according to Regulation (EC) No. 1907/2006

### **High Pure Viral RNA Kit**

Version Revision Date: Date of last issue: 09.02.2023
1.2 Date of first issue: 27.01.2023

# Roche

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

1.1 Product identifier

Trade name : High Pure Viral RNA Kit

Product code : 11858882001

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 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 +49(0)621-759-2203

Roche Diagnostics GmbH

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

### **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 : Danger

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

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H315 Causes skin irritation.

H318 Causes serious eye damage.

Precautionary statements : Prevention:

P261 Avoid breathing mist or vapours.P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON

CENTER/ doctor if you feel unwell.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a

POISON CENTER/ doctor.

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**

### Poly (A), lyophylized

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

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

### Wash Buffer I / Inhibitor Removal Buffer

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

Acute toxicity, Category 4 H302: Harmful if swallowed.

Acute toxicity, Category 4 H332: Harmful if inhaled.

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation.

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Components

Observations	OAO NI-	01'6'6'	0
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		, , ,
	Registration number		
guanidinium chloride	50-01-1	Acute Tox. 4; H302	>= 50,0 - <
	200-002-3	Acute Tox. 4; H332	70,0
	607-148-00-0	Skin Irrit. 2, H315	,
	01-2119977063-35	Eye Irrit. 2; H319	
	0.12.1.00.7.000.00	2,0 11111 2, 11010	
		Acute toxicity esti-	
		•	
		mate	
		Acute oral toxicity:	
		-	
		475 mg/kg	
		Acute inhalation tox-	
		icity (dust/mist): 3,2	
		mg/l	

For explanation of abbreviations see section 16.

#### Wash Buffer

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

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

### Elution Buffer (EB)

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

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

### Binding buffer

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

Acute toxicity, Category 4 H302: Harmful if swallowed.

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage.

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Components

Chemical name	CAS-No. EC-No.	Classification	Concentration
	Index-No.		(% w/w)
	Registration number		
guanidinium chloride	50-01-1 200-002-3 607-148-00-0 01-2119977063-35	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Irrit. 2; H319  Acute toxicity estimate  Acute oral toxicity: 475 mg/kg Acute inhalation toxicity (dust/mist): 3,2 mg/l	>= 20,0 - < 30,0
Polidocanol	9002-92-0 500-002-6	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412 ————————————————————————————————————	>= 20,0 - < 25,0

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.

Consult a physician.

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 : Small amounts splashed into eyes can cause irreversible tis-

sue damage and blindness.

In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

Continue rinsing eyes during transport to hospital.

Remove contact lenses.

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Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

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

Keep respiratory tract clear. Do NOT induce vomiting.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

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

Rinse mouth with water.

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

Symptoms : No information available.

### 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

Do not allow run-off from fire fighting to enter drains or water

courses.

Hazardous combustion prod: :

ucts

In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

Nitrogen oxides (NOx)

Ammonia

Gaseous hydrogen chloride (HCI).

#### 5.3 Advice for firefighters

Special protective equipment :

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Further information : Collect contaminated fire extinguishing water separately. This

must not be discharged into drains.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

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#### **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.

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 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.

To prevent leaks or spillages from spreading, provide a suita-

ble liquid retention system.

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. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological

safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Storage class (TRGS 510) : 12

Further information on stor- : No decomposition if stored and applied as directed.

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age stability

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

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

### 8.1 Control parameters

### Poly (A), lyophylized

Contains no substances with occupational exposure limit values.

### Wash Buffer I / Inhibitor Removal Buffer

Contains no substances with occupational exposure limit values.

### Wash Buffer

Contains no substances with occupational exposure limit values.

### Elution Buffer (EB)

Contains no substances with occupational exposure limit values.

### Binding buffer

Contains no substances with occupational exposure limit values.

#### 8.2 Exposure controls

### **Engineering measures**

No data available

### Personal protective equipment

Eye/face protection : Use eye protection according to EN 166.

