

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

MagNA Pure Compact RNA Isolation Kit

Version
7.0

Revision Date:
07.02.2023

Date of last issue: 02.02.2022
Date of first issue: 08.05.2013

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

1.1 Product identifier

Trade name : MagNA Pure Compact RNA Isolation Kit
Product code : 04802993001

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

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

1.4 Emergency telephone number

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

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- Hazard statements : H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H336 May cause drowsiness or dizziness.
H412 Harmful to aquatic life with long lasting effects.
- Supplemental Hazard Statements : EUH032 Contact with acids liberates very toxic gas.
EUH071 Corrosive to the respiratory tract.
- Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing mist or vapours.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.

Additional Labelling

- EUH210 Safety data sheet available on request.
- EUH208 Contains DNase I, Desoxyribonuclease I from bovine pancreas EC 3.1.21.1, Grade II. May produce an allergic reaction.

2.3 Other hazards

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

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

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SECTION 3: Composition/information on ingredients

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.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|--|---|--------------------------|
| propan-2-ol | 67-63-0 200-661-7 603-117-00-0 01-2119457558-25 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 (Central nervous system) | >= 70,0 - < 90,0 |

For explanation of abbreviations see section 16.

Proteinase K Incubation Buffer

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

Proteinase K (d-PrK)

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.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------------------------------|---|---|--------------------------|
| Proteinase, Tritirachium album serine | 39450-01-6 254-457-8 | Skin Irrit. 2; H315 Eye Irrit. 2; H319 | >= 1,0 - < 10,0 |

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| | | | |
|--|--|--|---------------------|
| | 647-014-00-9 | Resp. Sens. 1; H334 Skin Sens. 1; H317 STOT SE 3; H335 (Respiratory system) | |
| Substances with a workplace exposure limit : | | | |
| glycerol | 56-81-5 200-289-5 01-2119471987-18 | Not classified | >= 50,0 - < 70,0 |

For explanation of abbreviations see section 16.

Lysis Buffer

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4

H302: Harmful if swallowed.

Skin corrosion, Sub-category 1C

H314: Causes severe skin burns and eye damage.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting effects.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------------|---|---|--------------------------|
| guanidinium thiocyanate | 593-84-0 209-812-1 615-004-00-3 01-2120735072-65 | Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1C; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH032, EUH071 Acute toxicity estimate Acute oral toxicity: 593 mg/kg | >= 30,0 - < 50,0 |
| Polidocanol | 9002-92-0 500-002-6 | Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity estimate Acute oral toxicity: 1.000 mg/kg | >= 10,0 - < 20,0 |
| (R*,R*)-1,4-dimercaptobutane- | 3483-12-3 | Acute Tox. 4; H302 | >= 1,0 - < 2,5 |

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| | | | |
|----------|-------------------------------|--|--|
| 2,3-diol | 222-468-7 01-2120856806-42 | Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity estimate Acute oral toxicity: 300,03 mg/kg | |
|----------|-------------------------------|--|--|

For explanation of abbreviations see section 16.

Incubation Buffer

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

Tissue Lysis Buffer MP

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4

H302: Harmful if swallowed.

Skin corrosion, Sub-category 1C

H314: Causes severe skin burns and eye damage.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting effects.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------|---|--|--------------------------|
| guanidinium thiocyanate | 593-84-0 209-812-1 615-004-00-3 01-2120735072-65 | Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1C; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH032, EUH071 Acute toxicity estimate | >= 30,0 - < 50,0 |

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| | | | |
|---|--|---|----------------|
| | | Acute oral toxicity: 593 mg/kg | |
| (R*,R*)-1,4-dimercaptobutane- 2,3-diol | 3483-12-3 222-468-7 01-2120856806-42 | Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity esti- mate Acute oral toxicity: 300,03 mg/kg | >= 1,0 - < 2,5 |

For explanation of abbreviations see section 16.

Binding Buffer

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 2

H225: Highly flammable liquid and vapour.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|--|---|--------------------------|
| ethanol | 64-17-5 200-578-6 603-002-00-5 01-2119457610-43 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 | >= 50,0 - < 70,0 |
| Polidocanol | 9002-92-0 500-002-6 | Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity esti- mate Acute oral toxicity: 1.000 mg/kg | >= 3,0 - < 10,0 |

For explanation of abbreviations see section 16.

Wash Buffer I (d-WB I m/l)

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3

H226: Flammable liquid and vapour.

Acute toxicity, Category 4

H302: Harmful if swallowed.

Skin irritation, Category 2

H315: Causes skin irritation.

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Eye irritation, Category 2

H319: Causes serious eye irritation.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|----------------------|--|--|--------------------------|
| guanidinium chloride | 50-01-1 200-002-3 607-148-00-0 01-2119977063-35 | Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Acute toxicity estimate Acute oral toxicity: 475 mg/kg Acute inhalation toxicity (dust/mist): 3,2 mg/l | >= 30,0 - < 50,0 |
| ethanol | 64-17-5 200-578-6 603-002-00-5 01-2119457610-43 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 | >= 20,0 - < 30,0 |

For explanation of abbreviations see section 16.

Wash Buffer II

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3

H226: Flammable liquid and vapour.

Eye irritation, Category 2

H319: Causes serious eye irritation.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|--|--|--------------------------|
| ethanol | 64-17-5 200-578-6 603-002-00-5 01-2119457610-43 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 | >= 30,0 - < 50,0 |

For explanation of abbreviations see section 16.

Elution Buffer (EB)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

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For explanation of abbreviations see section 16.

DNase I, RNase-free

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|--|---|---|--------------------------|
| Nuclease, deoxyribo- | 9003-98-9 232-667-0 | Resp. Sens. 1; H334 Skin Sens. 1; H317 | >= 0,1 - < 1,0 |
| Substances with a workplace exposure limit : | | | |
| glycerol | 56-81-5 200-289-5 01-2119471987-18 | Not classified | >= 50,0 - < 70,0 |

For explanation of abbreviations see section 16.

Tissue Lysis Buffer

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4

H302: Harmful if swallowed.

Skin corrosion, Sub-category 1C

H314: Causes severe skin burns and eye damage.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting effects.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------|---|--|--------------------------|
| guanidinium thiocyanate | 593-84-0 209-812-1 615-004-00-3 01-2120735072-65 | Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1C; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH032, EUH071 Acute toxicity estimate | >= 30,0 - < 50,0 |

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| | | | |
|---------------------------------------|--|--|----------------|
| | | Acute oral toxicity: 593 mg/kg | |
| (R*,R*)-1,4-dimercaptobutane-2,3-diol | 3483-12-3 222-468-7 01-2120856806-42 | Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 Acute toxicity estimate Acute oral toxicity: 300,03 mg/kg | >= 1,0 - < 2,5 |

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 : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
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.

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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.

Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Hydrogen cyanide (hydrocyanic acid)

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.
For safety reasons in case of fire, cans should be stored separately 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 concentrations. Vapours can accumulate in low areas.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

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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 absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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 application 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 suitable 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. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

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Storage class (TRGS 510) : 3

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

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/m ³ | DE TRGS 900 |
| Peak-limit: excursion factor (category): 2;(II) | | | | |
| Further information: 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 |
|----------------|---------|--------------------------|---|----------|
| propan-2-ol | 67-63-0 | Acetone: 25 mg/l (Blood) | Immediately after exposure or after working hours | TRGS 903 |
| | | Acetone: 25 mg/l (Urine) | Immediately after exposure or after working hours | TRGS 903 |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|----------------------------|-----------------------|
| propan-2-ol | Workers | Dermal | Long-term systemic effects | 888 mg/kg |
| | Workers | Inhalation | Long-term systemic effects | 500 mg/m ³ |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|------------|
| propan-2-ol | Fresh water | 140,9 mg/l |
| | Marine water | 140,9 mg/l |
| | Fresh water sediment | 552 mg/kg |
| | Marine sediment | 552 mg/kg |
| | Soil | 28 mg/kg |

Proteinase K Incubation Buffer

Contains no substances with occupational exposure limit values.

