

# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

#### **SECTION 1. IDENTIFICATION**

Product name : KIT COBAS LIAT CDIFF IVD

Product code : 07454945190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road

Indianapolis, IN 46250

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 the OSHA Hazard Communication Standard (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 GHS Label elements contains the resulting labelling for the kit

## **GHS** label elements

Hazard pictograms :







Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.



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P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P285 In case of inadequate ventilation wear respiratory protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

#### Storage:

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**

#### METAL 3

#### **GHS Classification**

Not a hazardous substance or mixture.

## Components

No hazardous ingredients

## MMX-2

#### **GHS Classification**

Not a hazardous substance or mixture.

#### Components



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Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 1 - < 5
DNA-dependent DNA polymerase	9012-90-2	< 0.1
Uracil DNA Glycosylase	59088-21-0	< 0.1

Actual concentration is withheld as a trade secret

## MMX-1

## **GHS Classification**

Not a hazardous substance or mixture.

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Methane, 1,1'-sulfinylbis-	67-68-5	>= 10 - < 20

Actual concentration is withheld as a trade secret

# EB

## **GHS Classification**

Not a hazardous substance or mixture.

## Components

No hazardous ingredients

# WASH

## **GHS Classification**

Not a hazardous substance or mixture.

## Components

No hazardous ingredients

# Lysis

# **GHS Classification**

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Skin corrosion : Category 1B

Serious eye damage : Category 1

# Components

Chemical name	CAS-No.	Concentration (% w/w)
Thiocyanic acid, compd. with	593-84-0	>= 30 - < 50
guanidine (1:1)		
Poly(oxy-1,2-ethanediyl), .alpha	9002-92-0	>= 1 - < 5
dodecylomegahydroxy-		



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Actual concentration is withheld as a trade secret

#### **LMP**

#### **GHS Classification**

Not a hazardous substance or mixture.

#### Components

No hazardous ingredients

#### **PROK**

#### **GHS Classification**

Respiratory sensitization : Category 1

Skin sensitization : Category 1

## Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 30 - < 50
Proteinase K	39450-01-6	>= 1 - < 5

Actual concentration is withheld as a trade secret

# IC

## **GHS Classification**

Not a hazardous substance or mixture.

## Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 30 - < 50

Actual concentration is withheld as a trade secret

# **SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.

Consult a physician.

Show this material safety data sheet to the doctor in

attendance.

Do not leave the victim unattended.

If inhaled : Call a physician or poison control center immediately.

Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

In case of skin contact : Immediate medical treatment is necessary as untreated

wounds from corrosion of the skin heal slowly and with

difficulty.



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If on skin, rinse well with water. If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible

tissue damage and blindness.

In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

Continue rinsing eyes during transport to hospital.

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 induce vomiting.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician. Take victim immediately to hospital.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

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

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.

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.



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Prevent product from entering drains. **Environmental precautions** 

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform

respective authorities.

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**

fire and explosion

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

Avoid formation of aerosol. Advice on safe handling

Do not breathe vapors/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.

Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national

regulations.

Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being

used.

To prevent leaks or spillages from spreading, provide a

suitable liquid retention system.

Keep container tightly closed in a dry and well-ventilated Conditions for safe storage

place.

Containers which are opened must be carefully resealed and

kept upright to prevent leakage.

Electrical installations / working materials must comply with

the technological safety standards.

Further information on storage conditions

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

#### METAL 3

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

#### MMX-2



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# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
DNA-dependent DNA polymerase	9012-90-2	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Uracil DNA Glycosylase	59088-21-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

# MMX-1

# Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control	Basis
		(Form of	parameters /	
		exposure)	Permissible	
			concentration	
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL

# EΒ

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

# **WASH**

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

# Lysis

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Thiocyanic acid, compd. with guanidine (1:1)	593-84-0	IOEL	100 microgram per cubic meter	Category 1 (Roche Group Directive K1, Annex 3):



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OEL = 100 μg/m3

**LMP** 

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

# **PROK**

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
Proteinase K	39450-01-6	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

IC

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0

**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



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In case of contact through splashing:

Material Nitrile rubber Break through time > 30 min Glove thickness > 0.11 mm

In case of full contact:

Material butyl-rubber Break through time > 480 min Glove thickness > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye wash bottle with pure water Eye protection

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.

When using do not eat or drink. Hygiene measures

When using do not smoke.

Wash hands before breaks and at the end of workday.

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

#### METAL 3

Appearance liquid

Color colorless

Odor characteristic

Odor Threshold No data available

pΗ 6.3

Melting point/range No data available

No data available Boiling point/boiling range

Flash point does not flash

Evaporation rate No data available

Flammability (solid, gas) Does not sustain combustion.

Flammability (liquids) Does not sustain combustion.



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Self-ignition : Not applicable

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

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

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

MMX-2

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 8.28

Melting point/range : No data available



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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) : Does not sustain combustion.

