



cOmplete,Mini,EDTA-free,EASYpack,30 Tab.

Version 1.10 Revision Date: 05-08-2023 Date of last issue: 03-21-2022
 Date of first issue: 12-15-2015

SECTION 1. IDENTIFICATION

Product name : cOmplete,Mini,EDTA-free,EASYpack,30 Tab.
 Product code : 04693159001

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)

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H315 Causes skin irritation.
 H319 Causes serious eye irritation.

Precautionary Statements : **Prevention:**
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/ eye protection/ face protection.
Response:
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ atten-



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tion.
P362 Take off contaminated clothing and wash before reuse.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

cOmplete mini EDTA free tablets

GHS Classification

Skin irritation : Category 2
Eye irritation : Category 2A

Components

Chemical name	CAS-No.	Concentration (% w/w)
D-Mannitol	69-65-8	>= 70 - < 90
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	>= 1 - < 5
Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-	25322-68-3	>= 1 - < 5
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride	30827-99-7	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.



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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 : No information available.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : No information available.

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 : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

Environmental precautions : Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.



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- Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL

Engineering measures : No data available

Personal protective equipment

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 : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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- Appearance : tablet

- Color : white

- Odor : none

- Odor Threshold : Not applicable

- pH : Not applicable

- 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 : completely soluble

 - Solubility in other solvents : No data available

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

- Autoignition temperature : No data available



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- Decomposition temperature : No data available
- Viscosity
 - Viscosity, dynamic : Not applicable
 - Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive

- 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.
No decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : No data available
- Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

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Acute toxicity

Not classified based on available information.

Components:

D-Mannitol:

- Acute oral toxicity : LD50 Oral (Rat): 13,500 mg/kg
LD50 Oral (Mouse): 22,000 mg/kg
- Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

- Acute oral toxicity : LD50 Oral (Rat): 100,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

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

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

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 28,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Acute oral toxicity : LD50 Oral (Mouse): 2,800 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Result : Causes burns.
Remarks : Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : May cause irreversible eye damage.

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.

Carcinogenicity

Not classified based on available information.

Components:

D-Mannitol:

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.



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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.

STOT-single exposure

Not classified based on available information.

Components:

D-Mannitol:

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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:

D-Mannitol:

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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

Aspiration toxicity

Not classified based on available information.

Components:

D-Mannitol:

No data available

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

No data available

Further information

Components:

D-Mannitol:

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Remarks : Health injuries are not known or expected under normal use.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Remarks : No toxicology information is available.

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : Other dangerous properties can not be excluded.

SECTION 12. ECOLOGICAL INFORMATION
cOmplete mini EDTA free tablets**Ecotoxicity****Components:****D-Mannitol:**Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:**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

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
Exposure time: 4 d
Method: OECD Test Guideline 203

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
 Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:
Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability
Components:
D-Mannitol:

Biodegradability : Biodegradation: 68 %
 Exposure time: 28 d

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Biodegradability : Biodegradation: > 90 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301

Bioaccumulative potential
Components:
D-Mannitol:

Partition coefficient: n-octanol/water : log Pow: -3.10

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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



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Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

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

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

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

Mobility in soil

No data available

Other adverse effects

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

Adsorbed organic bound : Remarks: Not applicable
halogens (AOX)

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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



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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

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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 : Skin corrosion or irritation
Serious eye damage or eye irritation

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 1 - < 5 %
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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



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D-Mannitol	69-65-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

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 List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
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The ingredients of this product are reported in the following inventories:

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
 - 4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
 - Leupeptin hemisulfate
 - AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung
- 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 : On the inventory, or in compliance with the inventory
- TCSI : On the inventory, or 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.

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GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary Statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

SECTION 16. OTHER INFORMATION

Further information
cOmplete mini EDTA free tablets

SAFETY DATA SHEET



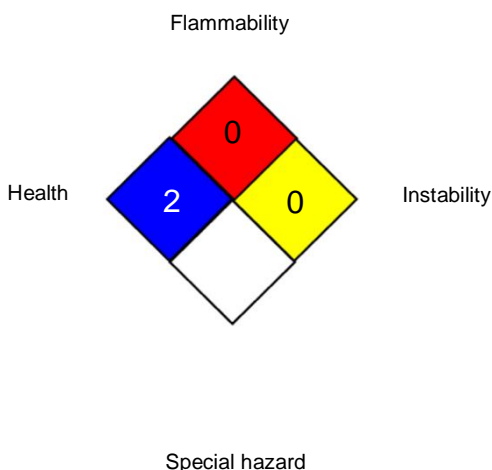
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NFPA 704:



HMIS® IV:

HEALTH	/	2
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.

Distributor

MilliporeSigma
3050 Spruce Street
SAINT LOUIS
MO 63103 USA

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

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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

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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 / 2204