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| Substance name | End Use | Exposure routes | Potential health effects | Value |
|------------------------------------|-----------|-----------------|----------------------------|------------------------|
| dipotassium hydrogenorthophosphate | Workers | Inhalation | Long-term systemic effects | 4,07 mg/m ³ |
| | Consumers | Inhalation | Long-term systemic effects | 3,04 mg/m ³ |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|------------------------------------|---------------------------|------------|
| dipotassium hydrogenorthophosphate | Fresh water | 0,05 mg/l |
| | Marine water | 0,005 mg/l |
| | Intermittent use/release | 0,5 mg/l |
| | Sewage treatment plant | 100 mg/l |

Proteinase K (d-PrK)**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------------------------|--|-------------------------------|---------------------------|---|
| glycerol | 56-81-5 | AGW (Inhalable fraction) | 200 mg/m ³ | DE TRGS 900 |
| | Peak-limit: excursion factor (category): 2;(I) | | | |
| | Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | |
| Proteinase, Tritirachium album serine | 39450-01-6 | IOEL | 0,00006 mg/m ³ | Roche Industrial Hygiene Committee (RIHC) |

Lysis Buffer**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-------------------------|----------|-------------------------------|-------------------------------|---|
| guanidinium thiocyanate | 593-84-0 | IOEL | 100 microgram per cubic meter | Category 1 (Roche Group Directive K1, Annex 3): OEL = 100 µg/m ³ |

Incubation Buffer

Contains no substances with occupational exposure limit values.

Tissue Lysis Buffer MP**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------|-------|
|------------|---------|-------------------------------|--------------------|-------|

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|--------------------------|----------|----------------------|-------------------------------|---|
| guanidinium thio-cyanate | 593-84-0 | of exposure) IOEL | 100 microgram per cubic meter | Category 1 (Roche Group Directive K1, Annex 3): OEL = 100 µg/m3 |
|--------------------------|----------|----------------------|-------------------------------|---|

Binding Buffer**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|---------|-------------------------------|----------------------|-------------|
| ethanol | 64-17-5 | AGW | 200 ppm 380 mg/m3 | DE TRGS 900 |
| Peak-limit: excursion factor (category): 4;(II) | | | | |
| Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | | |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------|------------|
| ethanol | Workers | Inhalation | Acute local effects | 1900 mg/m3 |
| | Workers | Dermal | Chronic effects | 343 mg/kg |
| | Workers | Inhalation | Chronic effects | 950 mg/m3 |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|------------|
| ethanol | Fresh water | 0,96 mg/l |
| | Marine water | 0,79 mg/l |
| | Fresh water sediment | 3,6 mg/kg |
| | Soil | 0,63 mg/kg |

Wash Buffer I (d-WB I m/l)**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|---------|-------------------------------|----------------------|-------------|
| ethanol | 64-17-5 | AGW | 200 ppm 380 mg/m3 | DE TRGS 900 |
| Peak-limit: excursion factor (category): 4;(II) | | | | |
| Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | | |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------|------------|
| ethanol | Workers | Inhalation | Acute local effects | 1900 mg/m3 |
| | Workers | Dermal | Chronic effects | 343 mg/kg |
| | Workers | Inhalation | Chronic effects | 950 mg/m3 |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------|
|----------------|---------------------------|-------|

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| | | |
|---------|----------------------|------------|
| ethanol | Fresh water | 0,96 mg/l |
| | Marine water | 0,79 mg/l |
| | Fresh water sediment | 3,6 mg/kg |
| | Soil | 0,63 mg/kg |

Wash Buffer II

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|---------|-------------------------------|----------------------------------|-------------|
| ethanol | 64-17-5 | AGW | 200 ppm 380 mg/m ³ | DE TRGS 900 |
| Peak-limit: excursion factor (category): 4;(II) | | | | |
| Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | | |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------|------------------------|
| ethanol | Workers | Inhalation | Acute local effects | 1900 mg/m ³ |
| | Workers | Dermal | Chronic effects | 343 mg/kg |
| | Workers | Inhalation | Chronic effects | 950 mg/m ³ |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|------------|
| ethanol | Fresh water | 0,96 mg/l |
| | Marine water | 0,79 mg/l |
| | Fresh water sediment | 3,6 mg/kg |
| | Soil | 0,63 mg/kg |

Elution Buffer (EB)

Contains no substances with occupational exposure limit values.

DNase I, RNase-free

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|-----------|-------------------------------|---------------------------|---|
| glycerol | 56-81-5 | AGW (Inhalable fraction) | 200 mg/m ³ | DE TRGS 900 |
| Peak-limit: excursion factor (category): 2;(I) | | | | |
| Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | | |
| Nuclease, deoxyribo- | 9003-98-9 | IOEL | 0,00006 mg/m ³ | Roche Industrial Hygiene Committee (RIHC) |

Tissue Lysis Buffer

Occupational Exposure Limits

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| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-------------------------|----------|-------------------------------|-------------------------------|--|
| guanidinium thiocyanate | 593-84-0 | IOEL | 100 microgram per cubic meter | Category 1 (Roche Group Directive K1, Annex 3): OEL = 100 µg/m ³ |

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

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

Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Hand protection

In case of contact through splashing:
Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0,11 mm

In case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0,4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Magnetic Glass Particles (MGPs) Suspension

| | |
|--|--|
| Physical state | : suspension |
| Colour | : black, brown |
| Odour | : alcohol-like |
| Odour Threshold | : No data available |
| Melting point/range | : -89 °C |
| Boiling point/boiling range | : 82 °C |
| Upper explosion limit / Upper flammability limit | : 12 %(V) |
| Lower explosion limit / Lower flammability limit | : 2 %(V) |
| Flash point | : 12 °C |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : Hazardous decomposition products formed under fire conditions. |
| pH | : No data available |
| Viscosity | |
| Viscosity, dynamic | : No data available |
| Viscosity, kinematic | : No data available |
| Solubility(ies) | |
| Water solubility | : partly miscible |
| Solubility in other solvents | : No data available |
| Partition coefficient: n-octanol/water | : No data available |
| Vapour pressure | : 42 hPa (20 °C) |
| Relative density | : No data available |
| Relative vapour density | : No data available |
| Particle characteristics | |
| Particle Size Distribution | : Not applicable |

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Proteinase K Incubation Buffer

| | | |
|--|---|-------------------------------------|
| Physical state | : | liquid |
| Colour | : | clear colourless |
| Odour | : | none |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 6,6 - 7,0 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

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Proteinase K (d-PrK)

| | |
|--|---|
| Physical state | : liquid |
| Colour | : clear, colourless |
| Odour | : very faint |
| Odour Threshold | : No data available |
| Melting point/range | : No data available |
| Boiling point/boiling range | : No data available |
| Flammability | : The product is not flammable., Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| | No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| pH | : 7,5 (25 °C) |
| Viscosity | |
| Viscosity, dynamic | : No data available |
| Viscosity, kinematic | : No data available |
| Solubility(ies) | |
| Water solubility | : completely miscible |
| Solubility in other solvents | : No data available |
| Partition coefficient: n-octanol/water | : No data available |
| Vapour pressure | : No data available |
| Relative density | : No data available |
| Density | : 1,126 g/cm ³ |
| Relative vapour density | : No data available |
| Particle characteristics | |
| Particle Size Distribution | : Not applicable |

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Lysis Buffer

| | | |
|--|---|--|
| Physical state | : | liquid |
| Colour | : | colourless |
| Odour | : | sulphurous |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | Hazardous decomposition products formed under fire conditions. |
| pH | : | 5,0 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

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Incubation Buffer

| | | |
|--|---|------------------------------|
| Physical state | : | liquid |
| Colour | : | colourless |
| Odour | : | none |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 6,8 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Tissue Lysis Buffer MP

| | | |
|----------------|---|--------|
| Physical state | : | liquid |
|----------------|---|--------|

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| | | |
|--|---|--|
| Colour | : | colourless |
| Odour | : | sulphurous |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | Hazardous decomposition products formed under fire conditions. |
| pH | : | 5,0 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Binding Buffer

| | | |
|----------------|---|--------|
| Physical state | : | liquid |
|----------------|---|--------|

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| | | |
|--|---|---------------------------------|
| Colour | : | clear colourless |
| Odour | : | alcohol-like |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available 18 °C |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | 43 hPa |
| Relative density | : | No data available |
| Density | : | 0,878 g/cm ³ (25 °C) |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Wash Buffer I (d-WB I m/l)

| | | |
|----------------|---|--------|
| Physical state | : | liquid |
|----------------|---|--------|

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| | | |
|--|---|-------------------------|
| Colour | : | colourless |
| Odour | : | characteristic |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Sustains combustion |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | 29 °C |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 6,6 (25 °C) |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | 43 hPa |
| Relative density | : | No data available |
| Density | : | 1,057 g/cm ³ |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Wash Buffer II

| | | |
|----------------|---|--------|
| Physical state | : | liquid |
|----------------|---|--------|

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| | | |
|--|---|------------------------|
| Colour | : | colourless |
| Odour | : | characteristic |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | 24 °C |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | ca. 7,4 (25 °C) |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | 43 hPa |
| Relative density | : | No data available |
| Density | : | 0,95 g/cm ³ |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Elution Buffer (EB)

| | | |
|----------------|---|------------|
| Physical state | : | liquid |
| Colour | : | colourless |

