

High Pure FFPE Micro Kit

Version
1.5

Revision Date:
16.02.2015

Date of last issue: 12.08.2014
Date of first issue: 24.10.2013

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

1.1 Product identifier

Commercial Product Name : High Pure FFPE Micro Kit
Mat.-No./ Genisys-No. : 04823125001

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240
Munich +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 + H312 + H332 Harmful if swallowed, in contact with skin 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.

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	H335	May cause respiratory irritation.
	H412	Harmful to aquatic life with long lasting effects.
Supplemental Hazard Statements	: EUH032	Contact with acids liberates very toxic gas.
Precautionary statements	: Prevention:	
	P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
	P280	Wear eye protection/ face protection.
	P284	Wear respiratory protection.
	Response:	
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
	P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
	P362 + P364	Take off contaminated clothing and wash it before reuse.

Additional Labelling:

EUH210 Safety data sheet available on request.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

Tissue Lysis 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

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	Xn; Xn; R20	Acute Tox. 4; H332	>= 1 - < 10

For explanation of abbreviations see section 16.

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.

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Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

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

H335: May cause respiratory irritation.

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

Sensitising

R42/43: May cause sensitisation by inhalation and skin contact.

Irritant

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

Hazardous components

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

For explanation of abbreviations see section 16.

Binding Buffer

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4

H302: Harmful if swallowed.

Acute toxicity, Category 4

H332: Harmful if inhaled.

Acute toxicity, Category 4

H312: Harmful in contact with skin.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Chronic aquatic toxicity, Category 3

H412: Harmful to aquatic life with long lasting effects.

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 environment.

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Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
guanidinium thiocyanate	593-84-0 209-812-1	Xn; R20/21/22 R32 R52-R53	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Aquatic Chronic 3; H412	>= 50 - < 70
Triton X-100	9002-93-1	Xn; R22 Xi; R41	Acute Tox. 4; H302 Eye Dam. 1; H318	>= 20 - < 25
(R*,R*)-1,4-dimercaptobutane-2,3-diol	3483-12-3 222-468-7	Xn; R22 Xi; R36/38	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412	>= 1 - < 2,5

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.

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

Harmful

R22: Harmful if swallowed.

Irritant

R36/38: Irritating to eyes and skin.

Hazardous components

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

For explanation of abbreviations see section 16.

Wash Buffer

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

DNase I

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)

Harmful R42: May cause sensitisation by inhalation.

Irritant R43: May cause sensitisation by skin contact.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
Nuclease, deoxyribo-	9003-98-9 232-667-0	Xn; R42 Xi; R43	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 70 - < 90
Calcium chloride dihydrate	10035-04-8 233-140-8	Xi; R36 Xn; R22	Acute Tox. 4; H302 Eye Irrit. 2; H319	>= 1 - < 3

For explanation of abbreviations see section 16.

Incubation Buffer (10x)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

Elution Buffer (EB)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

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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 : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

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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 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.
If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in suitable, closed containers for disposal.
Wipe up with absorbent material (e.g. cloth, fleece).

Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapours/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Provide sufficient air exchange and/or exhaust in work rooms.

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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, Non Combustible Solids

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

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Tissue Lysis Buffer

Contains no substances with occupational exposure limit values.

Proteinase K, PCR grade

Contains no substances with occupational exposure limit values.

Binding Buffer

Contains no substances with occupational exposure limit values.

Wash Buffer I / Inhibitor Removal Buffer

Contains no substances with occupational exposure limit values.

Wash Buffer

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Contains no substances with occupational exposure limit values.

DNase I

Contains no substances with occupational exposure limit values.

Incubation Buffer (10×)

Contains no substances with occupational exposure limit values.