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

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

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

MMX-1

Appearance : liquid

Color : No data available



# KIT COBAS LIAT CDIFF IVD

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Odor : characteristic

Odor Threshold : No data available

pH : 8.75

Melting point/range : 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) : Does not sustain combustion.

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

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

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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



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EB

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 8.7

Melting point/range : 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) : Does not sustain combustion.

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

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



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Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

WASH

Appearance : liquid

Color : colorless

Odor : characteristic

Odor Threshold : No data available

pH : 4.1

Melting point/range : No data available

Boiling point/boiling range : ca. 212 °F / 100 °C

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

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 : 1.007 g/cm3



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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

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Lysis

Appearance : liquid

Color : colorless

Odor : none

Odor Threshold : No data available

pH : 4.0

Melting point/range : 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) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper : No data available



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flammability limit

Lower explosion limit / Lower : No data available

flammability limit

Vapor pressure No data available

Relative vapor density No data available

Relative density No data available

1.131 g/cm3 Density

Solubility(ies)

Water solubility completely miscible

Solubility in other solvents No data available

Partition coefficient: n-

octanol/water

No data available

No data available Autoignition temperature

Hazardous decomposition products formed under fire Decomposition temperature

conditions.

Viscosity

Viscosity, dynamic No data available

Viscosity, kinematic No data available

Explosive properties No data available

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

**LMP** 

**Appearance** suspension

Color brown

Odor none

Odor Threshold No data available

6 - 7 рΗ

Melting point/range No data available

Boiling point/boiling range No data available



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Flash point : does not flash

Evaporation rate : No data available

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

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 g/cm3

Solubility(ies)

Water solubility : partly 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

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

**PROK** 

Appearance : liquid

Color : No data available

Odor : No data available



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Odor Threshold : No data available

pH : 7.0 - 8.0

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable.

Flammability (liquids) : Does not sustain combustion.

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

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

Viscosity, kinematic : No data available

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



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Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 7.5

Melting point/range : 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) : Does not sustain combustion.

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

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

Viscosity, kinematic : No data available



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Explosive properties : Not explosive

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.

Possibility of hazardous

reactions

No decomposition if stored and applied as directed.

Hazardous decomposition

products

No decomposition if stored and applied as directed.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### METAL 3

#### **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 sensitization

# Skin sensitization

Not classified based on available information.

# Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### 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.



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## 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.

## MMX-2

## **Acute toxicity**

Not classified based on available information.

## **Components:**

## 1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m3

Exposure time: 7 h
Test atmosphere: vapor

GLP: no

Assessment: The component/mixture is minimally toxic after

short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

GLP: no

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

# 1,2,3-Propanetriol:

Species : Rabbit Exposure time : 24 h

Result : No skin irritation

GLP : no

## Serious eye damage/eye irritation

Not classified based on available information.

## **Components:**

# 1,2,3-Propanetriol:

Species : Rabbit

Result : No eye irritation

Exposure time : 7 d GLP : no



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## Respiratory or skin sensitization

## Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

#### 1,2,3-Propanetriol:

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

# Germ cell mutagenicity

Not classified based on available information.

## **Components:**

# 1,2,3-Propanetriol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

GLP: No information available.

## Carcinogenicity

Not classified based on available information.

## Components:

## 1,2,3-Propanetriol:

Species : Rat, male and female

Application Route : Oral Exposure time : 2 Years Frequency of Treatment : daily

GLP : No information available.

Remarks : 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.

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.



# KIT COBAS LIAT CDIFF IVD

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## Reproductive toxicity

Not classified based on available information.

#### Components:

1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study

Species: Rat, male and female

Application Route: Oral Dose: 2000 mg/kg bw/day

Fertility: NOAEL: 2,000 mg/kg body weight

GLP: no

Effects on fetal development : Species: Rabbit, female

Application Route: Oral

Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day

Duration of Single Treatment: 29 d

Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day

GLP: no

## STOT-single exposure

Not classified based on available information.

#### **Components:**

## **DNA-dependent DNA polymerase:**

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

**Uracil DNA Glycosylase:** 

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

# STOT-repeated exposure

Not classified based on available information.

#### Components:

# **DNA-dependent DNA polymerase:**

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Uracil DNA Glycosylase:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

#### Repeated dose toxicity

# Components:

## 1,2,3-Propanetriol:

Species : Rat, male and female

NOAEL : 4580 mg/kg NOAEL : 4,580 mg/kg



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Application Route : Oral Exposure time : 90 d Number of exposures : daily

Dose : 4580 - 25,800 mg/kg/day

GLP : no

Species : Rat, male and female

Application Route : Inhalation
Test atmosphere : dust/mist
Exposure time : 13 Weeks

Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m3
GLP : No information available.

Species : Rat

NOAEL : 5040 mg/kg
NOAEL : 5,040 mg/kg
Application Route : dermal
Exposure time : 45 Weeks

Number of exposures : 8 hours/day, 5 days/week

Dose : 0.5-4.0 ml/kg

GLP : no

Repeated dose toxicity -

Assessment

: Mild eye irritant, Mild respiratory irritant, No skin irritation

# **Aspiration toxicity**

Not classified based on available information.

