

BONIVA(R) F. C. Tablets (150 mg)

Version
0.0

Revision Date:
03-03-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

SECTION 1. IDENTIFICATION

Product name : BONIVA(R) F. C. Tablets (150 mg)

Product code : RO200-5450/F07

Common name(s), syno- : BONVIVA Film Coated Tablets
nym(s) of the substance : BONIVA F.C. Tablets

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : DNA Way 1
94080 South San Francisco
CA
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 29 CFR 1910.1200

Skin corrosion : Category 1B

Serious eye damage : Category 1

Carcinogenicity : Category 2

Specific target organ toxicity : Category 2
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or re-
peated 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/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**
 P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
 P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
 P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P363 Wash contaminated clothing before reuse.
- 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)
Ibandronate	138926-19-9	36.3
Lactose-1-Hydrate	64044-51-5	35.0
Cellulose	9004-34-6	12.9
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	4.8
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	4.8
Octadecanoic acid	57-11-4	1.9
Titanium oxide (TiO ₂)	13463-67-7	1.8
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	0.5

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non hazardous compounds	Not Assigned	2.0
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SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Consult a physician.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
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 induce vomiting.
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 : Causes serious eye damage.
Suspected of causing cancer.
May cause damage to organs through prolonged or repeated exposure.
Causes severe burns.
- 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

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- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Nitrogen oxides (NO_x)
Oxides of phosphorus
Carbon monoxide
Carbon oxides
- 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 : Avoid exposure
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.
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.

SAFETY DATA SHEET

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Electrical installations / working materials must comply with the technological safety standards.

- Storage temperature : Protected from heat and light
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, Polyethylene bag in metal drum, glass, Blister packages

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ibandronate	138926-19-9	IOEL	0.002 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
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
Octadecanoic acid	57-11-4	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH
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	10 mg/m ³ (Titanium dioxide)	ACGIH
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL

Engineering measures : No data available

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Personal protective equipment

 Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
 Effective dust mask

Hand protection

Material : Protective gloves

 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
 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.

Protective measures : Instruction of employees mandatory

 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 : white, off-white
 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

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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: 2,124 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 45.42 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

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Acute oral toxicity : LD50 Oral (Rat): 811 mg/kg

Cellulose:

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

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

Octadecanoic acid:Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 Dermal (Rat): > 5,000 mg/kg

Titanium oxide (TiO₂):

Acute oral toxicity : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 28,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 5.1 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg

Skin corrosion/irritation

Causes severe burns.

Product:

Remarks : Extremely corrosive and destructive to tissue.

Components:**Ibandronate:**

Result : Causes burns.

Remarks : Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

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Components:

Ibandronate:

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Ibandronate:

Species : Guinea pig
Result : Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:

Ibandronate:

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

Genotoxicity in vivo : Test Type: in vivo assay
Species: laboratory animal
Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:

Ibandronate:

Species : laboratory animal
Result : negative

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.

Octadecanoic acid:

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

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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

Not classified based on available information.

Components:

Ibandronate:

Effects on fertility : Species: laboratory animal
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Species: laboratory animal
Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ibandronate:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ibandronate:

Species : laboratory animal
NOAEL : mg/kg/w, 0,15
Application Route : i.v.
Exposure time : 26 Weeks
Symptoms : kidney toxicity
Remarks : Chronic toxicity

Aspiration toxicity

Not classified based on available information.

Components:

Ibandronate:

No data available

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- Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 200 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
- LC0 (Cyprinus carpio (Carp)): 86 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 180 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
- NOEC (Daphnia magna (Water flea)): 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 0.390 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- EyC50 (Desmodesmus subspicatus (green algae)): 0.218 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- ErC50 (Selenastrum capricornutum (green algae)): 4.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
- EyC50 (Selenastrum capricornutum (green algae)): 1.4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

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NOEC (Selenastrum capricornutum (green algae)): 0.22 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to microorganisms : (activated sludge): 41.5 mg/l
 Exposure time: 28 d
 Test Type: aerobic
 Method: OECD Test Guideline 301B
 GLP: yes
 Remarks: no adverse influence on substrate biodegradation