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| | | |
|--|---|-----------------------------|
| Odour | : | none |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | 100 °C |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | 23 hPa (20 °C) |
| Relative density | : | No data available |
| Density | : | 1 g/cm ³ (20 °C) |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

DNase I, RNase-free

| | | |
|----------------|---|--------------|
| Physical state | : | liquid |
| Colour | : | light yellow |
| Odour | : | odourless |

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| | | |
|--|---|------------------------------|
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 7,6 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Density | : | ca. 1,15 g/cm ³ |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

Tissue Lysis Buffer

| | | |
|----------------|---|------------|
| Physical state | : | liquid |
| Colour | : | colourless |
| Odour | : | sulphurous |

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| | | |
|--|---|--|
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flammability | : | Does not sustain combustion. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| | | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | Hazardous decomposition products formed under fire conditions. |
| pH | : | 5,0 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Density | : | 1,1 g/cm ³ |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | Not applicable |

9.2 Other information

Magnetic Glass Particles (MGPs) Suspension

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

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Self-ignition : 485 °C

Evaporation rate : No data available

Miscibility with water : No data available

Proteinase K Incubation Buffer

Explosives : Not explosive

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

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

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

Proteinase K (d-PrK)

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : completely miscible

Lysis Buffer

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

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

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

Incubation Buffer

Explosives : Not explosive

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

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| | | |
|------------------------|---|---|
| Flammability (liquids) | : | The product is not flammable., Does not sustain combustion. |
| Self-ignition | : | No data available |
| Evaporation rate | : | No data available |
| Miscibility with water | : | No data available |

Tissue Lysis Buffer MP

| | | |
|------------------------|---|---|
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Flammability (liquids) | : | The product is not flammable., Does not sustain combustion. |
| Self-ignition | : | No data available |
| Evaporation rate | : | No data available |
| Miscibility with water | : | No data available |

Binding Buffer

| | | |
|------------------------|---|--|
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Self-ignition | : | No data available |
| Evaporation rate | : | No data available |
| Miscibility with water | : | No data available |
| Conductivity | : | 8 - 22 µS/cm at 25 °C |

Wash Buffer I (d-WB I m/l)

| | | |
|------------------------|---|--|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Flammability (liquids) | : | Sustains combustion |
| Self-ignition | : | 425 °C |
| Evaporation rate | : | No data available |
| Miscibility with water | : | completely miscible |

Wash Buffer II

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

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The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

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| | |
|------------------------|-----------------------|
| Self-ignition | : 425 °C |
| Evaporation rate | : No data available |
| Miscibility with water | : completely miscible |
| Conductivity | : 4.590 µS/cm |

Elution Buffer (EB)

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

DNase I, RNase-free

| | |
|------------------------|---|
| Explosives | : Not explosive |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Flammability (liquids) | : The product is not flammable., Does not sustain combustion. |
| Self-ignition | : No data available |
| Evaporation rate | : No data available |

Tissue Lysis Buffer

| | |
|------------------------|---|
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Flammability (liquids) | : The product is not flammable., Does not sustain combustion. |
| Self-ignition | : No data available |
| Evaporation rate | : No data available |
| Miscibility with water | : No data available |

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SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Keep away from heat and sources of ignition.
Contact with acids liberates very toxic gas.
Reacts with the following substances:
sodium hypochlorite
Nitric acid
Hydrogen halides
Reacts violently with peroxides.
Oxidizing agents
Nitriles
Alkali metals
Alkaline earth metals
Amines
Aldehydes
Iron
No decomposition if stored and applied as directed.

Vapours may form explosive mixture with air.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Strong bases
Strong oxidizing agents
Nitric acid
Peroxides
Cyanides
Alkali metals
Alkaline earth metals
Iron
Amines
Aldehydes
sodium hypochlorite
Strong acids

10.6 Hazardous decomposition products

Heating can release hazardous gases.
Heating can release vapours which can be ignited.
Hazardous decomposition products formed under fire conditions.
In case of fire hazardous decomposition products may be produced such as:
Gaseous hydrogen chloride (HCl).
Nitrogen oxides (NO_x)
Carbon oxides
Sulphur oxides

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Ammonia
Hydrogen cyanide (hydrocyanic acid)

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Magnetic Glass Particles (MGPs) Suspension

Acute toxicity

Not classified based on available information.

Components:

propan-2-ol:

| | |
|---------------------------|--|
| Acute oral toxicity | : LD50 (Rat): 5.840 mg/kg Method: OECD Test Guideline 401 GLP: no |
| Acute inhalation toxicity | : LC50 (Rat, male and female): > 10000 ppm Exposure time: 6 h Test atmosphere: vapour Method: OECD Test Guideline 403 GLP: yes |
| Acute dermal toxicity | : LD50 (Rabbit): 13.900 mg/kg Method: OECD Test Guideline 402 GLP: no |

Skin corrosion/irritation

Not classified based on available information.

Components:

propan-2-ol:

| | |
|---------------|----------------------|
| Species | : Rabbit |
| Exposure time | : 4 h |
| Result | : No skin irritation |
| GLP | : no |

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

propan-2-ol:

| | |
|---------|--------------------------------------|
| Species | : Rabbit |
| Method | : OECD Test Guideline 405 |
| Result | : Irritating to eyes. |
| GLP | : no |
| Remarks | : May cause irreversible eye damage. |

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

propan-2-ol:

| | |
|------------|--------------------------------------|
| Test Type | : Buehler Test |
| Species | : Guinea pig |
| Assessment | : Does not cause skin sensitisation. |
| Method | : OECD Test Guideline 406 |
| GLP | : yes |

Germ cell mutagenicity

Not classified based on available information.

Components:

propan-2-ol:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 476 Result: negative GLP: yes |
|-----------------------|---|

| | |
|--|--|
| | : Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative GLP: no |
|--|--|

| | |
|----------------------|---|
| Genotoxicity in vivo | : Test Type: In vivo micronucleus test Species: Mouse (male and female) Cell type: Bone marrow Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative GLP: yes |
|----------------------|---|

Carcinogenicity

Not classified based on available information.

Components:

propan-2-ol:

| | |
|------------------------|------------------------|
| Species | : Rat, male and female |
| Application Route | : inhalation (vapour) |
| Exposure time | : 104 weeks |
| Frequency of Treatment | : 5 days/week |

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Method : OECD Test Guideline 451
GLP : yes

Reproductive toxicity

Not classified based on available information.

Components:

propan-2-ol:

Effects on fertility : Species: Rat, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: 853 mg/kg body weight
Method: OECD Test Guideline 415
GLP: yes

Effects on foetal development : Species: Rat, male and female
Application Route: Oral
Dose: 596, 1242, 1605 mg/kg bw/day
Duration of Single Treatment: 6 - 16 d
General Toxicity Maternal: NOAEL: 596 mg/kg body weight
Developmental Toxicity: NOAEL: 596 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

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.

Repeated dose toxicity

Components:

propan-2-ol:

Species : Rat, male and female
NOAEC : 5000
Application Route : Inhalation
Test atmosphere : vapour
Exposure time : 104 Weeks
Dose : 500, 2500, 5000 ppm parts per million
GLP : yes

Aspiration toxicity

Not classified based on available information.

Proteinase K Incubation Buffer

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Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Proteinase K (d-PrK)

Acute toxicity

Not classified based on available information.

Components:

glycerol:

Acute oral toxicity : LC50 (Mouse): 11.500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m3

Exposure time: 7 h

Test atmosphere: vapour

GLP: no

Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56.750 mg/kg
GLP: no

Skin corrosion/irritation

Not classified based on available information.

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Components:

Proteinase, Tritirachium album serine:

Result : Irritating to skin.
Remarks : May cause skin irritation and/or dermatitis.

glycerol:

Species : Rabbit
Exposure time : 24 h
Result : No skin irritation
GLP : no

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.

glycerol:

Species : Rabbit
Exposure time : 7 d
Result : No eye irritation
GLP : no

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.

glycerol:

Assessment : Mild eye irritant
Mild respiratory irritant
No skin irritation

Germ cell mutagenicity

Not classified based on available information.

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Components:

glycerol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

Components:

glycerol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
Frequency of Treatment : daily
GLP : No information available.
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.

Components:

glycerol:

Effects on fertility : Test Type: Two-generation study
Species: Rat, male and female
Application Route: Oral
Dose: 2000 mg/kg bw/day
Fertility: NOAEL: 2.000 mg/kg body weight
GLP: no

Effects on foetal development : Species: Rabbit, female
Application Route: Oral
Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
Duration of Single Treatment: 29 d
Developmental Toxicity: NOAEL: 1.180 mg/kg bw/day
GLP: no

STOT - single exposure

Not classified based on available information.

