

**1. Product and Company Identification**

Product name	BONIVA(R) F. C. Tablets (100 mg)	
Product code	03 4628 4	
Use	- Boniva is used in the treatment and prevention of osteoporosis in postmenopausal women.	
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 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

**2. Hazards identification****Emergency Overview**

Form	tablets
Color	white
Hazard Overview	- May cause gastrointestinal effects.
Potential Health Effects	- Exposure: Ingestion - Target Organs: gastrointestinal system  - Acute Effects: May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.  - Chronic Effects: No adverse effects known  - Carcinogenicity: formulation not listed by NTP, IARC or OSHA - Carcinogenicity: IARC Gr3 not classifiable *1
Additional Health Information	- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Uncorrected hypocalcemia. Severe renal impairment.
*1 referring to:	Silicon dioxide colloidal (Aerosil 200, silica)

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### 3. Composition/Information on ingredients

Characterization	final product
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 %

### 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

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### 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 (Internal Occupational Exposure Limit): 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 tablets

### 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	- not readily biodegradable ≤ 3 %, 28 d (CO <sub>2</sub> Evolution Test, Modified Sturm Test, OECD No. 301B)	*3
	- not readily biodegradable 0 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*3
Inherent biodegradability	- not inherently biodegradable < 10 %, 1 d < 10 %, 15 d < 10 %, 28 d (Zahn-Wellens test, OECD No. 302 B)	*3
	- not inherently biodegradable < 10 %, 28 d (Zahn-Wellens test, OECD No. 302 B)	*3
Abiotic degradation	- stable in water, no photodegradation (200 mg/l, water) < 2 %, 14 d, ~ 22 °C, under illumination	*3
Ecotoxicity	- <i>Oncorhynchus kisutch</i> LC <sub>50</sub> (96 d) 12 mg/l	*4
	- no adverse influence on substrate biodegradation (activated sludge) concentration (28 d) 41.5 mg/l (OECD No. 301B, Modified Sturm Test)	*3
	- barely toxic for planktonic crustaceans ( <i>Daphnia magna</i> ) NOEC (48 h) 100 mg/l EC <sub>50</sub> (48 h) > 180 mg/l (OECD No. 202)	*3
	- 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
	- 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
	- barely inhibitory on aerobic bacterial reproduction (activated sludge) NOEC (5 h) 1300 mg/l (growth test)	*3
	- highly toxic for algae ( <i>Scenedesmus (=Desmodesmus) 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) < 0.1 mg/l (nominal concentration) (OECD No. 201)	*3
	- highly toxic for algae ( <i>Scenedesmus (=Desmodesmus) 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
	- no adverse influence on substrate biodegradation concentration (28 d) 100 mg/l (Manometric Respirometry Test, OECD No. 301 F)	*3

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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 - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.	
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.	
RCRA waste	- not regulated under RCRA	

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14. Transport information							
IATA	Class	UN/ID	PG		PI	Label	
	9	3077	III		911/911	9	
IMDG	Class	UN	PG	EmS	PI	Label	Mark
	9	3077	III	F-A S-F	P002/IBC08	9	
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Classif.code
	9	3077	III	90	P002/IBC08	9	M7
DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no
	9	3077	III			9	
DOT Remark:		- NON-REGULATED IN NON-BULK PACKAGINGS TRANSPORTED BY MOTOR VEHICLES, RAIL CARS OR AIRCRAFT (49CFR 171.4(c)).					
Proper shipping name		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.					
Technical name		Ibandronate					
15. Regulatory information							
TSCA Status		- FDA Exemption - not on inventory					
Reporting Requirements		<ul style="list-style-type: none"> <li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li> <li>- 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.</li> <li>- State and local regulations vary and may impose additional reporting requirements.</li> </ul>					
16. Other information							
Edition documentation		- changes from previous version in sections 13					
<p>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.</p>							