Elution Buffer (EB)

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

- Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.
- Hand protection
- Material : Protective gloves
- Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
- Skin and body protection : Choose body protection according to the amount and 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

Tissue Lysis Buffer

Appearance : liquid

Colour : colourless

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Odour	: none
Odour Threshold	: No data available
pH	: 7,4
Melting point/freezing point	: No data available
Initial boiling point and 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
Density	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

Proteinase K, PCR grade

Appearance	: solid
Colour	: white
Odour	: very faint
Odour Threshold	: No data available
pH	: 6,5 (as aqueous solution)
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available

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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
Density : No data available
Solubility(ies)
Water solubility : completely soluble

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

Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

Binding Buffer

Appearance : liquid

Colour : blue

Odour : none

Odour Threshold : No data available
pH : 6,0

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
Density : No data available
Solubility(ies) : No data available
Partition coefficient: n-octanol/water : No data available
Ignition temperature : No data available

Auto-ignition temperature : No data available
Decomposition temperature : No data available

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Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

Wash Buffer I / Inhibitor Removal Buffer

Appearance : liquid
Colour : colourless
Odour : none
Odour Threshold : No data available
pH : 6,6
Melting point/freezing point : No data available
Initial boiling point and boiling 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
Density : No data available
Solubility(ies)
 Water solubility : completely miscible
Partition coefficient: n-octanol/water : No data available
Ignition temperature : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

Wash Buffer

Appearance : liquid
Colour : colourless
Odour : none
Odour Threshold : No data available

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pH	: 7,5
Melting point/freezing point	: No data available
Initial boiling point and 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
Density	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

DNase I

Appearance	: solid
Colour	: light yellow
Odour	: odourless
Odour Threshold	: No data available
pH	: 6,5 - 7,5 (as aqueous solution)
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available

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Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : soluble

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

Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

Incubation Buffer (10x)

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available
pH : 7,9

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
Density : No data available
Solubility(ies)
Water solubility : completely miscible

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

Auto-ignition temperature : No data available
Decomposition temperature : No data available

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Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

Elution Buffer (EB)

Appearance : liquid
Colour : colourless
Odour : none
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Boiling point/boiling range : 100 °C
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : No data available
Upper explosion limit : No data available
Lower explosion limit : No data available
Vapour pressure : 23 hPa (20 °C)
Relative vapour density : No data available
Relative density : No data available
Density : 1 g/cm³ (20 °C)
Solubility(ies)
Water solubility : completely miscible
Partition coefficient: n-octanol/water : No data available
Ignition temperature : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Tissue Lysis Buffer

No data available

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Proteinase K, PCR grade

No data available

Binding Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

DNase I

No data available

Incubation Buffer (10x)

No data available

Elution Buffer (EB)

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Contact with acids liberates very toxic gas.
Keep away from heat and sources of ignition.

No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : Exposure to light.
Exposure to moisture
Heat

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

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Acids
Cyanides

10.6 Hazardous decomposition products

Thermal decomposition can lead to release of irritating gases and vapours., In case of fire hazardous decomposition products may be produced such as:, Carbon oxides, Nitrogen oxides (NOx), Gaseous hydrogen chloride (HCl)., Ammonia

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Tissue Lysis Buffer

Acute toxicity

Not classified based on available information.

Components:

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Acute oral toxicity : LD50 Oral (Rat): > 2.000 mg/kg
Test substance: anhydrous substance

LD50 Oral (Rabbit): 2.300 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1 - 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Test substance: anhydrous substance

Acute toxicity estimate: 1,5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

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.

Components:

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Genotoxicity in vitro : Test Type: Ames test
Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity

Not classified based on available information.

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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

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.

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:

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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:

No data available

Binding Buffer

Acute toxicity

Harmful if swallowed, in contact with skin or if inhaled

Components:

guanidinium thiocyanate:

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

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

Triton X-100:

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

Acute toxicity estimate: 500 mg/kg
Method: Expert judgement

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

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Acute toxicity (other routes of administration) : Symptoms: May cause cardiac arrhythmia., Convulsions, Vomiting

Skin corrosion/irritation

Not classified based on available information.

Components:

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to skin.