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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.

Repeated dose toxicity

Components:

glycerol:

Species : Rat, male and female
NOAEL : 4580 mg/kg
NOAEL : 4.580 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily
Dose : 4580 - 25,800 mg/kg/day
GLP : no

Species : Rat, male and female
Application Route : Inhalation
Test atmosphere : dust/mist
Exposure time : 13 Weeks
Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m³
GLP : No information available.

Species : Rat
NOAEL : 5040 mg/kg
NOAEL : 5.040 mg/kg
Application Route : Dermal
Exposure time : 45 Weeks
Number of exposures : 8 hours/day, 5 days/week
Dose : 0.5-4.0 ml/kg
GLP : no

Aspiration toxicity

Not classified based on available information.

Components:

Proteinase, Tritirachium album serine:

No data available

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Lysis Buffer

Acute toxicity

Harmful if swallowed.

Components:

guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat, female): 593 mg/kg
Method: OECD Test Guideline 401
Symptoms: Vomiting
GLP: yes

Acute toxicity estimate: 593 mg/kg
Method: Calculation method

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after single contact with skin.

Polidocanol:

Acute oral toxicity : LD50 Oral (Rat): 1.000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute toxicity estimate: 1.000 mg/kg
Method: Calculation method

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2.000 mg/kg
Method: OECD Test Guideline 402
GLP: yes

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

Acute oral toxicity : LD50 (Rat, female): > 300 - < 2.000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute toxicity estimate: 300,03 mg/kg
Method: Calculation method

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

Skin corrosion/irritation

Causes severe burns.

Components:

guanidinium thiocyanate:

Species : Rabbit
Exposure time : 4 h

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Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
GLP : yes

Polidocanol:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

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

Species : human keratinocytes
Exposure time : 4 h
Method : OECD Test Guideline 431
Result : Irritating to skin.
GLP : yes

Species : reconstructed human epidermis (RhE)
Exposure time : 60 min
Method : OECD Test Guideline 439
Result : Irritating to skin.
GLP : yes

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Polidocanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Risk of serious damage to eyes.
GLP : yes

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

Species : Chicken eye
Exposure time : 10 s
Method : OECD Test Guideline 438
Result : Risk of serious damage to eyes.
GLP : yes

Species : Human
Exposure time : 6 h
Method : OECD Test Guideline 492
Result : Risk of serious damage to eyes.
GLP : yes

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

Polidocanol:

Test Type : Draize Test
Species : Guinea pig
Result : Does not cause skin sensitisation.
GLP : no

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

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 429
GLP : yes

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: no

Test Type: gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Polidocanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Chromosome aberration test in vitro

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Test system: Chinese hamster cells
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Species: Mouse (male)
Strain: B6C3F1
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Exposure time: 72 h
Dose: 125 mg/kg
Result: negative

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

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Effects on fertility : Species: Rat, female
Application Route: Oral
Dose: 25
GLP: no
Remarks: No significant adverse effects were reported
Based on data from similar materials

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 50, 150, 350 mg/kg bw/day
General Toxicity Maternal: NOAEL: 150 mg/kg bw/day
Embryo-foetal toxicity: NOAEL: 350 mg/kg body weight
Method: OECD Test Guideline 414

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GLP: yes

Polidocanol:

Effects on foetal development : Test Type: Two-generation study
Species: Rat, female
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg bw/day

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

guanidinium thiocyanate:

Species : Rat, male and female
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily
Dose : 25, 100, 300 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

Polidocanol:

Species : Rat, male
NOAEL : 390 mg/kg bw/day
Application Route : Oral
Exposure time : 22 d

Aspiration toxicity

Not classified based on available information.

Incubation 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.

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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.

Tissue Lysis Buffer MP

Acute toxicity

Harmful if swallowed.

Components:

guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat, female): 593 mg/kg
Method: OECD Test Guideline 401
Symptoms: Vomiting
GLP: yes

Acute toxicity estimate: 593 mg/kg
Method: Calculation method

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after single contact with skin.

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

Acute oral toxicity : LD50 (Rat, female): > 300 - < 2.000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute toxicity estimate: 300,03 mg/kg
Method: Calculation method

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

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Skin corrosion/irritation

Causes severe burns.

Components:

guanidinium thiocyanate:

| | |
|---------------|--|
| Species | : Rabbit |
| Exposure time | : 4 h |
| Method | : OECD Test Guideline 404 |
| Result | : Corrosive after 1 to 4 hours of exposure |
| GLP | : yes |

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

| | |
|---------------|---------------------------|
| Species | : human keratinocytes |
| Exposure time | : 4 h |
| Method | : OECD Test Guideline 431 |
| Result | : Irritating to skin. |
| GLP | : yes |

| | |
|---------------|---------------------------------------|
| Species | : reconstructed human epidermis (RhE) |
| Exposure time | : 60 min |
| Method | : OECD Test Guideline 439 |
| Result | : Irritating to skin. |
| GLP | : yes |

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

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

| | |
|---------------|-----------------------------------|
| Species | : Chicken eye |
| Exposure time | : 10 s |
| Method | : OECD Test Guideline 438 |
| Result | : Risk of serious damage to eyes. |
| GLP | : yes |

| | |
|---------------|-----------------------------------|
| Species | : Human |
| Exposure time | : 6 h |
| Method | : OECD Test Guideline 492 |
| Result | : Risk of serious damage to eyes. |
| GLP | : yes |

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

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

| | |
|-----------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
|-----------|---------------------------------|

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Species : Mouse
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 429
GLP : yes

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: no

Test Type: gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

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

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

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Components:

guanidinium thiocyanate:

Effects on fertility : Species: Rat, female
Application Route: Oral
Dose: 25
GLP: no
Remarks: No significant adverse effects were reported
Based on data from similar materials

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 50, 150, 350 mg/kg bw/day
General Toxicity Maternal: NOAEL: 150 mg/kg bw/day
Embryo-foetal toxicity: NOAEL: 350 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

guanidinium thiocyanate:

Species : Rat, male and female
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily
Dose : 25, 100, 300 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified based on available information.

Binding Buffer

Acute toxicity

Not classified based on available information.

Components:

ethanol:

Acute oral toxicity : LD50 (Rat, male and female): 10.470 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 124,7 mg/l
Exposure time: 4 h

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Test atmosphere: vapour
Method: OECD Test Guideline 403
GLP: no

Acute dermal toxicity : (Rabbit): 17.100 mg/kg
GLP: No information available.
Remarks: Based on data from similar materials

Polidocanol:

Acute oral toxicity : LD50 Oral (Rat): 1.000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute toxicity estimate: 1.000 mg/kg
Method: Calculation method

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2.000 mg/kg
Method: OECD Test Guideline 402
GLP: yes

Skin corrosion/irritation

Not classified based on available information.

Components:

ethanol:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

Polidocanol:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

ethanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritating to eyes.
GLP : No information available.

Polidocanol:

Species : Rabbit
Method : OECD Test Guideline 405

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Result : Risk of serious damage to eyes.
GLP : yes

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

ethanol:

Test Type : Maximisation Test
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.
GLP : no

Remarks : Based on data from similar materials

Polidocanol:

Test Type : Draize Test
Species : Guinea pig
Result : Does not cause skin sensitisation.
GLP : no

Germ cell mutagenicity

Not classified based on available information.

Components:

ethanol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Mouse (male)
Application Route: Oral
Dose: 10 or 40% ethanol in water
Method: OECD Test Guideline 478

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Result: negative
GLP: No information available.

Polidocanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Species: Mouse (male)
Strain: B6C3F1
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Exposure time: 72 h
Dose: 125 mg/kg
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

ethanol:

Species : Mouse, male and female
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Control Group : yes
Frequency of Treatment : 19 hours/day
Method : OECD Test Guideline 453
Result : negative
GLP : No information available.
Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:

ethanol:

Effects on fertility : Test Type: Two-generation study
Species: Mouse, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: 20.700 mg/kg body weight
Method: OECD Test Guideline 416
Result: No effects on fertility

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GLP: No information available.

Effects on foetal development : Species: Rat, female
Strain: Sprague-Dawley
Application Route: Ingestion
Duration of Single Treatment: 6 Weeks
Developmental Toxicity: NOAEL: 5.200 mg/kg body weight
GLP: No information available.

