according to Regulation (EC) No. 1907/2006



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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : KAPA HiFi HotStart Library Amplification Kits + Primer Premix

Product code : 07958986001

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions : For professional users only.

on use

1.3 Details of the supplier of the safety data sheet

: Roche Diagnostics Deutschland GmbH Company

Sandhoferstrasse 116 68305 Mannheim Deutschland

: +496217590 Telephone Telefax : +496217592890 Responsible Department : +49(0)621-759-4223 E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: Central Works Security +49(0)621-759-2203

Roche Diagnostics GmbH

Centre for detoxification: +49(0)6131-19240 Mainz

Munich +49(0)89-19240

#### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

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.

#### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)



according to Regulation (EC) No. 1907/2006



# KAPA HiFi HotStart Library Amplification Kits + Primer Premix

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Hazard statements : H371 May cause damage to organs.

Precautionary statements : Prevention:

P260 Do not breathe mist or vapours.P264 Wash skin thoroughly after handling.

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

Response:

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### 2.3 Other hazards

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### **SECTION 3: Composition/information on ingredients**

# KAPA HiFi HotStart ReadyMix (2X)

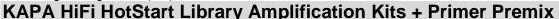
### Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - single exposure, Category 2 H371: May cause damage to organs.

### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
tetramethylammonium chloride	75-57-0 200-880-8 01-2119970924-26	Acute Tox. 2; H300 Acute Tox. 3; H311 Skin Irrit. 2; H315 STOT SE 1; H370 Aquatic Chronic 2; H411 Acute toxicity estimate Acute oral toxicity: 47	>= 1,0 - < 2,5

according to Regulation (EC) No. 1907/2006



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		mg/kg Acute dermal toxicity: 200,02 mg/kg	
Nucleotidyltransferase, deoxyribonucleate	9012-90-2 232-741-2	Not classified	< 0,1

For explanation of abbreviations see section 16.

# KAPA Library Amplification Primer Premixes (10X)

# Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

General advice : Move out of dangerous area.

Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

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

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

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.

Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

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

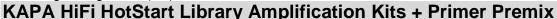
Rinse mouth with water.

### 4.2 Most important symptoms and effects, both acute and delayed

None known.



according to Regulation (EC) No. 1907/2006



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### 4.3 Indication of any immediate medical attention and special treatment needed

**Treatment** The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

### **SECTION 5: Firefighting measures**

5.1 Extinguishing media

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

cumstances and the surrounding environment.

Unsuitable extinguishing

media

: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

: No information available.

5.3 Advice for firefighters

for firefighters

Special protective equipment : Wear self-contained breathing apparatus for firefighting if nec-

essary.

Further information Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

#### **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

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

> Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages

cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for 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.

#### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

### **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

according to Regulation (EC) No. 1907/2006



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Advice on safe handling : 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.

Dispose of rinse water in accordance with local and national

regulations.

Advice on protection against

fire and explosion

Normal measures for preventive fire protection.

Hygiene measures : When using do not eat or drink. When using do not smoke.

Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep container tightly closed in a dry and well-ventilated place. Observe label precautions. Electrical installations / working materials must comply with the technological safety

standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Storage class (TRGS 510) : 12, Non Combustible Liquids

Further information on stor-

age stability

No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

**SECTION 8: Exposure controls/personal protection** 

8.1 Control parameters

KAPA HiFi HotStart ReadyMix (2X)

**Occupational Exposure Limits** 

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
glycerol	56-81-5	AGW (Inhalable	200 mg/m3	DE TRGS	
		fraction)		900	
	Peak-limit: excursion factor (category): 2;(I)				
	Further information: When there is compliance with the OEL and biological				
	tolerance values, there is no risk of harming the unborn child				
Nucleotidyltrans- ferase, deoxyribo- nucleate	9012-90-2	IOEL	0,00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)	

according to Regulation (EC) No. 1907/2006



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# KAPA Library Amplification Primer Premixes (10X)

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

### **Engineering measures**

No data available

### Personal protective equipment

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Use eye protection according to EN 166.

Hand protection

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 : The selected protective gloves have to satisfy the specifica-

tions of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective

gloves.

Skin and body protection : Impervious clothing

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

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

proved filter.

