according to Regulation (EC) No. 1907/2006



## **High Pure Viral NA Large Volume Kit**

Version Revision Date: Date of last issue: 07.08.2014 1.6 23.02.2015 Date of first issue: 15.11.2012

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

1.1 Product identifier

Commercial Product Name : High Pure Viral NA Large Volume Kit

Mat.-No./ Genisys-No. : 05114403001

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

E-mail address : mannheim.umweltschutz@roche.com

Telephone : +496217590 Telefax : +496217592890

Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

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

Roche Diagnostics GmbH

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

Munich +49(0)89-19240

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

#### 2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms







Signal word : Danger

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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

H335 May cause respiratory irritation.

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Precautionary statements : **Prevention:** 

P261 Avoid breathing dust/ fume/ gas/ mist/ va-

pours/ spray.

P280 Wear eye protection/ face protection.

P280 Wear protective gloves. P284 Wear respiratory protection.

Response:

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 or doctor/ physician.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P362 + P364 Take off contaminated clothing and wash it

before reuse.

#### 2.3 Other hazards

See SECTION 3

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

## Lysis/Binding Buffer/DNA PBB

#### 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.

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

Harmful R22: Harmful if swallowed.

Irritant R38: Irritating to skin.

R41: Risk of serious damage to eyes.

#### **Hazardous components**

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
guanidinium chloride	50-01-1 200-002-3	Xn; R22 Xi; R36/38	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Irrit. 2; H319	>= 30 - < 50
Triton X-100	9002-93-1	Xn; R22 Xi; R41	Acute Tox. 4; H302 Eye Dam. 1; H318	>= 10 - < 20

For explanation of abbreviations see section 16.

#### Poly (A), lyophylized

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#### 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

## Proteinase K, PCR grade

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

Skin irritation, Category 2 H315: Causes skin irritation.

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

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Specific target organ toxicity - single exposure, Category 3, Respiratory system

H335: May cause respiratory irritation.

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

Sensitising R42/43: May cause sensitisation by inhalation and

skin contact.

Irritant R36/37/38: Irritating to eyes, respiratory system

and skin.

## **Hazardous components**

Chemical Name	CAS-No.	Classification	Classification	Concentration
	EC-No.	(67/548/EEC)	(REGULATION	(%)
	Registration	,	(EC) No	` '
	number		1272/2008)	
Proteinase, Tritirachium	39450-01-6	Xi; R36/37/38	Skin Irrit. 2; H315	>= 70 - < 90
album serine	254-457-8	R42	Eye Irrit. 2; H319	
		Xi; Xi; R36/37/38	Resp. Sens. 1;	
		Xn; R42	H334	
		Xi; R43	Skin Sens. 1; H317	
			STOT SE 3; H335	

For explanation of abbreviations see section 16.

#### 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.

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

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

Harmful R22: Harmful if swallowed.

Irritant R36/38: Irritating to eyes and skin.

#### **Hazardous components**

Chemical Name	CAS-No.	Classification	Classification	Concentration
	EC-No.	(67/548/EEC)	(REGULATION	(%)
	Registration		(EC) No	
	number		1272/2008)	
guanidinium chloride	50-01-1	Xn; R22	Acute Tox. 4; H302	>= 50 - < 70
	200-002-3	Xi; R36/38	Acute Tox. 4; H332	
			Skin Irrit. 2; H315	
			Eye Irrit. 2; H319	

For explanation of abbreviations see section 16.

#### Wash Buffer

#### 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

## Elution Buffer (EB)

## 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

#### **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 : Call a physician or poison control centre immediately.

Move to fresh air.

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If unconscious place in recovery position and seek medical

advice.

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. 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.

#### 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.

#### 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.

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Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

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

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

Personal precautions : Use personal protective equipment.

Avoid dust formation.

Avoid breathing dust.

Ensure adequate ventilation.

#### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform

respective authorities.

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

Methods for cleaning up : Keep in suitable, closed containers for disposal.

Wipe up with absorbent material (e.g. cloth, fleece).