Polidocanol:

Effects on foetal development : Test Type: Two-generation study
Species: Rat, female
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg bw/day

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

ethanol:

Species : Rat, male and female
LOAEL : 3156 mg/kg
Application Route : Oral
Exposure time : 14 Weeks
Dose : 0, 5, 10, 20 mg/Kg
Method : OECD Test Guideline 408
GLP : yes

Polidocanol:

Species : Rat, male
NOAEL : 390 mg/kg bw/day
Application Route : Oral
Exposure time : 22 d

Aspiration toxicity

Not classified based on available information.

Wash Buffer I (d-WB I m/l)

Acute toxicity

Harmful if swallowed.

Components:

guanidinium chloride:

Acute oral toxicity : LD50 Oral (Rat, female): 475 mg/kg
Method: OECD Test Guideline 401

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GLP: yes

Acute toxicity estimate: 475 mg/kg
Method: Calculation method

Acute inhalation toxicity : LC50 (Rat, female): 3,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: yes

LC50 (Rat, male and female): 5,32 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: yes

LC50 (Rat, male): 7,7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: yes

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

Acute dermal toxicity : LD50 Dermal (Rabbit, male and female): > 2.000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.

ethanol:

Acute oral toxicity : LD50 (Rat, male and female): 10.470 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403
GLP: no

Acute dermal toxicity : (Rabbit): 17.100 mg/kg
GLP: No information available.
Remarks: Based on data from similar materials

Skin corrosion/irritation

Causes skin irritation.

Components:

guanidinium chloride:

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Species : Rabbit
Exposure time : 24 h
Result : Irritating to skin.
GLP : yes

ethanol:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

guanidinium chloride:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritating to eyes.
GLP : yes

ethanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritating to eyes.
GLP : No information available.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

guanidinium chloride:

Test Type : Buehler Test
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 406
GLP : yes

ethanol:

Test Type : Maximisation Test
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.
GLP : no

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Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium chloride:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster fibroblasts
Method: OECD Test Guideline 473
Result: negative
GLP: no

ethanol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Mouse (male)
Application Route: Oral
Dose: 10 or 40% ethanol in water
Method: OECD Test Guideline 478
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

Components:

ethanol:

Species : Mouse, male and female
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Control Group : yes

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Frequency of Treatment : 19 hours/day
Method : OECD Test Guideline 453
Result : negative
GLP : No information available.
Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:

guanidinium chloride:

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 50, 150, 350 mg/kg bw/day
Duration of Single Treatment: 5 - 19 d
Developmental Toxicity: NOAEL: 350 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

ethanol:

Effects on fertility : Test Type: Two-generation study
Species: Mouse, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: 20.700 mg/kg body weight
Method: OECD Test Guideline 416
Result: No effects on fertility
GLP: No information available.

Effects on foetal development : Species: Rat, female
Strain: Sprague-Dawley
Application Route: Ingestion
Duration of Single Treatment: 6 Weeks
Developmental Toxicity: NOAEL: 5.200 mg/kg body weight
GLP: No information available.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

guanidinium chloride:

Species : Rat, male and female
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Dose : 25, 100, 300 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

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ethanol:

Species : Rat, male and female
LOAEL : 3156 mg/kg
Application Route : Oral
Exposure time : 14 Weeks
Dose : 0, 5, 10, 20 mg/Kg
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified based on available information.

Wash Buffer II

Acute toxicity

Not classified based on available information.

Components:

ethanol:

Acute oral toxicity : LD50 (Rat, male and female): 10.470 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403
GLP: no

Acute dermal toxicity : (Rabbit): 17.100 mg/kg
GLP: No information available.
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

ethanol:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

ethanol:

Species : Rabbit
Method : OECD Test Guideline 405

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Result : Irritating to eyes.
GLP : No information available.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

ethanol:

Test Type : Maximisation Test
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.
GLP : no

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

ethanol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Mouse (male)
Application Route: Oral
Dose: 10 or 40% ethanol in water
Method: OECD Test Guideline 478
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

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Components:

ethanol:

Species : Mouse, male and female
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Control Group : yes
Frequency of Treatment : 19 hours/day
Method : OECD Test Guideline 453
Result : negative
GLP : No information available.
Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:

ethanol:

Effects on fertility : Test Type: Two-generation study
Species: Mouse, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: 20.700 mg/kg body weight
Method: OECD Test Guideline 416
Result: No effects on fertility
GLP: No information available.

Effects on foetal development : Species: Rat, female
Strain: Sprague-Dawley
Application Route: Ingestion
Duration of Single Treatment: 6 Weeks
Developmental Toxicity: NOAEL: 5.200 mg/kg body weight
GLP: No information available.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

ethanol:

Species : Rat, male and female
LOAEL : 3156 mg/kg
Application Route : Oral
Exposure time : 14 Weeks
Dose : 0, 5, 10, 20 mg/Kg
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified based on available information.

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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.

DNase I, RNase-free

Acute toxicity

Not classified based on available information.

Components:

glycerol:

Acute oral toxicity : LC50 (Mouse): 11.500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³

Exposure time: 7 h

Test atmosphere: vapour

GLP: no

Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56.750 mg/kg

GLP: no

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Skin corrosion/irritation

Not classified based on available information.

Components:

glycerol:

| | | |
|---------------|---|--------------------|
| Species | : | Rabbit |
| Exposure time | : | 24 h |
| Result | : | No skin irritation |
| GLP | : | no |

Serious eye damage/eye irritation

Not classified based on available information.

Components:

glycerol:

| | | |
|---------------|---|-------------------|
| Species | : | Rabbit |
| Exposure time | : | 7 d |
| Result | : | No eye irritation |
| GLP | : | no |

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Nuclease, deoxyribo-:

| | | |
|------------|---|--|
| Assessment | : | May cause sensitisation by inhalation. |
| Assessment | : | May cause sensitisation by skin contact. |

glycerol:

| | | |
|------------|---|---------------------------|
| Assessment | : | Mild eye irritant |
| | | Mild respiratory irritant |
| | | No skin irritation |

Germ cell mutagenicity

Not classified based on available information.

Components:

glycerol:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Microbial mutagenesis assay (Ames test) |
| | | Test system: Salmonella typhimurium |
| | | Metabolic activation: with and without metabolic activation |
| | | Result: negative |
| | | GLP: No information available. |

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Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

Components:

glycerol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
Frequency of Treatment : daily
GLP : No information available.
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.

Components:

glycerol:

Effects on fertility : Test Type: Two-generation study
Species: Rat, male and female
Application Route: Oral
Dose: 2000 mg/kg bw/day
Fertility: NOAEL: 2.000 mg/kg body weight
GLP: no

Effects on foetal development : Species: Rabbit, female
Application Route: Oral
Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
Duration of Single Treatment: 29 d
Developmental Toxicity: NOAEL: 1.180 mg/kg bw/day
GLP: no

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

glycerol:

Species : Rat, male and female
NOAEL : 4580 mg/kg
NOAEL : 4.580 mg/kg

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| | |
|---------------------|-------------------------------------|
| Application Route | : Oral |
| Exposure time | : 90 d |
| Number of exposures | : daily |
| Dose | : 4580 - 25,800 mg/kg/day |
| GLP | : no |
| Species | : Rat, male and female |
| Application Route | : Inhalation |
| Test atmosphere | : dust/mist |
| Exposure time | : 13 Weeks |
| Number of exposures | : 6 hours/day, 5 days/week |
| Dose | : 33, 165 and 660 mg/m ³ |
| GLP | : No information available. |
| Species | : Rat |
| NOAEL | : 5040 mg/kg |
| NOAEL | : 5.040 mg/kg |
| Application Route | : Dermal |
| Exposure time | : 45 Weeks |
| Number of exposures | : 8 hours/day, 5 days/week |
| Dose | : 0.5-4.0 ml/kg |
| GLP | : no |

Aspiration toxicity

Not classified based on available information.

Tissue Lysis Buffer

Acute toxicity

Harmful if swallowed.

Components:

guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat, female): 593 mg/kg
Method: OECD Test Guideline 401
Symptoms: Vomiting
GLP: yes

Acute toxicity estimate: 593 mg/kg
Method: Calculation method

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after single contact with skin.

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

Acute oral toxicity : LD50 (Rat, female): > 300 - < 2.000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute toxicity estimate: 300,03 mg/kg

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Method: Calculation method

Acute toxicity (other routes of administration)

Symptoms: May cause cardiac arrhythmia., Convulsions, Vomiting

Skin corrosion/irritation

Causes severe burns.

