

KIT cobas 4800 SYS SAMPLE PREP 240T IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : KIT cobas 4800 SYS SAMPLE PREP 240T IVD

Mat.-No./ Genisys-No. : 05235782190

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 : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. -
No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/
equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/
face protection.

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Response:

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor/ physician if you feel unwell.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P403 + P235 Store in a well-ventilated place. Keep cool.

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

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

Flammable liquids, Category 2

H225: Highly flammable liquid and vapour.

Eye irritation, Category 2A

H319: Causes serious eye irritation.

Specific target organ toxicity - single exposure, Category 3 (Central nervous system)

H336: May cause drowsiness or dizziness.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
propan-2-ol	67-63-0	>= 90 - <= 100

EB**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

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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. Consult a physician after significant exposure. If unconscious place in recovery position and seek medical advice.
In case of skin contact	: If on skin, rinse well with water. If on clothes, remove clothes.
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	: Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
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. For safety reasons in case of fire, cans should be stored separately in closed containments. Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Ensure adequate ventilation.
Remove all sources of ignition.
Evacuate personnel to safe areas.
Refer to protective measures listed in sections 7 and 8.
Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.
- 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 : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid formation of aerosol.
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.
Take precautionary measures against static discharges.
Provide sufficient air exchange and/or exhaust in work rooms.
Open drum carefully as content may be under pressure.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : No smoking.
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.
Observe label precautions.
Electrical installations / working materials must comply with the technological safety standards.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		TWA	400 ppm 980 mg/m ³	NIOSH REL

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		ST	500 ppm 1,225 mg/m ³	NIOSH REL
		TWA	400 ppm 980 mg/m ³	OSHA Z-1
		TWA	400 ppm 980 mg/m ³	OSHA P0
		STEL	500 ppm 1,225 mg/m ³	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Isopropanol	67-63-0	Acetone	Urine	End of shift at end of workweek	40 mg/l	ACGIH BEI

EB
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
Wear face-shield and protective suit for abnormal processing problems.

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.

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

Appearance	: liquid
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: 12 °C
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.

EB

Appearance	: liquid
pH	: 8.5 - 8.9
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	: 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.

Vapours may form explosive mixture with air.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION***MGP*****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : 4,914 mg/kg
Method: Calculation method

Components:**propan-2-ol:**

Acute oral toxicity : LD50 Oral (Rat): 4,570 mg/kg
LD50 Oral (Mouse): 3,600 mg/kg
LD50 Oral (Rabbit): 6,410 mg/kg

Acute inhalation toxicity : LC50 (Rat): 30 mg/l, 16000 ppm
Exposure time: 4 h
LC50 (Mouse): 53 mg/l

Acute dermal toxicity : LD50 Dermal (Rabbit): 13,400 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**propan-2-ol:**

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

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Remarks: May cause irreversible eye damage.

Components:**propan-2-ol:**

Result: Irritating to eyes.

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.

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

May cause drowsiness or dizziness.

Components:**propan-2-ol:**

Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.

Components:**propan-2-ol:**

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

Aspiration toxicity

Not classified based on available information.

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Further information**Product:**

Remarks: Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting., Concentrations substantially above the TLV value may cause narcotic effects., Solvents may degrease the skin.

EB**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

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.

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.

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

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**propan-2-ol:**Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 10,000 mg/l
Method: OECD Test Guideline 203LC50 (Oncorhynchus mykiss (rainbow trout)): 12,250 mg/l
Method: OECD Test Guideline 203LC100 (Oncorhynchus mykiss (rainbow trout)): 15,000 mg/l
Method: OECD Test Guideline 203Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,500 mg/l
Exposure time: 24 hToxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): 1,800 mg/l
Exposure time: 168 h
Method: OECD Test Guideline 201Toxicity to bacteria : EC0 (Pseudomonas putida): 1,050 mg/l
Exposure time: 16 h

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****propan-2-ol:**Biodegradability : Biodegradation: 99 %
Exposure time: 11 d
Method: OECD Test Guideline 302Biodegradation: 57 %
Exposure time: 5 d
Method: OECD Test Guideline 302**Bioaccumulative potential****Components:**

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propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

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).

EB**Ecotoxicity****Product:**Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

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.

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Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.
Do not burn, or use a cutting torch on, the empty drum.

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

UN/ID No. : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : Flammable liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code

UN number : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : no

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**

UN/ID/NA number : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : Class 3 - Flammable Liquid
ERG Code : 129
Marine pollutant : no

SECTION 15. REGULATORY INFORMATION**MGP****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

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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 : The following components are subject to reporting levels established by SARA Title III, Section 313:

propan-2-ol	67-63-0	93 %
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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):

propan-2-ol	67-63-0	93 %
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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

propan-2-ol	67-63-0	90 - 100 %
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Pennsylvania Right To Know

propan-2-ol	67-63-0	90 - 100 %
Magnetische Glaspartikel (MGP)	Not Assigned	5 - 10 %

New Jersey Right To Know

propan-2-ol	67-63-0	90 - 100 %
Magnetische Glaspartikel (MGP)	Not Assigned	5 - 10 %

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.

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

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	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)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.


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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).

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

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

sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
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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

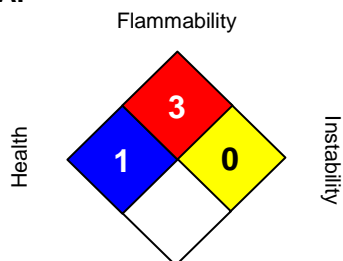
MGP

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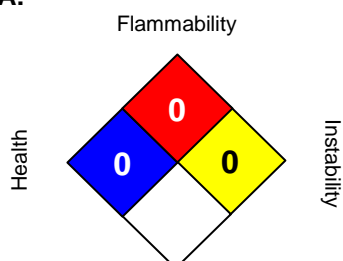
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NFPA:**HMIS III:**

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0

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

**EB
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.