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Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Triton X-100:

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to eyes.

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.

Wash Buffer I / Inhibitor Removal Buffer

Acute toxicity

Harmful if swallowed or if inhaled

Components:

guanidinium chloride:

Acute oral toxicity	:	LD50 Oral (Rat): 475 mg/kg
		LD50 Oral (Mouse): 571 mg/kg
		LD50 Oral (Rat): 1.120 mg/kg
Acute inhalation toxicity	:	LC50 (Rat, female): 3,2 mg/l
		Exposure time: 4 h
		Test atmosphere: dust/mist
		LC50 (Rat, male and female): 5,3 mg/l

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Exposure time: 4 h
Test atmosphere: dust/mist

LC50 (Rat, male): 7,7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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

Skin corrosion/irritation

Causes skin irritation.

Components:

guanidinium chloride:

Species: Rabbit

Result: Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

guanidinium chloride:

Species: Rabbit

Result: Irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

guanidinium chloride:

Assessment: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium chloride:

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

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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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.

DNase I

Acute toxicity

Not classified based on available information.

Components:

Calcium chloride dihydrate:

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

Acute dermal toxicity : LD50 (Rat): 2.630 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Calcium chloride dihydrate:

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Calcium chloride dihydrate:

Assessment: Irritating to eyes.

Result: Eye irritation

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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:

Nuclease, deoxyribo-:

Assessment: May cause sensitisation by inhalation.

Assessment: May cause sensitisation by skin contact.

Calcium chloride dihydrate:

Assessment: Did not cause sensitisation on laboratory animals.

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:

Calcium chloride dihydrate:

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

STOT - repeated exposure

Not classified based on available information.

Components:

Calcium chloride dihydrate:

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

Aspiration toxicity

Not classified based on available information.

Components:

Calcium chloride dihydrate:

No data available

Incubation Buffer (10x)

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

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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.

Elution Buffer (EB)

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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SECTION 12: Ecological information

12.1 Toxicity

Tissue Lysis Buffer

Components:

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

- Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l
Exposure time: 96 h
Test substance: anhydrous substance
- LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): > 100 mg/l
Exposure time: 24 h
- Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
- Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l
Exposure time: 8 h
Test substance: anhydrous substance
- 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, 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

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

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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
the environment : No data available

Triton X-100:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8,9 mg/l
Exposure time: 96 h

Toxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l
Exposure time: 48 h

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

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

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

Other organisms relevant to
the environment : No data available

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Toxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 27 mg/l
Exposure time: 48 h

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

Other organisms relevant to
the environment : No data available

Wash Buffer I / Inhibitor Removal Buffer

Components:

guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.759 mg/l
Exposure time: 48 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 89 mg/l
Exposure time: 18 h

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

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

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

Other organisms relevant to
the environment : No data available

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Wash Buffer

No data available

DNase I

Components:

Nuclease, deoxyribo-:

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Other organisms relevant to
the environment

: No data available

Calcium chloride dihydrate:

Toxicity to fish

: LC50 (Lepomis macrochirus (Bluegill sunfish)): 10.650 mg/l
Exposure time: 96 h

Toxicity to daphnia and other
aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 144 mg/l
Exposure time: 48 h

Toxicity to bacteria

: EC50 (Bacteria): > 100 mg/l

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Other organisms relevant to
the environment

: No data available

Incubation Buffer (10x)

No data available

Elution Buffer (EB)

No data available

12.2 Persistence and degradability

Tissue Lysis Buffer

Components:

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Biodegradability

: Biodegradation: 3 %
Method: Directive 67/548/EEC Annex V, C.4.C.
Remarks: According to the results of tests of biodegradability
this product is not readily biodegradable.

