

KLONOPIN(R) Tablets (1.0 mg)

Version 1.0 Revision Date: 10-09-2019 Date of last issue: -
Date of first issue: 10-09-2019

SECTION 1. IDENTIFICATION

Product name : KLONOPIN(R) Tablets (1.0 mg)
Product code : RO005-4023/F06

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 num- : US Chemtrec phone (800)-424-9300
ber

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**

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
Substance name : RIVOTRIL Tablets 1.0 mg

Components

Chemical name	CAS-No.	Concentration (% w/w)
Clonazepam	1622-61-3	0.6
Lactose-monohydrate	10039-26-6	71.56
Cellulose	9004-34-6	14.71
Starch	9005-25-8	11.76
non hazardous compounds	Not Assigned	0.78
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.59

KLONOPIN(R) Tablets (1.0 mg)

Version
1.0

Revision Date:
10-09-2019

Date of last issue: -
Date of first issue: 10-09-2019

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 : 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.

KLONOPIN(R) Tablets (1.0 mg)

Version 1.0 Revision Date: 10-09-2019 Date of last issue: -
Date of first issue: 10-09-2019

- 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
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
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019

Starch	9005-25-8	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Clonazepam	1622-61-3	IOEL	0.01 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH

Engineering measures : No data available**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

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

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 : blue

Odor : Not applicable

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019

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
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
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

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

Product:Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method**Components:****Clonazepam:**Acute oral toxicity : LD50 Oral (Rat): > 15,000 mg/kg
LD50 Oral (Mouse): 2,000 mg/kg**Lactose-monohydrate:**

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

Cellulose:Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg**Starch:**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**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**Octadecanoic acid, magnesium salt (2:1):**

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

KLONOPIN(R) Tablets (1.0 mg)

Version
1.0

Revision Date:
10-09-2019

Date of last issue: -
Date of first issue: 10-09-2019

Skin corrosion/irritation

Not classified based on available information.

Components:

Clonazepam:

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.

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

Not classified based on available information.

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.

Cellulose:

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.

KLONOPIN(R) Tablets (1.0 mg)

Version 1.0	Revision Date: 10-09-2019	Date of last issue: - Date of first issue: 10-09-2019
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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:

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:

Clonazepam:

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

Starch:

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.

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:

Clonazepam:

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

Starch:

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

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019

organ toxicant, repeated exposure.

non hazardous compounds:

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:**Clonazepam:**

No data available

Starch:

No data available

non hazardous compounds:

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

SECTION 12. ECOLOGICAL INFORMATION**Components:****Clonazepam:**Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 hToxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 30.3 mg/l
aquatic invertebrates : Exposure time: 48 hToxicity to algae : 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/lExposure time: 72 h
Method: OECD Test Guideline 201
GLP: no

ErC10 (Desmodesmus subspicatus (green algae)): 3.9 mg/l

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no**Cellulose:****Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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
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
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

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019**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 (25 °C / 25 °C)
octanol/water pH: 7.4**Lactose-monohydrate:**

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

Partition coefficient: n- : log Pow: -5.03
octanol/water**Cellulose:**Partition coefficient: n- : Remarks: No data available
octanol/water**Starch:**Partition coefficient: n- : Remarks: No data available
octanol/water**non hazardous compounds:**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**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).

KLONOPIN(R) Tablets (1.0 mg)

Version 1.0 Revision Date: 10-09-2019 Date of last issue: -
 Date of first issue: 10-09-2019

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 : No SARA Hazards

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).

KLONOPIN(R) Tablets (1.0 mg)

Version	Revision Date:	Date of last issue: -
1.0	10-09-2019	Date of first issue: 10-09-2019

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

Cellulose	9004-34-6
Starch	9005-25-8

Pennsylvania Right To Know

Lactose-monohydrate	10039-26-6
Cellulose	9004-34-6
Starch	9005-25-8

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 Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Starch	9005-25-8

The ingredients of this product are reported in the following inventories:

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

KLONOPIN(R) Tablets (1.0 mg)

Version
1.0

Revision Date:
10-09-2019

Date of last issue: -
Date of first issue: 10-09-2019

TCSI : Not in compliance with the inventory
TSCA : Substance(s) not listed on TSCA inventory

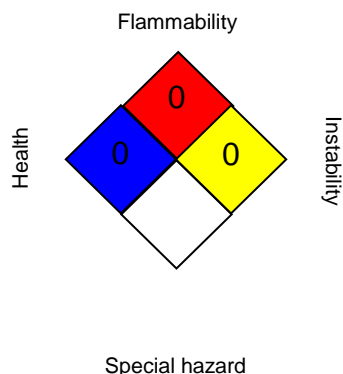
TSCA list

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
- 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

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 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

KLONOPIN(R) Tablets (1.0 mg)Version
1.0Revision Date:
10-09-2019Date of last issue: -
Date of first issue: 10-09-2019

- 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 : 10-09-2019

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