

KIT COBAS LIAT STREP AVersion
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**SECTION 1. IDENTIFICATION**

Product name : KIT COBAS LIAT STREP A

Product code : 07341911190

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

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Canada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : 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.
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 protec-

KIT COBAS LIAT STREP A
Version
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

tion.

Response:

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
COBAS LIAT STREP A**GHS Classification**

Skin corrosion : Category 1B

Serious eye damage : Category 1

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Thiocyanic acid, compd. with guanidine (1:1)	593-84-0	>= 10 - < 20
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-	9002-92-0	>= 1 - < 3
Proteinase K	39450-01-6	>= 1 - < 5

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

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.
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 : 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.

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NO_x)
Sulfur oxides
Hydrogen cyanide (hydrocyanic acid)
- 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.
- Environmental precautions : Prevent product from entering drains.
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

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : Avoid formation of aerosol.
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.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.

KIT COBAS LIAT STREP A
Version
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

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.

Technical measures/Precautions : See label, package insert or internal guidelines

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
COBAS LIAT STREP A
Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Proteinase K	39450-01-6	IOEL	0.00006 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

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

Material : Protective gloves

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

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

KIT COBAS LIAT STREP AVersion
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES****COBAS LIAT STREP A**

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	not determined
Evaporation rate	:	No data available
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	:	Hazardous decomposition products formed under fire conditions.
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

KIT COBAS LIAT STREP A
Version
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

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	:	Toxic gases may be released if in contact with the following: sodium hypochlorite Acids Strong oxidizing agents No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	Strong acids Strong oxidizing agents Cyanides sodium hypochlorite
Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NO _x) Sulfur oxides Hydrogen cyanide (hydrocyanic acid)

SECTION 11. TOXICOLOGICAL INFORMATION
COBAS LIAT STREP A
Acute toxicity

Not classified based on available information.

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

Acute oral toxicity	:	LD50 Oral (Rat): 593 mg/kg Symptoms: Vomiting
Acute inhalation toxicity	:	Acute toxicity estimate: 1.5 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: 1,100 mg/kg Method: Expert judgment

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

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

Causes severe burns.

KIT COBAS LIAT STREP AVersion
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**Ingredients:****Thiocyanic acid, compd. with guanidine (1:1):**

Result : Causes burns.

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

Result : Irritating to skin.

Proteinase K:

Result : Irritating to skin.

Remarks : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Causes serious eye damage.

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

Result : Risk of serious damage to eyes.

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.

Ingredients:**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.

Carcinogenicity

Not classified based on available information.

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

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 STREP AVersion
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

- 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.

Ingredients:**Proteinase K:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Proteinase K:**

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

Aspiration toxicity

Not classified based on available information.

Ingredients:**Proteinase K:**

No data available

SECTION 12. ECOLOGICAL INFORMATION***COBAS LIAT STREP A*****Ecotoxicity****Ingredients:****Thiocyanic acid, compd. with guanidine (1:1):**Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l
Exposure time: 96 hNOEC (Poecilia reticulata (guppy)): 25 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia): 42.4 mg/l

KIT COBAS LIAT STREP A
Version
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

aquatic invertebrates

Exposure time: 48 h

NOEC (Daphnia magna (Water flea)): 6.25 mg/l
Exposure time: 48 h**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 daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6.46 mg/l
Exposure time: 48 h**Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic to aquatic life.

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**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**

No data available

Bioaccumulative potential**Ingredients:****Thiocyanic acid, compd. with guanidine (1:1):**Partition coefficient: n- : log Pow: -1.38
octanol/water**Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:**Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 220
Exposure time: 72 h

Partition coefficient: n- : Remarks: No data available

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

octanol/water

Proteinase K:

Partition coefficient: n- : Remarks: No data available
octanol/water

Mobility in soil

No data available

Other adverse effects

Ingredients:

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

Additional ecological infor- : No data available
mation

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

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

SECTION 15. REGULATORY INFORMATION
COBAS LIAT STREP A
EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : Skin corrosion or irritation
Serious eye damage or eye irritation
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).

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

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

US State Regulations
Massachusetts Right To Know

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

Pennsylvania Right To Know

Water	7732-18-5
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

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

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

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Proteinase K

Magnetic glass particles (MGP)

DNA-dependent DNA polymerase

non hazardous compounds (liquid)

2'-Deoxyguanosine 5'-triphosphate trisodium salt

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

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

2'-Deoxycytidine 5'-triphosphate disodium salt

Glycols

Bovine Serum Albumin

Modified alkyl carboxylate

Primer / Oligonucleotide / Probe

AICS : Not in compliance with the inventory

NZIoC : Not 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 : Not On TSCA Inventory

KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

TSCA list

The following substance(s) is/are subject to a Significant New Use Rule:
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy- 9016-45-9

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

COBAS LIAT STREP A
GHS label elements

Hazard pictograms :



Signal Word :

Danger

Hazard Statements :

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.
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:

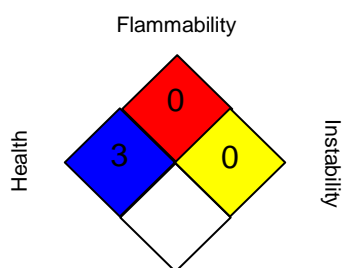
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a 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.

KIT COBAS LIAT STREP A
Version
2.2Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**Disposal:**

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

SECTION 16. OTHER INFORMATION
Further information**COBAS LIAT STREP A****NFPA:**

Special hazard.

HMIS® IV:

HEALTH	*	3
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC₅₀ - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC₅₀ - Lethal Concentration to 50 % of a test population; LD₅₀ - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

SAFETY DATA SHEET



KIT COBAS LIAT STREP A

Version
2.2

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-02-2018

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1711