

SAFETY DATA SHEET



KIT COBAS PCR URINE 100 PKT IVD

Version
1.4

Revision Date:
05/20/2016

Date of last issue: 11/30/2015
Date of first issue: 12/10/2013

SECTION 1. IDENTIFICATION

Product name : KIT COBAS PCR URINE 100 PKT IVD
Product code : 05170486190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostic Canada

Address : 201 Boulevard Armand-Frappier
H7V 4A2 Laval, QC, Canada

Telephone : 1-877-273-3433

Telefax : 1-877-686-1598

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300

Centre for detoxification: : Canadian Association of Poison Control Centres <http://www.capcc.ca>

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 elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.

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

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

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

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
R1 - cobas PCR Media**GHS Classification**

Acute toxicity (Oral) Category 4	H302: Harmful if swallowed.
Skin irritation Category 2	H315: Causes skin irritation.
Eye irritation Category 2A	H319: Causes serious eye irritation.
Substance name	: LBLD COBAS PCR MEDIA 4.3mL IVD

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Guanidine, monohydrochloride	50-01-1	>= 30 - < 50

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. Consult a physician after significant exposure. If unconscious place in recovery position and seek medical advice.
In case of skin contact	: If skin irritation persists, call a physician. 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.

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If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
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 fire-fighting : No information available.

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

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.
Ensure adequate ventilation.
Refer to protective measures listed in sections 7 and 8.

Environmental precautions : 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 protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : Avoid formation of aerosol.

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Do not breathe vapours/dust.
 Avoid contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Provide sufficient air exchange and/or exhaust in work rooms.
 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.
 Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
R1 - cobas PCR Media
Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

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

Hand protection
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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Appearance	:	liquid
Colour	:	colourless
Odour	:	No information available.
Odour Threshold	:	No data available
pH	:	7.5
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	The product is not flammable.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.097 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

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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
R1 - cobas PCR Media
Acute toxicity

Harmful if swallowed.

Components:
Guanidine, monohydrochloride:

Acute oral toxicity	:	LD50 Oral (Rat): 475 mg/kg LD50 Oral (Mouse): 571 mg/kg LD50 Oral (Rat): 1,120 mg/kg
Acute inhalation toxicity	:	LC50 (Rat, female): 3.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist LC50 (Rat, male and female): 5.3 mg/l Exposure time: 4 h Test atmosphere: dust/mist LC50 (Rat, male): 7.7 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 Dermal (Rabbit): > 2,001 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:
Guanidine, monohydrochloride:
Species: Rabbit
Result: Irritating to skin.

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Causes serious eye irritation.

Components:**Guanidine, monohydrochloride:**

Species: Rabbit

Result: Irritating to eyes.

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Guanidine, monohydrochloride:**

Assessment: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**Guanidine, monohydrochloride:**Germ cell mutagenicity - : Not mutagenic in Ames Test
Assessment**Carcinogenicity**

Not classified based on available information.

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 - cobas PCR Media*****Ecotoxicity****Components:****Guanidine, monohydrochloride:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1,759 mg/l

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Exposure time: 48 h

Toxicity to bacteria : EC50 (*Pseudomonas putida*): 89 mg/l
Exposure time: 18 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:****Guanidine, monohydrochloride:**Biodegradability : Biodegradation: < 70 %
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

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

Bioaccumulative potential**Components:****Guanidine, monohydrochloride:**

Partition coefficient: n-octanol/water : log Pow: ca. -1.7 (20 °C)

Mobility in soil

No data available

Other adverse effects

No data available

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 han-

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ding site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION
International Regulation**UNRTDG**

Not regulated as a dangerous good

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**TDG**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION
R1 - cobas PCR Media

WHMIS Classification : D1B: Toxic Material Causing Immediate and Serious Toxic Effects
D2B: Toxic Material Causing Other Toxic Effects

The components of this product are reported in the following inventories:

CH INV	On the inventory, or in compliance with the inventory
DSL	All components of this product are on the Canadian DSL
AICS	On the inventory, or in compliance with the inventory
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water Guanidine, monohydrochloride 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride
ISHL	Not in compliance with the inventory Water Guanidine, monohydrochloride 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride
KECI	On the inventory, or in compliance with the inventory
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or in compliance with the inventory

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No substances are subject to a Significant New Activity Notification.

R1 - cobas PCR Media**GHS label elements**

Hazard pictograms



Signal word

: Warning

Hazard statements

: H302 Harmful if swallowed.
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H319 Causes serious eye irritation.

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P270 Do not eat, drink or smoke when using this product.
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Response:
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P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dan-

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gerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Revision Date : 05/20/2016

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.

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