

KIT cobas 4800 CT/NG AMP DET 240T US-IVD

Version 1.0 Revision Date 05-22-2013 Print Date 11-25-2013

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

1.1 Product identifier

Commercial Product Name : KIT cobas 4800 CT/NG AMP DET 240T US-IVD

Mat.-No./ Genisys-No. : 05,235,936,190

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.

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

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.3 Other hazards

No information available.

3. Composition/information on ingredients

3.2 Mixtures



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CT/NG MMX

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

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

1907/2006

[CT Mn2+] / [CT/NG Mn]

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

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.



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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.

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 : No information available.

firefighting

5.3 Advice for firefighters

for firefighters

Special protective equipment : 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 : If the product contaminates rivers and lakes or drains inform

respective authorities.

6.3 Methods and materials for containment and cleaning up

: Wipe up with absorbent material (e.g. cloth, fleece). Methods for cleaning up

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

For personal protection see section 8. Advice on safe handling

Smoking, eating and drinking should be prohibited in the

application area.

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



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fire and explosion

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.

Further information on

storage conditions
Advice on common storage

: See label, package insert or internal guidelines

: No materials to be especially mentioned.

Other data : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

8. Exposure controls/personal protection

Exposure Guidelines

CT/NG MMX

Components with workplace control parameters

Components	CAS-No.	Value	Control parameters	Source
glycerol	56-81-5	TWA	5 mg/m3	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		TWA	15 mg/m3	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		TWA	10 mg/m3	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		TWA	5 mg/m3	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		TWA	10 mg/m3	USA. ACGIH Threshold Limit Values (TLV)

[CT Mn2+] / [CT/NG Mn]

Contains no substances with occupational exposure limit values.

Personal protective equipment



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Eve protection : Safety glasses

Hand protection

Protective gloves

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.

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally

required.

: Handle in accordance with good industrial hygiene and safety Hygiene measures

practice.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

CT/NG MMX

Appearance : liquid

: 8.0 - 8.4 pН

Melting point/range : no data available Boiling point/boiling range : no data available : does not flash Flash point : no data available Lower explosion limit Upper explosion limit : no data available Vapour pressure : no data available Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: no data available

Ignition temperature : no data available Thermal decomposition : no data available

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Viscosity, dynamic : no data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

[CT Mn2+] / [CT/NG Mn]

Appearance : liquid

pH : 6.1

Melting point/range : no data available
Boiling point/boiling range : no data available
Flash point : does not flash
Lower explosion limit : no data available
Upper explosion limit : no data available
Vapour pressure : no data available

Density : 1.00 g/cm3

Water solubility : completely miscible Partition coefficient: n- : no data available

octanol/water

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

CT/NG MMX

Conductivity : no data available

Oxidising potential : no data available

Surface tension : no data available

[CT Mn2+] / [CT/NG Mn]

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.



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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

11. Toxicological information

11.1 Information on toxicological effects

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.

[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12. Ecological information

12.1 Toxicity

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.

[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12.2 Persistence and degradability

CT/NG MMX

No ingredients are hazardous according to OHSA criteria. [CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12.3 Bioaccumulative potential

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.

[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12.4 Mobility in soil

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.



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[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12.5 Results of PBT and vPvB assessment

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.

[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

12.6 Other adverse effects

CT/NG MMX

No ingredients are hazardous according to OHSA criteria.

[CT Mn2+] / [CT/NG Mn]

No ingredients are hazardous according to OHSA criteria.

13. Disposal considerations

13.1 Waste treatment methods

Product : The product has to be disposed of as laboratory chemical in

accordance 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



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Not dangerous goods

IATA

Not dangerous goods

14.3 Transport hazard class

DOT

Not dangerous goods

IMDG

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

CT/NG MMX

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



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Components : sodium azide 1000 lbs

SARA 302 Reportable Quantity

Product : Calculated RQ exceeds reasonably attainable upper limit.

Components : sodium azide 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 : Calculated RQ exceeds reasonably attainable upper limit.

Components : sodium azide

Clean Air Act

Ozone-Depletion : This product neither contains, nor was manufactured with a **Potential**

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

glycerol 10.159 %

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

California Prop 65 : This product does not contain any chemicals known to State of

Components California to cause cancer, birth defects, or any other

reproductive harm.

[CT Mn2+] / [CT/NG Mn]

REGULATORY INFORMATION

OSHA Hazards : No OSHA Hazards

: Not Rated WHMIS Classification

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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

Components : sodium azide 1000 lbs

SARA 302 Reportable Quantity

Product : Calculated RQ exceeds reasonably attainable upper limit.

Components : sodium azide

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 : Calculated RQ exceeds reasonably attainable upper limit.

: sodium azide Components

Clean Air Act

Ozone-Depletion : This product neither contains, nor was manufactured with a Potential

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).

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

Mangan(II)-acetate Tetrahydrate

0.61 %

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

acetic acid 0.0149 %

Clean Water Act

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

acetic acid

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid

US State Regulations



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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.

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.