according to Regulation (EC) No. 1907/2006



# MagNA Pure 96 DNA and Viral NA LV Kit

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1.10 21.10.2016 Date of first issue: 11.07.2012

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

1.1 Product identifier

Commercial Product Name : MagNA Pure 96 DNA and Viral NA LV Kit

Mat.-No./ Genisys-No. : 06374891001

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 +496217590

Telephone : +496217590 Telefax : +496217592890

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

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

1.4 Emergency telephone number

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 : H225 Highly flammable liquid and vapour.

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.

H336 May cause drowsiness or dizziness.

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H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard

Statements

**EUH032** 

Contact with acids liberates very toxic gas.

Precautionary statements Prevention:

Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking.

Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P261 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.

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.

P370 + P378 In case of fire: Use dry sand, dry chemical or

alcohol-resistant foam to extinguish.

#### 2.3 Other hazards

See SECTION 3

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

# Wash Buffer I (WB I) / Inhib.Removal Buffer

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

Flammable liquids, Category 3 H226: Flammable liquid and vapour.

Skin irritation, Category 2 H315: Causes skin irritation.

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

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

Flammable R10: Flammable.

Harmful R22: Harmful if swallowed.

Irritant R36/38: Irritating to eyes and skin.

# **Hazardous components**

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Registration number		
guanidinium chloride	50-01-1	Acute Tox. 4; H302	>= 30 - < 50
	200-002-3	Acute Tox. 4; H332	
		Skin Irrit. 2; H315	
		Eye Irrit. 2; H319	



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ethanol 64-17-5 Flam. Liq. 2; H225 >= 20 - < 30 200-578-6

For explanation of abbreviations see section 16.

# Lysis/Binding Buffer

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

Acute toxicity, Category 4 H302: Harmful if swallowed.

Acute toxicity, Category 4 H332: Harmful if inhaled.

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

Chronic aquatic toxicity, Category 3 H412: Harmful to aquatic life with long lasting ef-

fects.

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

Harmful R20/21/22: Harmful by inhalation, in contact with

skin and if swallowed.

Irritant R41: Risk of serious damage to eyes.

R32: Contact with acids liberates very toxic gas.

Dangerous for the environment R52/53: Harmful to aquatic organisms, may cause

long-term adverse effects in the aquatic environ-

ment.

#### **Hazardous components**

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
guanidinium thiocyanate	593-84-0 209-812-1	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Aquatic Chronic 3; H412	>= 30 - < 50
alpha-(4-(1,1,3,3- Tetramethylbutyl)phenyl)-omega- hydroxypoly(oxy-1,2-ethanediyl)	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318	>= 20 - < 30

For explanation of abbreviations see section 16.

# Proteinase K (PK)

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

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.

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

Sensitising R42/43: May cause sensitisation by inhalation and

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skin contact.

# **Hazardous components**

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)
	Registration number		(11 )
Proteinase, Tritirachium album	39450-01-6	Skin Irrit. 2; H315	>= 1 - < 3
serine	254-457-8	Eye Irrit. 2; H319	
		Resp. Sens. 1; H334	
		Skin Sens. 1; H317	
		STOT SE 3; H335	

For explanation of abbreviations see section 16.

# **Elution 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

For explanation of abbreviations see section 16.

#### Wash Buffer III

#### 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

For explanation of abbreviations see section 16.

# Magnetic Glass Particles (MGPs) Suspension

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

Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.

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

Specific target organ toxicity - single exposure, Category 3, Central nervous

system

H336: May cause drowsiness or dizziness.

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

Highly flammable R11: Highly flammable.

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Irritant R36: Irritating to eyes.

R67: Vapours may cause drowsiness and dizzi-

ness.

# **Hazardous components**

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Registration number		, ,
propan-2-ol	67-63-0	Flam. Liq. 2; H225	>= 90 - <= 100
	200-661-7	Eye Irrit. 2; H319	
		STOT SE 3; H336	

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 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 : 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.

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#### 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 : Alcohol-resistant foam

Carbon dioxide (CO2)

Dry chemical

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.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

For safety reasons in case of fire, cans should be stored sepa-

rately in closed containments.

Use a water spray to cool fully closed containers.

