

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

High Pure Viral Nucleic Acid Kit

Version
1.2

Revision Date:
11.04.2023

Date of last issue: 09.02.2023
Date of first issue: 27.01.2023

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

1.1 Product identifier

Trade name : High Pure Viral Nucleic Acid Kit
Product code : 11858874001

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
Sandhoferstrasse 116
68305 Mannheim
Deutschland
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +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.
- 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.

Precautionary statements : **Prevention:**

- P261 Avoid breathing dust.
- 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.
- P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

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), lyophilized

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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.

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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.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Proteinase, Tritirachium album serine	39450-01-6 254-457-8 647-014-00-9	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 Skin Sens. 1; H317 STOT SE 3; H335 (Respiratory system)	>= 70,0 - < 90,0

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.

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.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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 esti-	>= 50,0 - < 70,0

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		mate	
		Acute oral toxicity: 475 mg/kg	
		Acute inhalation toxicity (dust/mist): 3,2 mg/l	

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, universal MBF**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.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 30,0 - < 50,0
Polidocanol	9002-92-0 500-002-6	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity esti-	>= 10,0 - < 20,0

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		mate	
		Acute oral toxicity: 1.000 mg/kg	

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 : Call a physician or poison control centre immediately.
Move to fresh air.
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 tissue 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.
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.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

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

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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.

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.

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : 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 application 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.

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 re-sealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage class (TRGS 510) : 13
- Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

- Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Poly (A), lyophilized

Contains no substances with occupational exposure limit values.

Proteinase K, PCR grade

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Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Proteinase, Tritirachium album serine	39450-01-6	IOEL	0,00006 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

Wash Buffer

Contains no substances with occupational exposure limit values.

Wash Buffer I / Inhibitor Removal Buffer

Contains no substances with occupational exposure limit values.

Elution Buffer (EB)

Contains no substances with occupational exposure limit values.

Binding buffer, universal MBF

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

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time

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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 concentration 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

Poly (A), lyophilized

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
Viscosity, kinematic	: Not applicable
Solubility(ies)	
Water solubility	: soluble
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 : Not applicable

Particle characteristics
Particle Size Distribution : No data available

Proteinase K, PCR grade

Physical state : solid

Colour : white

Odour : very faint

Odour Threshold : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flammability : Sustains 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 : 6,5
(as aqueous solution)

Viscosity
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : completely soluble

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 : Not applicable

Particle characteristics
Particle Size Distribution : No data available

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

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

Vapour pressure : No data available

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Relative density : No data available

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

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

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

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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

Vapour pressure : 23 hPa (20 °C)

Relative density : No data available

Density : 1 g/cm³ (20 °C)

Relative vapour density : No data available

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Particle characteristics

Particle Size Distribution : Not applicable

Binding buffer, universal MBF

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 : 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 : 3 - 5 (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

Vapour pressure : No data available

Relative density : No data available

Density : 1,148 g/cm³ (20 °C, 990 - 1.030 hPa)

Relative vapour density : No data available

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Particle characteristics
Particle Size Distribution : Not applicable

9.2 Other information

Poly (A), lyophilized

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

Proteinase K, PCR grade

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

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

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

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

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Evaporation rate : No data available
Miscibility with water : completely miscible

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, universal MBF

Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Flammability (liquids) : Does not sustain combustion.
Self-ignition : Not applicable
Evaporation rate : No data available
Miscibility with water : completely miscible

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.

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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

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), lyophilized

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.

Proteinase K, PCR grade

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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 inhaled.

Components:

Proteinase, Tritirachium album serine:

Assessment	:	May cause sensitisation by skin contact.
Remarks	:	Causes sensitisation.

Assessment	:	May cause sensitisation by inhalation.
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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

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

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Acute toxicity

Harmful if swallowed or if inhaled.

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.

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Components:

guanidinium chloride:

Species : Rabbit
Method : OECD Test Guideline 405
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.
Method : OECD Test Guideline 406
GLP : yes

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 development : Species: Rat, female
Application Route: Oral

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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

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.