# **Components:**

# **DNA-dependent DNA polymerase:**

No data available

# **Uracil DNA Glycosylase:**

No data available

## MMX-1

## **Acute toxicity**

Not classified based on available information.

# **Components:**

# Methane, 1,1'-sulfinylbis-:

Acute oral toxicity : LD50 (Rat, male and female): 28,300 mg/kg

Method: OECD Test Guideline 401

GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.33 mg/l

Exposure time: 4 h
Test atmosphere: vapor

Method: OECD Test Guideline 403

GLP: yes



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Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40,000 mg/kg

GLP: no

#### Skin corrosion/irritation

Not classified based on available information.

## **Components:**

# Methane, 1,1'-sulfinylbis-:

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

GLP : yes

Remarks : Mild skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

# Methane, 1,1'-sulfinylbis-:

Species : Rabbit Exposure time : 24 h

Method : OECD Test Guideline 405
GLP : No information available.
Remarks : Mild eye irritation

## Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

## Respiratory sensitization

Not classified based on available information.

# **Components:**

## Methane, 1,1'-sulfinylbis-:

Test Type : Local lymph node assay (LLNA)

Species : Mouse

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 429

GLP : No information available.

Assessment : Mild eye irritation, Mild skin irritation

## Germ cell mutagenicity

Not classified based on available information.

## **Components:**

# Methane, 1,1'-sulfinylbis-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium



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Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

GLP: No information available.

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

GLP: No information available.

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 479

Result: negative

GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Rat (male and female)

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Dose: 200, 1000, 5000 mg/kg/d Method: OECD Test Guideline 474

GLP: yes

## 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.

#### Components:

# Methane, 1,1'-sulfinylbis-:

Effects on fertility : Species: Rat, male and female

Application Route: Oral

Dose: 100, 300, 1000 mg/kg bw/day Fertility: NOAEL: 1,000 mg/kg body weight

Method: OECD Test Guideline 421

GLP: yes

Effects on fetal development : Species: Rat, female

Application Route: Oral

Dose: 200, 1000, 5000 milligram per kilogram

Duration of Single Treatment: 10 d



# KIT COBAS LIAT CDIFF IVD

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Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Method: OECD Test Guideline 414

GLP: yes

#### STOT-single exposure

Not classified based on available information.

## STOT-repeated exposure

Not classified based on available information.

## Repeated dose toxicity

## **Components:**

## Methane, 1,1'-sulfinylbis-:

Species : Monkey, male and female

NOAEL : 2970 mg/kg NOAEL : 2,970 mg/kg Application Route : Oral

Exposure time : 87 Weeks

Dose : 990, 2970, 8910 mg/kg
Method : OECD Test Guideline 452

GLP : no

Species : Rat, male and female

NOAEC : 2783 mg/l
Application Route : Inhalation
Test atmosphere : vapor
Exposure time : 13 Weeks

Dose : 0.310, 0.964, 2.783 mg/l Method : OECD Test Guideline 413

GLP : yes

Species : Monkey, male and female

NOAEL : > 8910 mg/kg NOAEL : > 8,910 mg/kg

Application Route : Dermal Exposure time : 18 Months

Dose : 990, 2970, 8910 mg/kg bw/da Method : OECD Test Guideline 452

GLP : no

Repeated dose toxicity -

Assessment

Mild eye irritation, Mild skin irritation

## **Aspiration toxicity**

Not classified based on available information.

## EB

## **Acute toxicity**

Not classified based on available information.

## Skin corrosion/irritation

Not classified based on available information.



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## Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

## Germ cell mutagenicity

Not classified based on available information.

## 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.

## STOT-repeated exposure

Not classified based on available information.

## **Aspiration toxicity**

Not classified based on available information.

## WASH

# **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 sensitization

# Skin sensitization

Not classified based on available information.

# Respiratory sensitization

Not classified based on available information.



# KIT COBAS LIAT CDIFF IVD

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## Germ cell mutagenicity

Not classified based on available information.

## 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.

#### STOT-repeated exposure

Not classified based on available information.

#### **Aspiration toxicity**

Not classified based on available information.

# Lysis

#### **Acute toxicity**

Harmful if swallowed or if inhaled.

#### Components:

## Thiocyanic acid, compd. with guanidine (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 593 mg/kg

Method: OECD Test Guideline 401

Symptoms: Vomiting

GLP: yes

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The

component/mixture is moderately toxic after short term

inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after

single contact with skin.

# Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 1,000 mg/kg

Method: OECD Test Guideline 423

GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg

Method: OECD Test Guideline 402

GLP: yes



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#### Skin corrosion/irritation

Causes severe burns.

#### **Components:**

#### Thiocyanic acid, compd. with guanidine (1:1):

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : Corrosive after 1 to 4 hours of exposure

GLP : yes

## Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : No skin irritation

GLP : yes

## Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

# Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species : Rabbit

Result : Irritating to eyes.