Eye wash bottle with pure water Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

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





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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 Poly (A),lyophylized

Physical state : solid

Colour : white

Odour : none

Odour Threshold : Not applicable

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 : Not applicable

Viscosity

Viscosity, dynamic : Not applicable

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Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : soluble

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

Relative vapour density : Not applicable

Particle characteristics

Particle Size Distribution : No data available

#### Wash Buffer I / Inhibitor Removal Buffer

Physical state : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flammability : The product is not flammable., Does not sustain combustion.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 6,6

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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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

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

Wash Buffer

Physical state : liquid

Colour : colourless

Odour : none

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

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7,5

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

Elution Buffer (EB)

Physical state : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : 100 °C

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

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

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Vapour pressure : 23 hPa (20 °C)

Relative density : No data available

Density : 1 g/cm3 (20 °C)

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

Binding buffer

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

Flammability : The product is not flammable., Does not sustain combustion.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

does not flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 6,4 - 6,8 (25 °C)

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

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Vapour pressure : No data available

Relative density : No data available

Density : 1,118 g/cm3 (20 °C, 990 - 1.030 hPa)

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

### 9.2 Other information

### Poly (A), lyophylized

Explosives : Not explosive

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

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

#### Wash Buffer I / Inhibitor Removal Buffer

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : completely miscible

#### Wash Buffer

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : completely miscible

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### Elution Buffer (EB)

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

### Binding buffer

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

Conductivity : 88.000 - 98.000 μS/cm

### **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 : Keep away from heat and sources of ignition.

Reacts with the following substances:

Acids

Oxidizing agents

No decomposition if stored and applied as directed.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

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### 10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents

Bases

### 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

### Poly (A), lyophylized

### **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.

### Wash Buffer I / Inhibitor Removal Buffer

#### **Acute toxicity**

Harmful if swallowed or if inhaled.



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### **Components:**

guanidinium chloride:

Acute oral toxicity : LD50 Oral (Rat, female): 475 mg/kg

Method: OECD Test Guideline 401

GLP: yes

Acute toxicity estimate: 475 mg/kg

Method: ATE value derived from LD50/LC50 value

Acute inhalation toxicity : LC50 (Rat, female): 3,2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

LC50 (Rat, male and female): 5,32 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

LC50 (Rat, male): 7,7 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

Acute toxicity estimate: 3,2 mg/l Test atmosphere: dust/mist

Method: ATE value derived from LD50/LC50 value

Acute dermal toxicity : LD50 Dermal (Rabbit, male and female): > 2.000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: No mortality observed at this dose.

### Skin corrosion/irritation

Causes skin irritation.

### **Components:**

### guanidinium chloride:

Species : Rabbit Exposure time : 24 h

Result : Irritating to skin.

GLP : yes

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### **Components:**

#### guanidinium chloride:



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Species Rabbit

OECD Test Guideline 405 Method

Result Irritating to eyes.

**GLP** yes

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### **Components:**

#### guanidinium chloride:

Test Type **Buehler Test Species** Guinea pig

Assessment Does not cause skin sensitisation.

OECD Test Guideline 406 Method

**GLP** ves

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

### guanidinium chloride:

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

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative GLP: yes

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster fibroblasts Method: OECD Test Guideline 473

Result: negative

GLP: no

#### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

### Components:

### guanidinium chloride:

Effects on foetal develop-Species: Rat, female ment Application Route: Oral

Dose: 50, 150, 350 mg/kg bw/day

Duration of Single Treatment: 5 - 19 d

Developmental Toxicity: NOAEL: 350 mg/kg body weight

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Method: OECD Test Guideline 414

GLP: yes

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### **Components:**

### guanidinium chloride:

Species : Rat, male and female

NOAEL : 100 mg/kg

Application Route : Oral Exposure time : 90 d

Dose : 25, 100, 300 mg/kg bw/day Method : OECD Test Guideline 408

GLP : yes

#### **Aspiration toxicity**

Not classified based on available information.

### Wash Buffer

#### **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.



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Not classified based on available information.

#### **Aspiration toxicity**

Not classified based on available information.

### Elution Buffer (EB)

### **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.

### Binding buffer

#### **Acute toxicity**

Harmful if swallowed.

