

KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

SECTION 1. IDENTIFICATION

Product name : KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Mat.-No./ Genisys-No. : 06768253190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Can-

ada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

GHS Label element

Hazard pictograms :







Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

Precautionary statements : **Prevention:**

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

P280 Wear eye protection/ face protection.

P280 Wear protective gloves. P284 Wear respiratory protection.

Response:

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



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

CENTER or doctor/ physician.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

PK

GHS Classification

Respiratory sensitisation

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Category 1

Skin sensitisation

H317: May cause an allergic skin reaction.

Category 1

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
glycerol	56-81-5	>= 30 - < 50
Proteinase, Tritirachium album serine	39450-01-6	>= 1 - < 5

SDS

GHS Classification

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
sodium dodecyl sulphate	151-21-3	>= 0.1 - < 1

Lysis Buffer / Lys 2

GHS Classification

Acute toxicity (Oral) H302: Harmful if swallowed.

Category 4

Acute toxicity (Inhalation) H332: Harmful if inhaled.

Category 4

Serious eye damage H318: Causes serious eye damage.

Category 1

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
guanidinium thiocyanate	593-84-0	>= 30 - < 50
Dodecyl alcohol, ethoxylated	9002-92-0	>= 1 - < 5
(R*,R*)-1,4-dimercaptobutane-2,3-diol	3483-12-3	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 Date of first issue: 11-22-2012

Consult a physician.

Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

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

Move to fresh air.

If unconscious place in recovery position and seek medical

advice.

In case of skin contact : If skin irritation persists, call a physician.

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

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

sue 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.

Most important symptoms and effects, both acute and

delayed

: No information available.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances 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 : Wear self-contained breathing apparatus for firefighting if nec-



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version **Revision Date:** Date of last issue: 09-18-2014 Date of first issue: 11-22-2012 1.5 04-25-2015

for firefighters essary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

tive equipment and emer-

gency procedures

Personal precautions, protec- : 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 vapours/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 ap-

plication 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 sensitisation 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 suita-

ble liquid retention system.

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated

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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

PK

Components with workplace control parameters

Componer	ts	CAS-No.	Value type	Control p	parame-	Basis	



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 Date of first issue: 11-22-2012

		(Form of exposure)	ters / Permissible concentration	
glycerol	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

Hazardous components without workplace control parameters

Components	CAS-No.
Proteinase, Tritirachium album	39450-01-6
serine	

SDS

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Components	CAS-No.
sodium dodecyl sulphate	151-21-3

Lysis Buffer / Lys 2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Components	CAS-No.
guanidinium thiocyanate	593-84-0
Dodecyl alcohol, ethoxylated	9002-92-0
(R*,R*)-1,4-dimercaptobutane-	3483-12-3
2,3-diol	

Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an ap-

proved filter.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifica-

tions of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 Date of first issue: 11-22-2012

used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be dis-

cussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

Skin and body protection : impervious clothing

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

Hygiene measures : When using do not eat or drink.

When using do not smoke.

Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PK

Appearance : liquid

Colour : No data available
Odour : No data available
Odour 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.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available Relative vapour density : No data available Relative density : No data available Density : No data available : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

SDS

Appearance : liquid

Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : 7.9 - 8.3

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.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

Lysis Buffer / Lys 2

Appearance : liquid

Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : 5.6 - 6.0

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.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 Date of first issue: 11-22-2012

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available Relative vapour density : No data available Relative density : No data available Density : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

: No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

PK

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

glycerol:

Acute oral toxicity : LD50 Oral (Rat): 12,600 mg/kg



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

LD50 Oral (Mouse): 4,090 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:

Proteinase, Tritirachium album serine:

Result: Irritating to skin.

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Components:

Proteinase, Tritirachium album serine:

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if in-

haled.

Product:

Remarks: Causes sensitisation.

Components:

glycerol:

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

Proteinase, Tritirachium album serine:

Assessment: May cause sensitisation by skin contact.

Remarks: Causes sensitisation.

Assessment: May cause sensitisation by inhalation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 Date of first issue: 11-22-2012

IARC No component of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHA No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

Proteinase, Tritirachium album serine:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

Proteinase, Tritirachium album serine:

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

Components:

glycerol:

Repeated dose toxicity - : Mild eye irritant, Mild respiratory irritant, No skin irritation

Assessment

Aspiration toxicity

Not classified based on available information.