Method : OECD Test Guideline 405

GLP : yes

## Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

## **Components:**

## Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Test Type : Draize Test Species : Guinea pig

Result : Does not cause skin sensitization.

GLP : no

# Germ cell mutagenicity

Not classified based on available information.

# **Components:**

# Thiocyanic acid, compd. with guanidine (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation



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Method: OECD Test Guideline 471

Result: negative GLP: yes

Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

GLP: no

Test Type: gene mutation test Test system: mouse lymphoma cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative GLP: yes

# Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Genotoxicity in vitro : Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster cells

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: negative

Genotoxicity in vivo : Test Type: in vivo assay

Species: Mouse (male)

Strain: B6C3F1

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Exposure time: 72 h Dose: 125 mg/kg Result: negative

## 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.



# KIT COBAS LIAT CDIFF IVD

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#### Reproductive toxicity

Not classified based on available information.

#### Components:

#### Thiocyanic acid, compd. with guanidine (1:1):

Effects on fertility : Species: Rat, female

**Application Route: Oral** 

Dose: 25 GLP: no

Remarks: No significant adverse effects were reported

Based on data from similar materials

Effects on fetal development : Species: Rat, female

Application Route: Oral

Dose: 50, 150, 350 mg/kg bw/day

General Toxicity Maternal: NOAEL: 150 mg/kg bw/day Embryo-fetal toxicity.: NOAEL: 350 mg/kg body weight

Method: OECD Test Guideline 414

GLP: yes

## Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Effects on fetal development : Test Type: Two-generation study

Species: Rat, female Application Route: Oral

Developmental Toxicity: NOAEL: 50 mg/kg bw/day

#### STOT-single exposure

Not classified based on available information.

## STOT-repeated exposure

Not classified based on available information.

## Repeated dose toxicity

#### Components:

## Thiocyanic acid, compd. with guanidine (1:1):

Species : Rat, male and female

NOAEL : 100 mg/kg

Application Route : Oral Exposure time : 90 d Number of exposures : daily

Dose : 25, 100, 300 mg/kg bw/day Method : OECD Test Guideline 408

GLP : ves

# Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species : Rat, male

NOAEL : 390 mg/kg bw/day

Application Route : Oral Exposure time : 22 d



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## **Aspiration toxicity**

Not classified based on available information.

## **LMP**

#### **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 sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### 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.

# STOT-repeated exposure

Not classified based on available information.

# Aspiration toxicity

Not classified based on available information.

#### **PROK**

## **Acute toxicity**

Not classified based on available information.

#### **Components:**

## 1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg



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Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m3

Exposure time: 7 h
Test atmosphere: vapor

GLP: no

Assessment: The component/mixture is minimally toxic after

short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

GLP: no

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

# 1,2,3-Propanetriol:

Species : Rabbit Exposure time : 24 h

Result : No skin irritation

GLP : no

**Proteinase K:** 

Result : Irritating to skin.

Remarks : May cause skin irritation and/or dermatitis.

# Serious eye damage/eye irritation

Not classified based on available information.

# **Components:**

# 1,2,3-Propanetriol:

Species : Rabbit

Result : No eye irritation

Exposure time : 7 d GLP : no

Proteinase K:

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

## Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

## Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

## **Components:**

#### 1,2,3-Propanetriol:

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation



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Proteinase K:

Assessment : May cause sensitization by skin contact.

Remarks : Causes sensitization.

Assessment : May cause sensitization by inhalation.

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

1,2,3-Propanetriol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

GLP: No information available.

Carcinogenicity

Not classified based on available information.

Components:

1,2,3-Propanetriol:

Species : Rat, male and female

Application Route : Oral Exposure time : 2 Years Frequency of Treatment : daily

GLP : No information available.

Remarks : 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.

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.

**Components:** 

1,2,3-Propanetriol:



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Effects on fertility : Test Type: Two-generation study

Species: Rat, male and female

Application Route: Oral Dose: 2000 mg/kg bw/day

Fertility: NOAEL: 2,000 mg/kg body weight

GLP: no

Effects on fetal development : Species: Rabbit, female

Application Route: Oral

Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day

Duration of Single Treatment: 29 d

Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day

GLP: no

## STOT-single exposure

Not classified based on available information.

## **Components:**

## **Proteinase K:**

Assessment : May cause respiratory irritation.

#### STOT-repeated exposure

Not classified based on available information.

## **Components:**

#### Proteinase K:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

# Repeated dose toxicity

#### **Components:**

#### 1,2,3-Propanetriol:

Species : Rat, male and female

NOAEL : 4580 mg/kg NOAEL : 4,580 mg/kg

Application Route : Oral Exposure time : 90 d Number of exposures : daily

Dose : 4580 - 25,800 mg/kg/day

GLP : no

Species : Rat, male and female

Application Route : Inhalation
Test atmosphere : dust/mist
Exposure time : 13 Weeks

Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m3
GLP : No information available.

