

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## ACCU-CHEK INFORM II CONTROLS US 6/CS

Version 1.0

Revision Date 06-11-2012

Print Date 10-25-2012

### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Commercial Product Name : ACCU-CHEK INFORM II CONTROLS US 6/CS  
Mat.-No./ Genisys-No. : 05213509001

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions : For professional users only.  
on use

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics  
9115 Hague Road  
46250 Indianapolis IN

E-mail address :  
Telephone : 1-800-428-5074  
Telefax :  
Responsible Department :  
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or  
Canada)  
1-703-527-3887  
(International)

### 2. Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

##### Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

##### Additional Labelling:

EUH210 Safety data sheet available on request.

EUH208 Contains: 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea May produce an allergic reaction.

#### 2.3 Other hazards



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No information available.

**3. Composition/information on ingredients**

**3.2 Mixtures**

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**Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

**Classification (67/548/EEC, 1999/45/EC)**

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

Remarks : No dangerous ingredients according to Regulation (EC) No. 1907/2006

**4. First aid measures**

**4.1 Description of 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.

**4.2 Most important symptoms and effects, both acute and delayed**

Symptoms : No information available.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.



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**5. Firefighting measures**

**5.1 Extinguishing media**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during firefighting : No information available.

**5.3 Advice for firefighters**

Special protective equipment for firefighters : Wear self contained breathing apparatus for fire fighting if necessary.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**6. Accidental release measures**

**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Refer to protective measures listed in sections 7 and 8.

**6.2 Environmental precautions**

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

**6.3 Methods and materials for containment and cleaning up**

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

**6.4 Reference to other sections**

Treat recovered material as described in the section "Disposal considerations".

**7. Handling and storage**

**7.1 Precautions for safe handling**

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

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

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Further information on storage conditions : See label or package insert  
Advice on common storage : No materials to be especially mentioned.  
Other data : No decomposition if stored and applied as directed.

### 7.3 Specific end uses

Specific use(s) : Laboratory chemicals

### 8. Exposure controls/personal protection

#### Exposure Guidelines

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#### Components with workplace control parameters

Components	CAS-No.	Value	Control parameters	Source
propane-1,2-diol	57-55-6	TWA	10 mg/m <sup>3</sup>	USA. Workplace Environmental Exposure Levels (WEEL)

#### Personal protective equipment

Eye protection : Safety glasses  
Hand protection : Protective gloves  
Skin and body protection : Protective suit  
Respiratory protection : No personal respiratory protective equipment normally required.  
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

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Appearance : liquid

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Melting point/range	: no data available
Boiling point/boiling range	: no data available
Flash point	: not applicable
Flammability (solid, gas)	: The product is not flammable.
Lower explosion limit	: no data available
Upper explosion limit	: no data available
Vapour pressure	: no data available
Water solubility	: soluble
Partition coefficient: n-octanol/water	: no data available
Ignition temperature	: no data available
Thermal decomposition	: no data available
Viscosity, dynamic	: no data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

<i>Ctrl 1/Ctrl 2</i>	
Conductivity	: no data available
Oxidising potential	: no data available
Surface tension	: no data available

## 10. Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Further information: Stable under recommended storage conditions., No hazards to be specially mentioned.

### 10.4 Conditions to avoid

Conditions to avoid : no data available

### 10.5 Incompatible materials

Materials to avoid : no data available

### 10.6 Hazardous decomposition products

Hazardous decomposition products : no data available



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### 11. Toxicological information

#### 11.1 Information on toxicological effects

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**Components:**

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

- |   |  |
|---|--|
| Acute oral toxicity                             | : LD50: 20,000 mg/kg, rat  |
|   | : LD50: 20,300 mg/kg, mouse  |
| Acute inhalation toxicity                       | : no data available  |
| Acute dermal toxicity                           | : LD50: 20,800 mg/kg, rabbit   |
| Acute toxicity (other routes of administration) | : no data available  |
| Skin corrosion/irritation                       | : This information is not available.   |
| Serious eye damage/eye irritation               | : This information is not available.   |
| Respiratory or skin sensitization               | : Result: no data available  |
| STOT - single exposure                          | : Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.   |
| STOT - repeated exposure                        | : Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure. |
| Aspiration toxicity                             | : no data available  |
| Further information                             | : no data available  |