Components:

Proteinase, Tritirachium album serine:

No data available

SDS

Acute toxicity

Not classified based on available information.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

sodium dodecyl sulphate:



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

Acute oral toxicity : LD50 Oral (Rat): 1,288 mg/kg

Acute inhalation toxicity : LC50 (Rat): >3900 mg/m3

Exposure time: 1 h

Acute dermal toxicity : LD50 Dermal (Rabbit): 580 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

sodium dodecyl sulphate:

Result: Irritating to skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

sodium dodecyl sulphate:

Result: Irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

sodium dodecyl sulphate:

Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No component of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHA No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

sodium dodecyl sulphate:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Lysis Buffer / Lys 2

Acute toxicity

Harmful if swallowed or if inhaled

Product:

Acute oral toxicity : Acute toxicity estimate: 1,273 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 3.52 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 2,565 mg/kg

Method: Calculation method

Components:

guanidinium thiocyanate:

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

Acute inhalation toxicity : Acute toxicity estimate: 1.5 mg/l

Test atmosphere: dust/mist Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg

Method: Expert judgement

Dodecyl alcohol, ethoxylated:

Acute oral toxicity : LD50 Oral (Rat): 2,000 mg/kg

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Acute toxicity (other routes of

administration) Symptoms: May cause cardiac arrhythmia., Convulsions,

Vomiting

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:

Dodecyl alcohol, ethoxylated:



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

Result: Irritating to skin.

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:

Dodecyl alcohol, ethoxylated:

Result: Risk of serious damage to eyes.

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No component of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHANo component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

PK

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: No data available

Components:

glycerol:

Toxicity to fish : LC50: > 100 mg/l

Exposure time: 96 h

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000

mg/l

Exposure time: 7 d

Toxicity to fish (Chronic tox-

icity)

: > 1 mg/l

Toxicity to bacteria : EC0 (Pseudomonas putida): > 10,000 mg/l

Exposure time: 16 h

Ecotoxicology Assessment

Acute aquatic toxicity

: This product has no known ecotoxicological effects.

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

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

Other organisms relevant to

the environment

: No data available

Proteinase, Tritirachium album serine:

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:

glycerol:

Biodegradability : Remarks: The product is miscible in water and readily biode-

gradable in both water and soil. Accumulation is not expected.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

Bioaccumulative potential

Components:

glycerol:

Partition coefficient: n-

octanol/water

: log Pow: -2.66

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SDS

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: No data available

Components:

sodium dodecyl sulphate:

Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): 26 mg/l

LC50 (Lepomis macrochirus (Bluegill sunfish)): 4.5 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l

Exposure time: 96 h

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 6 mg/l

Exposure time: 48 h

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 0.46 mg/l

Exposure time: 0.5 h

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Other organisms relevant to

the environment

: No data available



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

Persistence and degradability

Components:

sodium dodecyl sulphate:

Biodegradability : Biodegradation: 90 %

Exposure time: 28 d

Method: OECD Test Guideline 301

Remarks: Readily biodegradable, according to appropriate

OECD test.

Bioaccumulative potential

Components:

sodium dodecyl sulphate:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 3.9 - 5.3

Exposure time: 3 d

Partition coefficient: n-

octanol/water

: log Pow: 1.6

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

sodium dodecyl sulphate:

Additional ecological infor-

mation

: No data available

Lysis Buffer / Lys 2

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: No data available

Components:

guanidinium thiocyanate:

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

Exposure time: 96 h



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version **Revision Date:** Date of last issue: 09-18-2014 Date of first issue: 11-22-2012 1.5 04-25-2015

Toxicity to daphnia and other

aquatic invertebrates

EC50 (Daphnia (water flea)): 42.4 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

Dodecyl alcohol, ethoxylated: M-Factor (Acute aquatic tox- : 1

icity)

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

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

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 27 mg/l

aquatic invertebrates

Exposure time: 48 h

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:

Dodecyl alcohol, ethoxylated:

Biodegradability Biodegradation: > 99 %

Exposure time: 672 h

Method: OECD Test Guideline 302

Bioaccumulative potential

Components:

guanidinium thiocyanate:

Partition coefficient: n-

: log Pow: -1.38

octanol/water

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Partition coefficient: n-: log Pow: ca. -0.48

octanol/water

Mobility in soil

No data available

Other adverse effects

Product:



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological infor-

mation

: An environmental hazard cannot be excluded in the event of

unprofessional handling or disposal.

Harmful to aquatic life with long lasting effects.

Components:

Dodecyl alcohol, ethoxylated:

Additional ecological infor-

mation

Very toxic to aquatic life.

An environmental hazard cannot be excluded in the event of

unprofessional handling or disposal.

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 chemi-

cal 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 han-

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

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

PK



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 O4-25-2015 Date of first issue: 11-22-2012

TSCA list : Not relevant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 311/312 Hazards : Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting re-

quirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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):

glycerol 56-81-5 45.475 %

Clean Water Act

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

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

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

Massachusetts Right To Know

glycerol	56-81-5	30 - 50 %
Pennsylvania Right To Know		
glycerol	56-81-5	30 - 50 %
water	7732-18-5	5 - 10 %
New Jersey Right To Know		
glycerol	56-81-5	30 - 50 %
water	7732-18-5	5 - 10 %
Proteinase, Tritirachium album serine	39450-01-6	1 - 5 %

California Prop 65 This product does not contain any chemicals known to State

of California to cause cancer, birth defects, or any other re-

productive harm.