Species : Rat

NOAEL : 5040 mg/kg



# KIT COBAS LIAT CDIFF IVD

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NOAEL : 5,040 mg/kg Application Route : dermal Exposure time : 45 Weeks

Number of exposures : 8 hours/day, 5 days/week

Dose : 0.5-4.0 ml/kg

GLP : no

Repeated dose toxicity -

: Mild eye irritant, Mild respiratory irritant, No skin irritation

Assessment

## **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

#### Proteinase K:

No data available

## IC

## **Acute toxicity**

Not classified based on available information.

## **Components:**

# 1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m3

Exposure time: 7 h
Test atmosphere: vapor

GLP: no

Assessment: The component/mixture is minimally toxic after

short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

GLP: no

#### Skin corrosion/irritation

Not classified based on available information.

# **Components:**

# 1,2,3-Propanetriol:

Species : Rabbit Exposure time : 24 h

Result : No skin irritation

GLP : no

# Serious eye damage/eye irritation

Not classified based on available information.



# KIT COBAS LIAT CDIFF IVD

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# **Components:**

#### 1,2,3-Propanetriol:

Species : Rabbit

Result : No eye irritation

Exposure time : 7 d GLP : no

## Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

## Respiratory sensitization

Not classified based on available information.

# Components:

## 1,2,3-Propanetriol:

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

# Germ cell mutagenicity

Not classified based on available information.

## **Components:**

#### 1,2,3-Propanetriol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

GLP: No information available.

# Carcinogenicity

Not classified based on available information.

## **Components:**

# 1,2,3-Propanetriol:

Species : Rat, male and female

Application Route : Oral Exposure time : 2 Years Frequency of Treatment : daily

GLP : No information available.

Remarks : 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.



# KIT COBAS LIAT CDIFF IVD

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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.

#### Components:

# 1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study

Species: Rat, male and female

Application Route: Oral Dose: 2000 mg/kg bw/day

Fertility: NOAEL: 2,000 mg/kg body weight

GLP: no

Effects on fetal development : Species: Rabbit, female

Application Route: Oral

Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day

Duration of Single Treatment: 29 d

Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day

GLP: no

## STOT-single exposure

Not classified based on available information.

## STOT-repeated exposure

Not classified based on available information.

#### Repeated dose toxicity

#### **Components:**

## 1,2,3-Propanetriol:

Species : Rat, male and female

NOAEL : 4580 mg/kg NOAEL : 4,580 mg/kg

Application Route : Oral Exposure time : 90 d Number of exposures : daily

Dose : 4580 - 25,800 mg/kg/day

GLP : no

Species : Rat, male and female

Application Route : Inhalation
Test atmosphere : dust/mist
Exposure time : 13 Weeks

Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m3
GLP : No information available.



# KIT COBAS LIAT CDIFF IVD

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Species : Rat

NOAEL : 5040 mg/kg
NOAEL : 5,040 mg/kg
Application Route : dermal
Exposure time : 45 Weeks

Number of exposures : 8 hours/day, 5 days/week

Dose : 0.5-4.0 ml/kg

GLP : no

Repeated dose toxicity -

Assessment

Mild eye irritant, Mild respiratory irritant, No skin irritation

## **Aspiration toxicity**

Not classified based on available information.

## **SECTION 12. ECOLOGICAL INFORMATION**

# **METAL 3**

#### **Ecotoxicity**

No data available

# Persistence and degradability

No data available

#### Bioaccumulative potential

No data available

Other adverse effects

#### MMX-2

## **Ecotoxicity**

# **Components:**

## 1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

End point: mortality Exposure time: 96 h Test Type: static test

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 1,955 mg/l

End point: mortality Exposure time: 48 h Test Type: static test Analytical monitoring: no

GLP: no

Toxicity to algae/aquatic

plants

(Scenedesmus quadricauda (Green algae)): > 10,000 mg/l

End point: Growth rate Exposure time: 8 d



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Test Type: static test

GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l

End point: Growth rate Exposure time: 16 h Test Type: static test

GLP: No information available.

**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

**DNA-dependent DNA polymerase:** 

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

No data available

**Uracil DNA Glycosylase:** 

**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:** 

1,2,3-Propanetriol:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 226 mg/l Result: Readily biodegradable.

Biodegradation: 94 % Exposure time: 24 h

GLP: no

**Bioaccumulative potential** 

**Components:** 

1,2,3-Propanetriol:



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Partition coefficient: n-

octanol/water

log Pow: -1.75 (77 °F / 25 °C)

pH: 7.4

Method: OECD Test Guideline 107

GLP: no

**DNA-dependent DNA polymerase:** 

Partition coefficient: n-

octanol/water

Remarks: No data available

**Uracil DNA Glycosylase:** 

Partition coefficient: n-

octanol/water

: Remarks: No data available

Other adverse effects

MMX-1

**Ecotoxicity** 

**Components:** 

Methane, 1,1'-sulfinylbis-:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 25,000 mg/l

End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: yes

Method: OECD Test Guideline 203

GLP: yes

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 24,600 mg/l

Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes

Method: OECD Test Guideline 202 GLP: No information available.

