

ACCU-CHEK LINEARITY KIT U.S.Version
1.1Revision Date:
12-08-2015Date of last issue: 11-09-2015
Date of first issue: 11-09-2015**SECTION 1. IDENTIFICATION**

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

Mat.-No./ Genisys-No. : 05871166001

Manufacturer or supplier's detailsCompany name of supplier : Roche Diagnostics
-Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:

In case of emergencies : CHEMTREC 1-800-424-9300 (U.S. or Ca-
nada)
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**

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

GHS Label element

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.

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None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**Ctrl 1/Ctrl 2****GHS Classification**Skin sensitization
Category 1

H317: May cause an allergic skin reaction.

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (% w/w)
Propylene glycol	57-55-6	>= 10 - < 20
DIAZOLIDINYL UREA	78491-02-8	>= 0.1 - < 1

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.
- 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 cir-

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cumstances 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, 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.
- Technical : See label, package insert or internal guidelines

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measures/Precautions

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Ctrl 1/Ctrl 2
Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA	10 mg/m ³	US WEEL

Hazardous components without workplace control parameters

Ingredients	CAS-No.
DIAZOLIDINYL UREA	78491-02-8

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

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 gogglesSkin 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Ctrl 1/Ctrl 2

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

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Evaporation rate	: No data available
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
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	: 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

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Acute toxicity

Not classified based on available information.

Ingredients:**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 20,000 mg/kg

LD50 (Mouse): 20,300 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Method: Expert judgment

Acute dermal toxicity : LD50 (Rabbit): 20,800 mg/kg

DIAZOLIDINYL UREA:

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

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

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

Skin corrosion/irritation

Not classified based on available information.

Ingredients:**Propylene glycol:**

Remarks: This information is not available.

DIAZOLIDINYL UREA:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**Propylene glycol:**

Remarks: This information is not available.

DIAZOLIDINYL UREA:

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.

Ingredients:**DIAZOLIDINYL UREA:**

Assessment: May cause sensitization by skin contact.

Remarks: Causes sensitization.

Germ cell mutagenicity

Not classified based on available information.

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Carcinogenicity

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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

Ingredients:**Propylene glycol:**

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

DIAZOLIDINYL UREA:

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

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Propylene glycol:**

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

DIAZOLIDINYL UREA:

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

Aspiration toxicity

Not classified based on available information.

Ingredients:**Propylene glycol:**

No data available

DIAZOLIDINYL UREA:

No data available

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SECTION 12. ECOLOGICAL INFORMATION
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Ecotoxicity
Ingredients:
Propylene glycol:

- Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
Exposure time: 24 h
- NOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 34,400 mg/l
Exposure time: 48 h
- Toxicity to algae : EC50 (Chlorella pyrenoidosa): 92,000 mg/l
- Toxicity to fish (Chronic toxicity) : > 1 mg/l
- Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 26,800 mg/l
Exposure time: 0.5 h

**Ecotoxicology Assessment
Toxicity Data on Soil**

: Not expected to adsorb on soil.

Other organisms relevant to the environment

: No data available

DIAZOLIDINYL UREA:
**Ecotoxicology Assessment
Toxicity Data on Soil**

: Not expected to adsorb on soil.

Other organisms relevant to the environment

: No data available

Persistence and degradability
Ingredients:
Propylene glycol:

- Biodegradability : Zahn-Wellens Test
Result: Readily biodegradable.
Biodegradation: 98 %
Exposure time: 5 d
Method: OECD Test Guideline 302

Bioaccumulative potential
Ingredients:
Propylene glycol:

- Partition coefficient: n-octanol/water : log Pow: -0.92

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DIAZOLIDINYL UREA:

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

Mobility in soil

No data available

Other adverse effects

Ingredients:

DIAZOLIDINYL UREA:

Additional ecological information : No data available

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 Regulation

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 for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 12 (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):

Propylene glycol	57-55-6	10 %
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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

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	70 - 90 %
Propylene glycol	57-55-6	10 - 20 %
HEPES	7365-45-9	1 - 5 %
Sodium chloride	7647-14-5	1 - 5 %

New Jersey Right To Know

Water	7732-18-5	70 - 90 %
Propylene glycol	57-55-6	10 - 20 %
HEPES	7365-45-9	1 - 5 %
Sodium chloride	7647-14-5	1 - 5 %

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other repro-

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ductive defects.

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

CH INV	: Not in compliance with the inventory Dextrose
TSCA	: Not On TSCA Inventory Dextrose
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Dextrose Hepes, sodium salt
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 Water HEPES Hepes, sodium salt Dextrose DIAZOLIDINYL UREA
ISHL	: Not in compliance with the inventory HEPES Hepes, sodium salt Dextrose
KECI	: Not in compliance with the inventory HEPES Hepes, sodium salt Dextrose
PICCS	: Not in compliance with the inventory Hepes, sodium salt
IECSC	: On the inventory, or 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.

Ctrl 1/Ctrl 2
GHS Label element

Hazard pictograms :



Signal Word : Warning

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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
Full text of other abbreviations

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized 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; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECSC - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RCRA - Resource Conservation and Recovery Act; RQ - Reportable Quantity; SARA - Superfund Amendments and Reauthorization Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice; ERG - Emergency Response Guide; NTP - National Toxicology Program; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods

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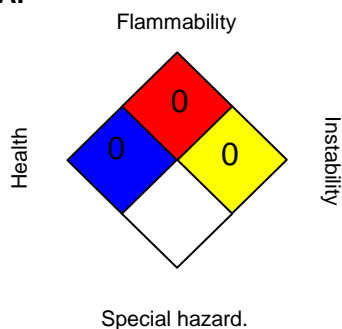
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Further information

Ctrl 1/Ctrl 2

NFPA:



HMIS III:

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and re-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.

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