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 : Avoid formation of respirable particles.

Do not breathe vapours/dust.

Avoid exposure - obtain special instructions before use.

Avoid contact with skin and eyes. For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the ap-

plication area.

Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national

regulations.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being

used.

Advice on protection against

fire and explosion

: Avoid dust formation. Provide appropriate exhaust ventilation

at places where dust is formed.

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. 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) : 13, Non Combustible Solids

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

## Lysis/Binding Buffer/DNA PBB

Contains no substances with occupational exposure limit values.

## Poly (A), lyophylized

Contains no substances with occupational exposure limit values.

#### Proteinase K, PCR grade

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.

#### 8.2 Exposure controls

#### Personal protective equipment

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

Hand protection

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Material : Protective gloves

Remarks The selected protective gloves have to satisfy the specifica-

> tions 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, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective

gloves.

Skin and body protection Choose body protection according to the amount and concen-

tration of the dangerous substance at the work place.

Respiratory protection : In the case of dust or aerosol formation use respirator with an

approved filter.

Effective dust mask

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

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

## Lysis/Binding Buffer/DNA PBB

**Appearance** : liquid

Colour colourless

Odour : none

Odour Threshold : No data available

pΗ : 4,4

Melting point/freezing point

Initial boiling point and boiling

range

Flash point No data available

Evaporation rate No data available

Flammability (solid, gas) The product is not flammable., Does not sustain combustion.

: No data available

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 : No data available

Solubility(ies)

Water solubility : completely miscible

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Partition coefficient: n-

octanol/water

: No data available

Ignition temperature : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

Poly (A), lyophylized

Appearance : solid

Colour : white

Odour : none

Odour Threshold : No data available pH : No data available Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available Flammability (solid, gas) : 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 : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: No data available

Ignition temperature : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

Proteinase K, PCR grade

Appearance : solid

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Colour : white

Odour : very faint

Odour Threshold : No data available

pH : 6,5 (as aqueous solution)

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available Flammability (solid, gas) : 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 : No data available

Solubility(ies)

Water solubility : completely soluble

Partition coefficient: n-

octanol/water

: No data available

Ignition temperature : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

#### Wash Buffer I / Inhibitor Removal Buffer

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 6,6

Melting point/freezing point : No data available Initial boiling point and boiling : No data available

range

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable., Does not sustain combustion.

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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 : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

Ignition temperature : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

: No data available

Wash Buffer

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 7,5

Melting point/freezing point Initial boiling point and boiling

range

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable., Does not sustain combustion.

: No data available

: 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 : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

Ignition temperature : No data available

: No data available

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Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

Elution Buffer (EB)

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available pH : No data available Melting point/freezing point : No data available

Boiling point/boiling range : 100 °C

Flash point : No data available

Evaporation rate : No data available Flammability (solid, gas) : No data available Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : 23 hPa (20 °C)

Relative vapour density : No data available Relative density : No data available Density : 1 g/cm3 (20 °C)

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: No data available

Ignition temperature : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available Explosive properties : No data available

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

#### 9.2 Other information

Lysis/Binding Buffer/DNA PBB

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No data available

## Poly (A), lyophylized

No data available

## Proteinase K, PCR grade

No data available

#### Wash Buffer I / Inhibitor Removal Buffer

No data available

#### Wash Buffer

No data available

## Elution Buffer (EB)

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 : Reacts with the following substances:

Oxidizing agents

Keep away from heat and sources of ignition.

No decomposition if stored and applied as directed.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

#### 10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents

Bases

## 10.6 Hazardous decomposition products

In case of fire hazardous decomposition products may be produced such as:, Carbon oxides, Nitrogen oxides (NOx), Gaseous hydrogen chloride (HCl)., Ammonia

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

#### 11.1 Information on toxicological effects

## Lysis/Binding Buffer/DNA PBB

#### **Acute toxicity**

Harmful if swallowed.

