

CK

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : CK
 Mat.-No./ Genisys-No. : 12132672216

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
 -
 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 : Danger

Hazard statements : H360 May damage fertility or the unborn child.

Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P281 Use personal protective equipment as required.
Response:
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
 P405 Store locked up.
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**R1 (B)****GHS Classification**

Reproductive toxicity, Category 1A

H360: May damage fertility or the unborn child.

Hazardous components

| Chemical Name | CAS-No. | Concentration (%) |
|---------------|----------|-------------------|
| imidazole | 288-32-4 | >= 0.1 - < 1 |

R2**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this 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 : Flush eyes with water as a precaution.
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.
Take victim immediately to hospital.

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.

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SECTION 5. FIREFIGHTING 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 firefighting : Do not allow run-off from fire fighting to enter drains or water courses.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : 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 safe handling : Do not breathe vapours/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.

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.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
R1 (B)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

R2**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

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

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 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 : 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 : 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
R1 (B)

| | |
|-----------------------------|---------------------|
| Appearance | : liquid |
| Colour | : colourless |
| Odour | : very faint |
| pH | : 6.6 |
| Melting point/range | : No data available |
| Boiling point/boiling range | : No data available |

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| | |
|---------------------------|--|
| 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 | : completely miscible |
| Auto-ignition temperature | : No data available |
| Thermal decomposition | : No data available |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |

R2

| | |
|-----------------------------|--|
| Appearance | : liquid |
| Colour | : colourless |
| Odour | : very faint |
| pH | : 9.3 |
| 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 |
| Density | : 1.04 g/cm3 |
| Solubility(ies) | |
| Water solubility | : completely miscible |
| 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. |

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| | |
|------------------------------------|---|
| 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

R1 (B)

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

Components:

imidazole:

| | |
|---------------------|------------------------------|
| Acute oral toxicity | : LD50 Oral (Rat): 970 mg/kg |
|---------------------|------------------------------|

Skin corrosion/irritation

Not classified based on available information.

Components:

imidazole:

Result: Causes burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

imidazole:

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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| | |
|--------------|---|
| 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

May damage fertility or the unborn child.

Components:

imidazole:

Reproductive toxicity - Assessment : May damage the unborn child., Known human reproductive toxicant

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

R2

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

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

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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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**R1 (B)****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**imidazole:**Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 100 - 500 mg/l
Exposure time: 48 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 341.5 mg/l
Exposure time: 48 hToxicity to algae : IC50 (Desmodesmus subspicatus (green algae)): 130 mg/l
Exposure time: 72 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 1,200 mg/l

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Exposure time: 17 h

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****imidazole:**Biodegradability : Biodegradation: 83 %
Exposure time: 8 d
Method: OECD Test Guideline 302**Bioaccumulative potential****Components:****imidazole:**Partition coefficient: n-octanol/water : log Pow: -0.02
Method: OECD Test Guideline 107**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:**imidazole:**

Additional ecological information : No data available

R2**Ecotoxicity****Product:**

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

No data available

Bioaccumulative potential

No data available

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).

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****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.

National Regulations**49 CFR**

Not regulated as a dangerous good

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SECTION 15. REGULATORY INFORMATION
R1 (B)
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

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

| | | |
|------------------|----------|--------|
| 2-phenoxyethanol | 122-99-6 | 0.09 % |
|------------------|----------|--------|

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 SOCMi Intermediate or Final VOC's (40 CFR 60.489):

| | | |
|------------------|----------|--------|
| 2-phenoxyethanol | 122-99-6 | 0.09 % |
|------------------|----------|--------|

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 | 90 - 100 % |
| 2-phenoxyethanol | 122-99-6 | 0 - 0.1 % |

New Jersey Right To Know

| | | |
|-------|-----------|------------|
| water | 7732-18-5 | 90 - 100 % |
|-------|-----------|------------|

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.

R2
EPCRA - Emergency Planning and Community Right-to-Know Act
CERCLA Reportable Quantity

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

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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

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

| | | |
|------------------|----------|--------|
| 2-phenoxyethanol | 122-99-6 | 0.09 % |
|------------------|----------|--------|

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 SOCMi Intermediate or Final VOC's (40 CFR 60.489):

| | | |
|------------------|----------|--------|
| 2-phenoxyethanol | 122-99-6 | 0.09 % |
|------------------|----------|--------|

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 | 90 - 100 % |
| phosphocreatine, sodium salt | 922-32-7 | 1 - 5 % |
| 2-phenoxyethanol | 122-99-6 | 0 - 0.1 % |

New Jersey Right To Know

| | | |
|------------------------------|------------|------------|
| water | 7732-18-5 | 90 - 100 % |
| phosphocreatine, sodium salt | 922-32-7 | 1 - 5 % |
| Dextrose | 14431-43-7 | 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****R1 (B)**

SAFETY DATA SHEET



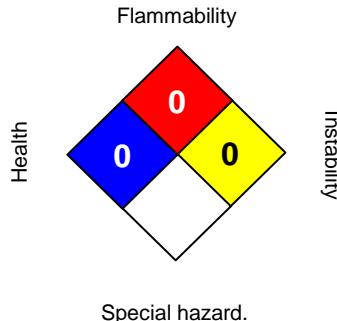
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NFPA:



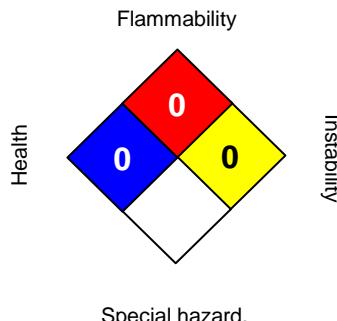
HMIS III:

| | |
|------------------------|----------|
| HEALTH | 0 |
| FLAMMABILITY | 0 |
| PHYSICAL HAZARD | 0 |

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

R2

NFPA:



HMIS III:

| | |
|------------------------|----------|
| HEALTH | 0 |
| FLAMMABILITY | 0 |
| PHYSICAL HAZARD | 0 |

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.