

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012**SECTION 1. IDENTIFICATION**

Product name : KIT COBAS PCR FEMALE SWAB 100 PKT IVD

Mat.-No./ Genisys-No. : 05170516190

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 Can-
ada)

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 : 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.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves.
Response:
P337 + P313 If eye irritation persists: Get medical advice/ atten-
tion.
P362 + P364 Take off contaminated clothing and wash it before
reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste dis-

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

posal plant.

Other hazards

None known.

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

Acute toxicity (Oral) H302: Harmful if swallowed.
Category 4
Skin irritation H315: Causes skin irritation.
Category 2
Eye irritation H319: Causes serious eye irritation.
Category 2A

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
guanidinium chloride	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.
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.
- 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.

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

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.
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. |

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION*****R1 - cobas PCR Media*****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Components	CAS-No.
guanidinium chloride	50-01-1

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.**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES*****R1 - cobas PCR Media***

Appearance : liquid

Colour : colourless

Odour : No information available.

Odour Threshold : No data available

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

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.
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
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available

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.

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012**Product:**

- Acute oral toxicity : Acute toxicity estimate: 1,300 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: 8.76 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**guanidinium chloride:**

- 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.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**guanidinium chloride:**Species: Rabbit
Result: Irritating to skin.**Serious eye damage/eye irritation**

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Components:**guanidinium chloride:**

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012Species: 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:****guanidinium chloride:**

Assessment: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**guanidinium chloride:**Germ cell mutagenicity - : Not mutagenic in Ames Test
Assessment**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.

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 - cobas PCR Media*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

Other organisms relevant to the environment : No data available

Components:**guanidinium chloride:**

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

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:****guanidinium chloride:**

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

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : 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).

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

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

SECTION 15. REGULATORY INFORMATION***R1 - cobas PCR Media***

TSCA list : Not relevant

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 311/312 Hazards : Acute Health Hazard**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

KIT COBAS PCR FEMALE SWAB 100 PKT IVDVersion
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

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 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).

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

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	50 - 70 %
guanidinium chloride	50-01-1	30 - 50 %

New Jersey Right To Know

water	7732-18-5	50 - 70 %
guanidinium chloride	50-01-1	30 - 50 %

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.

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

REACH	: Not in compliance with the inventory
	: guanidinium chloride
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride
	: trometamol
CH INV	: On the inventory, or in compliance with the inventory
TSCA	: On TSCA Inventory
DSL	: All components of this product are on the Canadian DSL.
AICS	: On the inventory, or in compliance with the inventory

KIT COBAS PCR FEMALE SWAB 100 PKT IVD
Version
1.6Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
	: water
	: guanidinium chloride
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride
ISHL	: Not in compliance with the inventory
	: water
	: guanidinium chloride
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol 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

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

R1 - cobas PCR Media**GHS Label element**

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 eye protection/ face protection.
P280 Wear protective gloves.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and 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/ atten-

SAFETY DATA SHEET



KIT COBAS PCR FEMALE SWAB 100 PKT IVD

Version
1.6

Revision Date:
04-25-2015

Date of last issue: 09-18-2014
Date of first issue: 05-16-2012

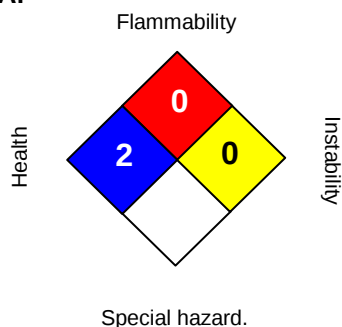
tion.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION

Further information

R1 - cobas PCR Media

NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

Revision Date : 04-25-2015

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.

US / EN