### **Components:**

### guanidinium chloride:

LD50 Oral (Rat, female): 475 mg/kg Acute oral toxicity

Method: OECD Test Guideline 401

GLP: yes

Acute toxicity estimate: 475 mg/kg

Method: ATE value derived from LD50/LC50 value



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Acute inhalation toxicity : LC50 (Rat, female): 3,2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

LC50 (Rat, male and female): 5,32 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

LC50 (Rat, male): 7,7 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

GLP: yes

Acute toxicity estimate: 3,2 mg/l Test atmosphere: dust/mist

Method: ATE value derived from LD50/LC50 value

Acute dermal toxicity : LD50 Dermal (Rabbit, male and female): > 2.000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: No mortality observed at this dose.

Polidocanol:

Acute oral toxicity : LD50 Oral (Rat): 1.000 mg/kg

Method: OECD Test Guideline 423

GLP: yes

Acute toxicity estimate: 1.000 mg/kg

Method: ATE value derived from LD50/LC50 value

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2.000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Skin corrosion/irritation

Causes skin irritation.

Components:

guanidinium chloride:

Species : Rabbit Exposure time : 24 h

Result : Irritating to skin.

GLP : yes

Polidocanol:

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according to Regulation (EC) No. 1907/2006

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Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : No skin irritation

GLP : yes

### Serious eye damage/eye irritation

Causes serious eye damage.

#### **Components:**

### guanidinium chloride:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritating to eyes.

GLP : yes

### Polidocanol:

Species : Rabbit

Method : OECD Test Guideline 405
Result : Risk of serious damage to eyes.

GLP : yes

### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### guanidinium chloride:

Test Type : Buehler Test Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Method : OECD Test Guideline 406

GLP : yes

#### Polidocanol:

Test Type : Draize Test Species : Guinea pig

Result : Does not cause skin sensitisation.

GLP : no

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

### guanidinium chloride:



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

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

GLP: yes

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster fibroblasts Method: OECD Test Guideline 473

Result: negative

GLP: no

Polidocanol:

Genotoxicity in vitro : Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster cells

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: negative

Genotoxicity in vivo : Test Type: in vivo assay

Species: Mouse (male)

Strain: B6C3F1

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Exposure time: 72 h Dose: 125 mg/kg Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

**Components:** 

guanidinium chloride:

Effects on foetal develop-

ment

Species: Rat, female Application Route: Oral

Dose: 50, 150, 350 mg/kg bw/day

Duration of Single Treatment: 5 - 19 d

Developmental Toxicity: NOAEL: 350 mg/kg body weight

Method: OECD Test Guideline 414

GLP: yes

Polidocanol:

according to Regulation (EC) No. 1907/2006

### **High Pure Viral RNA Kit**

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Effects on foetal develop-

ment

Test Type: Two-generation study

Species: Rat, female Application Route: Oral

Developmental Toxicity: NOAEL: 50 mg/kg bw/day

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### **Components:**

#### guanidinium chloride:

Species : Rat, male and female

NOAEL : 100 mg/kg Application Route : Oral Exposure time : 90 d

Dose : 25, 100, 300 mg/kg bw/day Method : OECD Test Guideline 408

GLP : yes

Polidocanol:

Species : Rat, male

NOAEL : 390 mg/kg bw/day

Application Route : Oral Exposure time : 22 d

#### **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.

### Poly (A), lyophylized

### **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.

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according to Regulation (EC) No. 1907/2006

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### Wash Buffer I / Inhibitor Removal Buffer

### **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.

#### Wash Buffer

### **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.

### Elution Buffer (EB)

### **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.

### Binding buffer

### **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

Poly (A), lyophylized

No data available

according to Regulation (EC) No. 1907/2006



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# Roche

### Wash Buffer I / Inhibitor Removal Buffer

### **Components:**

guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.758 mg/l

End point: mortality Exposure time: 48 h Test Type: static test

GLP: yes

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 70,2 mg/l

End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes

Method: OECD Test Guideline 202 GLP: No information available.

