

Cell-Free DNA Collection TubeVersion
2.0Revision Date:
04-16-2022Date of last issue: 10-26-2021
Date of first issue: 10-01-2015**SECTION 1. IDENTIFICATION**

Product name : Cell-Free DNA Collection Tube

Product code : 07832389001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)**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)**

Skin irritation : Category 2

Eye irritation : Category 2A

Specific target organ toxicity : Category 3 (Respiratory system)
- single exposure**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.Precautionary Statements : **Prevention:**
P261 Avoid breathing mist or vapors.
P264 Wash skin thoroughly after handling.

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P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

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.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Tripotassium hydrogen ethylenediaminetetraacetate	65501-24-8	≥ 20 - < 30
Urea, N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)-	39236-46-9	≥ 10 - < 20

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.

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- 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.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.
- 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.
- Hazardous combustion products : Carbon oxides
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 : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent further leakage or spillage if safe to do so.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : Avoid formation of aerosol.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Provide sufficient air exchange and/or exhaust in work rooms.
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.
Observe label precautions.
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**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

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

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

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.

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Eye protection	: Replace torn or punctured gloves promptly. Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	: Impervious clothing 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Color	: light yellow
Odor	: No data available
Odor Threshold	: No data available
pH	: 6.8 - 7.4
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)	: Does not sustain combustion.
Flammability (liquids)	: Does not sustain 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	: No data available
Relative density	: No data available

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Density	:	1.15 - 1.23 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
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	:	No data available
Viscosity, kinematic	:	No data available
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 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**Acute toxicity**

Not classified based on available information.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Urea, N,N"-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-:**

Acute oral toxicity : LD50 (Rat): 5,200 mg/kg

Acute inhalation toxicity : LC50: > 5.5 mg/l
Exposure time: 1 h

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Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks : May cause skin irritation in susceptible persons.

Components:**Tripotassium hydrogen ethylenediaminetetraacetate:**

Result : Irritating to skin.
Remarks : May cause skin irritation in susceptible persons.

Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-:

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks : May cause irreversible eye damage.

Components:**Tripotassium hydrogen ethylenediaminetetraacetate:**

Result : Irritating to eyes.

Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-:

Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Tripotassium hydrogen ethylenediaminetetraacetate:**

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

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Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:**Tripotassium hydrogen ethylenediaminetetraacetate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Result: negative
Remarks: Based on data from similar materials

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
Remarks: Based on data from similar materials

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

Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: in vivo assay
Species: Rat
Application Route: Oral
Result: negative

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Not classified based on available information.

Components:**Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-**

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:**Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-**

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Dose: 300 milligram per kilogram
Embryo-fetal toxicity.: NOAEL F1: 300
Result: No teratogenic effects.

Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Dose: 300 milligram per kilogram
Embryo-fetal toxicity.: NOAEL F1: 300
Result: No teratogenic effects.

STOT-single exposure

May cause respiratory irritation.

Components:**Tripotassium hydrogen ethylenediaminetetraacetate:**

Routes of exposure : Inhalation
Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

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Species : Rat
NOAEL : 200 mg/kg
LOAEL : 500 mg/kg
Application Route : Oral

Species : Rabbit
NOAEL : 200 mg/kg
Application Route : Dermal

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Tripotassium hydrogen ethylenediaminetetraacetate:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 792 mg/l
Exposure time: 96 h
Test Type: static test
Remarks: Based on data from similar materials

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,000 mg/l
Exposure time: 24 h
Test Type: static test

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 220 mg/l
Exposure time: 96 h
Test Type: static test
Method: OPPTS 850.1075

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l
End point: Growth inhibition
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Bacteria): 567 mg/l
Exposure time: 3 h

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Method: OECD Test Guideline 209

EC0 (Bacteria): 200 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209**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:****Tripotassium hydrogen ethylenediaminetetraacetate:**Biodegradability : Result: Inherently biodegradable.
Test substance: anhydrous substance**Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-:**Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: > 40 %
Exposure time: 28 d
Method: OECD Test Guideline 301B**Bioaccumulative potential****Components:****Tripotassium hydrogen ethylenediaminetetraacetate:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-
octanol/water : Remarks: No data available**Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]-:**Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water,
accumulation in organisms is not expected.Partition coefficient: n-
octanol/water : log Pow: 0.9 (68 °F / 20 °C)**Mobility in soil**

No data available

Other adverse effects**Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-
tection of Stratospheric Ozone - CAA Section 602 Class I
Substances

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Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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

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.

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SARA 311/312 Hazards : Skin corrosion or irritation
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

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):

Glycine	56-40-6	>= 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

Water	7732-18-5
Tripotassium hydrogen ethylenediaminetetraacetate	65501-24-8
Urea, N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-	39236-46-9

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Urea, N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-	39236-46-9
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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 that are not on the Canadian DSL nor NDSL.

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Tripotassium hydrogen ethylenediaminetetraacetate

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	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

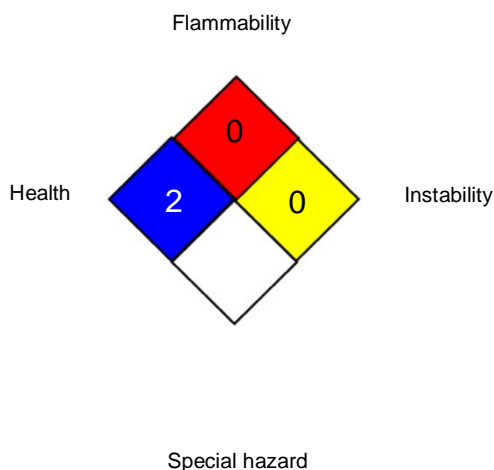
TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

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.

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

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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

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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 / 2104