

KIT CA CONJUGATE 200 TESTS IVD CE

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : KIT CA CONJUGATE 200 TESTS IVD CE

Mat.-No./ Genisys-No. : 20764213123

Manufacturer or supplier's detailsCompany 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

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**CN4****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
phenol	108-95-2	>= 0.1 - < 1

SECTION 4. FIRST AID MEASURESGeneral 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

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	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. 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	: Soak up with inert absorbent material (e.g. sand, silica gel,

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containment and cleaning up

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.
Persons susceptible to skin sensitisation 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.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**CN4****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment**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 : Wash hands before breaks and at the end of workday.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**CN4**

Appearance	: liquid
pH	: 7.3
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
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.

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**CN4****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

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Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : > 40 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

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

Components:**phenol:**

Acute oral toxicity : LD50 Oral (Rat): 317 mg/kg

LD50 Oral (Mouse): 270 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.9 mg/l
Exposure time: 8 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 Dermal (Rat): 669 mg/kg

LD50 Dermal (Rabbit): 630 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**phenol:**

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Components:**phenol:**

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.

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Not classified based on available information.

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Components:**phenol:**

Genotoxicity in vitro : Remarks: In vitro tests showed mutagenic effects

Germ cell mutagenicity-
Assessment : In vitro tests showed mutagenic effects**Carcinogenicity**

Not classified based on available information.

Components:**phenol:**

Remarks: 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.

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:**phenol:**

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:**phenol:**

Assessment: May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**phenol:**

No aspiration toxicity classification

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Further information**Components:****phenol:**

Remarks: Symptoms of overexposure are dizziness, headache, tiredness, nausea, unconsciousness, cessation of breathing.

SECTION 12. ECOLOGICAL INFORMATION**CN4****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**phenol:**Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 1.75 mg/l
Exposure time: 96 hLC50 (Carassius auratus (goldfish)): 46 mg/l
Exposure time: 24 hLC50 (Oncorhynchus mykiss (rainbow trout)): 5 mg/l
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 12 mg/l
Exposure time: 24 hEC50 (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 48 hEC50 (Daphnia magna (Water flea)): 4.2 mg/l
Exposure time: 48 hToxicity to algae : IC50 (Pseudokirchneriella subcapitata (green algae)): 150 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201EC50 (Chlorella vulgaris (Fresh water algae)): 370 mg/l
Exposure time: 96 h

Toxicity to bacteria : (Pseudomonas putida): 64 mg/l

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****phenol:**

Biodegradability : Biodegradation: 96 %
Exposure time: 28 d
Method: OECD Test Guideline 302
Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Biochemical Oxygen Demand (BOD) : 1,680 mg/g
Incubation time: 5 d

Chemical Oxygen Demand (COD) : 2,300 mg/g

Impact on Sewage Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

Bioaccumulative potential**Components:****phenol:**

Partition coefficient: n-octanol/water : log Pow: 1.46

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).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.

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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

SECTION 15. REGULATORY INFORMATION**CN4****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Phenol	108-95-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Phenol	108-95-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302

: The following components are subject to reporting levels established by SARA Title III, Section 302:

phenol	108-95-2	0.1 %
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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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

phenol	108-95-2	0.1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

phenol	108-95-2	0.1 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

phenol	108-95-2	0.1 - 1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
phenol	108-95-2	0.1 - 1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride	1185-53-1	1 - 5 %
Albumins, blood serum	9048-46-8	1 - 5 %
phenol	108-95-2	0.1 - 1 %

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.

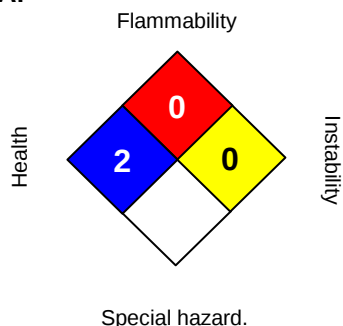
SECTION 16. OTHER INFORMATION**Further information****CN4**

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NFPA:**HMIS III:**

HEALTH	2*
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.