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 33,5

mg/

End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

EC50 (Pseudokirchneriella subcapitata (green algae)): 11,8

mg/l

Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 6,3

mg/l

End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

Toxicity to microorganisms : EC10 (Pseudomonas putida): 7.125 mg/l

End point: Growth rate Exposure time: 18 h Test Type: static test Method: DIN 38 412 Part 8

GLP: yes

Toxicity to fish (Chronic tox-

icity)

NOEC: > 181 mg/l

End point: mortality Exposure time: 35 d

Species: Pimephales promelas (fathead minnow)

according to Regulation (EC) No. 1907/2006

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Test Type: flow-through test Analytical monitoring: yes

Method: OECD Test Guideline 210 GLP: No information available.

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 2,9 mg/l

End point: reproduction rate

Exposure time: 21 d

Species: Daphnia magna (Water flea)

Analytical monitoring: yes

Method: OECD Test Guideline 211 GLP: No information available.

**Ecotoxicology Assessment** 

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

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

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

Other organisms relevant to

the environment

No data available

Wash Buffer

No data available

Elution Buffer (EB)

No data available

Binding buffer

**Components:** 

guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.758 mg/l

End point: mortality Exposure time: 48 h Test Type: static test

GLP: yes

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 70,2 mg/l

End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes

Method: OECD Test Guideline 202 GLP: No information available.

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 33,5

mg/l

End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

according to Regulation (EC) No. 1907/2006

### **High Pure Viral RNA Kit**

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EC50 (Pseudokirchneriella subcapitata (green algae)): 11,8

mg/l

Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 6,3

ma/l

End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes

Method: Regulation (EC) No. 440/2008, Annex, C.3

GLP: yes

Toxicity to microorganisms : EC10 (Pseudomonas putida): 7.125 mg/l

End point: Growth rate Exposure time: 18 h Test Type: static test Method: DIN 38 412 Part 8

GLP: yes

Toxicity to fish (Chronic tox-

icity)

NOEC: > 181 mg/l End point: mortality

Exposure time: 35 d

Species: Pimephales promelas (fathead minnow)

Test Type: flow-through test Analytical monitoring: yes

Method: OECD Test Guideline 210 GLP: No information available.

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 2,9 mg/l

End point: reproduction rate

Exposure time: 21 d

Species: Daphnia magna (Water flea)

Analytical monitoring: yes

Method: OECD Test Guideline 211 GLP: No information available.

**Ecotoxicology Assessment** 

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

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

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

Other organisms relevant to

the environment

No data available

Polidocanol:

Toxicity to fish : LC50 (Salmo salar (Atlantic salmon)): 1,5 mg/l

End point: mortality

according to Regulation (EC) No. 1907/2006

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Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 6,46 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 0,237 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EbC50 (Desmodesmus subspicatus (green algae)): 1.502

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : (Photobacterium phosphoreum): 2,5 mg/l

Test Type: EC50

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,144 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: QSAR

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic to aquatic life.

Remarks: Expert judgement

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Remarks: Expert judgement

### 12.2 Persistence and degradability

### Poly (A), lyophylized

No data available

### Wash Buffer I / Inhibitor Removal Buffer

#### **Components:**

guanidinium chloride:

Biodegradability : Test Type: aerobic

Inoculum: activated sludge, adapted

Concentration: 10 mg/l

Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 33 d

Method: OECD Test Guideline 301C

GLP: yes

Impact on Sewage Treat-

ment

Do not discharge product into the aquatic environment without

pretreatment (biological treatment plant).

### Wash Buffer

No data available

### Elution Buffer (EB)

according to Regulation (EC) No. 1907/2006

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No data available

### Binding buffer

### Components:

guanidinium chloride:

Biodegradability : Test Type: aerobic

Inoculum: activated sludge, adapted

Concentration: 10 mg/l

Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 33 d

Method: OECD Test Guideline 301C

GLP: yes

Impact on Sewage Treat-

ment

Do not discharge product into the aquatic environment without

pretreatment (biological treatment plant).

Polidocanol:

Biodegradability : Test Type: aerobic

Inoculum: activated sludge Concentration: 30 mg/l Result: Readily biodegradable.