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.

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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.

Binding buffer, universal MBF

Acute toxicity

Harmful if swallowed.

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.

Polidocanol:

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

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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:

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.

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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:

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

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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 development : 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:

Effects on foetal development : 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

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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 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.

Poly (A), lyophilized

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Proteinase K, PCR grade

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Wash Buffer

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Wash Buffer I / Inhibitor Removal Buffer

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

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(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 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.

Binding buffer, universal MBF

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Poly (A), lyophilized

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

No data available

Wash Buffer I / Inhibitor Removal Buffer

Components:

guanidinium chloride:

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- 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
- 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 toxicity) : 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.

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Toxicity to daphnia and other aquatic invertebrates (Chronic 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

Elution Buffer (EB)

No data available

Binding buffer, universal MBF

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

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

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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 toxicity)

: 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 (Chronic 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

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

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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 (Chronic 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), lyophilized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer

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 Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

Elution Buffer (EB)

No data available

Binding buffer, universal MBF

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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 Treatment : 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), lyophilized

No data available

Proteinase K, PCR grade

Components:

Proteinase, Tritirachium album serine:

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

Wash Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

Components:

guanidinium chloride:

Partition coefficient: n-octanol/water : log Pow: < -1,7 (20 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: yes

Elution Buffer (EB)

No data available

Binding buffer, universal MBF

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Components:

guanidinium chloride:

Partition coefficient: n-octanol/water : log Pow: < -1,7 (20 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: yes

Polidocanol:

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

12.4 Mobility in soil

Poly (A), lyophilized

No data available

Proteinase K, PCR grade

No data available

Wash Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Elution Buffer (EB)

No data available

Binding buffer, universal MBF

No data available

12.5 Results of PBT and vPvB assessment

Poly (A), lyophilized

Not relevant

Proteinase K, PCR grade

Not relevant

Wash Buffer

Not relevant

Wash Buffer I / Inhibitor Removal Buffer

Not relevant

Elution Buffer (EB)

Not relevant

Binding buffer, universal MBF

Not relevant

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

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levels of 0.1% or higher.

Poly (A), lyophilized

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Proteinase K, PCR grade

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Wash Buffer

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Wash Buffer I / Inhibitor Removal Buffer

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Elution Buffer (EB)

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Binding buffer, universal MBF

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Poly (A), lyophilized

No data available

Proteinase K, PCR grade

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No data available

Wash Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Elution Buffer (EB)

No data available

Binding buffer, universal MBF

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- | | | |
|------------------------|---|--|
| Product | : | The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations. |
| Contaminated packaging | : | Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling 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)

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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

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso III: Directive : Not applicable
2012/18/EU of the European
Parliament and of the Council
on the control of major-
accident hazards involving
dangerous substances.

Water hazard class (Germany) : WGK 2 obviously hazardous to water

Poly (A), lyophilized

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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 deplete the ozone layer : Not applicable

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Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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

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

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

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.

Proteinase K, PCR grade

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

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

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

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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

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

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Proteinase, Tritirachium album serine
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: On the inventory, or in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not 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	: 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)

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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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
P284 Wear respiratory 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.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

39450-01-6

Proteinase, Triticachium album serine

Wash Buffer

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: 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 deplete the ozone layer

: Not applicable

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

: Not applicable

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

: Not applicable

REACH - List of substances subject to authorisation

: Not applicable

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(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

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 deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import	: Not applicable

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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 : 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

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:

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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.

Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

Elution Buffer (EB)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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 deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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

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

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

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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)

Not a hazardous substance or mixture.

Binding buffer, universal MBF

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 deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (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

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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	:	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: 17,42 %

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

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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

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 difficulties if inhaled.
H335	: May cause respiratory irritation.
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
Resp. Sens.	: Respiratory sensitisation
Skin Irrit.	: Skin irritation
Skin Sens.	: Skin sensitisation
STOT SE	: Specific target organ toxicity - single exposure

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

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striction 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.

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