

**ACCU-CHEK LINEARITY KIT U.S.**

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

**SECTION 1. IDENTIFICATION**

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

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

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road  
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

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**

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/ vapours/ spray.  
P272 Contaminated work clothing should 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.

**Other hazards**

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None known.

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

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
propane-1,2-diol	57-55-6	$\geq 10$ - $< 20$
1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	78491-02-8	$\geq 0.1$ - $< 1$

**SECTION 4. FIRST AID MEASURES**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Specific hazards during firefighting : No information available.
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local

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circumstances and the surrounding environment.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
propane-1,2-diol	57-55-6	TWA	10 mg/m <sup>3</sup>	US WEEL

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the

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	product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	: Safety glasses
Skin and body protection	: Protective suit
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

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

Appearance	: liquid
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	
Water solubility	: soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: 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	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION*****Ctrl 1/Ctrl 2*****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

**Product:**Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg  
Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate : > 5,000 mg/kg  
Method: Calculation method**Components:****propane-1,2-diol:**Acute oral toxicity : LD50 (Rat): 20,000 mg/kg  
LD50 (Mouse): 20,300 mg/kgAcute inhalation toxicity : Acute toxicity estimate : > 30 mg/l  
Method: Expert judgement

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

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)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.

**Components:****propane-1,2-diol:**

Remarks: This information is not available.

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

Remarks: May cause skin irritation and/or dermatitis.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****propane-1,2-diol:**

Remarks: This information is not available.

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

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

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**Respiratory or skin sensitisation**

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: Not classified based on available information.

**Components:****1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

Assessment: May cause sensitisation by skin contact.

Remarks: Causes sensitisation.

**Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Not classified based on available information.

**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**OSHA**

No component 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 component 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:****propane-1,2-diol:**

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

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)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.

**Components:****propane-1,2-diol:**

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

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

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.

**Components:****propane-1,2-diol:**

No data available

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

No data available

**SECTION 12. ECOLOGICAL INFORMATION*****Ctrl 1/Ctrl 2*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

**Components:****propane-1,2-diol:**Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l  
Exposure time: 24 hNOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l  
Exposure time: 96 hToxicity 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 (aglae)): 92,000 mg/l

Toxicity to fish (Chronic toxicity) : &gt; 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

**1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

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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**Persistence and degradability****Components:****propane-1,2-diol:**

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

**Bioaccumulative potential****Components:****propane-1,2-diol:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Product:**

Regulation 40 CFR Protection of Environment; Part 82 Protection of  
Stratospheric Ozone - CAA Section 602 Class I Substances

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

**Components:****1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea:**

Additional ecological  
information : No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Can be disposed as waste water, when in compliance with  
local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste  
handling site for recycling or disposal.  
Do not re-use empty containers.

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**SECTION 14. TRANSPORT INFORMATION****International Regulation****IATA-DGR**




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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.

**National Regulations****49 CFR**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION**
**Ctrl 1/Ctrl 2****EPCRA - Emergency Planning and Community Right-to-Know Act****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** : 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 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):

propane-1,2-diol	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

**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 %
propane-1,2-diol	57-55-6	10 - 20 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	1 - 5 %
sodium chloride	7647-14-5	1 - 5 %

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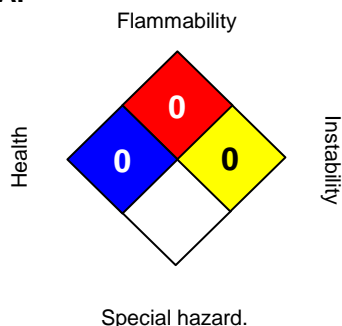
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**New Jersey Right To Know**

water	7732-18-5	70 - 90 %
propane-1,2-diol	57-55-6	10 - 20 %
4-(2-hydroxyethyl)piperazin-1- ylethanesulphonic acid	7365-45-9	1 - 5 %
sodium chloride	7647-14-5	1 - 5 %

**California Prop 65**

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**SECTION 16. OTHER INFORMATION**
**Further information**
**Ctrl 1/Ctrl 2**
**NFPA:**

**HMIS III:**

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>0</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

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

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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.