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000

mg/l

End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes

Method: OECD Test Guideline 201

GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): 10 - 100 mg/l

Exposure time: 0.5 h Analytical monitoring: no Method: ISO 8192

GLP: No information available.

**Ecotoxicology Assessment** 



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

Other organisms relevant to

the environment

: No data available

# Persistence and degradability

## **Components:**

Methane, 1,1'-sulfinylbis-:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 2 mg/l

Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d

Method: OECD Test Guideline 301D

GLP: yes

## **Bioaccumulative potential**

# **Components:**

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n- : log Pow: -1.35 (68 °F / 20 °C)

octanol/water pH: 7

GLP: No information available.

#### Other adverse effects

## EB

## **Ecotoxicity**

No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

No data available

Other adverse effects

# WASH

# **Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available



# KIT COBAS LIAT CDIFF IVD

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#### Other adverse effects

# Lysis

#### **Ecotoxicity**

## Components:

## Thiocyanic acid, compd. with guanidine (1:1):

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l

End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: no

Method: OECD Test Guideline 203

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia): 42.4 mg/l End point: Immobilization

Exposure time: 48 h Test Type: static test Analytical monitoring: no

Method: OECD Test Guideline 202

GLP: no

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l

End point: Growth rate Exposure time: 72 h Test Type: static test

GLP: No information available.

Toxicity to microorganisms : EC50 (activated sludge): > 185 mg/l

Exposure time: 28 d Test Type: static test

Method: OECD Test Guideline 302B

GLP: yes

## **Ecotoxicology Assessment**

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

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

Other organisms relevant to

the environment

No data available

#### Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Toxicity to fish : LC50 (Salmo salar (Atlantic salmon)): 1.5 mg/l

End point: mortality Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 6.46 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 0.237 mg/l



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plants Exposure time: 72 h

Method: OECD Test Guideline 201

EbC50 (Desmodesmus subspicatus (green algae)): 1,502

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 0.144 mg/l

Exposure time: 21 d Method: QSAR

Toxicity to microorganisms : (Photobacterium phosphoreum): 2.5 mg/l

Test Type: EC50

**Ecotoxicology Assessment** 

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Remarks: Expert judgment

Persistence and degradability

**Components:** 

Thiocyanic acid, compd. with guanidine (1:1):

Biodegradability : aerobic

Inoculum: activated sludge, non-adapted

Concentration: 343 mg/l

Result: Inherently biodegradable.

Biodegradation: 46 % Exposure time: 28 d

Method: OECD Test Guideline 302B

GLP: no

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 30 mg/l Result: Readily biodegradable.

Biodegradation: 74 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Bioaccumulative potential

**Components:** 

Thiocyanic acid, compd. with guanidine (1:1):

Partition coefficient: n- : log Pow: -1.11 (77  $^{\circ}$ F / 25  $^{\circ}$ C)

octanol/water pH: > 5.1

Method: Regulation (EC) No. 440/2008, Annex, A.8

GLP: no

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:



# KIT COBAS LIAT CDIFF IVD

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Partition coefficient: n-

octanol/water

: Remarks: No data available

Other adverse effects

**LMP** 

**Ecotoxicity** 

No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

No data available

Other adverse effects

**PROK** 

**Ecotoxicity** 

Components:

1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

End point: mortality Exposure time: 96 h Test Type: static test

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 1,955 mg/l

End point: mortality Exposure time: 48 h Test Type: static test Analytical monitoring: no

GLP: no

Toxicity to algae/aquatic

plants

(Scenedesmus quadricauda (Green algae)): > 10,000 mg/l

End point: Growth rate Exposure time: 8 d Test Type: static test

GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l

End point: Growth rate Exposure time: 16 h Test Type: static test

GLP: No information available.

**Ecotoxicology Assessment** 

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.



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

Other organisms relevant to

the environment

No data available

Proteinase K:

**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:** 

1,2,3-Propanetriol:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 226 mg/l Result: Readily biodegradable.

Biodegradation: 94 % Exposure time: 24 h

GLP: no

**Bioaccumulative potential** 

**Components:** 

1,2,3-Propanetriol:

Partition coefficient: n- : log Pow: -1.75 (77 °F / 25 °C)

octanol/water pH: 7.4

Method: OECD Test Guideline 107

GLP: no

Proteinase K:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Other adverse effects

IC

**Ecotoxicity** 

**Components:** 

1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

End point: mortality Exposure time: 96 h



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

Test Type: static test

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 1,955 mg/l

End point: mortality Exposure time: 48 h Test Type: static test Analytical monitoring: no

GLP: no

Toxicity to algae/aquatic

plants

(Scenedesmus quadricauda (Green algae)): > 10,000 mg/l

End point: Growth rate Exposure time: 8 d Test Type: static test

GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l

End point: Growth rate Exposure time: 16 h Test Type: static test

GLP: No information available.