#### **Components:**

guanidinium chloride:

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

LD50 Oral (Mouse): 571 mg/kg

LD50 Oral (Rat): 1.120 mg/kg

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

Exposure time: 4 h

Test atmosphere: dust/mist

LC50 (Rat, male and female): 5,3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2.001 mg/kg

Triton X-100:

Acute oral toxicity : LD50 Oral (Rat): 1.900 - 5.000 mg/kg

Acute toxicity estimate: 500 mg/kg

Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): > 3.000 mg/kg

#### Skin corrosion/irritation

Causes skin irritation.

## **Components:**

guanidinium chloride:

Species: Rabbit

Result: Irritating to skin.

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### **Components:**

guanidinium chloride:

Species: Rabbit

Result: Irritating to eyes.

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#### Triton X-100:

Result: Risk of serious damage to eyes. Remarks: May cause irreversible eye damage.

#### Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information. Respiratory sensitisation: Not classified based on available information.

#### **Components:**

#### guanidinium chloride:

Assessment: Did not cause sensitisation on laboratory animals.

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### guanidinium chloride:

Germ cell mutagenicity- As- : Not mutagenic in Ames Test sessment

## 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.

#### 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.

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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.

## Proteinase K, PCR grade

#### **Acute toxicity**

Not classified based on available information.

#### Skin corrosion/irritation

Causes skin irritation.

#### **Components:**

#### Proteinase, Tritirachium album serine:

Result: Irritating to skin.

Remarks: May cause skin irritation and/or dermatitis.

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

#### Proteinase, Tritirachium album serine:

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

## Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if in-

haled.

## **Components:**

#### Proteinase, Tritirachium album serine:

Assessment: May cause sensitisation by skin contact.

Remarks: Causes sensitisation.

Assessment: May cause sensitisation by inhalation.

#### 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 respiratory irritation.

#### **Components:**

#### Proteinase, Tritirachium album serine:

Assessment: May cause respiratory irritation.

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#### STOT - repeated exposure

Not classified based on available information.

## Components:

#### Proteinase, Tritirachium album serine:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

#### Aspiration toxicity

Not classified based on available information.

#### Components:

## Proteinase, Tritirachium album serine:

No data available

#### Wash Buffer I / Inhibitor Removal Buffer

#### **Acute toxicity**

Harmful if swallowed or if inhaled

#### **Components:**

#### guanidinium chloride:

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

LD50 Oral (Mouse): 571 mg/kg

LD50 Oral (Rat): 1.120 mg/kg

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

Exposure time: 4 h

Test atmosphere: dust/mist

LC50 (Rat, male and female): 5,3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2.001 mg/kg

#### Skin corrosion/irritation

Causes skin irritation.

#### **Components:**

#### guanidinium chloride:

Species: Rabbit

Result: Irritating to skin.

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### **Components:**

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#### guanidinium chloride:

Species: Rabbit

Result: Irritating to eyes.

#### Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

#### **Components:**

#### guanidinium chloride:

Assessment: Did not cause sensitisation on laboratory animals.

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### guanidinium chloride:

Germ cell mutagenicity- As- : Not mutagenic in Ames Test

sessment

## 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

## **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.

according to Regulation (EC) No. 1907/2006

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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.

## 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.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Lysis/Binding Buffer/DNA PBB

#### **Components:**

## guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.759 mg/l

Exposure time: 48 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 89 mg/l

Exposure time: 18 h

**Ecotoxicology Assessment** 

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

according to Regulation (EC) No. 1907/2006



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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

Triton X-100:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8,9 mg/l

Exposure time: 96 h

Toxicity to daphnia and other

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l

Exposure time: 48 h

**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

## Poly (A), lyophylized

No data available

#### Proteinase K, PCR grade

#### **Components:**

#### Proteinase, Tritirachium album serine:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: No data available

#### Wash Buffer I / Inhibitor Removal Buffer

#### **Components:**

guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.759 mg/l

Exposure time: 48 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 89 mg/l

Exposure time: 18 h

**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

according to Regulation (EC) No. 1907/2006



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#### Wash Buffer

No data available

Elution Buffer (EB)

No data available

## 12.2 Persistence and degradability

## Lysis/Binding Buffer/DNA PBB

#### Components:

guanidinium chloride:

Biodegradability : Biodegradation: < 70 %

Remarks: According to the results of tests of biodegradability

this product is not readily biodegradable.