Components:

guanidinium thiocyanate:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
GLP : yes

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

Species : human keratinocytes
Exposure time : 4 h
Method : OECD Test Guideline 431
Result : Irritating to skin.
GLP : yes

Species : reconstructed human epidermis (RhE)
Exposure time : 60 min
Method : OECD Test Guideline 439
Result : Irritating to skin.
GLP : yes

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

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

Species : Chicken eye
Exposure time : 10 s
Method : OECD Test Guideline 438
Result : Risk of serious damage to eyes.
GLP : yes

Species : Human
Exposure time : 6 h
Method : OECD Test Guideline 492
Result : Risk of serious damage to eyes.
GLP : yes

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

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

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 429
GLP : yes

Germ cell mutagenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: no

Test Type: gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

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

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Effects on fertility : Species: Rat, female
Application Route: Oral
Dose: 25
GLP: no
Remarks: No significant adverse effects were reported
Based on data from similar materials

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 50, 150, 350 mg/kg bw/day
General Toxicity Maternal: NOAEL: 150 mg/kg bw/day
Embryo-foetal toxicity: NOAEL: 350 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

guanidinium thiocyanate:

Species : Rat, male and female
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily
Dose : 25, 100, 300 mg/kg bw/day
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

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

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(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Magnetic Glass Particles (MGPs) Suspension

Endocrine disrupting properties

Product:

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

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.

Proteinase K Incubation Buffer

Endocrine disrupting properties

Product:

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

Proteinase K (d-PrK)

Endocrine disrupting properties

Product:

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

Lysis Buffer

Endocrine disrupting properties

Product:

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

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levels of 0.1% or higher.

Incubation Buffer

Endocrine disrupting properties

Product:

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

Tissue Lysis Buffer MP

Endocrine disrupting properties

Product:

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

Binding Buffer

Endocrine disrupting properties

Product:

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

Further information

Product:

Remarks : Solvents may degrease the skin.

Wash Buffer I (d-WB I m/l)

Endocrine disrupting properties

Product:

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

Further information

Product:

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Remarks : Solvents may degrease the skin.

Wash Buffer II

Endocrine disrupting properties

Product:

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

Further information

Product:

Remarks : Solvents may degrease the skin.

Elution Buffer (EB)

Endocrine disrupting properties

Product:

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

DNase I, RNase-free

Endocrine disrupting properties

Product:

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

Tissue Lysis Buffer

Endocrine disrupting properties

Product:

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

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SECTION 12: Ecological information

12.1 Toxicity

Magnetic Glass Particles (MGPs) Suspension

Components:

propan-2-ol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 10.000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: no
- Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 10.000 mg/l
End point: Immobilization
Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: no
- Toxicity to algae/aquatic plants : EC10 (Scenedesmus quadricauda (Green algae)): 1.800 mg/l
Exposure time: 7 d
Test Type: static test
Analytical monitoring: no
GLP: no
- Toxicity to microorganisms : (Pseudomonas putida): 1.050 mg/l
Exposure time: 16 h
Test Type: static test
Analytical monitoring: no
Method: DIN 38 412 Part 8
GLP: no

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Proteinase K Incubation Buffer

No data available

Proteinase K (d-PrK)

Components:

Proteinase, Tritirachium album serine:

Ecotoxicology Assessment

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

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Other organisms relevant to the environment : No data available

glycerol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: no

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1.955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10.000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10.000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

Lysis Buffer

Components:

guanidinium thiocyanate:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89,1 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other : EC50 (Daphnia (water flea)): 42,4 mg/l

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| | | |
|----------------------------------|---|---|
| aquatic invertebrates | | End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 202 GLP: no |
| Toxicity to algae/aquatic plants | : | EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test GLP: No information available. |
| Toxicity to microorganisms | : | EC50 (activated sludge): > 185 mg/l Exposure time: 28 d Test Type: static test Method: OECD Test Guideline 302B GLP: yes |

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 |

Polidocanol:

| | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Salmo salar (Atlantic salmon)): 1,5 mg/l End point: mortality Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 6,46 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): 0,237 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EbC50 (Desmodesmus subspicatus (green algae)): 1.502 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | (Photobacterium phosphoreum): 2,5 mg/l Test Type: EC50 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,144 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: QSAR |

Ecotoxicology Assessment

| | | |
|------------------------|---|------------------------|
| Acute aquatic toxicity | : | Toxic to aquatic life. |
|------------------------|---|------------------------|

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Remarks: Expert judgement

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

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 34,8 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 25,0 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): 24,3 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOErC (Raphidocelis subcapitata (freshwater green alga)): 3,2 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEyC (Raphidocelis subcapitata (freshwater green alga)): 1,0 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

Incubation Buffer

No data available

Tissue Lysis Buffer MP

Components:

guanidinium thiocyanate:

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- Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89,1 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 42,4 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: no
- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
GLP: No information available.
- Toxicity to microorganisms : EC50 (activated sludge): > 185 mg/l
Exposure time: 28 d
Test Type: static test
Method: OECD Test Guideline 302B
GLP: yes

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

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

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 34,8 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration
- NOEC (Daphnia magna (Water flea)): 25,0 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration
- Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): 24,3 mg/l

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End point: Growth rate
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOErC (Raphidocelis subcapitata (freshwater green alga)):
3,2 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEyC (Raphidocelis subcapitata (freshwater green alga)):
1,0 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

Binding Buffer

Components:

ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 15.300 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : LC50 (Ceriodaphnia dubia (water flea)): 5.012 mg/l
Exposure time: 48 h
Test Type: static test
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 5 d
Analytical monitoring: no
Method: OECD Test Guideline 201
GLP: No information available.

Toxicity to microorganisms : IC50 (activated sludge): > 1.000 mg/l
End point: Growth rate
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: No information available.
Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox- : NOEC: 250 mg/l

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icity)
Exposure time: 120 h
Species: Danio rerio (zebra fish)
GLP: No information available.

Toxicity to daphnia and other : NOEC: 9,6 mg/l
aquatic invertebrates (Chronic toxicity) Exposure time: 7 d
GLP: No information available.

Ecotoxicology Assessment

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

Other organisms relevant to : No data available
the environment

Polidocanol:

Toxicity to fish : LC50 (Salmo salar (Atlantic salmon)): 1,5 mg/l
End point: mortality
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 6,46 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 0,237 mg/l
plants Exposure time: 72 h
Method: OECD Test Guideline 201

EbC50 (Desmodesmus subspicatus (green algae)): 1.502 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : (Photobacterium phosphoreum): 2,5 mg/l
Test Type: EC50

Toxicity to daphnia and other : NOEC: 0,144 mg/l
aquatic invertebrates (Chronic toxicity) Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: QSAR

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.
Remarks: Expert judgement

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

Wash Buffer I (d-WB I m/l)

Components:

guanidinium chloride:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.758 mg/l
End point: mortality
Exposure time: 48 h

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Test Type: static test
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 70,2 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 33,5 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: Regulation (EC) No. 440/2008, Annex, C.3
GLP: yes

EC50 (Pseudokirchneriella subcapitata (green algae)): 11,8 mg/l
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: Regulation (EC) No. 440/2008, Annex, C.3
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 6,3 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: Regulation (EC) No. 440/2008, Annex, C.3
GLP: yes

Toxicity to microorganisms : EC10 (Pseudomonas putida): 7.125 mg/l
End point: Growth rate
Exposure time: 18 h
Test Type: static test
Method: DIN 38 412 Part 8
GLP: yes

Toxicity to fish (Chronic toxicity) : NOEC: > 181 mg/l
End point: mortality
Exposure time: 35 d
Species: Pimephales promelas (fathead minnow)
Test Type: flow-through test
Analytical monitoring: yes
Method: OECD Test Guideline 210
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 2,9 mg/l
End point: reproduction rate
Exposure time: 21 d

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Species: *Daphnia magna* (Water flea)
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: No information available.

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

ethanol:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 15.300 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : LC50 (*Ceriodaphnia dubia* (water flea)): 5.012 mg/l
Exposure time: 48 h
Test Type: static test
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (*Chlorella vulgaris* (Fresh water algae)): 275 mg/l
Exposure time: 5 d
Analytical monitoring: no
Method: OECD Test Guideline 201
GLP: No information available.

Toxicity to microorganisms : IC50 (activated sludge): > 1.000 mg/l
End point: Growth rate
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: No information available.
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 250 mg/l
Exposure time: 120 h
Species: *Danio rerio* (zebra fish)
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9,6 mg/l
Exposure time: 7 d
GLP: No information available.

Ecotoxicology Assessment

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

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Other organisms relevant to the environment : No data available

Wash Buffer II

Components:

ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 15.300 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : LC50 (Ceriodaphnia dubia (water flea)): 5.012 mg/l
Exposure time: 48 h
Test Type: static test
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 5 d
Analytical monitoring: no
Method: OECD Test Guideline 201
GLP: No information available.

