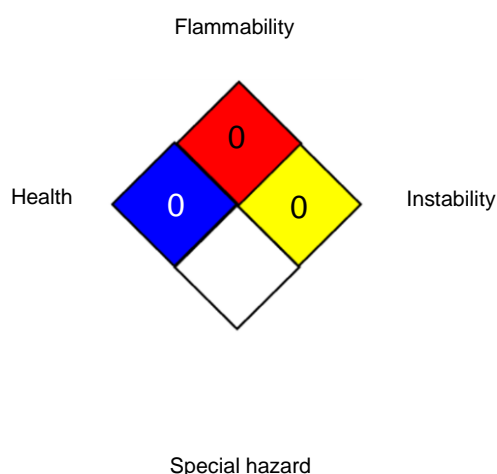
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No substances are subject to TSCA 12(b) export notification requirements.

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 CARC : OSHA Specifically Regulated Chemicals/Carcinogens
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- 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 CARC / PEL : Permissible exposure limit (PEL)
- 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

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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; 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

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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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