



Material Safety Data Sheet

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

### 1. Product and Company Identification

Product name	BONIVA(R) F. C. Tablets (150 mg)	
Product code	03 4631 4	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00	
	US Emergency phone: (800)-827-6243	
	US Chemtrec phone: (800)-424-9300	
Characterization	final product	

### 2. Composition/Information on ingredients

Ingredients	Concentration
Ibandronate CAS: 138926-19-9	~ 38 %
Microcrystalline cellulose CAS: 9004-34-6	~ 13 %
Stearic acid purified fine grade CAS: 57-11-4	~ 2 %
Silicon dioxide colloidal (Aerosil 200, silica) CAS: 7631-86-9	~ 1 %

### 3. Hazards identification

#### Emergency Overview

Form	solid
Color	white
Hazard Overview	- May cause gastrointestinal effects.

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Potential Health Effects	<ul style="list-style-type: none"><li>- Exposure: Ingestion</li><li>- Target Organs: gastrointestinal system</li> <li>- Acute Effects: May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.</li> <li>- Chronic Effects: No adverse effects known</li> <li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li><li>- Carcinogenicity: IARC Gr3 not classifiable <sup>*1</sup></li></ul>
Additional Health Information	<ul style="list-style-type: none"><li>- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Uncorrected hypocalcemia. Severe renal impairment.</li></ul>
*1 referring to:	Silicon dioxide colloidal (Aerosil 200, silica)

### 4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

### 5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

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

### 6. Accidental release measures

- |                          |  |
|--------------------------|--|
| Personal precautions     | - ensure adequate ventilation  |
| Environmental protection | - avoid release to the environment   |
| Methods for cleaning up  | - Scoop or shovel spilled material into a suitable labeled open head drum<br>- Secure the drum cover and move the container to a safe holding area<br>- Clean spill area thoroughly<br>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.<br>- Check area for residual material and repeat clean up if detected |

### 7. Handling and storage

#### Handling

- |                    |   |
|--------------------|---|
| Technical measures | - local exhaust ventilation necessary<br>- avoid dust formation; consider dust explosion hazard |
|--------------------|---|

#### Storage

- |                    |  |
|--------------------|--|
| Storage conditions | - keep containers tightly closed<br>- room temperature<br>- store in a dry place |
|--------------------|--|

### 8. Exposure controls/Personal protection

- |                      |          |
|----------------------|----------|
| Engineering Measures | - see 7. |
|----------------------|----------|

- |                           |   |    |
|---------------------------|---|----|
| Threshold value (USA) air | - ACGIH-TLV: 3 mg/m <sup>3</sup> (respirable fraction)      | *1 |
|                           | - ACGIH-TLV: 10 mg/m <sup>3</sup> (inhalable fraction)      | *1 |
|                           | - OSHA-PEL: 6 mg/m <sup>3</sup>                             | *1 |
|                           | - NIOSH-REL: 6 mg/m <sup>3</sup>                            | *1 |
|                           | - ACGIH-TLV: 10 mg/m <sup>3</sup>                           | *2 |
|                           | - OSHA-PEL: 5 mg/m <sup>3</sup> (respirable dust fraction)  | *2 |
|                           | - OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)               | *2 |
|                           | - NIOSH-REL: 5 mg/m <sup>3</sup> (respirable dust fraction) | *2 |
|                           | - NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)              | *2 |

- |                             |                                 |    |
|-----------------------------|---------------------------------|----|
| Threshold value (Roche) air | - IOEL: 0.002 mg/m <sup>3</sup> | *3 |
|-----------------------------|---------------------------------|----|

#### Personal protective equipment

- |                        |   |
|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.<br>- respiratory protection not necessary |
| Hand protection        | - protective gloves   |

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- Eye protection - safety glasses
- Body protection - protective clothing

- \*1 referring to: Silicon dioxide colloidal (Aerosil 200, silica)
- \*2 referring to: Microcrystalline cellulose
- \*3 referring to: Ibandronate

### 9. Physical and chemical properties

- Color white
- Form solid

### 10. Stability and reactivity

- Stability - stable under normal conditions
- Conditions to avoid - None known
- Materials to avoid - None known