### 12. Ecological information

#### 12.1 Toxicity

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**Components:**

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

- |   |  |
|---|--|
| Toxicity to fish                                    | : LC0: > 1,000 mg/l, 24 h, Oncorhynchus mykiss (rainbow trout) |
| Toxicity to daphnia and other aquatic invertebrates | : EC50: 34,400 mg/l, 48 h, Daphnia magna (Water flea)          |
| Toxicity to algae                                   | : EC50: 92,000 mg/l, Chlorella pyrenoidosa                     |
| Toxicity to bacteria                                | : EC50: 26,800 mg/l, 0.5 h, Photobacterium phosphoreum         |

**Ecotoxicology Assessment**

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



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Other organisms relevant to the environment : no data available

**12.2 Persistence and degradability**

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**Components:**

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

Biodegradability : 98 %, Exposure time: 5 d, OECD Test Guideline 302

**12.3 Bioaccumulative potential**

*Ctrl 1/Ctrl 2*

**Components:**

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

Bioaccumulation : no data available

**12.4 Mobility in soil**

*Ctrl 1/Ctrl 2*

**Components:**

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

Mobility : no data available

Distribution among environmental compartments : no data available

Environmental fate and pathways : no data available

Physico-chemical removability : no data available

**12.5 Results of PBT and vPvB assessment**

*Ctrl 1/Ctrl 2*

**Components:**

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

Assessment : This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)., This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

**12.6 Other adverse effects**



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**Components:**

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

- Biochemical Oxygen Demand (BOD) : no data available
- Dissolved organic carbon (DOC) : no data available
- Chemical Oxygen Demand (COD) : no data available
- Adsorbed organic bound halogens (AOX) : no data available

**13. Disposal considerations**

**13.1 Waste treatment methods**

- Product : 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.

**14. Transport information**

**14.1 UN number**

- DOT**  
Not dangerous goods
- IMDG**  
Not dangerous goods
- IATA**  
Not dangerous goods

**14.2 Proper shipping name**

- DOT**  
Not dangerous goods
- IMDG**  
Not dangerous goods
- IATA**  
Not dangerous goods

**14.3 Transport hazard class**

- DOT**  
Not dangerous goods
- IMDG**





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Not dangerous goods

**IATA**

Not dangerous goods

**14.4 Packing group**

**DOT**

Not dangerous goods

**IMDG**

Not dangerous goods

**IATA\_C**

Not dangerous goods

**IATA\_P**

Not dangerous goods

**14.5 Environmental hazards**

**DOT**

Not dangerous goods

**IMDG**

Not dangerous goods

**IATA**

Not dangerous goods

**14.6 Special precautions for user**

Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Remarks : not applicable

**15. Regulatory information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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**REGULATORY INFORMATION**

**OSHA Hazards** : No OSHA Hazards

**WHMIS Classification** : Not Rated

This product has been classified according to the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**CERCLA Reportable Quantity**

**SARA 302 Reportable Quantity**

Product : This material does not contain any components with a SARA 302 RQ.

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**SARA 311/312 Hazards** : No SARA Hazards

### EPCRA - Emergency Planning and Community Right-to-Know Act

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

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

### Clean Air Act

**Ozone-Depletion Potential** : 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 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 10 %

### 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.

### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

#### Pennsylvania Right To Know

Components	:	water	60 - 100 %
		propane-1,2-diol	10 - 30 %
		4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	1 - 5 %
		sodium chloride	1 - 5 %

#### New Jersey Right To Know

Components	:	water	60 - 100 %
		propane-1,2-diol	10 - 30 %
		4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	1 - 5 %
		sodium chloride	1 - 5 %

**California Prop 65 Components** : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.



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**15.2 Chemical Safety Assessment**

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

**16. Other information**

**Further information**

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.