**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:

## 1,2,3-Propanetriol:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 226 mg/l Result: Readily biodegradable.

Biodegradation: 94 % Exposure time: 24 h

GLP: no

## **Bioaccumulative potential**

# **Components:**

1,2,3-Propanetriol:

Partition coefficient: n- : log Pow: -1.75 (77  $^{\circ}$ F / 25  $^{\circ}$ C)

octanol/water pH: 7.4

Method: OECD Test Guideline 107

GLP: no



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

#### Other adverse effects

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : The product should not be allowed to enter drains, water

courses or the soil.

Do not contaminate ponds, waterways or ditches with

chemical or used container.

Send to a licensed waste management company.

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**

## **METAL 3**

# **CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

## **Clean Water Act**

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

Acetic acid 64-19-7 >= 0 - < 0.1 %

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

Acetic acid 64-19-7 >= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### **US State Regulations**

# **Massachusetts Right To Know**

Sodium azide (Na(N3)) 26628-22-8

# Pennsylvania Right To Know

Water 7732-18-5
Acetic acid, manganese(2+) salt, tetrahydrate 6156-78-1
Sodium azide (Na(N3)) 26628-22-8
Acetic acid 64-19-7

# 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

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

AIIC : On the inventory, or in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.



# KIT COBAS LIAT CDIFF IVD

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Acetic acid, manganese(2+) salt, tetrahydrate

Magnesium di(acetate)Tetrahydrate

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not 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 : Product contains substance(s) not listed 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.

## MMX-2

# **CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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).



# KIT COBAS LIAT CDIFF IVD

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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).

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):

1,2,3-Propanetriol 56-81-5  $\Rightarrow$  1 - < 5 %

#### **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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **US State Regulations**

# Massachusetts Right To Know

1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

## Pennsylvania Right To Know

Water	7732-18-5
Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-	1173-82-6
1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

## **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 Permissible Exposure Limits for Chemical Contaminants**

1,2,3-Propanetriol 56-81-5

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Guanosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Cytidine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Primer / Oligonucleotide / Probe

52 / 72



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

Uracil DNA Glycosylase

**DNA-dependent DNA polymerase** 

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed 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.

## MMX-1

# **CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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).



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

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).

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):

Methane, 1,1'-sulfinylbis- 67-68-5 >= 10 - < 20 %

**Clean Water Act** 

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

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 % ethanediylbis[N-

(carboxymethyl)-

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

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 %

ethanediylbis[N-(carboxymethyl)-

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations** 

Massachusetts Right To Know

Sodium azide (Na(N3)) 26628-22-8

Pennsylvania Right To Know

 Water
 7732-18-5

 Methane, 1,1'-sulfinylbis 67-68-5

 Acetic acid, potassium salt (1:1)
 127-08-2

 Glycine, N-[2-hydroxy-1,1-bis(hydroxymethyl)ethyl] 5704-04-1

 Sodium azide (Na(N3))
 26628-22-8

 Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl) 60-00-4

**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

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

AllC

: Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Primer / Oligonucleotide / Probe

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed 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.

# EΒ

#### **CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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 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.



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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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **US State Regulations**

# **Massachusetts Right To Know**

Sodium azide (Na(N3)) 26628-22-8

Pennsylvania Right To Know

Water 7732-18-5 Sodium azide (Na(N3)) 26628-22-8

## **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

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

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not 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 : All substances listed as active on the 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.

#### WASH

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.



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## 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.

SARA 311/312 Hazards : No SARA Hazards

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 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **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

# **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

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

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory



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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 : All substances listed as active on the 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.

## Lysis

#### **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.

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 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



# KIT COBAS LIAT CDIFF IVD

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This product does not contain any priority pollutants related to the U.S. Clean Water Act

# **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 Thiocyanic acid, compd. with guanidine (1:1) 593-84-0

#### **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

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

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not 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 : All substances listed as active on the 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.

#### **LMP**

#### **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.



# KIT COBAS LIAT CDIFF IVD

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## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### **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

# **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

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Magnetic glass particles (MGP)

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory



# KIT COBAS LIAT CDIFF IVD

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ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed 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.

#### **PROK**

#### **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.

SARA 311/312 Hazards : Respiratory or skin sensitization

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).

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):

1.2.3-Propanetriol 56-81-5 >= 30 - < 50 %

## **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

This product does not contain any priority pollutants related to the U.S. Clean Water Act



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**US State Regulations** 

Massachusetts Right To Know

1,2,3-Propanetriol 56-81-5

Pennsylvania Right To Know

Water 7732-18-5 1,2,3-Propanetriol 56-81-5

**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 Permissible Exposure Limits for Chemical Contaminants

1,2,3-Propanetriol 56-81-5

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Proteinase K

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : On the inventory, or in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not 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 : Product contains substance(s) not listed 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.

IC

## **CERCLA Reportable Quantity**

	Components	CAS-No.	Component RQ	Calculated product RQ
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		(lbs)	(lbs)
Glycine, N,N'-1,2-ethanediylbis[N-	60-00-4	5000	*
(carboxymethyl)-			

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

## SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium azide (Na(N3))	26628-22-8	1000	*

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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).