NOEC (activated sludge): 1,300 mg/l
 Exposure time: 5 h
 Test Type: Growth inhibition
 GLP: no
 Remarks: Barely inhibitory on aerobic bacterial reproduction
 (activated sludge)

Cellulose:**Ecotoxicology Assessment**

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

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

Titanium oxide (TiO₂):

Toxicity to fish : LC₀ (Leuciscus idus (Golden orfe)): > 1,000 mg/l
 Exposure time: 48 h

Toxicity to daphnia and other : EC₀ (Daphnia magna (Water flea)): 3 mg/l
 aquatic invertebrates Exposure time: 720 h

Ecotoxicology Assessment

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

Other organisms relevant to : No data available
 the environment

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Toxicity to fish : LC₅₀ (Cyprinus carpio (Carp)): > 100 mg/l
 Exposure time: 4 d
 Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC₅₀ (Daphnia magna (Water flea)): > 100 mg/l
 aquatic invertebrates Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC₅₀ (Desmodesmus subspicatus (green algae)): > 100 mg/l
 plants Exposure time: 72 h

Toxicity to fish (Chronic tox- : > 1 mg/l
 icity)

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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:

Ibandronate:

- Biodegradability : Concentration: 41.5 mg/l
Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes
- Concentration: 1,000 mg/l
Result: Not inherently biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

Octadecanoic acid:

- Biodegradability : Biodegradation: 44 %

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

- Biodegradability : Biodegradation: > 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301

Bioaccumulative potential

Components:

Ibandronate:

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

Cellulose:

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

Octadecanoic acid:

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Partition coefficient: n-octanol/water : log Pow: 8.23

Titanium oxide (TiO₂):

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

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

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

Mobility in soil

No data available

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.
 Very toxic to aquatic life with long lasting effects.

Components:**Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:**

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

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.
 Empty containers should be taken to an approved waste handling site for recycling or disposal.
 Do not re-use empty containers.

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UN number : UN 3261
Proper shipping name : CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : 8

IATA-DGR

UN/ID No. : UN 3261
Proper shipping name : Corrosive solid, acidic, organic, n.o.s.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels :
Packing instruction (cargo aircraft) : 864
Packing instruction (passenger aircraft) : 860
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3261
Proper shipping name : CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : 8
EmS Code : F-A, S-B
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3261
Proper shipping name : Corrosive solid, acidic, organic, n.o.s.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : Class 8 - Corrosive substances
ERG Code : 154
Marine pollutant : no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

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

US State Regulations

Massachusetts Right To Know

Cellulose 9004-34-6
 Titanium oxide (TiO2) 13463-67-7

Pennsylvania Right To Know

Ibandronate 138926-19-9
 Lactose-1-Hydrate 64044-51-5
 Cellulose 9004-34-6
 2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8
 2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8
 Titanium oxide (TiO2) 13463-67-7

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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 List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Titanium oxide (TiO ₂)	13463-67-7

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

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

ibandronate
non hazardous compounds

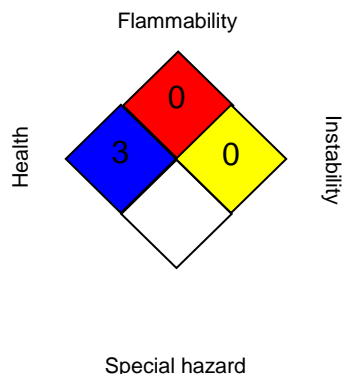
- AICS : Not in compliance with the inventory
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Substance(s) not listed on TSCA 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

BONIVA(R) F. C. Tablets (150 mg)Version
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03-03-2020Date of last issue: 06-10-2017
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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. 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
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
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
US WEEL / TWA	:	8-hr TWA

AICS - Australian Inventory of Chemical Substances; 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 sub-

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stance; 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; 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 : 03-03-2020

The information provided in this Material 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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