Impact on Sewage Treat-

ment

: Do not discharge product into the aquatic environment without

pretreatment (biological treatment plant).

Triton X-100:

Biodegradability : Biodegradation: > 60 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

## Poly (A), lyophylized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer I / Inhibitor Removal Buffer

## **Components:**

guanidinium chloride:

Biodegradability : Biodegradation: < 70 %

Remarks: According to the results of tests of biodegradability

this product is not readily biodegradable.

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)

No data available

#### 12.3 Bioaccumulative potential

## Lysis/Binding Buffer/DNA PBB

## **Components:**

guanidinium chloride:

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

according to Regulation (EC) No. 1907/2006

# Roche

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octanol/water

Triton X-100:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <=

4).

Poly (A), lyophylized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer I / Inhibitor Removal Buffer

**Components:** 

guanidinium chloride:

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

octanol/water

Wash Buffer

No data available

Elution Buffer (EB)

No data available

12.4 Mobility in soil

Lysis/Binding Buffer/DNA PBB

No data available

Poly (A), lyophylized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

Elution Buffer (EB)

No data available

12.5 Results of PBT and vPvB assessment

Lysis/Binding Buffer/DNA PBB

Not relevant

Poly (A), lyophylized

Not relevant

Proteinase K, PCR grade

Not relevant

Wash Buffer I / Inhibitor Removal Buffer

Not relevant

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# Roche

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#### Wash Buffer

Not relevant

Elution Buffer (EB)

Not relevant

#### 12.6 Other adverse effects

## Lysis/Binding Buffer/DNA PBB

No data available

Poly (A), lyophylized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

Elution Buffer (EB)

No data available

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

#### 13.1 Waste treatment methods

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

cal or used container.

Send to a licensed waste management company.

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

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

according to Regulation (EC) No. 1907/2006



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#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Remarks : No data available

#### 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

(Germany)

: WGK 2 water endangering

## Lysis/Binding Buffer/DNA PBB

## 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 eye protection/ face protection.

P280 Wear protective gloves.

Response:

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 or doctor/ physician.

Disposal:

P501 Dispose of contents/ container to an ap-

proved 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 quanidinium chloride

9002-93-1 Triton X-100

## Poly (A), lyophylized

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

## Proteinase K, PCR grade

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word : Danger

Hazard statements : H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

H335 May cause respiratory irritation.

Precautionary statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ va-

pours/ spray.

P280 Wear eye protection/ face protection.

P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:

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

air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if

you feel unwell.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

Hazardous components which must be listed on the label:

39450-01-6 Proteinase, Tritirachium album serine

#### Wash Buffer I / Inhibitor Removal Buffer

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006



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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 dust/ fume/ gas/ mist/ va-

pours/ spray.

P280 Wear eye protection/ face protection.

P280 Wear protective gloves.

Response:

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

air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if

you feel unwell.

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

attention.

Disposal:

P501 Dispose of contents/ container to an ap-

proved waste disposal plant.

Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

## Wash Buffer

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

Not a hazardous substance or mixture.

## Elution Buffer (EB)

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

Not a hazardous substance or mixture.

#### 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 R-Phrases**

R22 : Harmful if swallowed.

R36/37/38 : Irritating to eyes, respiratory system and skin.

R36/38 : Irritating to eyes and skin.
R41 : Risk of serious damage to eyes.

according to Regulation (EC) No. 1907/2006



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R42 : May cause sensitisation by inhalation. R43 : May cause sensitisation by skin contact.

**Full text of H-Statements** 

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

H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H335 : May cause respiratory irritation.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Resp. Sens. : Respiratory sensitisation

Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

STOT SE : Specific target organ toxicity - single exposure

#### **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.

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