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



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

REACH : Not in compliance with the inventory

: glycerol

: Proteinase, Tritirachium album serine

: trometamol

: Calcium acetate hydrate

: Calcium chloride dihydrate

: Edetic acid disodium salt dihydrate (EDTA-2Na-2H2O)

CH INV : On the inventory, or in compliance with the inventory

TSCA : Not On TSCA Inventory

: Proteinase, Tritirachium album serine

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

: Proteinase, Tritirachium album serine

AICS : Not in compliance with the inventory

: Proteinase, Tritirachium album serine

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

ENCS : Not in compliance with the inventory

: water

: Proteinase, Tritirachium album serine

ISHL : Not in compliance with the inventory

: water

KECI : Not in compliance with the inventory

: Proteinase, Tritirachium album serine

PICCS : Not in compliance with the inventory

Proteinase, Tritirachium album serine

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

Inventories

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

SDS



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

TSCA list : Not relevant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

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

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting re-

quirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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

Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
Pennsylvania Right To Know		
water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %
New Jersey Right To Know		
water	7732-18-5	90 - 100 %

California Prop 65 This product does not contain any chemicals known to State



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014
1.5 O4-25-2015 Date of first issue: 11-22-2012

of California to cause cancer, birth defects, or any other reproductive harm.

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

REACH : Not in compliance with the inventory

: sodium dodecyl sulphate

: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride

: trometamol

: sodium azide

CH INV : On the inventory, or in compliance with the inventory

TSCA : On TSCA Inventory

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

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

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

ENCS : Not in compliance with the inventory

: water

: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride

ISHL : Not in compliance with the inventory

: water

: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride

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

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

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

Inventories

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

Lysis Buffer / Lys 2

TSCA list : Not relevant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

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

SARA 311/312 Hazards : Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting re-

quirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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

Massachusetts Right To Know

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

Pennsylvania Right To Know

water	7732-18-5	30 - 50 %
guanidinium thiocyanate	593-84-0	30 - 50 %
Dodecyl alcohol, ethoxylated	9002-92-0	1 - 5 %

New Jersey Right To Know

water	7732-18-5	30 - 50 %
guanidinium thiocyanate	593-84-0	30 - 50 %
Dodecyl alcohol, ethoxylated	9002-92-0	1 - 5 %
(R*,R*)-1,4-dimercaptobutane-2,3-diol	3483-12-3	1 - 5 %
Sodium citrate	6132-04-3	1 - 5 %

California Prop 65 This product does not contain any chemicals known to State

of California to cause cancer, birth defects, or any other re-

productive harm.

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

REACH : Not in compliance with the inventory

: guanidinium thiocyanate



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

: Dodecyl alcohol, ethoxylated

: (R*,R*)-1,4-dimercaptobutane-2,3-diol

Sodium citrate

CH INV : On the inventory, or in compliance with the inventory

TSCA : On TSCA Inventory

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

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

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

ENCS : Not in compliance with the inventory

: water

: guanidinium thiocyanate

: (R*,R*)-1,4-dimercaptobutane-2,3-diol

ISHL : Not in compliance with the inventory

: water

: guanidinium thiocyanate

: (R*,R*)-1,4-dimercaptobutane-2,3-diol

KECI : Not in compliance with the inventory

: guanidinium thiocyanate

: (R*,R*)-1,4-dimercaptobutane-2,3-diol

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

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

Inventories

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

PK

GHS Label element

Hazard pictograms



Signal word : Danger



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version Revision Date: Date of last issue: 09-18-2014 1.5 O4-25-2015 Date of first issue: 11-22-2012

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/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

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

breathing.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

SDS

GHS Label element

Not a hazardous substance or mixture.

Lysis Buffer / Lys 2

GHS Label element

Hazard pictograms





Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled

H318 Causes serious eye damage.

Precautionary statements : **Prevention:**

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ 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 eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER

or doctor/ physician if you feel unwell.



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version **Revision Date:** Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

> 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 or doctor/ physician.

Disposal:

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

SECTION 16. OTHER INFORMATION

Further information

PK NFPA: Flammability 0 Health 0 2

Special hazard.

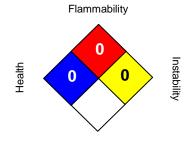
HMIS III:

HEALTH	2*
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High 4 = Extreme, * = Chronic

SDS NFPA:



Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High

4 = Extreme, * = Chronic

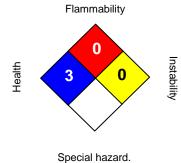
Lysis Buffer / Lys 2



KIT COBAS4800 MIXEDBATCH LYSIS1 240T IVD

Version **Revision Date:** Date of last issue: 09-18-2014 1.5 04-25-2015 Date of first issue: 11-22-2012

NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High 4 = Extreme, * = Chronic

Revision Date : 04-25-2015

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

US / EN