Toxicity to microorganisms : IC50 (activated sludge): > 1.000 mg/l
End point: Growth rate
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: No information available.
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 250 mg/l
Exposure time: 120 h
Species: Danio rerio (zebra fish)
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9,6 mg/l
Exposure time: 7 d
GLP: No information available.

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Elution Buffer (EB)

No data available

DNase I, RNase-free

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Components:

Nuclease, deoxyribo-:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

glycerol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: no

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1.955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10.000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10.000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

Tissue Lysis Buffer

Components:

guanidinium thiocyanate:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89,1 mg/l
End point: mortality
Exposure time: 96 h

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Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 42,4 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: no

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
GLP: No information available.

Toxicity to microorganisms : EC50 (activated sludge): > 185 mg/l
Exposure time: 28 d
Test Type: static test
Method: OECD Test Guideline 302B
GLP: yes

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

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 34,8 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 25,0 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): 24,3 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test

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Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOErC (Raphidocelis subcapitata (freshwater green alga)):
3,2 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEyC (Raphidocelis subcapitata (freshwater green alga)):
1,0 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

12.2 Persistence and degradability

Magnetic Glass Particles (MGPs) Suspension

Components:

propan-2-ol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Result: Readily biodegradable.
Biodegradation: 53 %
Exposure time: 5 d
GLP: no

Proteinase K Incubation Buffer

No data available

Proteinase K (d-PrK)

Components:

glycerol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 226 mg/l
Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 24 h
GLP: no

Lysis Buffer

Components:

guanidinium thiocyanate:

Biodegradability : Test Type: aerobic

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Inoculum: activated sludge, non-adapted
Concentration: 343 mg/l
Result: Inherently biodegradable.
Biodegradation: 46 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

Polidocanol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 30 mg/l
Result: Readily biodegradable.
Biodegradation: 74 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

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

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 64,3 mg/l
Result: Not readily biodegradable.
Biodegradation: 53 %
Exposure time: 43 d
Method: OECD Test Guideline 301B
GLP: yes
Remarks: The 10 day time window criterion is not fulfilled.

Physico-chemical removability : Method: see user defined free text
Remarks: Not abiotically degradable

Incubation Buffer

No data available

Tissue Lysis Buffer MP

Components:

guanidinium thiocyanate:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 343 mg/l
Result: Inherently biodegradable.
Biodegradation: 46 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

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

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 64,3 mg/l
Result: Not readily biodegradable.
Biodegradation: 53 %

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Exposure time: 43 d
Method: OECD Test Guideline 301B
GLP: yes
Remarks: The 10 day time window criterion is not fulfilled.

Physico-chemical removability : Method: see user defined free text
Remarks: Not abiotically degradable

Binding Buffer

Components:

ethanol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d
GLP: No information available.

Polidocanol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 30 mg/l
Result: Readily biodegradable.
Biodegradation: 74 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Wash Buffer I (d-WB I m/l)

Components:

guanidinium chloride:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, adapted
Concentration: 10 mg/l
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 33 d
Method: OECD Test Guideline 301C
GLP: yes

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

ethanol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d
GLP: No information available.

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Wash Buffer II

Components:

ethanol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d
GLP: No information available.

Elution Buffer (EB)

No data available

DNase I, RNase-free

Components:

glycerol:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 226 mg/l
Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 24 h
GLP: no

Tissue Lysis Buffer

Components:

guanidinium thiocyanate:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 343 mg/l
Result: Inherently biodegradable.
Biodegradation: 46 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

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

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 64,3 mg/l
Result: Not readily biodegradable.
Biodegradation: 53 %
Exposure time: 43 d
Method: OECD Test Guideline 301B
GLP: yes
Remarks: The 10 day time window criterion is not fulfilled.

Physico-chemical removability : Method: see user defined free text
Remarks: Not abiotically degradable

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12.3 Bioaccumulative potential

Magnetic Glass Particles (MGPs) Suspension

Components:

propan-2-ol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: 0,05 (25 °C)
GLP: no

Proteinase K Incubation Buffer

No data available

Proteinase K (d-PrK)

Components:

Proteinase, Tritirachium album serine:

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

glycerol:

Partition coefficient: n-octanol/water : log Pow: -1,75 (25 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: no

Lysis Buffer

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,11 (25 °C)
pH: > 5,1
Method: Regulation (EC) No. 440/2008, Annex, A.8
GLP: no

Polidocanol:

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

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

Partition coefficient: n-octanol/water : log Pow: 0,07 (25 °C)
pH: 5,0
Method: OECD Test Guideline 117
GLP: yes

Incubation Buffer

No data available

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Tissue Lysis Buffer MP

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,11 (25 °C)
pH: > 5,1
Method: Regulation (EC) No. 440/2008, Annex, A.8
GLP: no

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

Partition coefficient: n-octanol/water : log Pow: 0,07 (25 °C)
pH: 5,0
Method: OECD Test Guideline 117
GLP: yes

Binding Buffer

Components:

ethanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0,35 (24 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: No information available.

Polidocanol:

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

Wash Buffer I (d-WB I m/l)

Components:

guanidinium chloride:

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

ethanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0,35 (24 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: No information available.

Wash Buffer II

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Components:

ethanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0,35 (24 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: No information available.

Elution Buffer (EB)

No data available

DNase I, RNase-free

Components:

Nuclease, deoxyribo-:

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

glycerol:

Partition coefficient: n-octanol/water : log Pow: -1,75 (25 °C)
pH: 7,4
Method: OECD Test Guideline 107
GLP: no

Tissue Lysis Buffer

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,11 (25 °C)
pH: > 5,1
Method: Regulation (EC) No. 440/2008, Annex, A.8
GLP: no

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

Partition coefficient: n-octanol/water : log Pow: 0,07 (25 °C)
pH: 5,0
Method: OECD Test Guideline 117
GLP: yes

12.4 Mobility in soil

Magnetic Glass Particles (MGPs) Suspension

No data available

Proteinase K Incubation Buffer

No data available

Proteinase K (d-PrK)

No data available

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Lysis Buffer

No data available

Incubation Buffer

No data available

Tissue Lysis Buffer MP

No data available

Binding Buffer

No data available

Wash Buffer I (d-WB I m/l)

No data available

Wash Buffer II

No data available

Elution Buffer (EB)

No data available

DNase I, RNase-free

No data available

Tissue Lysis Buffer

No data available

12.5 Results of PBT and vPvB assessment

Magnetic Glass Particles (MGPs) Suspension

Not relevant

Proteinase K Incubation Buffer

Not relevant

Proteinase K (d-PrK)

Not relevant

Lysis Buffer

Not relevant

Incubation Buffer

Not relevant

Tissue Lysis Buffer MP

Not relevant

Binding Buffer

Not relevant

Wash Buffer I (d-WB I m/l)

Not relevant

Wash Buffer II

Not relevant

Elution Buffer (EB)

Not relevant

DNase I, RNase-free

Not relevant

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Tissue Lysis Buffer

Not relevant

12.6 Endocrine disrupting properties

Product:

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

Magnetic Glass Particles (MGPs) Suspension

Product:

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

Proteinase K Incubation Buffer

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

Proteinase K (d-PrK)

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

Lysis Buffer

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

Incubation Buffer

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

Tissue Lysis Buffer MP

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to

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REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Binding Buffer

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

Wash Buffer I (d-WB I m/l)

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

Wash Buffer II

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

Elution Buffer (EB)

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

DNase I, RNase-free

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

Tissue Lysis Buffer

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

12.7 Other adverse effects

Magnetic Glass Particles (MGPs) Suspension

No data available

Proteinase K Incubation Buffer

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No data available

Proteinase K (d-PrK)

No data available

Lysis Buffer

No data available

Incubation Buffer

No data available

Tissue Lysis Buffer MP

No data available

Binding Buffer

No data available

Wash Buffer I (d-WB I m/l)

No data available

Wash Buffer II

No data available

Elution Buffer (EB)

No data available

DNase I, RNase-free

No data available

Tissue Lysis Buffer

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.
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 or ID number

ADR : UN 3316

RID : UN 3316

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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)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| 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
Labels : 9
EmS Code : F-A, S-P

IATA (Cargo)
Packing instruction (cargo aircraft) : 960
Packing instruction (LQ) : Y960
Packing group : II
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 960
Packing instruction (LQ) : Y960
Packing group : II
Labels : Miscellaneous

14.5 Environmental hazards

ADR
Environmentally hazardous : no

RID

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Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

Remarks : No data available

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso III: Directive : P5c FLAMMABLE LIQUIDS
2012/18/EU of the European
Parliament and of the Council
on the control of major-
accident hazards involving
dangerous substances.

