SAFETY DATA SHEET

Phosphatase, acid

Version	Revision Date:	Date of last issue: 10-26-2021
2.0	04-16-2022	Date of first issue: 09-17-2015

SECTION 1. IDENTIFICATION

Product name : Phosphatase, acid

Product code : 10108227001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Germany

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
In case of emergencies: : CHEMTREC +1 703-741-5970 /
1-800-424-9300

Recommended use of the chemical and restrictions on use

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)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Acid phosphatase	9001-77-8	>= 70 - < 90
Sodium citrate	6132-04-3	>= 10 - < 20
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	77-86-1	>= 5 - < 10

Actual concentration is withheld as a trade secret

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 Sodium oxides May release combustible and toxic gases Nitrogen oxides (NOx)
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.
Further information on storage stability	:	No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Acid phosphatase	9001-77-8	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

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.
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	:	solid, (lyophilized)
Color	:	light brown
Odor	:	none
Odor Threshold	:	Not applicable
pH	:	5.4 - 5.6 (as aqueous solution)
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Flammability (liquids)	:	Sustains combustion
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	:	soluble
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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	:	No dangerous reaction known under conditions of normal use. Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	Exposure to moisture.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

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:

Acid phosphatase:

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

Sodium citrate:

Acute oral toxicity : LD50 Oral (Mouse): 5,400 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Acute oral toxicity : LD50 (Rat, female): > 5,000 mg/kg
Method: OECD Test Guideline 425
GLP: yes

Acute dermal toxicity : LD50 (Rat, male and female): > 5,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium citrate:

Species	:	Rabbit
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Test substance	:	anhydrous substance

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Species	:	Rabbit
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
GLP	:	yes

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium citrate:

Species	:	Rabbit
Result	:	No eye irritation
Exposure time	:	72 h
Method	:	OECD Test Guideline 405
Test substance	:	anhydrous substance

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Species	:	Rabbit
Result	:	No eye irritation
Exposure time	:	72 h
Method	:	OECD Test Guideline 405
GLP	:	yes

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium citrate:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Test substance	:	anhydrous substance

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Test Type	:	Direct Peptide Reactivity Assay (DPRA)
Assessment	:	Does not cause skin sensitization.
GLP	:	yes
Remarks	:	Based on data from similar materials Expert judgment
Test Type	:	Buehler Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
GLP	:	no
Remarks	:	Based on data from similar materials
Test Type	:	Intracutaneous test
Species	:	Guinea pig
GLP	:	no
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium citrate:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative Test Type: Micronucleus test

Test system: Human lymphocytes
Method: OECD Test Guideline 487
Result: positive

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Application Route: Oral
Method: Regulation (EC) No. 440/2008, Annex, B.22
Result: negative

Test Type: Chromosome aberration test in vitro
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Acid phosphatase:

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 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:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Effects on fertility : Test Type: reproductive and developmental toxicity study
Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Parent: NOAEL: > 1,000 mg/kg body weight
General Toxicity F1: NOAEL: > 1,000 mg/kg body weight
Method: OECD Test Guideline 421
Result: Animal testing did not show any effects on fertility.
GLP: yes

Effects on fetal development : Test Type: Pre-natal
Species: Rat, female
Strain: wistar
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Maternal: NOAEL: > 1,000 mg/kg body weight
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
Result: No effects on fetal development.
GLP: yes
Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

Components:

Acid phosphatase:

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:

Acid phosphatase:

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

Repeated dose toxicity

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Species	:	Rat, male and female
NOAEL	:	250 mg/kg
LOAEL	:	1,000 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Number of exposures	:	daily
Dose	:	62.5, 250, 1000 mg/kg bw
Method	:	OECD Test Guideline 408
GLP	:	yes
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Components:

Acid phosphatase:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Acid phosphatase:

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

Sodium citrate:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 18,000 - 32,000 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 5,600 - 10,000 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants	:	EC50 (Chlorella vulgaris (Fresh water algae)): 18,000 - 32,000 mg/l Exposure time: 96 h
Toxicity to microorganisms	:	EC50 (Bacteria): 1,800 - 3,200 mg/l Exposure time: 8 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

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Toxicity to fish	:	LC50 (Fish): > 4,000 mg/l Exposure time: 96 h Test Type: static test Analytical monitoring: no Method: DIN 38412 GLP: no
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 980 mg/l End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 473 mg/l End point: Growth rate Exposure time: 48 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 201 GLP: No information available.
Toxicity to microorganisms	:	EC50 (activated sludge): > 1,000 mg/l End point: Respiration inhibition Exposure time: 3 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 209 GLP: yes

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to	:	No data available

the environment

Persistence and degradability

Components:

Sodium citrate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge
Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Bioaccumulative potential

Components:

Acid phosphatase:

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

Sodium citrate:

Bioaccumulation : Bioconcentration factor (BCF): 3.2
Remarks: Based on data from similar materials

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

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -2.31 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: no

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).

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

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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 : Combustible dust

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 SOCMI 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

Acid phosphatase	9001-77-8
Sodium citrate	6132-04-3
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	77-86-1

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 listed on the Canadian NDSL. All other components are on the Canadian DSL.

Acid phosphatase

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	:	On the inventory, or in compliance with the inventory
TSCA	:	All substances listed as active on the TSCA inventory
TECI	:	Not in compliance with the inventory

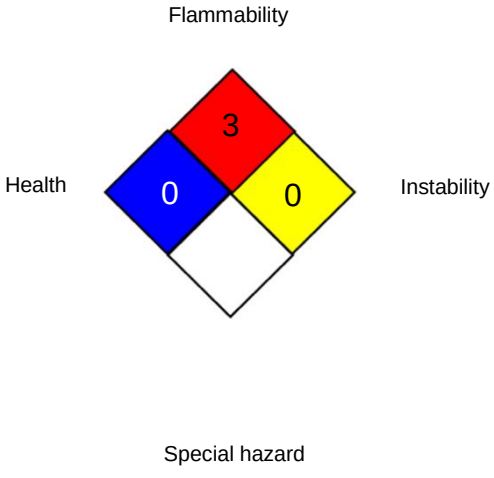
TSCA list

No substances are subject to a Significant New Use Rule.

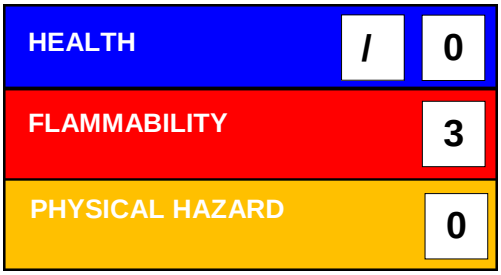
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



HMIS® IV:



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.

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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; 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; TECI - 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

Revision Date : 04-16-2022

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 / 2104