# **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties KAPA HiFi HotStart ReadyMix (2X)

Physical state : liquid

according to Regulation (EC) No. 1907/2006



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Colour : colourless

Odour : odourless

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flammability : Does not sustain combustion.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : does not flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 8,7

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Density : 1,044 g/cm3

Relative vapour density : No data available

# KAPA Library Amplification Primer Premixes (10X)

Physical state : liquid

Colour : colourless

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according to Regulation (EC) No. 1907/2006



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Odour : odourless

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : ca. 100 °C

Flammability : Does not sustain combustion.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point does not flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7,7

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Density : 0,996 g/cm3

Relative vapour density : No data available

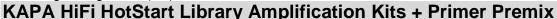
#### 9.2 Other information

### KAPA HiFi HotStart ReadyMix (2X)

Explosives : Not explosive

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

according to Regulation (EC) No. 1907/2006



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Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Evaporation rate : No data available

### KAPA Library Amplification Primer Premixes (10X)

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Evaporation rate : No data available

### **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

No decomposition if stored and applied as directed.

### 10.4 Conditions to avoid

No data available

# 10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

### 10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

### **SECTION 11: Toxicological information**

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 KAPA HiFi HotStart ReadyMix (2X)





according to Regulation (EC) No. 1907/2006



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### **Acute toxicity**

Not classified based on available information.

#### **Components:**

### tetramethylammonium chloride:

Acute oral toxicity : LD50 Oral (Rat): 47 mg/kg

Method: OECD Test Guideline 401

GLP: no

Acute toxicity estimate: 47 mg/kg Method: Calculation method

Acute dermal toxicity : LD50 Dermal (Rabbit): > 200 - < 500 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Acute toxicity estimate: 200,02 mg/kg

Method: Calculation method

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

#### tetramethylammonium chloride:

Result : Irritating to skin.

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

### tetramethylammonium chloride:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

# Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### tetramethylammonium chloride:

Test Type : Local lymph node assay (LLNA)

Species : Mouse

Assessment : Does not cause skin sensitisation.

Method : OECD Test Guideline 429

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according to Regulation (EC) No. 1907/2006



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### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### tetramethylammonium chloride:

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

Test system: Salmonella typhimurium

Result: negative

Test Type: Microbial mutagenesis assay (Ames test)

Test system: Escherichia coli

Result: negative

#### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

### STOT - single exposure

May cause damage to organs.

#### **Components:**

# tetramethylammonium chloride:

Exposure routes : Ingestion

Target Organs : Central nervous system
Assessment : Causes damage to organs.

### Nucleotidyltransferase, deoxyribonucleate:

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:

### Nucleotidyltransferase, deoxyribonucleate:

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

organ toxicant, repeated exposure.

### Repeated dose toxicity

### **Components:**

# tetramethylammonium chloride:

Species : Rat NOAEL : 5 mg/kg Application Route : Oral

Method : OECD Test Guideline 421

GLP : yes

according to Regulation (EC) No. 1907/2006



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Kits + Primer Prem

### **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

# Nucleotidyltransferase, deoxyribonucleate:

No data available

# KAPA Library Amplification Primer Premixes (10X)

#### **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 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.

#### 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.

### 11.2 Information on other hazards

### **Endocrine disrupting properties**

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

# KAPA HiFi HotStart ReadyMix (2X)

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according to Regulation (EC) No. 1907/2006



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#### **Endocrine disrupting properties**

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

**Further information** 

**Components:** 

tetramethylammonium chloride:

Remarks : Other dangerous properties can not be excluded.

KAPA Library Amplification Primer Premixes (10X)

**Endocrine disrupting properties** 

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

**SECTION 12: Ecological information** 

12.1 Toxicity

KAPA HiFi HotStart ReadyMix (2X)

**Components:** 

tetramethylammonium chloride:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 462 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,16 mg/l

Exposure time: 11 d

GLP: yes

NOEC (Daphnia magna (Water flea)): 0,03 mg/l

Exposure time: 11 d

GLP: yes

LC50 (Daphnia magna (Water flea)): 1,86 mg/l

Exposure time: 48 h

GLP: yes

according to Regulation (EC) No. 1907/2006



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Toxicity to algae/aquatic

plants

: ErC50 (Pseudokirchneriella subcapitata (green algae)): 115

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

**Ecotoxicology Assessment** 

Chronic aquatic toxicity : Toxic 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

