

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Lib Quant Kit (Ion/ABI)

Version
1.0

Revision Date:
17.05.2016

Date of last issue: -
Date of first issue: 17.05.2016

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

1.1 Product identifier

Commercial Product Name : Lib Quant Kit (Ion/ABI)
Mat.-No./ Genisys-No. : 07960212001

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

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
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

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.

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.

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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 Library Quantification DNA Standards 1-6

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

KAPA Library Quantification Primer Premix (10X)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Classification (REGULATION (EC) No 1272/2008)

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

Classification (67/548/EEC, 1999/45/EC)

Harmful R68/22: Harmful: possible risk of irreversible effects if swallowed.

Hazardous components

Chemical name	CAS-No.	Classification	Concentration
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	EC-No. Registration number		(% w/w)
tetramethylammonium chloride	75-57-0 200-880-8	Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 Aquatic Chronic 2; H411	>= 1 - < 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.
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- 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 : 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.

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

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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.

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

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.

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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
- Other data : 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 Library Quantification DNA Standards 1-6

Contains no substances with occupational exposure limit values.

KAPA Library Quantification Primer Premix (10X)

Contains no substances with occupational exposure limit values.

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

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

Hand protection
Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications 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 used, such as the danger of cuts, abrasion,

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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 Library Quantification DNA Standards 1-6

- Appearance : liquid
- Colour : colourless
- Odour : odourless
- Odour Threshold : No data available
- pH : 7,7
- 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 : 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 : 0,996 g/cm³
- 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

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Relative self-ignition temperature for solids : Not applicable

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.

KAPA Library Quantification Primer Premix (10X)

Appearance : liquid

Colour : colourless

Odour : odourless

Odour Threshold : No data available

pH : 7,7

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 : 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 : 0,996 g/cm³

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

Relative self-ignition temperature for solids : Not applicable

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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.

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Appearance : liquid

Colour : light orange

Odour : No data available

Odour Threshold : No data available

pH : 9,0

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 : 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 : 1,044 g/cm³

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

Relative self-ignition temperature for solids : Not applicable

Decomposition temperature : No data available

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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 Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

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

Conditions to avoid : Extremes of temperature and direct sunlight.

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 toxicological effects

KAPA Library Quantification DNA Standards 1-6

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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.

KAPA Library Quantification Primer Premix (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.

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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.

KAPA SYBR Fast ABI Prism qPCR Master Mix (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.

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.

Components:

tetramethylammonium chloride:

Assessment: Causes damage to organs.

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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.

SECTION 12: Ecological information

12.1 Toxicity

KAPA Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Components:

tetramethylammonium chloride:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 462 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0,16 mg/l
aquatic invertebrates : 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

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GLP: yes

Toxicity to algae : 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

12.2 Persistence and degradability

KAPA Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Components:

tetramethylammonium chloride:

Biodegradability : Remarks: Expected to be biodegradable

12.3 Bioaccumulative potential

KAPA Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Components:

tetramethylammonium chloride:

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

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12.4 Mobility in soil

KAPA Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

No data available

12.5 Results of PBT and vPvB assessment

KAPA Library Quantification DNA Standards 1-6

Not relevant

KAPA Library Quantification Primer Premix (10X)

Not relevant

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

Not relevant

12.6 Other adverse effects

KAPA Library Quantification DNA Standards 1-6

No data available

KAPA Library Quantification Primer Premix (10X)

No data available

KAPA SYBR Fast ABI Prism qPCR Master Mix (2X)

No data available

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. |
| Contaminated packaging | : | Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste han- |

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ding 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, ADNR,
IMDG-Code, ICAO/IATA-DGR

14.7 Transport in bulk according to Annex II of MARPOL 73/78 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 II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

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 water endangering
(Germany)

KAPA Library Quantification DNA Standards 1-6

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

KAPA Library Quantification Primer Premix (10X)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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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 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.
H370 : Causes damage to organs.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Chronic aquatic toxicity
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 -

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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; 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 / 1511