Biochemical Oxygen De-
mand (BOD)

: 10 mg/g
Incubation time: 5 d

Proteinase K, PCR grade

No data available

Binding Buffer

Components:

Triton X-100:

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Biodegradability : Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Wash Buffer I / Inhibitor Removal Buffer

Components:

guanidinium chloride:

Biodegradability : Biodegradation: < 70 %
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

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

Wash Buffer

No data available

DNase I

No data available

Incubation Buffer (10x)

No data available

Elution Buffer (EB)

No data available

12.3 Bioaccumulative potential

Tissue Lysis Buffer

No data available

Proteinase K, PCR grade

No data available

Binding Buffer

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,38

Triton X-100:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Partition coefficient: n-octanol/water : log Pow: ca. -0,48

Wash Buffer I / Inhibitor Removal Buffer

Components:

guanidinium chloride:

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

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Wash Buffer

No data available

DNase I

No data available

Incubation Buffer (10×)

No data available

Elution Buffer (EB)

No data available

12.4 Mobility in soil

Tissue Lysis Buffer

No data available

Proteinase K, PCR grade

No data available

Binding Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

DNase I

No data available

Incubation Buffer (10×)

No data available

Elution Buffer (EB)

No data available

12.5 Results of PBT and vPvB assessment

Tissue Lysis Buffer

Not relevant

Proteinase K, PCR grade

Not relevant

Binding Buffer

Not relevant

Wash Buffer I / Inhibitor Removal Buffer

Not relevant

Wash Buffer

Not relevant

DNase I

Not relevant

Incubation Buffer (10×)

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Not relevant

Elution Buffer (EB)

Not relevant

12.6 Other adverse effects

Tissue Lysis Buffer

No data available

Proteinase K, PCR grade

No data available

Binding Buffer

No data available

Wash Buffer I / Inhibitor Removal Buffer

No data available

Wash Buffer

No data available

DNase I

No data available

Incubation Buffer (10x)

No data available

Elution Buffer (EB)

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.
- 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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

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14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

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

Water contaminating class (Germany) : WGK 2 water endangering

Tissue Lysis Buffer

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling:

EUH210 Safety data sheet available on request.

Proteinase K, PCR grade

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves.
P284 Wear respiratory protection.
Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

Hazardous components which must be listed on the label:
39450-01-6 Proteinase, Tritirachium album serine

Binding Buffer

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Danger

Hazard statements : H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements : EUH032 Contact with acids liberates very toxic gas.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves/ protective clothing.
Response:
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER or doctor/ physician 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

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POISON CENTER or doctor/ physician.

Hazardous components which must be listed on the label:

593-84-0 guanidinium thiocyanate
9002-93-1 Triton X-100

Wash Buffer I / Inhibitor Removal Buffer

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 dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves.
Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

Wash Buffer

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

DNase I

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms

:



Signal word

: Danger

Hazard statements

: H317
H334

May cause an allergic skin reaction.
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 or doctor/ physician.

Hazardous components which must be listed on the label:

9003-98-9

Nuclease, deoxyribo-

Incubation Buffer (10x)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Elution Buffer (EB)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

15.2 Chemical Safety Assessment

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

SECTION 16: Other information

Full text of R-Phrases

R20

: Harmful by inhalation.

R20/21/22

: Harmful by inhalation, in contact with skin and if swallowed.

R22

: Harmful if swallowed.

R32

: Contact with acids liberates very toxic gas.

R36

: Irritating to eyes.

R36/37/38

: Irritating to eyes, respiratory system and skin.

R36/38

: Irritating to eyes and skin.

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R41	: Risk of serious damage to eyes.
R42	: May cause sensitisation by inhalation.
R43	: May cause sensitisation by skin contact.
R52	: Harmful to aquatic organisms.
R53	: May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H302	: Harmful if swallowed.
H312	: Harmful in contact with skin.
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	: Chronic aquatic toxicity
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Resp. Sens.	: Respiratory sensitisation
Skin Irrit.	: Skin irritation
Skin Sens.	: Skin sensitisation
STOT SE	: Specific target organ toxicity - single exposure

Further information

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

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