Nucleotidyltransferase, deoxyribonucleate:

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

No data available

KAPA Library Amplification Primer Premixes (10X)

No data available

12.2 Persistence and degradability

KAPA HiFi HotStart ReadyMix (2X)

**Components:** 

tetramethylammonium chloride:

Biodegradability : Remarks: Expected to be biodegradable

KAPA Library Amplification Primer Premixes (10X)

No data available

12.3 Bioaccumulative potential

KAPA HiFi HotStart ReadyMix (2X)

Components:

tetramethylammonium chloride:

Partition coefficient: n-

: Remarks: No data available

octanol/water

Nucleotidyltransferase, deoxyribonucleate:

Partition coefficient: n-

: Remarks: No data available

octanol/water

KAPA Library Amplification Primer Premixes (10X)

No data available

according to Regulation (EC) No. 1907/2006



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12.4 Mobility in soil

KAPA HiFi HotStart ReadyMix (2X)

No data available

KAPA Library Amplification Primer Premixes (10X)

No data available

12.5 Results of PBT and vPvB assessment

KAPA HiFi HotStart ReadyMix (2X)

Not relevant

KAPA Library Amplification Primer Premixes (10X)

Not relevant

12.6 Endocrine disrupting properties

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

KAPA HiFi HotStart ReadyMix (2X)

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

KAPA Library Amplification Primer Premixes (10X)

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

KAPA HiFi HotStart ReadyMix (2X)

No data available

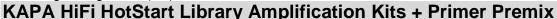
KAPA Library Amplification Primer Premixes (10X)

No data available

**SECTION 13: Disposal considerations** 

13.1 Waste treatment methods

according to Regulation (EC) No. 1907/2006



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Product Do not contaminate ponds, waterways or ditches with chemi-

cal or used container.

Send to a licensed waste management company.

Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging Empty remaining contents.

Dispose of as unused product.

Empty containers should be taken to an approved waste han-

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

### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

#### 14.4 Packing group

Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Remarks Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable Remarks

### **SECTION 15: Regulatory information**

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

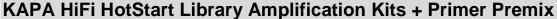
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of majoraccident hazards involving dangerous substances.

Not applicable

ny)

Water hazard class (Germa: WGK 1 slightly hazardous to water

according to Regulation (EC) No. 1907/2006



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# . . . •

# KAPA HiFi HotStart ReadyMix (2X)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

Conditions of restriction for the following entries should be considered:

Number on list 3

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Not applicable

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Not applicable

REACH - List of substances subject to authorisation

(Annex XIV)

: Not applicable

# Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### The components 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.

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

um salt

2'-deoxyadenosine 5'-(tetrahydrogen triphosphate)
Thymidine 5'-(tetrahydrogen triphosphate), sodium salt

2'-Deoxycytidine 5'-triphosphate disodium salt

Antibodies

dUTP diphosphatase

Nucleotidyltransferase, deoxyribonucleate

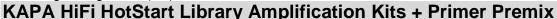
NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI: Not in compliance with the inventory

according to Regulation (EC) No. 1907/2006



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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.

TECI: Not in compliance with the inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial

emissions (integrated pollution prevention and control)

Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word : Warning

Hazard statements : H371 May cause damage to organs.

Precautionary statements : Prevention:

P260 Do not breathe mist or vapours.P264 Wash skin thoroughly after handling.

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

Response:

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Hazardous components which must be listed on the label:

75-57-0 tetramethylammonium chloride

# KAPA Library Amplification Primer Premixes (10X)

REACH - Restrictions on the manufacture, placing on : Not applicable the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

according to Regulation (EC) No. 1907/2006



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REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

: Not applicable

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Not applicable

Not applicable

REACH - List of substances subject to authorisation

(Annex XIV)

The components 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.

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.

TECI: Not in compliance with the inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial

emissions (integrated pollution prevention and control)

Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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according to Regulation (EC) No. 1907/2006



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#### 15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

#### **SECTION 16: Other information**

#### **Full text of H-Statements**

H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H315 : Causes skin irritation.
H370 : Causes damage to organs.

H411 : Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Skin Irrit. : Skin irritation

STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP -Good Laboratory Practice; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States): UN - United Nations: vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

according to Regulation (EC) No. 1907/2006



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