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

Magnetic Glass Particles (MGPs) Suspension

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

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

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

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

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

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Other regulations:

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

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

| | | |
|----------------------------|---|--|
| AIIC | : | Not in compliance with the inventory |
| DSL | : | This product contains the following components that are not on the Canadian DSL nor NDSL. Magnetic glass particles (MGP) |
| NZIoC | : | On the inventory, or in compliance with the inventory |
| ENCS | : | Not in compliance with the inventory |
| ISHL | : | Not in compliance with the inventory |
| KECI | : | Not in compliance with the inventory |
| PICCS | : | Not in compliance with the inventory |
| IECSC | : | Not in compliance with the inventory |
| TCSI | : | Not in compliance with the inventory |
| TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI | : | Not in compliance with the inventory |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable |

Labelling (REGULATION (EC) No 1272/2008)

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.

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P261 Avoid breathing mist or vapours.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
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

Proteinase K Incubation Buffer

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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| | | |
|----------------------------|---|--|
| IECSC | : | On the inventory, or in compliance with the inventory |
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | All substances listed as active on the TSCA inventory |
| TECI | : | On the inventory, or in compliance with the inventory |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable |

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Proteinase K (d-PrK)

| | | |
|--|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 3 |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

Other regulations:

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

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

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

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| | | |
|----------------------------|---|--|
| ENCS | : | Not in compliance with the inventory |
| ISHL | : | On the inventory, or in compliance with the inventory |
| KECI | : | Not in compliance with the inventory |
| PICCS | : | Not in compliance with the inventory |
| IECSC | : | On the inventory, or in compliance with the inventory |
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI | : | Not in compliance with the inventory |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable |

Labelling (REGULATION (EC) No 1272/2008)

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 mist or vapours.
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, Triticium album serine

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Lysis Buffer

| | | |
|--|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 3 |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

Other regulations:

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

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

| | | |
|----------------------------|---|--|
| AIIC | : | On the inventory, or in compliance with the inventory |
| DSL | : | All components of this product are on the Canadian DSL |
| NZIoC | : | Not in compliance with the inventory |
| ENCS | : | Not in compliance with the inventory |
| ISHL | : | Not in compliance with the inventory |
| KECI | : | Not in compliance with the inventory |
| PICCS | : | On the inventory, or in compliance with the inventory |
| IECSC | : | On the inventory, or in compliance with the inventory |
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | All substances listed as active on the TSCA inventory |
| TECI | : | Not in compliance with the inventory |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) |

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Volatile organic compounds (VOC) content: 15 %

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

:



Signal word

: Danger

Hazard statements

: H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard
Statements

: EUH032 Contact with acids liberates very toxic
gas.
EUH071 Corrosive to the respiratory tract.

Precautionary statements

: **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.

Hazardous components which must be listed on the label:

| | |
|-----------|---------------------------------------|
| 593-84-0 | guanidinium thiocyanate |
| 9002-92-0 | Polidocanol |
| 3483-12-3 | (R*,R*)-1,4-dimercaptobutane-2,3-diol |

Incubation Buffer

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

TECI : Not in compliance with the inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Tissue Lysis Buffer MP

REACH - Restrictions on the manufacture, placing on : Conditions of restriction for the fol-

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the market and use of certain dangerous substances,
mixtures and articles (Annex XVII)

lowing entries should be considered:
Number on list 3

REACH - Candidate List of Substances of Very High
Concern for Authorisation (Article 59).

: Not applicable

Regulation (EC) No 1005/2009 on substances that de-
plete the ozone layer

: Not applicable

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

: Not applicable

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

: Not applicable

REACH - List of substances subject to authorisation
(Annex XIV)

: Not applicable

Other regulations:

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

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

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

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

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

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

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

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

TSCA : All substances listed as active on the TSCA inventory

TECI : Not in compliance with the inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial
emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 0,3 %

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Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

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

EUH071 Corrosive to the respiratory tract.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.

Hazardous components which must be listed on the label:

593-84-0 guanidinium thiocyanate

3483-12-3 (R*,R*)-1,4-dimercaptobutane-2,3-diol

Binding Buffer

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

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

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plete the ozone layer

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

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

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

Other regulations:

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

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

| | |
|----------------------------|--|
| AIIC | : On the inventory, or in compliance with the inventory |
| DSL | : All components of this product are on the Canadian DSL |
| NZIoC | : On the inventory, or in compliance with the inventory |
| ENCS | : Not in compliance with the inventory |
| ISHL | : Not in compliance with the inventory |
| KECI | : On the inventory, or in compliance with the inventory |
| PICCS | : On the inventory, or in compliance with the inventory |
| IECSC | : On the inventory, or in compliance with the inventory |
| TCSI | : On the inventory, or in compliance with the inventory |
| TSCA | : All substances listed as active on the TSCA inventory |
| TECI | : On the inventory, or in compliance with the inventory |
| Volatile organic compounds | : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 58,3 % |

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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- Signal word : Danger
- Hazard statements : H225 Highly flammable liquid and vapour.
H318 Causes serious eye damage.
- Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
- Response:**
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
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.
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:

9002-92-0 Polidocanol

Wash Buffer I (d-WB I m/l)

- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

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

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

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| | | |
|----------------------------|---|--|
| DSL | : | All components of this product are on the Canadian DSL |
| NZIoC | : | On the inventory, or in compliance with the inventory |
| ENCS | : | On the inventory, or in compliance with the inventory |
| ISHL | : | On the inventory, or in compliance with the inventory |
| KECI | : | On the inventory, or in compliance with the inventory |
| PICCS | : | On the inventory, or in compliance with the inventory |
| IECSC | : | On the inventory, or in compliance with the inventory |
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | All substances listed as active on the TSCA inventory |
| TECI | : | On the inventory, or in compliance with the inventory |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 28,4 % |

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements :
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or

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alcohol-resistant foam to extinguish.

Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

Wash Buffer II

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

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

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Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 30,34 %

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.
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/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

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.

Elution Buffer (EB)

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

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

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

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

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

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of dangerous chemicals

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

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

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

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

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

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

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

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

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

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

DNase I, RNase-free

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

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

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

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

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

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

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
Nuclease, deoxyribo-

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

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

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

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI : Not in compliance with the inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling

EUH210 Safety data sheet available on request.

EUH208 Contains DNase I, Desoxyribonuclease I from bovine pancreas EC 3.1.21.1, Grade II. May produce an allergic reaction.

Tissue Lysis Buffer

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| | |
|--|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : Conditions of restriction for the following entries should be considered: Number on list 3 |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : Not applicable |
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer | : Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : Not applicable |
| Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : Not applicable |

Other regulations:

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

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

| | |
|----------------------------|---|
| AIIC | : On the inventory, or in compliance with the inventory |
| DSL | : All components of this product are on the Canadian DSL |
| NZIoC | : Not in compliance with the inventory |
| ENCS | : Not in compliance with the inventory |
| ISHL | : Not in compliance with the inventory |
| KECI | : Not in compliance with the inventory |
| PICCS | : On the inventory, or in compliance with the inventory |
| IECSC | : On the inventory, or in compliance with the inventory |
| TCSI | : On the inventory, or in compliance with the inventory |
| TSCA | : All substances listed as active on the TSCA inventory |
| TECI | : Not in compliance with the inventory |
| Volatile organic compounds | : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 0,3 % |

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Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements :
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements :
EUH032 Contact with acids liberates very toxic gas.
EUH071 Corrosive to the respiratory tract.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.

Hazardous components which must be listed on the label:

593-84-0 guanidinium thiocyanate
3483-12-3 (R*,R*)-1,4-dimercaptobutane-2,3-diol

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

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| | |
|------|--|
| H302 | : Harmful if swallowed. |
| H312 | : Harmful in contact with skin. |
| H314 | : Causes severe skin burns and eye damage. |
| 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. |
| H336 | : May cause drowsiness or dizziness. |
| H412 | : Harmful to aquatic life with long lasting effects. |

Full text of other abbreviations

| | |
|-----------------|--|
| Acute Tox. | : Acute toxicity |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| Eye Dam. | : Serious eye damage |
| Eye Irrit. | : Eye irritation |
| Flam. Liq. | : Flammable liquids |
| Resp. Sens. | : Respiratory sensitisation |
| Skin Corr. | : Skin corrosion |
| Skin Irrit. | : Skin irritation |
| Skin Sens. | : Skin sensitisation |
| STOT SE | : Specific target organ toxicity - single exposure |

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MagNA Pure Compact RNA Isolation Kit

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- 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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