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

# 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas.

Refer to protective measures listed in sections 7 and 8. Beware of vapours accumulating to form explosive concentra-

tions. Vapours can accumulate in low areas.

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 : Contain spillage, and then collect with non-combustible ab-

sorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local

/ national regulations (see section 13).

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#### 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 aerosol.

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.

Take precautionary measures against static discharges. Provide sufficient air exchange and/or exhaust in work rooms. Open drum carefully as content may be under pressure. 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.

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

ble liquid retention system.

Advice on protection against

fire and explosion

Do not spray on a naked flame or any incandescent material. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Use only explosion-proof equipment. Keep away from open flames, hot

surfaces and sources of ignition.

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

No smoking. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Observe label precautions. 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) : 3, Flammable liquids

Other data : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

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

### 8.1 Control parameters

# Wash Buffer I (WB I) / Inhib.Removal Buffer

# **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
ethanol	64-17-5	AGW	500 ppm 960 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(II)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

# Lysis/Binding Buffer

Contains no substances with occupational exposure limit values.

# Proteinase K (PK)

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
Proteinase, Tritira- chium album ser- ine	39450-01-6	IOEL	0,00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

### **Elution Buffer**

Contains no substances with occupational exposure limit values.

# Wash Buffer III

Contains no substances with occupational exposure limit values.

# Magnetic Glass Particles (MGPs) Suspension

# **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
propan-2-ol	67-63-0	AGW	200 ppm 500 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(II)			
Further information	Senate commission for the review of compounds at the work place dangerous			

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for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child

# **Biological occupational exposure limits**

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Isopropanol	67-63-0	Acetone: 25 mg/l	Immediately after	TRGS 903
		(Blood)	exposition or after	
			working hours	
		Acetone: 25 mg/l	Immediately after	TRGS 903
		(Urine)	exposition or after	
			working hours	

# 8.2 Exposure controls

# **Engineering measures**

No data available

#### 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

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 : Impervious clothing

Choose body protection according to the amount and concen-

tration of the dangerous substance at the work place.

Respiratory protection : In the case of vapour formation use a respirator with an ap-

proved filter.

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

# 9.1 Information on basic physical and chemical properties Wash Buffer I (WB I) / Inhib.Removal Buffer

Appearance : liquid

Colour : colourless

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Odour : characteristic

Odour Threshold : No data available

pH : 6,6 (25 °C)

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : 29 °C

Evaporation rate : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : 43 hPa

Relative vapour density : No data available

Relative density : No data available

Density : 1,057 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

Lysis/Binding Buffer

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 6,0 - 7,0

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Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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

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

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

Proteinase K (PK)

Appearance : liquid

Colour : clear, colourless

Odour : very faint

Odour Threshold : No data available

pH : 7,5

Melting point/range : No data available

Boiling point/boiling range : No data available

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Flash point : No data available

Evaporation rate : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1,126 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

# **Elution Buffer**

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 5-9

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Upper explosion limit : No data available

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Lower explosion limit No data available

Vapour pressure No data available

Relative vapour density No data available

Relative density No data available

Solubility(ies)

Water solubility completely miscible

Solubility in other solvents No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature No data available

No data available Decomposition temperature

Viscosity

Viscosity, dynamic No data available

Viscosity, kinematic No data available

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

# Wash Buffer III

Appearance liquid

Colour colourless

Odour none

Odour Threshold No data available

рΗ 4,0

Melting point/range No data available

Boiling point/boiling range No data available

Flash point No data available

No data available Evaporation rate

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

Upper explosion limit No data available

Lower explosion limit No data available

Vapour pressure No data available

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Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

# Magnetic Glass Particles (MGPs) Suspension

Appearance : liquid

Colour : black

Odour : strong

Odour Threshold : No data available

pH : No data available

Melting point/range : -89 °C

Boiling point/boiling range : 82 °C

Flash point : 12 °C

Evaporation rate : No data available

Upper explosion limit : 12 %(V)

Lower explosion limit : 2 %(V)

Vapour pressure : 42 hPa (20 °C)

Relative vapour density : No data available

Relative density : No data available

Density : 0,78 g/cm3

Solubility(ies)

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Water solubility : partly miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : Hazardous decomposition products formed under fire condi-

tions.

