

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015**SECTION 1. IDENTIFICATION**

Product name : KLONOPIN(R) Tablets (2.0 mg)
Product code : RO005-4023/F04

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 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 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/ attention.

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015**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

Substance name : RIVOTRIL Tablets 2.0 mg

Components

Chemical name	CAS-No.	Concentration (% w/w)
Clonazepam	1622-61-3	1.33
Lactose-monohydrate	10039-26-6	60.0
Starch	9005-25-8	36.33
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	1.8
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.54

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.

KLONOPIN(R) Tablets (2.0 mg)

Version
2.0

Revision Date:
10-10-2019

Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

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
In case of fire hazardous decomposition products may be produced such as:
Gaseous hydrogen chloride (HCl).
Nitrogen oxides (NO_x)
- 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 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.

KLONOPIN(R) Tablets (2.0 mg)
Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

- 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: 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
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable fraction)	2 mg/m ³	ACGIH
Clonazepam	1622-61-3	IOEL	0.01 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

SAFETY DATA SHEET

KLONOPIN(R) Tablets (2.0 mg)

Version
2.0

Revision Date:
10-10-2019

Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

Material : Protective gloves

Remarks : 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 : tablet

Color : white

Odor : Not applicable

Odor Threshold : Not applicable

pH : No data available

: No data available

Boiling point/boiling range : No data available

Flash point : does not flash

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

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

KLONOPIN(R) Tablets (2.0 mg)

Version 2.0 Revision Date: 10-10-2019 Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

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 reac- : Stable under recommended storage conditions.
tions : No hazards to be specially mentioned.
Conditions to avoid : Exposure to light.
 : Exposure to moisture.
 : Heat.
Incompatible materials : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Lactose-monohydrate:**

Acute oral toxicity : LD50 Oral (Rat): > 10,000 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
 : Test atmosphere: dust/mist
 : Method: Expert judgment

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

Clonazepam:

Acute oral toxicity : LD50 Oral (Rat): > 15,000 mg/kg
 : LD50 Oral (Mouse): 2,000 mg/kg

Octadecanoic acid, magnesium salt (2:1):

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

KLONOPIN(R) Tablets (2.0 mg)

Version
2.0

Revision Date:
10-10-2019

Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

Skin corrosion/irritation

Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Clonazepam:

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Clonazepam:

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.

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:

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.

Clonazepam:

Remarks : No ingredient of this product present at levels greater than or

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

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 (Mg ₃ H ₂ (SiO ₃) ₄) (Silica, Crystalline (Respirable Size))	14807-96-6

Reproductive toxicity

Not classified based on available information.

Components:**Clonazepam:**

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

STOT-single exposure

Not classified based on available information.

Components:**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.

Clonazepam:

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.

STOT-repeated exposure

Not classified based on available information.

Components:**Starch:**

Assessment : The substance or mixture is not classified as specific target

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

organ toxicant, repeated exposure.

Talc (Mg₃H₂(SiO₃)₄):

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

Clonazepam:

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.

Aspiration toxicity

Not classified based on available information.

Components:**Starch:**

No data available

Talc (Mg₃H₂(SiO₃)₄):

No data available

Clonazepam:

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Starch:**Toxicity to fish : LC50: > 100 mg/l
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 : No data available

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

the environment

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**Clonazepam:**Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 hToxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 30.3 mg/l
Exposure time: 48 hToxicity to algae/aquatic
plants : ErC50 (Desmodesmus subspicatus (green algae)): > 240 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: noNOEC (Desmodesmus subspicatus (green algae)): < 2.46
mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: noErC10 (Desmodesmus subspicatus (green algae)): 3.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no**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

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015**Persistence and degradability****Components:****Clonazepam:**Biodegradability : Biodegradation: 0 %
Exposure time: 21 d
GLP: no**Bioaccumulative potential****Components:****Lactose-monohydrate:**

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

Partition coefficient: n-octanol/water : log Pow: -5.03

Starch:

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

Talc (Mg₃H₂(SiO₃)₄):

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

Clonazepam:Partition coefficient: n-octanol/water : log Pow: 2.41 (25 °C / 25 °C)
pH: 7.4**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n-octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107**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).**Components:****Talc (Mg₃H₂(SiO₃)₄):**

KLONOPIN(R) Tablets (2.0 mg)

Version 2.0 Revision Date: 10-10-2019 Date of last issue: 06-10-2017
 Date of first issue: 12-04-2015

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

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)
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SARA 311/312 Hazards : Carcinogenicity

KLONOPIN(R) Tablets (2.0 mg)

Version
2.0

Revision Date:
10-10-2019

Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

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

Starch	9005-25-8
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6

Pennsylvania Right To Know

Lactose-monohydrate	10039-26-6
Starch	9005-25-8
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6

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 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 List of Hazardous Substances

Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6
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California Permissible Exposure Limits for Chemical Contaminants

Starch	9005-25-8
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The ingredients of this product are reported in the following inventories:

- DSL : All components of this product are on the Canadian DSL
- AICS : On the inventory, or in compliance with the inventory
- 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

SAFETY DATA SHEET

KLONOPIN(R) Tablets (2.0 mg)

Version
2.0

Revision Date:
10-10-2019

Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : On the inventory, or in compliance with the inventory
TSCA : Substance(s) not listed on TSCA inventory

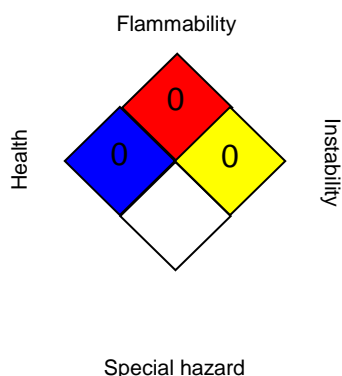
TSCA list

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

NFPA:



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

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

KLONOPIN(R) Tablets (2.0 mg)Version
2.0Revision Date:
10-10-2019Date of last issue: 06-10-2017
Date of first issue: 12-04-2015

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 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; 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 : 10-10-2019

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.

US / Z8 / 1810