

KLONOPIN(R) Tablets 0.5 mgVersion
2.2Revision Date:
10-14-2021Date of last issue: 10-07-2021
Date of first issue: 12-04-2015**SECTION 1. IDENTIFICATION**

Product name : KLONOPIN(R) Tablets 0.5 mg

Product code : RO005-4023/F01

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

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

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

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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)
Clonazepam	1622-61-3	0.33
Starch	9005-25-8	72.6
Lactose-monohydrate	10039-26-6	26.7
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	0.22
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.06
non hazardous compounds	Not Assigned	> 0.05

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 : May cause cancer.

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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 : Carbon oxides
- 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 : Avoid exposure
Avoid dust formation.
- Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- 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.
- Storage temperature : Protected from heat and light

SAFETY DATA SHEET

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Protect from moisture.

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Polyethylene bag in metal drum, Plastic container of HDPE, glass bottles, 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
Starch	9005-25-8	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
Clonazepam	1622-61-3	IOEL	0.01 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
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

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Clonazepam	Surface waters	6.92 µg/l
	Remarks: Based on acute data	

Engineering measures : No data available

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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 mmIn case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mmRemarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.
Eye protection : Safety glasses
Skin and body protection : Protective suit
Protective measures : Instruction of employees recommended
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**Appearance : tablet
Color : yellow, orange
Odor : Not applicable
Odor Threshold : Not applicable
pH : No data available
Melting point/range : No data available
Boiling point/boiling range : No data available
Evaporation rate : No data available
Self-ignition : No data available
Upper explosion limit / Upper flammability limit : No data available

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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

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

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Clonazepam:**

Acute oral toxicity : LD50 Oral (Rat): > 15,000 mg/kg

Starch:Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

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Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment**Lactose-monohydrate:**

Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg

Octadecanoic acid, magnesium salt (2:1):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

non hazardous compounds:Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgmentAcute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment**Skin corrosion/irritation**

Not classified based on available information.

Components:**Clonazepam:**

Remarks : This information is not available.

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Clonazepam:**

Remarks : This information is not available.

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

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Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Clonazepam:

Germ cell mutagenicity - Assessment : The substance has been tested for mutagenicity and other types of genotoxic effects in in vitro and in vivo experiments and is evaluated as being non-mutagenic.

Carcinogenicity

May cause cancer.

Components:

Clonazepam:

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.

Lactose-monohydrate:

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

Reproductive toxicity

Not classified based on available information.

Components:

Clonazepam:

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: <= 40 mg/kg bw/day
Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure

Not classified based on available information.

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Components:

Clonazepam:

Target Organs : Central nervous system
Assessment : May cause drowsiness or dizziness.

Starch:

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.

Octadecanoic acid, magnesium salt (2:1):

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

non hazardous compounds:

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:

Starch:

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.

Octadecanoic acid, magnesium salt (2:1):

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

non hazardous compounds:

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

Aspiration toxicity

Not classified based on available information.

Components:

Clonazepam:

No data available

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No data available

Talc (Mg₃H₂(SiO₃)₄):

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

non hazardous compounds:

No data available

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

- Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 30.3 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 240 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- EyC50 (Desmodesmus subspicatus (green algae)): 6.92 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- ErC10 (Desmodesmus subspicatus (green algae)): 3.90 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration
- NOEC (Desmodesmus subspicatus (green algae)): < 2.46 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

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Exposure time: 96 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**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**Octadecanoic acid, magnesium salt (2:1):****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**non hazardous compounds:**Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 hToxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h**Ecotoxicology Assessment**

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

Other organisms relevant to : No data available

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the environment

Persistence and degradability**Components:****Clonazepam:**Biodegradability : Biodegradation: 0 %
Exposure time: 21 d
GLP: no**Bioaccumulative potential****Components:****Clonazepam:**Partition coefficient: n- : log Pow: 2.41 (77 °F / 25 °C)
octanol/water pH: 7.4**Starch:**Partition coefficient: n- : Remarks: No data available
octanol/water**Lactose-monohydrate:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n- : log Pow: -5.03
octanol/water**Talc (Mg₃H₂(SiO₃)₄):**Partition coefficient: n- : Remarks: No data available
octanol/water**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n- : log Pow: 0.8
octanol/water Method: OECD Test Guideline 107**non hazardous compounds:**Partition coefficient: n- : Remarks: No data available
octanol/water**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

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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).

Components:

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 : 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.

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

SARA 311/312 Hazards : 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 I 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**

Starch 9005-25-8

Pennsylvania Right To KnowStarch 9005-25-8
Lactose-monohydrate 10039-26-6**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. 65WARNING: This product can expose you to chemicals including Clonazepam, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.**California Permissible Exposure Limits for Chemical Contaminants**

Starch 9005-25-8

California Regulated CarcinogensTalc (Mg₃H₂(SiO₃)₄) 14807-96-6**The ingredients of this product are reported in the following inventories:**

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- AIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
non hazardous compounds
- 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

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

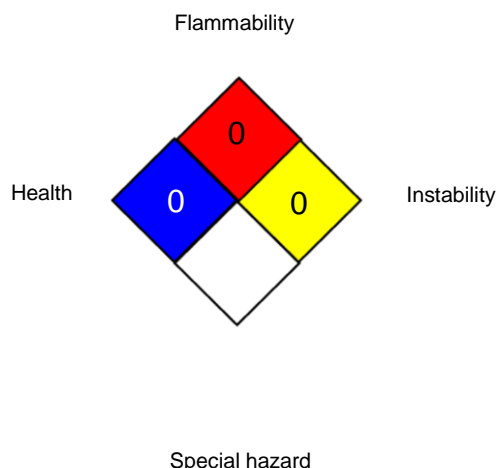
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NFPA 704:



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

- 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
- 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 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

AllC - 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; 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

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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.

US / Z8 / 2010