

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## KAPA HiFi HS Library Amp Kit (50rxn)

Version  
1.6

Revision Date:  
22.06.2019

Date of last issue: 02.02.2019  
Date of first issue: 13.05.2016

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

#### 1.1 Product identifier

Trade name : KAPA HiFi HS Library Amp Kit (50rxn)  
Product code : 07958951001

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

Recommended restrictions on use : For professional users only.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
-  
Sandhoferstrasse 116  
68305 Mannheim  
Deutschland  
Telephone : +496217590  
Telefax : +496217592890  
Responsible Department : +49(0)621-759-2012, +49(0)621-759-4848  
+49(0)8856-60-2629  
E-mail address : mannheim.umweltschutz@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: : Mainz +49(0)6131-19240  
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)

Hazard pictograms :



Signal word : Warning

Hazard statements : H371 May cause damage to organs.

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Precautionary statements : **Prevention:**  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
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

See SECTION 3

## 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-XXXX	Acute Tox. 2; H300 Acute Tox. 3; H311 Skin Irrit. 2; H315 STOT SE 1; H370 Aquatic Chronic 2; H411	>= 1,0 - < 2,5

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.

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- 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.

### 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.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment.

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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".

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

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 application 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 storage conditions : See label, package insert or internal guidelines

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

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

### 7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

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### 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 fraction)	200 mg/m <sup>3</sup>	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
sulphuric acid	7664-93-9	AGW (Inhalable fraction)	0,1 mg/m <sup>3</sup>	DE TRGS 900
Peak-limit: excursion factor (category)	1;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., European Union (The EU has established a limit value: deviations in value and peak limit are possible), When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
		TWA (Mist)	0,05 mg/m <sup>3</sup>	2009/161/EU
Further information	Indicative, When selecting an appropriate exposure monitoring method, account should be taken of potential limitations and interferences that may arise in the presence of other sulphur compounds., The mist is defined as the thoracic fraction.			
edetic acid	60-00-4	IOEL	1,5 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Nucleotidyltransferase, deoxyribonucleate	9012-90-2	IOEL	0,00006 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)

#### 8.2 Exposure controls

##### Engineering measures

No data available

##### Personal protective equipment

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Hand protection  
Material : Protective gloves

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- Remarks : The selected protective gloves have to satisfy the specifications 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 approved filter.

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

##### *KAPA HiFi HotStart ReadyMix (2X)*

- Appearance : liquid
- Colour : colourless
- Odour : odourless
- Odour Threshold : No data available
- pH : 8,7
- Melting point/range : No data available
- Boiling point/boiling range : No data available
- Flash point : does not flash
- Evaporation rate : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : No data available
- Relative vapour density : No data available
- Relative density : No data available

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Density	:	1,044 g/cm <sup>3</sup>
Solubility(ies)	:	
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

#### **KAPA HiFi HotStart ReadyMix (2X)**

Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	Not applicable

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## 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
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### 10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### **KAPA HiFi HotStart ReadyMix (2X)**

##### **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 dermal toxicity : LD50 Dermal (Rat): 537 mg/kg

LD50 Dermal (Rabbit): > 200 - < 500 mg/kg  
Method: OECD Test Guideline 402  
GLP: yes

##### **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.

##### **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**

May cause damage to organs.



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### Components:

#### **tetramethylammonium chloride:**

Assessment : Causes damage to organs.

#### **STOT - repeated exposure**

Not classified based on available information.

#### **Repeated dose toxicity**

### Components:

#### **tetramethylammonium chloride:**

Species : Rat  
NOAEL : 5 mg/kg  
Application Route : Oral  
Method : OECD Test Guideline 421  
GLP : yes

#### **Aspiration toxicity**

Not classified based on available information.

#### **Further information**

### Components:

#### **tetramethylammonium chloride:**

Remarks : Other dangerous properties can not be excluded.

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## 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

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 115 mg/l

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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

### 12.2 Persistence and degradability

#### ***KAPA HiFi HotStart ReadyMix (2X)***

##### Components:

##### **tetramethylammonium chloride:**

Biodegradability : Remarks: Expected to be biodegradable

### 12.3 Bioaccumulative potential

#### ***KAPA HiFi HotStart ReadyMix (2X)***

##### Components:

##### **tetramethylammonium chloride:**

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

### 12.4 Mobility in soil

#### ***KAPA HiFi HotStart ReadyMix (2X)***

No data available

### 12.5 Results of PBT and vPvB assessment

#### ***KAPA HiFi HotStart ReadyMix (2X)***

Not relevant

### 12.6 Other adverse effects

#### ***KAPA HiFi HotStart ReadyMix (2X)***

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

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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

#### 14.1 UN 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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable

### 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 major-accident hazards involving dangerous substances.  
Not applicable

Water contaminating class : WGK 1 slightly hazardous to water  
(Germany)

#### **KAPA HiFi HotStart ReadyMix (2X)**

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pol- : Not applicable

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Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

### The components 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.

2'-Deoxyguanosine 5'-triphosphate trisodium salt  
2'-Deoxycytidine 5'-triphosphate disodium salt  
Thymidine 5'-(tetrahydrogen triphosphate), sodium salt  
Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-MAB / PAB  
dUTP diphosphatase  
DNA Polymerase

AICS : Not in compliance with the inventory

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 : Substance(s) not listed on TSCA inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Remarks: Not applicable

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H371 May cause damage to organs.

Precautionary statements : **Prevention:**

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P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
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

## 15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

## 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; AICS - Australian Inventory of Chemical Substances; 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

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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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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.

DE / EN / 1810