

BONIVA(R) Injection (3 mg/3 ml pre-filled syringes)Version
1.2Revision Date:
11-16-2021Date of last issue: 03-03-2020
Date of first issue: 06-09-2017**SECTION 1. IDENTIFICATION**

Product name : BONIVA(R) Injection (3 mg/3 ml pre-filled syringes)
Product code : RO200-5450/F03
Common name(s),
synonym(s) of the substance : Ibandronat 0,1125 % aqueous solution with excipients

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 : US Chemtrec phone (800)-424-9300
number

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)**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

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	0.1125
Sodium chloride (NaCl)	7647-14-5	0.86
Sodium acetate trihydrate	6131-90-4	0.02
Water	7732-18-5	> 99.0

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SECTION 4. FIRST AID MEASURES

- General advice : 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.
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.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- 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.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- 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 : Refer to protective measures listed in sections 7 and 8.

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- Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.
- Storage temperature : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Vials, Prefilled syringes

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)

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Ibandronate	Surface waters	0.39 µg/l
	Remarks:	
	Based on acute data	

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Respiratory protection : No personal respiratory protective equipment normally required.

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.
Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution, Clear liquid, sterile

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 3.8 - 4.4

Melting point/range : No data available

Boiling point/boiling range : No data available

Evaporation rate : No data available

Self-ignition : No data available

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flammability limit : No data availableLower explosion limit / Lower
flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : ca. 1 g/cm³

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 : No data available

Viscosity, kinematic : 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 : Stable under recommended storage conditions.
No hazards to be specially mentioned.

Incompatible materials : No data available

Hazardous decomposition
products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Ibandronate:**

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

Sodium chloride (NaCl):

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

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

Sodium acetate trihydrate:Acute oral toxicity : LD50 (Rat): 3,530 mg/kg
LD50 (Mouse): 4,960 mg/kgAcute inhalation toxicity : LC50 (Rat): > 30 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Ibandronate:**Result : Causes burns.
Remarks : Extremely corrosive and destructive to tissue.**Sodium chloride (NaCl):**Species : Rabbit
Result : No skin irritation**Sodium acetate trihydrate:**

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ibandronate:**

Remarks : May cause irreversible eye damage.

Sodium chloride (NaCl):Species : Rabbit
Result : No eye irritation

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Remarks : This information is not available.

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.**Sodium chloride (NaCl):**

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:**Ibandronate:**Genotoxicity in vitro : Test Type: in vitro test
Result: negativeGenotoxicity in vivo : Test Type: in vivo assay
Species: laboratory animal
Result: negative**Sodium chloride (NaCl):**Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (micronucleus test)
Result: negativeGenotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat (female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 475
Result: positive**Carcinogenicity**

Not classified based on available information.

Components:**Ibandronate:**Species : laboratory animal
Result : negative

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- IARC** 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.
- 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.

Sodium chloride (NaCl):
STOT-single exposure

Not classified based on available information.

Components:
Sodium acetate trihydrate:

- Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:
Ibandronate:

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

Sodium acetate trihydrate:

- Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity
Components:
Ibandronate:

- Species : laboratory animal
 NOAEL : 0,15 mg/kg/w
 Application Route : i.v.

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Exposure time : 26 Weeks
 Symptoms : kidney toxicity
 Remarks : Chronic toxicity

Aspiration toxicity

Not classified based on available information.

Components:**Ibandronate:**

No data available

Sodium acetate trihydrate:

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Ibandronate:**

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

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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

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)

Sodium chloride (NaCl):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l
 Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 874 mg/l
 Exposure time: 48 h
 Test Type: static test

LC50 (Daphnia magna (Water flea)): 4,136 mg/l
 Exposure time: 48 h
 Test Type: static test
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50: 2,430 mg/l
 Exposure time: 120 h
 Test Type: static test
 Method: OECD Test Guideline 201

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Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d
Test Type: flow-through test
Method: OECD Test Guideline 210
GLP: no

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia): 314 mg/l
Exposure time: 21 d
Test Type: semi-static test
Method: OECD Test Guideline 211

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

Sodium acetate trihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,000 mg/l
Exposure time: 24 h

LC50 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 7,200 mg/l
Exposure time: 18 h

EC50 (Photobacterium phosphoreum): 22,500 mg/l
Exposure time: 0.25 h

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:****Ibandronate:**

Biodegradability : Concentration: 41.5 mg/l
Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d

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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

Sodium chloride (NaCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Sodium acetate trihydrate:

Biodegradability : Biodegradation: 99 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Ibandronate:

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

Sodium chloride (NaCl):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Sodium acetate trihydrate:

Partition coefficient: n-octanol/water : log Pow: -4.22

Water:

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).

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Can be disposed as waste water, when in compliance with local regulations.
- Contaminated packaging : 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

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

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 : No SARA Hazards

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).

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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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Water

7732-18-5

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

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.

Ibandronate
- NZIoC : On the inventory, or 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

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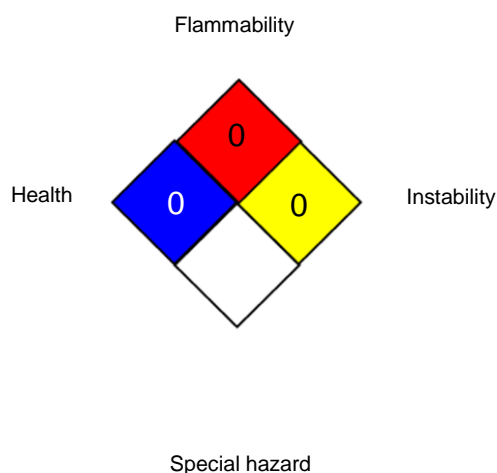
TSCA list

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

NFPA 704:



HMIS® IV:

HEALTH	/	0
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

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; KECl - 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 -

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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.

US / Z8 / 2010