### 11. Toxicological information

- Acute toxicity - LD<sub>50</sub> 811 mg/kg (oral, rat) \*3
- LD<sub>50</sub> 30 mg/kg (i.v., rat) \*3
- Subacute toxicity - NOAEL 0.09 mg/kg/d (i.v., dog, 28 d); higher doses cause kidney damage \*3
- Local effects - skin: moderately irritating (rabbit) \*4
- skin, eyes, mucous membranes: corrosive \*3
- Sensitization - non-sensitizing (guinea pig) \*3
- Chronic toxicity - NOAEL 0.15 mg/kg/w (i.v., several species; 26 weeks); higher doses cause kidney damage \*3
- Mutagenicity - not mutagenic (various in vivo and in vitro test systems) \*3
- Carcinogenicity - not carcinogenic (oral, several species) \*3
- Reproduction toxicity - not teratogenic, not embryotoxic (i.v., several species) \*3
- does not lower parental fertility (i.v., several species) \*3
- Note - dosage (oral): 2.5 to 50 mg/d \*3
- dosage (i.v.): 0.5 mg/3 months to 2.5 mg/day \*3
- high doses cause: liver damages, kidney damages \*3
- decrease in serum calcium level possible \*3
- inhibits mechanisms reducing bone mass by long-term binding to bone tissue \*3

- \*3 referring to: Ibandronate
- \*4 referring to: Stearic acid purified fine grade

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### 12. Ecological information

Ready biodegradability	<ul style="list-style-type: none"> <li>- not readily biodegradable ≤ 3 %, 28 d (CO<sub>2</sub> Evolution Test, Modified Sturm Test, OECD No. 301B) *3</li> <li>- not readily biodegradable 0 %, 28 d (Manometric Respirometry Test, OECD No. 301 F) *3</li> </ul>
Inherent biodegradability	<ul style="list-style-type: none"> <li>- not inherently biodegradable &lt; 10 %, 1 d &lt; 10 %, 15 d &lt; 10 %, 28 d (Zahn-Wellens test, OECD No. 302 B) *3</li> <li>- not inherently biodegradable &lt; 10 %, 28 d (Zahn-Wellens test, OECD No. 302 B) *3</li> </ul>
Abiotic degradation	<ul style="list-style-type: none"> <li>- stable in water, no photodegradation (200 mg/l, water) &lt; 2 %, 14 d, ~ 22 °C, under illumination *3</li> </ul>
Ecotoxicity	<ul style="list-style-type: none"> <li>- <i>Oncorhynchus kisutch</i> LC<sub>50</sub> (96 d) 12 mg/l *4</li> <li>- no adverse influence on substrate biodegradation (activated sludge) concentration (28 d) 41.5 mg/l (OECD No. 301B, Modified Sturm Test) *3</li> <li>- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) NOEC (48 h) 100 mg/l EC<sub>50</sub> (48 h) &gt; 180 mg/l (OECD No. 202) *3</li> <li>- barely toxic for fish (carp) LC<sub>50</sub> (96 h) 200 mg/l LC<sub>0</sub> (96 h) 86 mg/l (OECD No. 203) *3</li> <li>- strongly toxic for algae (<i>Selenastrum capricornutum</i>) EbC<sub>50</sub> (72 h) 1.4 mg/l ErC<sub>50</sub> (72 h) 4.7 mg/l NOEC (72 h) 0.22 mg/l (OECD No. 201) *3</li> <li>- barely inhibitory on aerobic bacterial reproduction (activated sludge) NOEC (5 h) 1300 mg/l (growth test) *3</li> <li>- highly toxic for algae (<i>Scenedesmus subspicatus</i>) EbC<sub>50</sub> (72 h) 0.218 mg/l (nominal concentration) ErC<sub>50</sub> (72 h) 0.390 mg/l (nominal concentration) NOEC (72 h) &lt; 0.1 mg/l (nominal concentration) (OECD No. 201) *3</li> <li>- highly toxic for algae (<i>Scenedesmus subspicatus</i>) EC<sub>50</sub> (14 d) 0.5 mg/l (nominal concentration) NOEC (14 d) 0.1 mg/l (nominal concentration) (OECD No. 201) *3</li> <li>- no adverse influence on substrate biodegradation concentration (28 d) 100 mg/l (Manometric Respirometry Test, OECD No. 301 F) *3</li> </ul>

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Mobility	- no significant adsorption (, 28 d, ~22 °C) K <sub>d</sub> = 1210 l/kg (activated sludge) (Adsorption to activated sludge in biodegradability test)	*3
Note	- after the regular 28 days in the Zahn-Wellens test, without significant degradation and still 400 mg DOC/l, 200 mg DOC/l benzoate was added as a well degradable substrate; after 5 days, only 150 mg DOC/l was left, showing some cometabolic degradation	*3
*3 referring to:	Ibandronate	
*4 referring to:	Stearic acid purified fine grade	
<b>13. Disposal considerations</b>		
Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal	
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.	
RCRA waste	- not regulated under RCRA	
<b>14. Transport information</b>		
Note	- not classified by transport regulations, proper shipping name non-regulated	
<b>15. Regulatory information</b>		
TSCA Status	- FDA Exemption - not on inventory	
Reporting Requirements	- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements.	
<b>16. Other information</b>		
Use	- Boniva is used in the treatment and prevention of osteoporosis in postmenopausal women.	
Edition documentation	- first edition	
The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.		