

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015**SECTION 1. IDENTIFICATION**

Product name : KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

Product code : 07958021190

Manufacturer or supplier's detailsCompany name of supplier : Roche Diagnostics
-Address : 9115 Hague Road
46250 Indianapolis IN
USA

Telephone : 1-800-428-5074

Emergency telephone

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 in accordance with 29 CFR 1910.1200**

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 soap and water.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

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 Take off contaminated clothing and wash 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
Skin irritation : Category 2
Eye irritation : Category 2A

Hazardous ingredients

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

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material 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.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

- 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. FIRE-FIGHTING 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 fire-fighters : 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.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

Do not breathe vapors/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.
- Technical measures/Precautions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION***R1 - cobas PCR Media*****Ingredients 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 vapor formation use a respirator with an approved filter.

Hand protection

- Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.
- 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.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

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

Appearance	: liquid
Color	: colorless
Odor	: No information available.
Odor 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.
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor 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
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

Viscosity, kinematic : 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.

Ingredients:**Guanidine, hydrochloride (1:1):**

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.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

Version
1.4

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

Ingredients:**Guanidine, hydrochloride (1:1):**

Species : Rabbit
Result : Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Ingredients:**Guanidine, hydrochloride (1:1):**

Species : Rabbit
Result : Irritating to eyes.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:**Guanidine, hydrochloride (1:1):**

Assessment : Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:**Guanidine, hydrochloride (1:1):**

Germ cell mutagenicity - : Not mutagenic in Ames Test.
Assessment

Carcinogenicity

Not classified based on available information.

IARC No ingredient 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 on OSHA's list of regulated carcinogens.

NTP No ingredient 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.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015**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****Ingredients:****Guanidine, hydrochloride (1:1):**Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1,759 mg/l
Exposure time: 48 hToxicity to microorganisms : 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**Ingredients:****Guanidine, hydrochloride (1:1):**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**Ingredients:****Guanidine, hydrochloride (1:1):**

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

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

Version
1.4

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

Mobility in soil

No data available

Other adverse effects

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 Regulations****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

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION***R1 - cobas PCR Media*****EPCRA - Emergency Planning and Community Right-to-Know****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 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVDVersion
1.4Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation

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 112 (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

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Water	7732-18-5
Guanidine, hydrochloride (1:1)	50-01-1

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

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

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

Version
1.4

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

ISHL	:	Not in compliance with the inventory
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
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

R1 - cobas PCR Media
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 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/ attention.
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

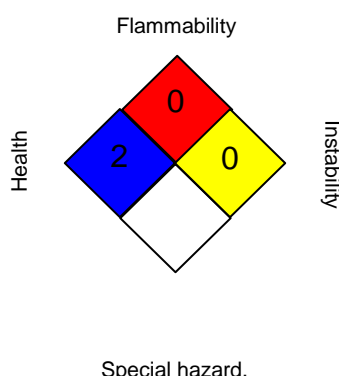
KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

 Version
1.4

 Revision Date:
08-02-2018

 Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

disposal plant.

SECTION 16. OTHER INFORMATION
Further information
R1 - cobas PCR Media
NFPA:

HMIS® IV:

HEALTH	/	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Dangerous 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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)

KIT COBAS PCR MEDIA DUAL SWB 100 PKT IVD

Version
1.4

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 11-30-2015

tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

Revision Date : 08-02-2018

The information provided in this Material 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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