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):

1,2,3-Propanetriol 56-81-5 >= 30 - < 50 %

#### **Clean Water Act**

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

Glycine, N,N'-1,2- 60-00-4 >= 0.1 - < 1 %

ethanediylbis[N-(carboxymethyl)-

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

Glycine, N,N'-1,2- 60-00-4 >= 0.1 - < 1 %

ethanediylbis[N-(carboxymethyl)-

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### **US State Regulations**

#### Massachusetts Right To Know

1,2,3-Propanetriol 56-81-5

Pennsylvania Right To Know

Water 7732-18-5 1,2,3-Propanetriol 56-81-5 Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)- 60-00-4

#### **Maine Chemicals of High Concern**



# KIT COBAS LIAT CDIFF IVD

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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 Permissible Exposure Limits for Chemical Contaminants** 

1,2,3-Propanetriol 56-81-5

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Glycols

Modified alkyl carboxylate

Primer / Oligonucleotide / Probe

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed 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.

# **METAL 3**

## **GHS** label elements

Not a hazardous substance or mixture.

## MMX-2

#### **GHS** label elements

Not a hazardous substance or mixture.

#### MMX-1



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#### **GHS** label elements

Not a hazardous substance or mixture.

#### EB

#### **GHS** label elements

Not a hazardous substance or mixture.

## WASH

#### **GHS label elements**

Not a hazardous substance or mixture.

# Lysis

#### **GHS** label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled.

H314 Causes severe skin burns and eye damage.

Precautionary Statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

## Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER/ doctor if you feel unwell. Rinse mouth.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT

induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately

all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON

CENTER/ doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON

CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.



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# **LMP**

#### **GHS** label elements

Not a hazardous substance or mixture.

#### **PROK**

#### **GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves.

P285 In case of inadequate ventilation wear respiratory

protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

IC

**GHS** label elements

Not a hazardous substance or mixture.

#### **SECTION 16. OTHER INFORMATION**

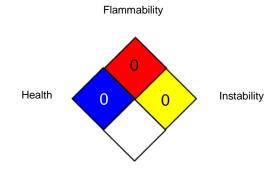
## **Further information**



# KIT COBAS LIAT CDIFF IVD

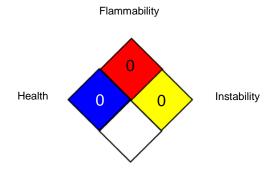
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# NFPA 704:



Special hazard

NFPA 704:



Special hazard

## HMIS® IV:



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.

#### HMIS® IV:

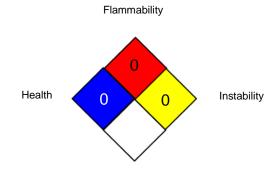




# KIT COBAS LIAT CDIFF IVD

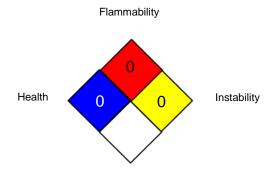
Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

# NFPA 704:



Special hazard

# NFPA 704:



Special hazard

## HMIS® IV:



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.

#### HMIS® IV:

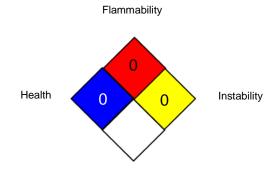




# KIT COBAS LIAT CDIFF IVD

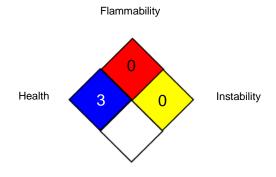
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#### NFPA 704:



Special hazard

NFPA 704:



Special hazard

#### HMIS® IV:



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.

#### HMIS® IV:

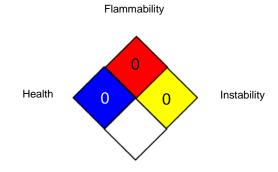




# KIT COBAS LIAT CDIFF IVD

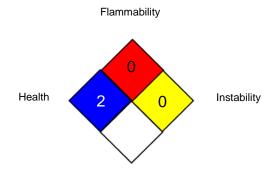
Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

# NFPA 704:



Special hazard

NFPA 704:



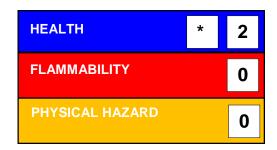
Special hazard

#### HMIS® IV:



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.

#### HMIS® IV:

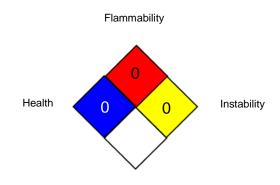




# KIT COBAS LIAT CDIFF IVD

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# NFPA 704:



Special hazard

#### HMIS® IV:



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

AIIC - Australian Inventory of Industrial Chemicals; 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 Cooperation 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; 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG -



# KIT COBAS LIAT CDIFF IVD

Version Revision Date: Date of last issue: 02-08-2021 1.3 Date of first issue: 10-26-2020

United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 10-12-2021

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