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

#### 9.2 Other information

# Wash Buffer I (WB I) / Inhib.Removal Buffer

Self-ignition : 425 °C

# Lysis/Binding Buffer

No data available

# Proteinase K (PK)

No data available

### **Elution Buffer**

No data available

### Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

Self-ignition : 485 °C

# **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.



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# 10.3 Possibility of hazardous reactions

Hazardous reactions : Reacts with the following substances:

Alkali metals

Alkaline earth metals Oxidizing agents

Amines Nitric acid Aldehydes Iron Aluminium

Hydrogen halides

Reacts violently with peroxides.

No decomposition if stored and applied as directed.

Vapours may form explosive mixture with air.

10.4 Conditions to avoid

Conditions to avoid : No data available

Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Aluminium

Oxidizing agents Alkali metals

Alkaline earth metals

Iron Amines Peroxides Acids

# 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

Heating can release hazardous gases.

# **SECTION 11: Toxicological information**

# 11.1 Information on toxicological effects

# Wash Buffer I (WB I) / Inhib.Removal Buffer

# **Acute toxicity**

Not classified based on available information.

#### 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

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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

ethanol:

Acute oral toxicity : LD50 Oral (Rat): 7.060 mg/kg

LD50 Oral (Mouse): 3.450 mg/kg

Acute inhalation toxicity : LC50 (Rat): 20000 ppm

Exposure time: 10 h
Test atmosphere: vapour

LC50 (Mouse): 39 g/m3 Exposure time: 4 h Test atmosphere: vapour

# 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:**

# 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:



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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.

#### **Further information**

#### **Product:**

Remarks: Solvents may degrease the skin.

# Lysis/Binding Buffer

# **Acute toxicity**

Harmful if swallowed or if inhaled

# **Components:**

# guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat): 593 mg/kg

Symptoms: Vomiting

Acute inhalation toxicity : Acute toxicity estimate: 1,5 mg/l

Test atmosphere: dust/mist Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 1.100 mg/kg

Method: Expert judgement

# alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

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

according to Regulation (EC) No. 1907/2006

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#### Skin corrosion/irritation

Not classified based on available information.

### Serious eye damage/eye irritation

Causes serious eye damage.

#### **Components:**

#### alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

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.

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

## **Components:**

# guanidinium thiocyanate:

Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

# 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 (PK)

# **Acute toxicity**

Not classified based on available information.

# Skin corrosion/irritation

Not classified based on available information.

# **Components:**

## Proteinase, Tritirachium album serine:

Result: Irritating to skin.

Remarks: May cause skin irritation and/or dermatitis.

according to Regulation (EC) No. 1907/2006

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# Serious eye damage/eye irritation

Not classified based on available information.

# **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.

# 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.

#### Components:

#### Proteinase, Tritirachium album serine:

Assessment: May cause respiratory irritation.

# 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:

according to Regulation (EC) No. 1907/2006

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Roche

No data available

# **Elution 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 III

#### **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.

according to Regulation (EC) No. 1907/2006

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#### 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.

# Magnetic Glass Particles (MGPs) Suspension

# **Acute toxicity**

Not classified based on available information.

#### **Components:**

# propan-2-ol:

Acute oral toxicity : LD50 Oral (Rat): 4.570 mg/kg

LD50 Oral (Mouse): 3.600 mg/kg

LD50 Oral (Rabbit): 6.410 mg/kg

Acute inhalation toxicity : LC50 (Rat): 30 mg/l, 16000 ppm

Exposure time: 4 h
Test atmosphere: vapour

LC50 (Mouse): 53 mg/l Test atmosphere: vapour

Acute dermal toxicity : LD50 Dermal (Rabbit): 13.400 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

### propan-2-ol:

Remarks: May cause skin irritation in susceptible persons.

# Serious eye damage/eye irritation

Causes serious eye irritation.

### **Components:**

# propan-2-ol:

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

according to Regulation (EC) No. 1907/2006

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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.

### Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Not classified based on available information.

# STOT - single exposure

May cause drowsiness or dizziness.

#### **Components:**

#### propan-2-ol:

Assessment: May cause drowsiness or dizziness.

#### STOT - repeated exposure

Not classified based on available information.

