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

1.1 Product identifier

Trade name : KAPA HiFi HotStart Uracil+ ReadyMix Kit

Product code : 07959079001

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)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies:	:	Central Works Security Roche Diagnostics GmbH	+49(0)621-759-2203
Centre for detoxification:	:	Mainz Munich	+49(0)6131-19240 +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 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 Uracil+ 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

		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.

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 : 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 : High volume water jet

media

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.
Dispose of rinse water in accordance with local and national regulations.

Handle all samples as if potentially infectious, using safe laboratory procedures. As the sensitivity and titer of potential pathogens in the sample material can vary, the operator must optimize pathogen inactivation and follow the appropriate measures according to local safety regulations.

Do not eat, drink, or smoke in the laboratory area.
Do not pipette by mouth.

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

KAPA HiFi HotStart Uracil+ 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/m3	DE TRGS 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			
Nucleotidyltransferase, deoxyribonucleate	9012-90-2	IOEL	0,00006 mg/m3	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 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 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.
Protective measures	:	Wear protective disposable gloves, laboratory coats and eye protection, when handling samples and kit reagents. Wash hands thoroughly after handling samples and reagents.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Physical state	:	liquid
Colour	:	colourless
Odour	:	odourless
Odour Threshold	:	No data available

Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
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	:	1,080 g/cm3
Relative vapour density	:	No data available

9.2 Other information

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion. The product is not flammable.
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 Uracil+ 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 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

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

Aspiration toxicity

Not classified based on available information.

Components:

Nucleotidyltransferase, deoxyribonucleate:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	:	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.

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Endocrine disrupting properties

Product:

Assessment : 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.

Further information

Components:

tetramethylammonium chloride:

Remarks : Other dangerous properties can not be excluded.

SECTION 12: Ecological information

12.1 Toxicity

KAPA HiFi HotStart Uracil+ 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

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

12.2 Persistence and degradability

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Components:

tetramethylammonium chloride:

Biodegradability : Remarks: Expected to be biodegradable

12.3 Bioaccumulative potential

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Components:

tetramethylammonium chloride:

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

Nucleotidyltransferase, deoxyribonucleate:

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

12.4 Mobility in soil

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

No data available

12.5 Results of PBT and vPvB assessment

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Not relevant

12.6 Endocrine disrupting properties

Product:

Assessment : 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.

KAPA HiFi HotStart Uracil+ ReadyMix (2X)

Product:

Assessment : 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.

12.7 Other adverse effects

KAPA HiFi HotStart Uracil+ ReadyMix (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.

Discard unused reagents and waste in accordance with country, federal, state and local regulations.

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 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

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 hazard class (Germany) : WGK 1 slightly hazardous to water

KAPA HiFi HotStart Uracil+ 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 deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (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. thymidine 5'-(tetrahydrogen triphosphate) 2'-deoxyguanosine 5'-(tetrahydrogen triphosphate) 2'-deoxyadenosine 5'-(tetrahydrogen triphosphate) Cytidine 5'-(tetrahydrogen triphosphate), 2'-deoxy- Antibodies 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
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) Volatile organic compounds (VOC) content: < 0,01 %

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

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 Speci-

fied; 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

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 / 2104