Biodegradation: 74 % Exposure time: 28 d

Method: OECD Test Guideline 301C

#### 12.3 Bioaccumulative potential

### Poly (A), lyophylized

No data available

### Wash Buffer I / Inhibitor Removal Buffer

### **Components:**

guanidinium chloride:

Partition coefficient: n- : log Pow: < -1,7 (20 °C)

octanol/water pH: 7,4

Method: OECD Test Guideline 107

GLP: yes

Wash Buffer

No data available

Elution Buffer (EB)

No data available

Binding buffer

#### **Components:**

guanidinium chloride:

Partition coefficient: n- : log Pow: < -1,7 (20 °C)

octanol/water pH: 7,4

Method: OECD Test Guideline 107

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GLP: yes

Polidocanol:

Partition coefficient: n-

octanol/water

Remarks: No data available

### 12.4 Mobility in soil

### Poly (A), lyophylized

No data available

### Wash Buffer I / Inhibitor Removal Buffer

No data available

### Wash Buffer

No data available

### Elution Buffer (EB)

No data available

### Binding buffer

No data available

### 12.5 Results of PBT and vPvB assessment

### Poly (A), lyophylized

Not relevant

### Wash Buffer I / Inhibitor Removal Buffer

Not relevant

### Wash Buffer

Not relevant

### Elution Buffer (EB)

Not relevant

### Binding buffer

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.

### Poly (A), lyophylized

#### **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.





according to Regulation (EC) No. 1907/2006

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### Wash Buffer I / Inhibitor Removal Buffer

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.

Wash Buffer

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.

Elution Buffer (EB)

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.

Binding buffer

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

Poly (A), lyophylized

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

Elution Buffer (EB)

No data available

Binding buffer

No data available

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water

according to Regulation (EC) No. 1907/2006



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courses or the soil.

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

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : 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

according to Regulation (EC) No. 1907/2006



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### 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

Not applicable

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

Water hazard class (Germa- : WGK 2 obviously hazardous to water

ny)

Poly (A), lyophylized

REACH - Restrictions on the manufacture, placing on : Not applicable

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

Regulation (EC) No 1005/2009 on substances that de: Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(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.

Polyadenylic acid, poly(A)lyophilized potassiumsalt

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

according to Regulation (EC) No. 1907/2006

## Roche

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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.

### Wash Buffer I / Inhibitor Removal Buffer

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

mixtures 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

: Not applicable

(Annex XIV)

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

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

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

according to Regulation (EC) No. 1907/2006

### **High Pure Viral RNA Kit**

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

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

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

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

TECI: On the inventory, or 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 : H302 + H332 Harmful if swallowed or if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements : Prevention:

P261 Avoid breathing mist or vapours.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh

air and keep comfortable for breathing. Call a POISON

CENTER/ doctor if you feel unwell.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.



according to Regulation (EC) No. 1907/2006

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Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

Wash Buffer

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

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

plete the ozone layer

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

tants (recast)

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

of dangerous chemicals

or dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

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

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

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

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

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

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

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

TECI: On the inventory, or 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

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Roche

according to Regulation (EC) No. 1907/2006

### **High Pure Viral RNA Kit**

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Not applicable

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

Not a hazardous substance or mixture.

Elution Buffer (EB)

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

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

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

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

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

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

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

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

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

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

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

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

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

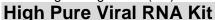
IECSC : On the inventory, or in compliance with the inventory

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

TSCA : All substances listed as active on the TSCA inventory

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

according to Regulation (EC) No. 1907/2006



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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.

Binding buffer

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

mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered:

Number on list 3

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

of dangerous chemicals

Not applicable

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

REACH - List of substances subject to authorisation

(Annex XIV)

Not applicable

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

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

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

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 : On the inventory, or in compliance with the inventory

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

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

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

according to Regulation (EC) No. 1907/2006

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TSCA : All substances listed as active on the 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: 22,36 %

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

Hazard pictograms



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.P280 Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER/ doctor if you feel unwell. Rinse mouth.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a

POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

9002-92-0 Polidocanol

### 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**



according to Regulation (EC) No. 1907/2006



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H302 : Harmful if swallowed. H315 : Causes skin irritation.

H318 : Causes serious eye damage. H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H412 : Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation Skin Irrit. : Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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**

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.

according to Regulation (EC) No. 1907/2006



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