



ACCU-CHEK LINEARITY KIT U.S.

Version 1.8 Revision Date: 02-06-2021 Date of last issue: 09-18-2019
Date of first issue: 11-09-2015

SECTION 1. IDENTIFICATION

Product name : ACCU-CHEK LINEARITY KIT U.S.
Product code : 05871166001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-
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 further information, refer to the product technical data sheet.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.



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P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Ctrl 1/Ctrl 2

GHS Classification

Skin sensitization : Category 1

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2-Propanediol	57-55-6	>= 10 - < 20
Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-	78491-02-8	>= 0.1 - < 1

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 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.
Keep eye wide open while rinsing.
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.

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- 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.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : 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.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma,



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allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Ctrl 1/Ctrl 2

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2-Propanediol	57-55-6	TWA	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

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 : Wash hands before breaks and at the end of workday.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Ctrl 1/Ctrl 2

- Appearance : liquid

- Color : No data available

- Odor : characteristic

- Odor Threshold : No data available

- pH : neutral

- 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) : The product is not flammable.

- 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

- 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



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- Viscosity
 - Viscosity, dynamic : No data available
 - Viscosity, kinematic : No data available
- 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 decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : No data available
- Hazardous decomposition products : In case of fire hazardous decomposition products may be produced such as:
 - Carbon oxides
 - Nitrogen oxides (NOx)
 - Sulfur oxides
 - Gaseous hydrogen chloride (HCl).
 - Sodium oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Ctrl 1/Ctrl 2

Acute toxicity

Not classified based on available information.

Components:

1,2-Propanediol:

- Acute oral toxicity : LD50 (Rat, male and female): 22,000 mg/kg
GLP: no
- Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
GLP: no
Assessment: The substance or mixture has no acute dermal toxicity

Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

- Acute oral toxicity : LD50 Oral (Rat): 2,570 mg/kg



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LD50 Oral (Rat): 2,600 mg/kg

LD50 Oral (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

1,2-Propanediol:

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

Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

Remarks : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

1,2-Propanediol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
GLP : No information available.

Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

1,2-Propanediol:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 429
GLP : No information available.

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.



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Method : OECD Test Guideline 406
 GLP : No information available.

Test Type : Split adjuvant test
 Species : Guinea pig
 Assessment : Does not cause skin sensitization.
 GLP : No information available.

Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

Assessment : May cause sensitization by skin contact.
 Remarks : Causes sensitization.

Germ cell mutagenicity

Not classified based on available information.

Components:

1,2-Propanediol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Result: negative
 GLP: No information available.

Test Type: Chromosome aberration test in vitro
 Test system: Human lymphocytes
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: yes

Genotoxicity in vivo : Species: Rat (male)
 Cell type: Bone marrow
 Application Route: Oral
 Exposure time: single dose or 5 doses
 Dose: 30, 2500, and 5000 mg/kg
 Result: negative
 GLP: no

Test Type: dominant lethal test
 Species: Rat (male)
 Application Route: Oral
 Exposure time: single dose or 5 consecutive d
 Dose: 30, 2500 or 5000 mg/kg
 Result: negative
 GLP: no

Test Type: Micronucleus test
 Species: Mouse (male)
 Application Route: Intraperitoneal injection
 Exposure time: Single injection
 Dose: 2500, 5000, 10000, 15000 mg/kg
 Result: negative
 GLP: No information available.

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Not classified based on available information.

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:**1,2-Propanediol:**Effects on fertility : Test Type: Two-generation study
Species: Mouse, male and female
Application Route: Oral
Dose: 1820, 4800, 10,100 mg/kg bw/day
Fertility: NOAEL: 10,100 mg/kg bw/day
GLP: No information available.Effects on fetal development : Test Type: Pre-natal
Species: Mouse, female
Application Route: Oral
Dose: 520, 5.200, 10.400 mg/kg bw/day
Duration of Single Treatment: 18 d
General Toxicity Maternal: NOAEL: 520 mg/kg body weight
Developmental Toxicity: NOAEL: 1,040 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 1,040 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes**STOT-single exposure**

Not classified based on available information.

Components:**Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:**

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:**Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:**

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

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Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION
Ctrl 1/Ctrl 2
Ecotoxicity
Components:
1,2-Propanediol:

- | | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
GLP: no |
| Toxicity to daphnia and other aquatic invertebrates | : | LC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
GLP: No information available. |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 19,100 mg/l
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 13,200 mg/l
Exposure time: 7 d
Analytical monitoring: yes
GLP: No information available. |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l
End point: Growth rate
Exposure time: 18 h
Test Type: No data available
Analytical monitoring: no
GLP: no
Remarks: Information taken from reference works and the literature. |

Ecotoxicology Assessment

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



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Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

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:

1,2-Propanediol:

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 100 mg/l
Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Bioaccumulative potential

Components:

1,2-Propanediol:

Partition coefficient: n-octanol/water : log Pow: -1.07 (68.9 °F / 20.5 °C)
pH: 6.2 - 6.4
Method: Regulation (EC) No. 440/2008, Annex, A.8
GLP: yes

Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-:

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

Mobility in soil

No data available

Other adverse effects

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.



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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

Ctrl 1/Ctrl 2

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 : Respiratory or skin sensitization

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):

1,2-Propanediol	57-55-6	>= 10 - < 20 %
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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
1,2-Propanediol	57-55-6
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9
Sodium chloride (NaCl)	7647-14-5

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:

- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Dextrose

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-, sodium salt (1:1)
- AICS : On the inventory, or in compliance with the inventory
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- 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.

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TSCA list

No substances are subject to a Significant New Use Rule.

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

Ctrl 1/Ctrl 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Disposal:

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

SECTION 16. OTHER INFORMATION

Further information

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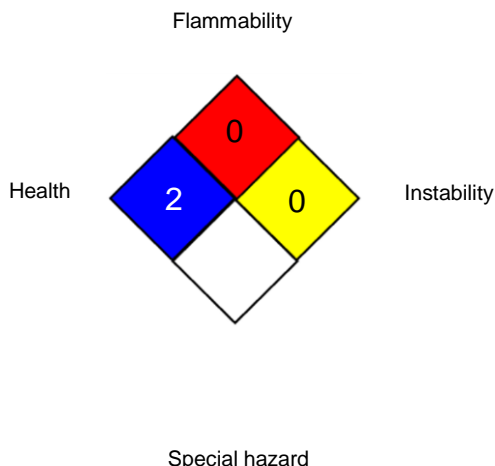
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NFPA 704:



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.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC₅₀ - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC₅₀ - Lethal Concentration to 50 % of a test population; LD₅₀ - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations;

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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 / 2004