#### **Components:**

#### propan-2-ol:

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

# **Aspiration toxicity**

Not classified based on available information.

# **Further information**

# **Product:**

Remarks: Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Concentrations substantially above the TLV value may cause narcotic effects.

Solvents may degrease the skin.

# **SECTION 12: Ecological information**

# 12.1 Toxicity

# Wash Buffer I (WB I) / Inhib.Removal Buffer

#### **Components:**

### guanidinium chloride:

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

Exposure time: 48 h

according to Regulation (EC) No. 1907/2006

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Toxicity to microorganisms : 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

ethanol:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 8.100 mg/l

Exposure time: 48 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 7.100 mg/l

Method: OECD Test Guideline 203

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 5.400 mg/l

Exposure time: 48 h

GLP: no

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): 5.000 mg/l

Exposure time: 7 d

Toxicity to microorganisms : EC0 (Pseudomonas putida): 6.500 mg/l

Exposure time: 16 h

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

No data available

# Lysis/Binding Buffer

# **Components:**

guanidinium thiocyanate:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89,1 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia (water flea)): 42,4 mg/l

Exposure time: 48 h

**Ecotoxicology Assessment** 

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

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

Other organisms relevant to : No data available

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according to Regulation (EC) No. 1907/2006

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the environment

alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

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

# Proteinase K (PK)

# **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

### **Elution Buffer**

No data available

# Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

#### **Components:**

propan-2-ol:

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 10.000 mg/l

Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 12.250 mg/l

Method: OECD Test Guideline 203

LC100 (Oncorhynchus mykiss (rainbow trout)): 15.000 mg/l

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 9.500 mg/l

Exposure time: 24 h

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): 1.800 mg/l

Exposure time: 168 h

according to Regulation (EC) No. 1907/2006



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Method: OECD Test Guideline 201

Toxicity to microorganisms : EC0 (Pseudomonas putida): 1.050 mg/l

Exposure time: 16 h

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

No data available

# 12.2 Persistence and degradability

# Wash Buffer I (WB I) / Inhib.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).

ethanol:

Biodegradability : Biodegradation: 97 %

Exposure time: 28 d

Method: OECD Test Guideline 301D

### Lysis/Binding Buffer

# **Components:**

# alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

Biodegradability : Biodegradation: > 60 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

# Proteinase K (PK)

No data available

#### Elution Buffer

No data available

#### Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

# **Components:**

propan-2-ol:

Biodegradability : Biodegradation: 99 %

Exposure time: 11 d

Method: OECD Test Guideline 302

according to Regulation (EC) No. 1907/2006

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Biodegradation: 57 % Exposure time: 5 d

Method: OECD Test Guideline 302

# 12.3 Bioaccumulative potential

# Wash Buffer I (WB I) / Inhib.Removal Buffer

# **Components:**

guanidinium chloride:

Partition coefficient: n-

octanol/water

: log Pow: ca. -1,7 (20 °C)

ethanol:

Partition coefficient: n-

octanol/water

: Remarks: No data available

# Lysis/Binding Buffer

# **Components:**

guanidinium thiocyanate:

Partition coefficient: n-

octanol/water

log Pow: -1,38

### alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

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

4).

Partition coefficient: n-

octanol/water

: Remarks: No data available

# Proteinase K (PK)

# **Components:**

# Proteinase, Tritirachium album serine:

Partition coefficient: n- : Remarks: No data available

octanol/water

## **Elution Buffer**

No data available

#### Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

# **Components:**

propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0,05

according to Regulation (EC) No. 1907/2006

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# 12.4 Mobility in soil

# Wash Buffer I (WB I) / Inhib.Removal Buffer

No data available

# Lysis/Binding Buffer

No data available

# Proteinase K (PK)

No data available

# **Elution Buffer**

No data available

## Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

No data available

# 12.5 Results of PBT and vPvB assessment

# Wash Buffer I (WB I) / Inhib.Removal Buffer

Not relevant

# Lysis/Binding Buffer

Not relevant

# Proteinase K (PK)

Not relevant

#### **Elution Buffer**

Not relevant

## Wash Buffer III

Not relevant

# Magnetic Glass Particles (MGPs) Suspension

Not relevant

# 12.6 Other adverse effects

# Wash Buffer I (WB I) / Inhib.Removal Buffer

No data available

# Lysis/Binding Buffer

No data available

# Proteinase K (PK)

No data available

### **Elution Buffer**

No data available

# Wash Buffer III

No data available

# Magnetic Glass Particles (MGPs) Suspension

No data available

according to Regulation (EC) No. 1907/2006

# Roche

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# **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 chemi-

cal or used container.

Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.

Dispose of as unused product. Do not re-use empty containers.

Do not burn, or use a cutting torch on, the empty drum.

# **SECTION 14: Transport information**

### 14.1 UN number

 ADR
 : UN 3316

 RID
 : UN 3316

 IMDG
 : UN 3316

 IATA
 : UN 3316

## 14.2 UN proper shipping name

ADR : CHEMICAL KIT
RID : CHEMICAL KIT
IMDG : CHEMICAL KIT
IATA : Chemical kit

#### 14.3 Transport hazard class(es)

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

# 14.4 Packing group

**ADR** 

Packing group : II
Classification Code : M11
Labels : 9
Tunnel restriction code : (E)

RID

Packing group : II
Classification Code : M11
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : II

according to Regulation (EC) No. 1907/2006



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Labels

F-A, S-P **EmS Code** 

IATA (Cargo)

Packing instruction (cargo 960

aircraft)

Packing instruction (LQ) Y960 Packing group Ш

Labels Miscellaneous Dangerous Goods

IATA (Passenger)

Packing instruction (passen-960

ger aircraft)

Packing instruction (LQ) Y960 Packing group Ш

Labels Miscellaneous Dangerous Goods

14.5 Environmental hazards

**ADR** 

Environmentally hazardous

Environmentally hazardous no

**IMDG** 

Marine pollutant no

14.6 Special precautions for user

Remarks : No data available

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable

# **SECTION 15: Regulatory information**

# 15.1 Safety, health and environmental regulations/legislation specific for the substance or mix-

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of majoraccident hazards involving dangerous substances

Quantity 1 Quantity 2 7b Highly flammable 5.000 t 50.000 t

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

P<sub>5</sub>c 5.000 t 50.000 t FLAMMABLE LIQUIDS

Water contaminating class : WGK 2 significantly water endangering

(Germany)

# Wash Buffer I (WB I) / Inhib.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 H226 Flammable liquid and vapour.

> H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements **Prevention:** 

> P210 Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P337 + P313 If eye irritation persists: Get medical advice/

attention.

P370 + P378 In case of fire: Use dry sand, dry chemical or

alcohol-resistant foam to extinguish.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

# Lysis/Binding Buffer

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





Signal word Danger

H302 + H332 Harmful if swallowed or if inhaled Hazard statements

> Causes serious eye damage. H318

Harmful to aquatic life with long lasting effects. H412

Supplemental Hazard

Statements

**EUH032** 

Contact with acids liberates very toxic gas.

Precautionary statements Prevention:

> P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

Avoid release to the environment. P273 P280

Wear 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.

according to Regulation (EC) No. 1907/2006

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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:

593-84-0 guanidinium thiocyanate

9002-93-1 alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-

ethanediyl)

# Proteinase K (PK)

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P280 Wear protective gloves.P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/doctor.

Hazardous components which must be listed on the label:

39450-01-6 Proteinase, Tritirachium album serine

#### Elution Buffer

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

Not a hazardous substance or mixture.

# Wash Buffer III

according to Regulation (EC) No. 1907/2006

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

Not a hazardous substance or mixture.

# Magnetic Glass Particles (MGPs) Suspension

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements : Prevention:

P210 Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear protective gloves/ eye protection/ face protection.

-200 Wear protective gloves/ eye protection/ race protect

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P370 + P378 In case of fire: Use dry sand, dry chemical or

alcohol-resistant foam to extinguish.

Hazardous components which must be listed on the label:

67-63-0 propan-2-ol

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

# **SECTION 16: Other information**

### **Full text of H-Statements**

H225 : Highly flammable liquid and vapour.
H319 : Causes serious eve irritation.

H336 : May cause drowsiness or dizziness.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Chronic aquatic toxicity Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Resp. Sens. : Respiratory sensitisation

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

according to Regulation (EC) No. 1907/2006



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STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx -Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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